

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

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BLUE CROSS AND BLUE SHIELD	)	
OF ARIZONA, INC.,	)	
	)	No. 18-282C
Plaintiff,	)	
v.	)	Judge Elaine D. Kaplan
	)	
THE UNITED STATES OF AMERICA,	)	
	)	
Defendant.	)	
	)	

FIRST AMENDED COMPLAINT

Plaintiff Blue Cross and Blue Shield of Arizona, Inc. (“BCBS-AZ”) brings this action against the United States Government (“United States” or “Defendant”) for money damages resulting from the U.S. Department of Health and Human Services’ (“HHS” or “Secretary” or the “Government”) failure to make full payments to BCBS-AZ to compensate BCBS-AZ for certain losses resulting from its sale of qualified health plans for calendar years 2014, 2015, and 2016, as mandated by Section 1342 of the Patient Protection and Affordable Care Act (the “Affordable Care Act” or “ACA”), the risk corridors program administered by HHS. BCBS-AZ states and alleges as follows:

NATURE OF THE CASE

1. Section 1342 of the Affordable Care Act mandates a risk corridors program through which issuers of qualified health plans (“QHPs”), such as BCBS-AZ, and the Government must annually share in losses and profits exceeding certain thresholds from the sale of QHPs during the three benefit and calendar years 2014, 2015, and 2016 (“CY 2014,” “CY 2015,” and “CY 2016” respectively), the first three years of operation of the health insurance exchanges

established by the ACA (the “Marketplaces”). Pub. L. No. 111-148 § 1342, 124 Stat. 119, as amended by Pub. L. No. 111-152, 124 Stat. 1029 (2010) [42 U.S.C. § 18062].

2. Section 1342 mandates that when “a participating plan’s [*i.e.*, QHP issuer’s] allowable costs for any plan year are more than 103 percent . . . of the target amount,” defined as “total premiums . . . reduced by the administrative costs of the plan,” the “Secretary *shall pay* to the plan an amount” specified by a statutory formula. 42 U.S.C. § 18062(b)(1)(A), (c)(2) (emphasis added). When, on the other hand, a QHP issuer’s allowable costs are less than the target amount by a certain percentage, then “the plan [*i.e.*, the QHP issuer] shall pay to the Secretary an amount” set by statute. *Id.* at § 18062(b)(2)(A).

3. The Government has admitted its obligations to make payments to BCBS-AZ pursuant to the risk corridors program but has failed to pay the full amount due to BCBS-AZ for CY 2014 and has failed to pay any amounts due to BCBS-AZ for CY 2015 and CY 2016.

4. The ACA created a new health insurance market – the Marketplaces – to expand access to affordable healthcare coverage, including to individuals who previously were unable to obtain or to afford such coverage, such as individuals with pre-existing conditions. Health insurance issuers such as BCBS-AZ lacked reliable data and experience in assessing the risks and setting premiums for this new population of insureds created by the ACA, including their health status and health care needs. The ACA therefore mandated implementation of three premium-stabilization programs – including the risk corridors program – to support the launch of the new Marketplaces. These programs were intended, *inter alia*, to encourage health insurance issuers to participate in the Marketplaces, to reduce the likelihood that the insurers would include in their premium development an additional amount to guard against the risk and uncertainty of insuring

this new and unknown population, and to provide for some year-over-year stability in premiums for consumers, particularly during the initial years of the Marketplaces' operations.

5. The Centers for Medicare & Medicaid Services ("CMS"), which is part of HHS, is charged with implementing the risk corridors program. CMS has explained that the program requires "the Federal Government and [QHP issuers] to share in profits or losses resulting from inaccurate rate setting from 2014 to 2016." 78 Fed. Reg. 15,410, 15,412 (March 11, 2013) (Exhibit 1). It is designed to permit issuers such as BCBS-AZ "to lower rates by not adding a risk premium to account for perceived uncertainties in the 2014 through 2016 markets." *Id.* at 15,413.

6. Between the enactment of the ACA in 2010 and the launch of the Marketplaces on January 1, 2014, BCBS-AZ designed and priced QHPs to be sold on the Arizona Marketplace. BCBS-AZ recognized the substantial uncertainty regarding the cost of providing health coverage to a previously uninsured population. Consistent with the plain terms of the ACA, its regulations, and the assurances provided by CMS and HHS, BCBS-AZ understood that the Government would annually share in BCBS-AZ's losses and profits from the sale of QHPs during CY 2014, CY 2015, and CY 2016.

7. For CY 2014, the first year of the Marketplaces and the risk corridors program, QHP issuers who made profits in excess of a certain threshold paid in the aggregate a total of \$362 million into the risk corridors program. In the Small Group Market for CY 2014, BCBS-AZ made profits in excess of this threshold and accordingly paid the Government \$216,623.22. However, BCBS-AZ suffered losses in the Individual Market triggering the Government's obligation under the program to compensate BCBS-AZ for the federal government's share of those losses (\$11,688,096.55). In total, 2014 QHP issuers that experienced excess losses requested compensation of \$2.87 billion under the risk corridors program

8. For CY 2015, the second year of the Marketplaces and the risk corridors program, QHP issuers who made profits in excess of a certain threshold were required to pay into the program. Unlike with CY 2014, BCBS-AZ did not make profits in excess of this threshold in the CY 2015 Small Group Market. BCBS-AZ did, however, suffer losses in the Individual Market for CY 2015, triggering the Government's obligation under the program to compensate BCBS-AZ for the Government's share of those losses in the amount of \$51,990,665.22.

9. For CY 2016, the third and final year of the risk corridors program, QHP issuers who made profits in excess of a certain threshold were again required to pay into the program. As with CY 2014 and 2015, however, BCBS-AZ suffered losses in the Individual Market for CY 2016, triggering the Government's obligation to compensate BCBS-AZ for the Government's share of its losses in the amount of \$10,845,468.60.

10. Before and after BCBS-AZ decided to offer QHPs in the individual market in 2014, CMS and HHS repeatedly acknowledged that "the Affordable Care Act requires the Secretary to make full payments to issuers." 80 Fed. Reg. 10,750, 10,779 (Feb. 27, 2015) (Exhibit 2); *see also* 78 Fed. Reg. at 15,473 ("Regardless of the balance of payments and receipts, HHS will remit payment as required under section 1342 of the Affordable Care Act.") (Exhibit 1). Despite the unequivocal mandate in the ACA that the Government must annually share profits and losses with issuers, the Government has not paid BCBS-AZ in full for the Government's share of BCBS-AZ's CY 2014 losses, or at all for its share of BCBS-AZ's CY 2015 and CY 2016 losses.

11. Instead, for CY 2014, CMS prorated the \$362 million of payments received from QHP issuers across the \$2.87 billion in due compensation for the Government's share of losses under the risk corridors program. In late 2015, CMS announced that BCBS-AZ would be paid

only about 12.6% of what it was owed under the program for CY 2014. *See* CMS, Risk Corridors Payments for the 2014 Benefit Year, Nov. 19, 2015 (Exhibit 3). CMS advised that it was “recording those amounts that remain unpaid” after about 87.4% of what is owed, or approximately \$10,213,308.13 for BCBS-AZ—“as fiscal year 2015 obligation[s] of the United States Government for which full payment is required.” *Id.*; *see* CMS, Risk Corridors Payment and Charge Amounts for Benefit Year 2014, Nov. 19, 2015, at Table 3 (Exhibit 6).

12. In September 2016, CMS and HHS stated that “all 2015 benefit collections [would] be used towards remaining 2014 benefit year risk corridors payments, and no funds will be available at this time for 2015 benefit year risk corridors payments.” *See* CMS, Risk Corridors Payments for 2015, Sept. 9, 2016 (Exhibit 4).

13. On November 18, 2016, CMS and HHS announced the issuer-level risk corridors payments and charges for CY 2015. *See* CMS, Risk Corridors Payments and Charge Amounts for the 2015 Benefit Year, Nov. 18 2016 (Exhibit 5). CMS announced that BCBS-AZ would be paid an additional amount still owed to BCBS-AZ for CY 2014 at the time. CMS announced that BCBS-AZ is owed \$51,990,665.22 for its losses in the 2015 Individual Market – none of which would be paid in 2016. *Id.*

14. On November 15, 2017, CMS and HHS announced the issuer-level risk corridors payments and charges for CY 2016, the final year of the program. *See* CMS, Risk Corridors Payment and Charge Amounts for the 2016 Benefit Year, Nov. 15, 2017 (Exhibit 15). As in CY 2015, HHS announced that it will use “2016 benefit year collections to make additional payments toward 2014 year payment balances.” *Id.* CMS announced that BCBS-AZ would be paid an additional amount still owed to BCBS-AZ for CY 2014. CMS also announced that the

Government's share of BCBS-AZ's CY 2016 losses is \$10,845,468.60, and none of BCBS-AZ's CY 2015 or CY 2016 losses will be paid in 2017 or 2018. *Id.*

15. CMS unambiguously stated that it would not make full and timely risk corridors payments to owed issuers for CY 2015 in 2016 and CY 2016 in 2017. *See id.* (Exhibit 15) ("Because 2015 benefit year collections were insufficient to pay 2014 benefit year payment balances in full, HHS will use 2016 benefit year risk corridors collections to make additional payments toward 2014 benefit year payment balances."); *see also* Exhibit 5 ("Today, we are confirming that all 2015 benefit year risk corridors collections will be used to pay a portion of balances on 2014 benefit year risk corridors payments."). This deferral of payment violates the ACA. The risk corridors program requires payment on an annual basis. The risk corridors program was designed for issuers to share with the Government the financial risk of offering QHPs in the new Marketplaces for CY 2014, CY 2015, and CY 2016 and thus to encourage issuers to offer QHPs at lower premiums in the first three years of the Marketplaces. The effectiveness of the risk corridors program necessitates that the Government and participating health insurance issuers share financial risk *on an annual basis* in order to encourage issuers against building into premiums for QHPs sold in each of CY 2014, CY 2015, and CY 2016 an additional financial cushion due to the unknown cost of providing health insurance to the newly-covered population.

16. Pursuant to the Tucker Act, 28 U.S.C. § 1491, BCBS-AZ brings this action for money damages resulting from the Government's failure to pay BCBS-AZ for a share of its losses from the sale of QHPs in CY 2014, CY 2015, and CY 2016, as required by a money-mandating statute, § 1342 of the ACA, and its implied-in-fact contract with BCBS-AZ.

PARTIES

17. Plaintiff Blue Cross Blue Shield of Arizona, Inc. is a non-profit corporation formed under the laws of Arizona with its principal place of business at 2444 W. Las Palmaritas Drive, Phoenix, Arizona 85021. BCBS-AZ has offered and continues to offer QHPs on the Arizona Marketplace since its launch in 2014.

18. Defendant is the United States of America. HHS and CMS are agencies of Defendant.

JURISDICTION

19. Jurisdiction and venue in this Court are proper pursuant to the Tucker Act, 28 U.S.C. § 1491(a), which allows the United States Court of Federal Claims to hear claims for monetary damages against the United States “founded either upon the Constitution, or any Act of Congress, or any regulation of an executive department, or upon any express or implied contract with the Government, or for liquidated or unliquidated damages in cases not sounding in tort.”

20. Jurisdiction is founded on Section 1342 of the ACA, which specifies that the “Secretary shall establish and administer a program of risk corridors for calendar years 2014, 2015, and 2016,” 42 U.S.C. § 18062(a), and the implied-in-fact contract with the Government for payment of certain losses under the risk corridors program.

21. This controversy is ripe because CMS and HHS have recognized that additional amounts are presently due to BCBS-AZ for CY 2014, CY 2015, and CY 2016, but the Government has not paid those amounts in the manner required by Section 1342 of the ACA.

STATUTORY AND REGULATORY FRAMEWORK

22. The ACA substantially altered the rules governing the provision of health insurance coverage, including the pricing and benefits of health insurance coverage. Among other

things, the ACA provides that “each health insurance issuer that offers health insurance coverage in the individual . . . market in a State must accept every . . . individual in the State that applies for such coverage.” 42 U.S.C. §§ 300gg-1(a). The ACA also bars issuers from charging higher premiums on the basis of a person’s gender or health status, including pre-existing conditions. *See* 42 U.S.C. §§ 300gg-1. To prevent adverse selection that occurs when consumers wait to obtain coverage until they have an injury or illness, the ACA imposes a financial penalty on individuals who do not obtain health care coverage.

23. The ACA established the Marketplaces through which consumers purchasing coverage in the individual or small group markets could compare different QHPs. The Marketplaces provide a number of mechanisms, also established by the ACA, to make QHPs more affordable; these mechanisms include the availability of premium tax credits and cost-sharing subsidies for eligible consumers purchasing certain QHPs.

24. As a result of the ACA’s changes, insurers expected that a substantial number of people who had not previously had health insurance would purchase QHPs. Like all insurers, BCBS-AZ faced substantial uncertainty as to who would enroll, the health status of new enrollees, and the cost of providing health care coverage for these newly-insured individuals. At the time, neither the insurance industry, including BCBS-AZ, nor the Government, had data or models to accurately predict the total cost to provide this new coverage.

25. To mitigate the financial risk insurers faced due to these uncertainties, the ACA Section 1342 mandates a temporary risk corridors program through which all QHP issuers and the Government share in losses and profits exceeding certain thresholds for QHPs offered during the first three years of the Marketplaces’ operations. By enacting Section 1342 of the ACA, Congress recognized that, due to uncertainty about the population entering the Marketplaces

during the first few years, QHP issuers may not be able to predict their risk accurately, and their premiums may reflect assumptions regarding costs that are ultimately lower or higher than anticipated.

26. Congress intended the ACA's three-year risk corridors program to be an important protection for consumers and health insurance issuers as millions of Americans obtained newly available, affordable coverage in newly established Marketplaces. The risk corridors program was one of three premium stabilization programs intended to induce participation in the Marketplaces by reducing the potential financial loss posed to health insurers, like BCBS-AZ, when estimating enrollments and costs for the unknown population gaining access to affordable health care coverage. This risk mitigation program provided for sharing of the financial risk between the Government and issuers of QHPs in each of the first three years of the Marketplace.

27. The risk corridors program is designed to “protect against uncertainty in rate setting for qualified health plans by limiting the extent of issuers’ financial losses and gains.” 78 Fed. Reg. 15,410, 15,411 (Mar. 11, 2013) (Exhibit 1). In addition, the program is designed to maintain affordability in the first three years of the health insurance exchanges by “permit[ting] issuers to lower rates by not adding a risk premium to account for perceived uncertainties in the 2014 through 2016 markets.” *Id.* at 15,413. It does so by permitting the “Federal government and QHPs to share in profits or losses resulting from inaccurate rate setting from 2014 to 2016.” *Id.* at 15,412.

28. Section 1342(a) is the statutory mandate for the risk corridors program:

(a) IN GENERAL.—The Secretary **shall** establish and administer a program of risk corridors for calendar years 2014, 2015, and 2016 under which a qualified health plan offered in the individual or small group market **shall** participate in a payment adjustment system based on the ratio of the allowable costs of the plan to the

plan's aggregate premiums. Such program **shall** be based on the program for regional participating provider organizations under part D of title XVIII of the Social Security Act.

42 U.S.C. § 18062(a) (emphasis added).

29. Section 1342(b)(1) specifies when and how the Government must reimburse QHP Issuers, such as BCBS-AZ, for a share of losses sustained during CYs 2014, 2015, and 2016:

(a) PAYMENT METHODOLOGY. —

(1) PAYMENTS OUT.—The Secretary **shall** provide under the program established under subsection (a) that if—

(A) a participating plan's allowable costs for any plan year are more than 103 percent but not more than 108 percent of the target amount, the Secretary **shall** pay to the plan an amount equal to 50 percent of the target amount in excess of 103 percent of the target amount; and

(B) a participating plan's allowable costs for any plan year are more than 108 percent of the target amount, the Secretary **shall** pay to the plan an amount equal to the sum of 2.5 percent of the target amount plus 80 percent of allowable costs in excess of 108 percent of the target amount.

Id. § 18062(b)(1) (emphasis added). The “target amount” is premiums net the administrative costs of the QHP. *Id.* § 18062(c)(2).

30. Section 1342(b)(2) specifies when and how QHP issuers must pay a share of profits earned during CYs 2014, 2015, and 2016 to the Government:

(1) PAYMENTS IN.—The Secretary shall provide under the program established under subsection (a) that if—

(A) a participating plan's allowable costs for any plan year are less than 97 percent but not less than 92 percent of the target amount, the plan shall pay to the Secretary an amount equal to 50 percent of the excess of 97 percent of the target amount over the allowable costs; and

(B) a participating plan's allowable costs for any plan year are less than 92 percent of the target amount, the plan shall pay to the Secretary an amount equal to the sum of 2.5 percent of the target amount plus 80

percent of the excess of 92 percent of the target amount over the allowable costs.

Id. § 18062(b)(2). Section 1342 of the Affordable Care Act has not been amended or repealed since its enactment in 2010.

31. Consistent with Section 1342(a) of the ACA, HHS and CMS established regulations to further clarify their implementation of the risk corridors program. *See* 45 C.F.R. §§ 153.500 *et seq.*

32. Section 153.510 of the Code of Federal Regulations specifies the circumstances when the Government must pay QHP issuers for losses pursuant to the risk corridors program:

(b) HHS payments to health insurance issuers. **QHP issuers will receive payment** from HHS in the following amounts, **under the following circumstances:**

(1) When a QHP's allowable costs for any benefit year are more than 103 percent but not more than 108 percent of the target amount, **HHS will pay the QHP issuer** an amount equal to 50 percent of the allowable costs in excess of 103 percent of the target amount; and

(2) When a QHP's allowable costs for any benefit year are more than 108 percent of the target amount, **HHS will pay to the QHP issuer** an amount equal to the sum of 2.5 percent of the target amount plus 80 percent of allowable costs in excess of 108 percent of the target amount.

45 C.F.R. § 153.510 (emphasis added).

33. QHP issuers are obligated to bear the risk of potential gains and losses for offering QHPs on the Marketplaces *up to a specific threshold* set forth in Section 1342. Issuers of QHPs that pay more in benefits than they collect in premiums by a pre-determined percentage, though, are entitled under the risk corridors program to receive a payment from the Government, and issuers of QHPs that pay less in benefits than they collect in premiums by a pre-determined percentage must make a payment to the Government under the program. Thus, the risk corridors program allows issuers of QHPs and the Government to annually share in the risk of inaccurate

calculation of premiums for QHPs during the first three years of the Marketplaces.

34. If a QHP issuer such as BCBS-AZ owes the Government money under the program, the issuer must make that payment within 30 days after being notified of the amount owed. 45 C.F.R. § 153.510(d). The ACA equally calls for CMS and HHS to remit payment annually to QHP issuers on behalf of the Government.

35. HHS and CMS acknowledged in the Federal Register on July 15, 2011 and again on March 23, 2012, that “QHP issuers who are owed these amounts will want prompt payment” and that risk corridors “payment deadlines should be the same for HHS and QHP issuers.” 76 Fed. Reg. 41930, 41943 (July 15, 2011) (Exhibit 7); 77 Fed. Reg. 17220, 17238 (Mar. 23, 2012) (Exhibit 8). This prompt payment of amounts due for a prior benefit year is necessary to effectuate the purpose of the risk corridors program, to share between the Government and QHP issuers the financial risk associated with offering QHPs during the initial years of the Marketplaces and to encourage QHP issuers to refrain from increasing premiums in CYs 2014, 2015, and 2016 to account for the cost uncertainty in connection with the same.

36. In Section 1342(a), Congress instructed that the ACA risk corridors program “shall be based on the program for regional participating provider organizations under part D of title XVIII of the Social Security Act.” The referenced program is colloquially known as “Medicare Part D” – the program that provides Medicare coverage of outpatient prescription drugs. See Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, 42 U.S.C. §§ 1395w-101 *et seq.* (2003). Under Medicare Part D, HHS makes annual risk corridors payments to Part D Plan Sponsors without regard for budget neutrality. See Government Accountability Office, Report GAO-15-447, at 14 (April 2015) (“For the Medicare Advantage and Medicare Part D risk mitigation programs, the payments that

CMS makes to issuers are not limited to issuer contributions.”) (Exhibit 9). Although the statutory language for the ACA risk corridors program differs slightly from the Medicare Part D risk corridors program, the differences do not equate to an intentional departure from annual payments for the ACA risk corridors program. Rather, the express direction that the risk corridor program “shall be based on . . .” the Part D risk corridors program indicates Congress intended to incorporate into the ACA risk corridors program the key features of the Part D risk corridors program, including annual payments into and out of the program by the Government and participating issuers, and the absence of budget neutrality in such payments.

FACTUAL BACKGROUND

37. Since the enactment of the ACA, HHS and CMS have publicly acknowledged their statutory and regulatory obligation to make full and timely payments under the risk corridors program to BCBS-AZ and other QHP issuers.

38. These public statements by HHS and CMS were made by representatives of the Government who had actual authority to bind it, including but not limited to Kevin Counihan, Director of the CMS Center for Consumer Information and Insurance Oversight (“CCIIO”) and CEO of the Health Insurance Marketplaces, and his predecessors in that position; Andrew Slavitt, Administrator of CMS, and his predecessors in that position; and/or other CMS officials, all of whom had actual authority to bind the Government.

39. In March 2013, HHS issued the Notice of Benefit and Payment Parameters for 2014, the first year of the Marketplaces and the risk corridors program. HHS and CMS stated, “The risk corridors program is not statutorily required to be budget neutral. Regardless of the balance of payments and receipts, HHS will remit payments as required under section 1342 of the Affordable Care Act.” *See* 78 Fed. Reg. at 15,473 (Exhibit 1).

40. BCBS-AZ decided to participate in the individual market by selling QHPs both “on” and “off” the Arizona Marketplace. In designing and pricing its QHPs, BCBS-AZ relied on the Government’s representation that it would share in the risk of providing universal QHP coverage on the Marketplace by making annual payments under the risk corridors program.

41. For CY 2014, QHP issuers like BCBS-AZ had to elect to participate on the Marketplaces by September 2013, with open enrollment beginning on October 1, 2013. BCBS-AZ designed and priced its QHPs for CY 2014 in the spring and summer of 2013, and began selling these QHPs in October 2013. Coverage under the QHPs was effective on January 1, 2014.

42. On March 11, 2014, after BCBS-AZ had already designed, priced, and sold many of its CY 2014 QHPs in the Arizona Marketplace, and could no longer withdraw from selling QHPs for CY 2014, HHS proposed that its implementation of the risk corridors program would be budget neutral—that is, payments out under the program would be funded only by payments in. HHS’s proposed rulemaking stated:

We intend to implement this program in a budget neutral manner, and may make future adjustments, either upward or downward to this program (for example, as discussed below, we may modify the ceiling on allowable administrative costs) to the extent necessary to achieve this goal.

79 Fed. Reg. 13,744, 13,787 (Mar. 11, 2014) (Exhibit 10).

43. One month later, however, CMS abandoned its proposal to fund risk corridors payments solely by risk corridors receipts. Instead, CMS explained that “if risk corridors collections are insufficient to make risk corridors payments for a year, all risk corridors payments for that year will be reduced pro rata to the extent of any shortfall. Risk corridors collections received for the next year will first be used to pay off the payment reductions issuers experienced in the previous year” CMS, Risk Corridors Budget Neutrality, A1, Apr. 11, 2014 (Exhibit

11). HHS later explained that it “recognizes that the Affordable Care Act requires the Secretary to make full payments to issuers.” 80 Fed. Reg. 10,750, 10,779 (Feb. 27, 2015) (Exhibit 2). HHS stated that if “risk corridors collections . . . are insufficient to make risk corridors payments” after 2016, then “HHS will use other sources of funding for the risk corridors payments, subject to the availability of appropriations.” *Id.*

44. For CY 2015, QHP issuers had to elect to participate by October 2014, with open enrollment beginning on November 15, 2014. BCBS-AZ designed and priced its CY 2015 QHPs in the spring and summer of 2014, and began selling CY 2015 QHPs on the Marketplace in November 2014; the coverage was effective January 1, 2015.

45. In December 2014, Congress passed the Consolidated and Further Continuing Appropriations Act of 2015, which included an appropriations rider that prohibited CMS and HHS from using three specific sources of funds to make ACA risk corridors program payments:

SEC. 227. None of the funds made available by this Act from the Federal Hospital Insurance Trust Fund or the Federal Supplemental Medical Insurance Trust Fund, or transferred from other accounts funded by this Act to the “Centers for Medicare and Medicaid Services—Program Management” account, may be used for payments under section 1342(b)(1) of Public Law 111-148 (relating to risk corridors).

Pub. L. No. 113-235, at 362.

46. Congress’s failure to appropriate sufficient funds for the risk corridors program payments due for CY 2014 and the restrictions enacted on the use of funds “made available by this Act” did not modify or repeal ACA Section 1342 and did not affect the Government’s statutory obligation under Section 1342 to make a fully and timely risk corridor payment to BCBS-AZ. Moreover, the passage of the appropriations rider in December 2014 came more than a year after BCBS-AZ agreed to offer (and had priced, designed and sold) QHPs through the Arizona Marketplace and only two weeks before the end of BCBS-AZ’s provision of health

coverage under those plans for 2014. Thus, BCBS-AZ already had determined the premiums for QHPs sold on the Arizona Marketplace in CY 2014 and already had incurred significant losses by paying for health care services covered under these QHPs prior to the passage of the appropriations rider.

47. Furthermore, at the time of the enactment of the appropriation in December 2014, QHP issuers that intended to offer QHPs on the Marketplaces in CY 2015 had already been required to commit to participate in the Marketplaces for CY 2015. *See* 45 C.F.R. § 155 Subpart K; CCIIO, 2015 Letter to Issuers in Federally-facilitated Marketplaces, at 8, 27 (Mar. 14, 2014) (requiring issuers to commit by September 2014 to offer plans for the upcoming plan year) (Exhibit 12).

48. Once a QHP issuer has signed its QHP agreement with CMS, the issuer may not withdraw any of its QHPs from the Marketplaces and must accept all eligible applicants for coverage. *See* 45 C.F.R. § 156.290(a)(2); 45 C.F.R. § 147.104. Thus, by the time the December 2014 appropriations rider was enacted, BCBS-AZ already had incurred significant losses associated with offering QHPs in the Arizona Marketplace in CY 2014, had already designed and priced the QHPs BCBS-AZ would offer on the Arizona Marketplace in CY 2015 and already had committed to providing such QHPs on the Marketplace for CY 2015. BCBS-AZ could not reverse its losses for CY 2014, nor could BCBS-AZ withdraw its CY 2015 QHPs from the Marketplace, nor change the pricing for such QHPs, nor deny any eligible applicants such coverage.

49. On July 21, 2015, CMS issued a letter to state insurance commissioners for consideration as premium rates for CY 2016 were being finalized. The letter includes a paragraph entitled “CMS remains committed to the risk corridor program” and states a belief that the 2014 risk corridors payments should be taken into account before decisions are made on final rates for

2016. Letter from Kevin J. Counihan, CEO of Health Insurance Marketplaces, CMS, to State Insurance Commissioners (July 21, 2015) (Exhibit 13).

50. In 2014, the Government's share of BCBS-AZ's claimed losses under the risk corridors program is \$11,688,096.55, meaning BCBS-AZ was due that amount from CMS under the risk corridors program for CY 2014 even though BCBS-AZ incurred greater losses from offering QHPs in the Arizona Marketplace in CY 2014. CMS, Risk Corridors Payment and Charge Amounts for Benefit Year 2014, Nov. 19, 2015, at Table 3 (Exhibit 6).

51. On November 19, 2015, CMS announced that it would pay \$1,474,788.42 to BCBS-AZ during the winter of 2015-2016, which is only about 12.6 percent of payments due from the Government. *Id.* The Government calculated this percentage by prorating the \$363 million paid into the program by QHP issuers across the \$2.8 billion due to QHP issuers for 2014. *Id.*

52. Prior to this CMS announcement on November 19, 2015, CMS had required issuers like BCBS-AZ to design and price their CY 2016 QHPs, to decide whether to participate in the Marketplaces for CY 2016 and to begin selling CY 2016 QHPs. *See* CCIIO, FINAL 2016 Letter to Issuers in the Federally-facilitated Marketplaces (Feb. 20, 2015) (setting the deadline for commitment to offer plans by September 25, 2015 and the commencement of open enrollment as November 1, 2015) (Exhibit 14). BCBS-AZ was thus locked into participation in the Arizona Marketplace for each of the CYs 2015, and 2016 prior to HHS or CMS issuing statements that the full risk corridors program payment due for 2014 would not be paid and that BCBS-AZ would receive only a small pro rata share of the payment due.

53. In December 2015, Congress passed the Consolidated Appropriations Act, 2016, which included an appropriations rider that again prohibited CMS and HHS from using three specific sources of funds to make ACA risk corridors program payments:

None of the funds made available by this Act from the Federal Hospital Insurance Trust Fund or the Federal Supplemental Medical Insurance Trust Fund, or transferred from other accounts funded by this Act to the “Centers for Medicare and Medicaid Services—Program Management” account, may be used for payments under section 1342(b)(1) of Public Law 111-148 (relating to risk corridors).

Pub. L. No. 114-113.

54. Again, this restriction on the use of funds “made available by this Act” did not modify or repeal Section 1342 of the Affordable Care Act or otherwise change the Government’s statutory obligation to make payment to BCBS-AZ under Section 1342.

55. In September 2016, CMS announced that it would make additional risk corridors payments to QHP issuers during the winter of 2016-2017 for their CY 2014 losses. CMS, Risk Corridors Payments for 2015, Sept. 9, 2016 (Exhibit 4). CMS further announced that it would make no risk corridors payments for CY 2015 losses during the winter of 2016-2017. *Id.*

56. On November 18, 2016, CMS confirmed that none of its CY 2015 risk corridors collections would be used to pay CY 2015 risk corridors payments. CMS, Risk Corridors Payment and Charge Amounts for the 2015 Benefit Year, Nov. 18, 2016 (Exhibit 5).

57. On November 18, 2016, CMS announced that it would pay an additional \$388,258.91 to BCBS-AZ for its CY 2014 losses, beginning in December 2016 (as collections are received). *Id.*

58. In May 2017, Congress passed the Consolidated Appropriations Act, 2017, which again included an appropriations rider that prohibited CMS and HHS from using three specific sources of funds to make ACA risk corridors program payments:

SEC. 223. None of the funds made available by this Act from the Federal Hospital Insurance Trust Fund or the Federal Supplemental Medical Insurance Trust Fund, or transferred from other accounts funded by this Act to the “Centers for Medicare and Medicaid—Program Management” account, may be used for payments under Section 1342(b)(1) of Public Law 111-148 (relating to risk corridors).

Pub. L. No. 115-31. This restriction on the use of funds “made available by this Act” did not modify or repeal Section 1342 of the Affordable Care Act or otherwise change the Government’s statutory obligation to make payment to BCBS-AZ under Section 1342.

59. On November 15, 2017, CMS announced that none of its CY 2016 risk corridors collections would be used to pay CY 2015 or CY 2016 risk corridors payments. CMS, Risk Corridors Payment and Charge Amounts for the 2016 Benefit Year, Nov. 15, 2017 (Exhibit 15). Furthermore, according to CMS, BCBS-AZ will only be paid an additional \$101,672.21 for its CY 2014 losses. *Id.*

60. To date, BCBS-AZ received from CMS only \$1,957,224.44 owed to it for CY 2014. BCBS-AZ has received no payments from CMS for CY 2015 or CY 2016.

61. BCBS-AZ offered QHPs in the Arizona Marketplace for each of the CYs 2014, 2015, and 2016 to which the risk corridors program applies, and BCBS-AZ has complied in all material respects with all of the statutory and regulatory requirements to be eligible for the Government’s payment of its share of its losses under the risk corridors program, but BCBS-AZ has not been paid. *See* 45 C.F.R. § 153.500 *et seq.*

62. Congress’ failure to appropriate sufficient funds for risk corridors payments due for CYs 2014, 2015, and 2016, without modifying or repealing Section 1342 of the ACA, did not eliminate or abrogate the Government’s obligation to make full and timely risk corridors payments to QHP issuers, including BCBS-AZ.

63. HHS recorded the 2014 amounts “that remain unpaid . . . as fiscal year 2015 obligation[s] of the United States Government for which full payment is required.” CMS, Risk Corridors Payments for the 2014 Benefit Year, Nov. 19, 2015 (Exhibit 3). In September 2016, HHS announced that it was recording the 2014 and 2015 amounts that would remain unpaid as fiscal year 2016 obligations for which full payment is required. *See* CMS, Risk Corridors Payments for 2015, Sept. 9, 2016 (Exhibit 4). In November 2017, HHS announced 2016 risk corridors charges collected would be used for 2014 benefit year payment balances. CMS, Risk Corridors Payment and Charge Amounts for the 2016 Benefit Year, Nov. 15, 2017 (Exhibit 15). Payment is presently due for the remainder of the Government’s share of BCBS-AZ’s losses from the sale of QHPs in the Arizona Marketplace in CYs 2014, 2015, and 2016. No appropriation is available, however, for HHS to make the payment.

64. On June 17, 2016, BCBS-AZ sent a demand letter to HHS and CMS for prompt payment of the amounts due and owing to BCBS-AZ under the risk corridors program. As of this filing, BCBS-AZ has received no response from HHS or CMS.

COUNT I

Violation of Statutory Mandate to Make Payments

65. BCBS-AZ incorporates by reference paragraphs 1 through 64 above as if fully set forth herein.

66. Pursuant to Section 1342 of the ACA, the United States “shall establish” a risk corridors program under which the “Secretary shall pay to the plan an amount equal to the sum of 2.5 percent of the target amount plus 80 percent of allowable costs in excess of 108 percent of the target amount” for CYs 2014, 2015, and 2016.

67. BCBS-AZ offered certified QHPs on the Arizona Marketplace in accordance with the processes prescribed by statute and regulation, and BCBS-AZ is a QHP issuer for purposes of payment under the risk corridors program. *See* 45 C.F.R. §§ 153.500, 155.20.

68. In 2014, 2015, and 2016, BCBS-AZ's allowable costs exceeded its target amount by more than 108%. BCBS-AZ timely submitted all of the necessary data and complied with all other requirements for obtaining a payment under the risk corridors program. *See* 45 C.F.R. § 153.530.

69. Accordingly, ACA § 1342 mandates payment to BCBS-AZ in the amount of \$11,688,096.55 for CY 2014, \$51,990,665.22 for CY 2015, and \$10,845,468.60 for CY 2016.

70. To date, the Government has made payments to BCBS-AZ in the amounts of \$1,957,224.44 for CY 2014, \$0 for CY 2015, and \$0 for CY 2016.

71. BCBS-AZ is entitled to damages for the Government's failure to provide full payments required by ACA § 1342 to BCBS-AZ in the amounts of \$9,730,872.11 for CY 2014, \$51,990,665.22 for CY 2015, and \$10,845,468.60 for CY 2016.

COUNT II

Breach of Implied-In-Fact Contract

72. BCBS-AZ incorporates by reference paragraphs 1 through 71 above as if fully set forth herein.

73. BCBS-AZ entered into a valid implied-in-fact contract with the Government regarding its obligation to make full and timely payments under the risk corridors program to BCBS-AZ in exchange for BCBS-AZ becoming a QHP issuer and offering QHPs on the Arizona Marketplace in CYs 2014, 2015, and 2016.

74. The Government made an unambiguous offer to BCBS-AZ of a contract, provided that BCBS-AZ fulfilled certain criteria, which BCBS-AZ could accept by performance.

75. Specifically, ACA § 1342 authorized HHS to enter into contracts to share in the profits and losses of issuers who offered QHPs on the Marketplaces in CYs 2014, 2015, and 2016. HHS's Notices of Benefit and Payment Parameters represented an offer to BCBS-AZ that if it sold QHPs, "[r]egardless of the balance of payments and receipts, HHS will remit payment as required under section 1342 of the Affordable Care Act," 78 Fed. Reg. at 15,473, meaning the Government would reimburse BCBS-AZ for a share of its losses if its allowable costs were "more than 108 percent of the target amount," 42 U.S.C. § 18062(b)(1)(B).

76. ACA § 1342 is an objective manifestation of the Government's intent to contract with insurers like BCBS-AZ.

77. By complying with its obligations under Section 1342 as well as 45 C.F.R. § 153.500, *et seq.*, and submitting all required data for risk corridors calculations by the deadline, BCBS-AZ accepted the Government's offer and thereby manifested BCBS-AZ's assent in the manner required by the ACA.

78. There was an implied-in-fact contract between BCBS-AZ and the Government.

79. The implied-in-fact contract was authorized or ratified by and through the words and actions of Kevin Counihan, Director of CCIIO and CEO of the Health Insurance Marketplaces, and his predecessors in that position; Andrew Slavitt, Administrator of CMS, and his predecessors in that position; and/or other CMS officials, all of whom had actual authority to bind the Government, and was entered into with the mutual assent and consideration by both parties.

80. BCBS-AZ satisfied and complied with its obligations and/or conditions that existed under the implied-in-fact contract.

81. Pursuant to the implied-in-fact contract, the Government was obliged to reimburse BCBS-AZ for the Government's share of BCBS-AZ's eligible losses of \$11,688,096.55 for CY 2014, \$51,990,665.22 for CY 2015, and \$10,845,468.60 for CY 2016.

82. On behalf of the Government, CMS and HHS have acknowledged their obligation to render full risk corridors payments.

83. BCBS-AZ is entitled to damages equal to the benefit of its bargain with the Government: reimbursement as alleged in this lawsuit.

84. The Government breached its contract with BCBS-AZ by failing to timely pay BCBS-AZ the full amount owed for CYs 2014, 2015, and 2016 in accordance with the terms of the risk corridors program.

85. BCBS-AZ has not been paid amounts owed by the Government for CYs 2014, 2015, and 2016, which has resulted in injury and damages to BCBS-AZ as a result of the Government's breach of its contractual obligations in the amount of \$9,730,872.11 for CY 2014, \$51,990,665.22 for CY 2015, and \$10,845,468.60 for CY 2016.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff BCBS-AZ prays for judgment as follows:

A. Award BCBS-AZ monetary damages of \$72,567,005.93 for the Government's nonpayment of the amount to which BCBS-AZ is entitled under Section 1342 of the ACA for CY 2014, CY 2015, and CY 2016, and any such other amounts due through the date of judgment;

B. Award post-judgment interest at the maximum rate permitted by law;

C. Award BCBS-AZ consequential damages, special damages, or other damages that result as a consequence of the Government's non-performance;

D. Award BCBS-AZ costs and attorney's fees as are available under applicable law;
and

E. Award such other relief with respect to all risk corridor payments due BCBS-AZ
under the risk corridors program for CY 2014 through CY 2016 as justice may require.

Dated: May 15, 2020

Respectfully Submitted:

/s/ Robert K. Huffman

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EXHIBIT 1



FEDERAL REGISTER

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Part II

Department of Health and Human Services

45 CFR Parts 153, 155, 156, et al.

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2014 and Amendments to the HHS Notice of Benefit and Payment Parameters for 2014; Final Rules; Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Small Business Health Options Program; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES**45 CFR Parts 153, 155, 156, 157 and 158****[CMS–9964–F]****RIN 0938–AR51****Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2014**

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule provides detail and parameters related to: the risk adjustment, reinsurance, and risk corridors programs; cost-sharing reductions; user fees for Federally-facilitated Exchanges; advance payments of the premium tax credit; the Federally-facilitated Small Business Health Option Program; and the medical loss ratio program. Cost-sharing reductions and advance payments of the premium tax credit, combined with new insurance market reforms, are expected to significantly increase the number of individuals with health insurance coverage, particularly in the individual market. In addition, we expect the premium stabilization programs—risk adjustment, reinsurance, and risk corridors—to protect against the effects of adverse selection. These programs, in combination with the medical loss ratio program and market reforms extending guaranteed availability (also known as guaranteed issue) and prohibiting the use of factors such as health status, medical history, gender, and industry of employment to set premium rates, will help to ensure that every American has access to high-quality, affordable health insurance.

DATES: This final rule is effective on April 30, 2013.

FOR FURTHER INFORMATION CONTACT:

Sharon Arnold, (301) 492–4286; Laurie McWright, (301) 492–4311; or Jeff Wu, (301) 492–4305, for general information.

Kelly Horney, (410) 786–0558, for matters related to the risk adjustment program generally.

Michael Cohen, (301) 492–4277, for matters related to the risk adjustment methodology and the methodology for determining the reinsurance contribution rate and payment parameters.

Adrianne Glasgow, (410) 786–0686, for matters related to the reinsurance program.

Jaya Ghildiyal, (301) 492–5149, for matters related to the risk corridors

program and user fees for Federally-facilitated Exchanges.

Johanna Lauer, (301) 492–4397, for matters related to cost-sharing reductions and advance payments of the premium tax credit.

Bobbie Knickman, (410) 786–4161, for matters related to the distributed data collection approach for the HHS-operated risk adjustment and reinsurance programs.

Rex Cowdry, (301) 492–4387, for matters related to the Small Business Health Options Program.

Carol Jimenez, (301) 492–4457, for matters related to the medical loss ratio program.

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Acronyms

Affordable Care Act The Affordable Care Act of 2010 (which is the collective term for the Patient Protection and Affordable Care Act (Pub. L. 111–148) and the Health Care and Education Reconciliation Act (Pub. L. 111–152))

APTC Advance payments of the premium tax credit

ASO Administrative services only contractor

AV Actuarial Value

CFR Code of Federal Regulations

CHIP Children's Health Insurance Program

CMS Centers for Medicare & Medicaid Services

COBRA Consolidated Omnibus Budget Reconciliation Act

EHB Essential health benefits

ERISA Employee Retirement Income Security Act

FFE Federally-facilitated Exchange

FF-SHOP Federally-facilitated Small Business Health Options Program Exchange
 FPL Federal poverty level
 HCC Hierarchical condition category
 HHS United States Department of Health and Human Services
 HIPAA Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-191)
 IHS Indian Health Service
 IRS Internal Revenue Service
 MLR Medical loss ratio
 NAIC National Association of Insurance Commissioners
 OMB United States Office of Management and Budget
 OPM United States Office of Personnel Management
 PHS Act Public Health Service Act
 PRA Paperwork Reduction Act of 1985
 QHP Qualified health plan
 SHOP Small Business Health Options Program
 The Code Internal Revenue Code of 1986
 TPA Third party administrator

I. Executive Summary

A. Purpose

Beginning in 2014, individuals and small businesses will be able to purchase private health insurance through competitive marketplaces called Affordable Insurance Exchanges, “Exchanges,” or “Marketplaces.” Individuals who enroll in qualified health plans through Exchanges may receive premium tax credits that make health insurance more affordable and financial assistance to cover some or all cost sharing for essential health benefits. We expect that the premium tax credits, combined with the new insurance reforms, will significantly increase the number of individuals with health insurance coverage, particularly in the individual market. Premium stabilization programs—risk adjustment, reinsurance, and risk corridors—are expected to protect against the effects of adverse selection. These programs, in combination with the medical loss ratio program and market reforms extending guaranteed availability (also known as guaranteed issue), and prohibiting the use of factors such as health status, medical history, gender, and industry of employment to set premium rates, will help to ensure that every American has access to high-quality, affordable health care.

Premium stabilization programs: The Affordable Care Act establishes a permanent risk adjustment program, a transitional reinsurance program, and a temporary risk corridors program to provide payments to health insurance issuers that cover higher-risk populations and to more evenly spread the financial risk borne by issuers.

The transitional reinsurance program and the temporary risk corridors program, which begin in 2014, are designed to provide issuers with greater payment stability as insurance market reforms are implemented and Exchanges facilitate increased enrollment. The reinsurance program will reduce the uncertainty of insurance risk in the individual market by partially offsetting issuers’ risk associated with high-cost enrollees. The risk corridors program will protect against uncertainty in rate setting for qualified health plans by limiting the extent of issuers’ financial losses and gains. On an ongoing basis, the risk adjustment program is intended to provide increased payments to health insurance issuers that attract higher-risk populations, such as those with chronic conditions, and reduce the incentives for issuers to avoid higher-risk enrollees. Under this program, funds are transferred from issuers with lower-risk enrollees to issuers with higher-risk enrollees.

In the Premium Stabilization Rule¹ we laid out a regulatory framework for these three programs. In that rule, we stated that the specific payment parameters for those programs would be published in this final rule. In this final rule, we describe these standards, and include payment parameters for these programs.

Advance payments of the premium tax credit and cost-sharing reductions: This final rule establishes standards for advance payments of the premium tax credit and for cost-sharing reductions. These programs assist eligible low- and moderate-income Americans in affording health insurance on an Exchange. Section 1401 of the Affordable Care Act amended the Internal Revenue Code (26 U.S.C.) to add section 36B, allowing an advance, refundable premium tax credit to help individuals and families afford health insurance coverage. Section 36B of the Code was subsequently amended by the Medicare and Medicaid Extenders Act of 2010 (Pub. L. 111-309) (124 Stat. 3285 (2010)); the Comprehensive 1099 Taxpayer Protection and Repayment of Exchange Subsidy Overpayments Act of 2011 (Pub. L. 112-9) (125 Stat. 36 (2011)); and the Department of Defense and Full-Year Continuing Appropriations Act, 2011 (Pub. L. 112-10) (125 Stat. 38 (2011)). The section 36B credit is designed to make a qualified health plan (QHP) purchased on an Exchange affordable by reducing an eligible taxpayer’s out-of-pocket premium cost.

Under sections 1401, 1411, and 1412 of the Affordable Care Act and 45 CFR part 155 subpart D, an Exchange makes an advance determination of tax credit eligibility for individuals who enroll in QHP coverage through the Exchange and seek financial assistance. Using information available at the time of enrollment, the Exchange determines whether the individual meets the income and other requirements for advance payments and the amount of the advance payments that can be used to pay premiums. Advance payments are made periodically under section 1412 of the Affordable Care Act to the issuer of the QHP in which the individual enrolls.

Section 1402 of the Affordable Care Act provides for the reduction of cost sharing for certain individuals enrolled in a QHP through an Exchange, and section 1412 of the Affordable Care Act provides for the advance payment of these reductions to issuers. This assistance will help eligible low- and moderate-income qualified individuals and families afford the out-of-pocket spending associated with health care services provided through Exchange-based QHP coverage. The statute directs issuers to reduce cost sharing for essential health benefits for individuals with household incomes between 100 and 400 percent of the Federal poverty level (FPL) who are enrolled in a silver level QHP through an individual market Exchange and are eligible for advance payments of the premium tax credit. The statute also directs issuers to eliminate cost sharing for Indians (as defined in section 4(d) of the Indian Self-Determination and Education Assistance Act) with a household income at or below 300 percent of the FPL who are enrolled in a QHP of any “metal” level (that is, bronze, silver, gold, or platinum) through the individual market in the Exchange, and prohibits issuers of QHPs from requiring cost sharing for Indians, regardless of household income, for items or services furnished directly by the Indian Health Service, an Indian Tribe, a Tribal Organization, or an Urban Indian Organization, or through referral under contract health services.

HHS published a bulletin² outlining an intended regulatory approach to calculating actuarial value and implementing cost-sharing reductions on February 24, 2012 (AV/CSR Bulletin). The AV/CSR Bulletin outlined an intended regulatory approach governing the calculation of AV, de minimis variation standards, silver plan

¹ 77 FR 17220 (March 23, 2012).

² Available at: <http://cciio.cms.gov/resources/files/Files2/02242012/Av-csr-bulletin.pdf>.

variations for individuals eligible for cost-sharing reductions, and advance payments of cost-sharing reductions to issuers, among other topics. In the Exchange Establishment Rule,³ we set forth eligibility standards for these cost-sharing reductions. In this final rule, we make minor revisions to the eligibility standards for families and establish standards governing the administration of cost-sharing reductions and provide specific payment parameters for the program.

Federally-facilitated Exchange user fees: Section 1311(d)(5)(A) of the Affordable Care Act contemplates an Exchange charging assessments or user fees to participating issuers to generate funding to support its operations. When operating a Federally-facilitated Exchange under section 1321(c)(1) of the Affordable Care Act, HHS has the authority under sections 1321(c)(1) and 1311(d)(5)(A) of the statute to collect and spend such user fees. In addition, 31 U.S.C. 9701 permits a Federal agency to establish a charge for a service provided by the agency. Office of Management and Budget Circular A-25 Revised (Circular A-25R) establishes Federal policy regarding user fees and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public. In this final rule, we establish a user fee for issuers participating in a Federally-facilitated Exchange.

Small Business Health Options Program (SHOP): Section 1311(b)(1)(B) of the Affordable Care Act directs each State that chooses to operate an Exchange to establish a SHOP that provides QHP options for small businesses. The Exchange Establishment Rule sets forth standards for the administration of SHOP Exchanges. In this final rule, we clarify and expand upon the standards established in the Exchange Establishment Rule.

Medical loss ratio (MLR) program: Section 2718 of the Public Health Service Act (PHS Act) generally requires health insurance issuers to submit an annual MLR report to HHS and provide rebates of premium if they do not achieve specified MLRs. On December 1, 2010, we published an interim final rule entitled “Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements under the Patient Protection and Affordable Care Act” (75 FR 74864) which established standards for the MLR program. Since then, we have made several revisions and technical corrections to those rules. This

final rule amends the regulations to specify how issuers are to account for payments or receipts from the risk adjustment, reinsurance, and risk corridors programs, and to change the timing of the annual MLR report and distribution of rebates required of issuers to account for the premium stabilization programs. This final rule also amends the regulations to revise the treatment of community benefit expenditures in the MLR calculation for issuers exempt from Federal income tax to promote a level playing field.

B. Summary of the Major Provisions

This final rule fills in the framework established by the Premium Stabilization Rule with provisions and parameters for the three premium stabilization programs—the permanent risk adjustment program, the transitional reinsurance program, and the temporary risk corridors program. It also establishes key provisions governing advance payments of the premium tax credit, cost-sharing reductions, and user fees for Federally-facilitated Exchanges. Finally, the final rule includes a number of amendments relating to the SHOP and the MLR program.

Risk Adjustment: The goal of the Affordable Care Act risk adjustment program is to mitigate the impact of possible adverse selection and stabilize the premiums in the individual and small group markets as and after insurance market reforms are implemented. We are finalizing a number of standards and parameters for implementing the risk adjustment program, including:

- Provisions governing a State operating a risk adjustment program;
- The risk adjustment methodology HHS will use when operating risk adjustment on behalf of a State, including the risk adjustment model, the payments and charges methodology, and the data collection approach; and
- An outline of the data validation process we expect to use when operating risk adjustment on behalf of a State.

Reinsurance: The Affordable Care Act directs that a transitional reinsurance program be established in each State to help stabilize premiums for coverage in the individual market from 2014 through 2016. In this final rule, we establish a number of standards and parameters for implementing the reinsurance program, including:

- Provisions excluding certain types of health insurance coverage and plans from reinsurance contributions;
- The national per capita contribution rate and the methodology for calculating

the contributions to be paid by health insurance issuers and self-insured group health plans;

- Provisions establishing eligibility for reinsurance payments;
- The uniform reinsurance payment parameters and the approach that HHS will use to calculate and administer the reinsurance program on behalf of a State; and
- The distributed data collection approach we will use to implement the reinsurance program.

Risk Corridors: The temporary risk corridors program permits the Federal government and QHPs to share in profits or losses resulting from inaccurate rate setting from 2014 through 2016. We are finalizing a change to the risk corridors calculation in which reinsurance contributions will be treated as a regulatory fee instead of an adjustment to allowable costs, and are replacing the term “taxes” in our proposed definition of taxes with the term “taxes and regulatory fees.” We are also finalizing provisions governing the treatment of profits and taxes and regulatory fees within the risk corridors calculation. This provision aligns the risk corridors calculation with the MLR calculation. We are also finalizing an annual schedule for the program and standards for data submissions.

Advance Payments of the Premium Tax Credit: Sections 1401 and 1411 of the Affordable Care Act provide for advance payments of the premium tax credit for low- and moderate-income enrollees in a QHP through an Exchange. In this final rule, we are finalizing a number of standards governing the administration of this program, including:

- Provisions governing the reduction of premiums by the amount of any advance payments of the premium tax credit; and
- Provisions governing the allocation of premiums to essential health benefits.

Cost-Sharing Reductions: Sections 1402 and 1412 of the Affordable Care Act provide for reductions in cost sharing on essential health benefits for low- and moderate-income enrollees in silver level health plans offered in the individual market on Exchanges. It also provides for reductions in cost sharing for Indians enrolled in QHPs at any metal level. In this final rule, we establish a number of standards governing the cost-sharing reduction program, including:

- Provisions governing the design of variations of QHPs with cost-sharing structures for enrollees of various income levels and for Indians to implement cost-sharing reductions;

³ 77 FR 18310 (March 27, 2012).

- The maximum annual limitations on cost sharing applicable to the plan variations;
- Provisions governing the assignment and reassignment of enrollees to plan variations based on eligibility for cost-sharing reductions;
- Provisions governing issuer submissions of estimates of cost-sharing reductions, which are paid in advance to QHP issuers by the Federal government; and
- Provisions governing reconciliation of these advance estimates against actual cost-sharing reductions provided.

User Fees: This final rule establishes a user fee, calculated as a percentage of the premium for a QHP, applicable to issuers participating in a Federally-facilitated Exchange. This final rule also outlines HHS's approach to calculating the fee.

SHOP: Beginning in 2014, SHOP Exchanges will allow small employers to offer employees a variety of QHPs. In this final rule, we establish a number of standards and processes for implementing SHOP Exchanges, including:

- Standards governing the definitions and counting methods used to determine whether an employer is a small or large employer and whether an employee is a full-time employee;
- A method for employers to make a QHP available to employees in the Federally-facilitated SHOP (FF-SHOP);
- The default minimum participation rate in the FF-SHOP;
- QHP standards linking FFE and FF-SHOP participation and ensuring broker commissions in FF-SHOP that are the same as those in the outside market; and
- Allowing Exchanges and SHOPs to selectively list only brokers registered with the Exchange or SHOP (and adopting that policy for FFEs and FF-SHOPs).

MLR: The MLR program requires an issuer to rebate a portion of premiums if its medical loss ratio falls short of the applicable standard for the reporting year. This ratio is calculated as the sum of health care claims costs and amounts spent on quality improvement activities divided by premium revenue, excluding taxes and regulatory fees, and after accounting for the premium stabilization programs. In this final rule, we establish a number of standards governing the MLR program, including:

- Provisions accounting for risk adjustment, reinsurance, and risk corridors payments and charges in the MLR calculation;
- A revised timeline for MLR reporting and rebates; and
- Provisions modifying the treatment of community benefit expenditures.

C. Costs and Benefits

The provisions of this final rule, combined with other provisions in the Affordable Care Act, will improve the individual insurance market by making insurance more affordable and accessible to millions of Americans who currently do not have affordable options available to them. The shortcomings of the individual market today have been widely documented.⁴

These limitations of the individual market are made evident by how few people actually purchase coverage in the individual market. In 2011, approximately 48.6 million people were uninsured in the United States,⁵ while only around 10.8 million were enrolled in the individual market.⁶ The relatively small fraction of the target market that actually purchases coverage in the individual market in part reflects people's resources, how expensive the product is relative to its value, and how difficult it is for many people to access coverage.

The provisions of this final rule, combined with other provisions in the Affordable Care Act, will improve the functioning of both the individual and the small group markets while stabilizing premiums. The transitional reinsurance program will help to stabilize premiums in the individual market. Reinsurance will attenuate individual market rate increases that might otherwise occur because of the immediate enrollment of higher risk individuals, potentially including those currently in State high-risk pools. In 2014, it is anticipated that reinsurance payments will result in premium decreases in the individual market of between 10 and 15 percent relative to the expected cost of premiums without reinsurance.

The risk corridors program will protect QHP issuers in the individual and small group market against inaccurate rate setting and will permit issuers to lower rates by not adding a

risk premium to account for perceived uncertainties in the 2014 through 2016 markets.

The risk adjustment program protects against the potential of adverse selection by allowing issuers to set premiums according to the average actuarial risk in the individual and small group market without respect to the type of risk selection the issuer would otherwise expect to experience with a specific product offering in the market. This should lower the risk issuers would otherwise price into premiums in the expectation of enrolling individuals with unknown health status. In addition, it mitigates the incentive for health plans to avoid unhealthy members. The risk adjustment program also serves to level the playing field inside and outside of the Exchange.

Provisions addressing advance payments of the premium tax credit and cost-sharing reductions will help provide financial assistance for certain eligible individuals enrolled in QHPs through the Exchanges. This assistance will help many low-and moderate-income individuals and families obtain health insurance. For many people, cost sharing is a significant barrier to obtaining needed health care.⁷ The availability of premium tax credits and cost-sharing reductions through Exchanges starting in 2014 will result in lower net premium rates for many people currently purchasing coverage in the individual market, and will encourage younger and healthier enrollees to enter the market, leading to a healthier risk pool and to reductions in premium rates for current policyholders.⁸

The provisions addressing SHOP Exchanges will reduce the burden and costs of enrolling employees in small group plans, and give small businesses many of the cost advantages and choices that large businesses already have. Additionally, SHOP Exchanges will

⁴ Michelle M. Doty et al., *Failure to Protect: Why the Individual Insurance Market Is Not a Viable Option for Most U.S. Families: Findings from the Commonwealth Fund Biennial Health Insurance Survey, 2007*, The Commonwealth Fund, July 2009; Sara R. Collins, *Invited Testimony: Premium Tax Credits Under The Affordable Care Act: How They Will Help Millions Of Uninsured And Underinsured Americans Gain Affordable, Comprehensive Health Insurance*, The Commonwealth Fund, October 27, 2011.

⁵ Source: U.S. Census Bureau, *Current Population Survey, 2012 Annual Social and Economic Supplement*, Table HI01. *Health Insurance Coverage Status and Type of Coverage by Selected Characteristics*: 2011.

⁶ Source: CMS analysis of June 2012 Medical Loss Ratio Annual Reporting data for 2011 MLR reporting year, available at <http://ccio.cms.gov/resources/data/mlr.html>.

⁷ Brook, Robert H., John E. Ware, William H. Rogers, Emmett B. Keeler, Allyson Ross Davies, Cathy D. Sherbourne, George A. Goldberg, Kathleen N. Lohr, Patricia Camp and Joseph P. Newhouse, *The Effect of Coinsurance on the Health of Adults: Results from the RAND Health Insurance Experiment*. Santa Monica, CA: RAND Corporation, 1984. Available at: <http://www.rand.org/pubs/reports/R3055>.

⁸ Congressional Budget Office, *Letter to Honorable Evan Bayh, providing an Analysis of Health Insurance Premiums Under the Patient Protection and Affordable Care Act*, November 30, 2009; Sara R. Collins, *Invited Testimony: Premium Tax Credits Under The Affordable Care Act: How They Will Help Millions Of Uninsured And Underinsured Americans Gain Affordable, Comprehensive Health Insurance*, The Commonwealth Fund, October 27, 2011; Fredric Blavin et al., *The Coverage and Cost Effects of Implementation of the Affordable Care Act in New York State*, Urban Institute, March 2012.

allow for small employers to preserve control over health plan choices while saving employers money by spreading issuers' administrative costs across more employers.

The provisions addressing the MLR program will result in a more accurate calculation of MLR and rebate amounts, since it will reflect issuers' claims-related expenditures, after adjusting for the premium stabilization programs.

Issuers may incur some one-time fixed costs to comply with the provisions of the final rule, including administrative and hardware costs. However, issuer revenues and expenditures are also expected to increase substantially as a result of the expected increase in the number of people purchasing individual market coverage. In addition, States may incur administrative and operating costs if they choose to establish their own programs. In accordance with Executive Orders 12866 and 13563, we believe that the benefits of this regulatory action would justify the costs.

II. Background

Starting in 2014, individuals and small businesses will be able to purchase qualified health plans—private health insurance that has been certified as meeting certain standards—through competitive marketplaces, called Exchanges. The Department of Health and Human Services, the Department of Labor, and the Department of the Treasury have been working in close coordination to release guidance related to qualified health plans and Exchanges in several phases. The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act (Pub. L. 111–152) was enacted on March 30, 2010. We refer to the two statutes collectively as the Affordable Care Act in this final rule. HHS published detail and parameters related to the risk adjustment, reinsurance, and risk corridors programs; cost-sharing reductions; user fees for Federally-facilitated Exchanges; advance payments of the premium tax credit; the Federally-facilitated Small Business Health Option Program; and the medical loss ratio program, in a December 7, 2012 **Federal Register** proposed rule entitled “Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2014” (77 FR 73118).

A. Premium Stabilization

A proposed regulation was published in the **Federal Register** on July 15, 2011 (76 FR 41930) to implement health

insurance premium stabilization policies in the Affordable Care Act. The Premium Stabilization Rule implementing the health insurance premium stabilization programs (that is, risk adjustment, reinsurance, and risk corridors) (Premium Stabilization Rule) (77 FR 17220) was published in the **Federal Register** on March 23, 2012. A white paper on risk adjustment concepts was published on September 12, 2011 (Risk Adjustment White Paper). A bulletin was published on May 1, 2012, outlining our intended approach to implementing risk adjustment when we are operating risk adjustment on behalf of a State (Risk Adjustment Bulletin). On May 7 and 8, 2012, we hosted a public meeting in which we discussed that approach (Risk Adjustment Spring Meeting).

A bulletin was published on May 31, 2012, outlining our intended approach to making reinsurance payments to issuers when we are operating the reinsurance program on behalf of a State (Reinsurance Bulletin). HHS solicited comment on proposed operations for both reinsurance and risk adjustment when we are operating the program on behalf of a State.

B. Cost-Sharing Reductions

The AV/CSR Bulletin was published on February 24, 2012 outlining an intended regulatory approach to calculating actuarial value and implementing cost-sharing reductions. In that bulletin, we outlined an intended regulatory approach for the design of plan variations for individuals eligible for cost-sharing reductions and advance payments and reimbursement of cost-sharing reductions to issuers, among other topics. We reviewed and considered comments to the AV/CSR Bulletin in developing the provisions relating to cost-sharing reductions in this final rule.

C. Advance Payments of the Premium Tax Credit

A proposed regulation relating to the health insurance premium tax credit was published by the Department of the Treasury in the **Federal Register** on August 17, 2011 (76 FR 50931). A final rule relating to the health insurance premium tax credit was published by the Department of the Treasury in the **Federal Register** on May 23, 2012 (77 FR 30377, to be codified at 26 CFR parts 1 and 602).

D. Exchanges

A Request for Comment relating to Exchanges was published in the **Federal Register** on August 3, 2010 (75 FR 45584). An Initial Guidance to States on

Exchanges was issued on November 18, 2010. A proposed regulation was published in the **Federal Register** on July 15, 2011 (76 FR 41866) to implement components of the Exchange. A proposed regulation regarding Exchange functions in the individual market, eligibility determinations, and Exchange standards for employers was published in the **Federal Register** on August 17, 2011 (76 FR 51202). A final rule implementing components of the Exchanges and setting forth standards for eligibility for Exchanges (Exchange Establishment Rule) was published in the March 27, 2012 **Federal Register** (77 FR 18310).

A proposed rule which, among other things, reflects new statutory eligibility provisions, titled “Medicaid, Children’s Health Insurance Programs, and Exchanges: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes for Medicaid and Exchange Eligibility Appeals and Other Provisions Related to Eligibility and Enrollment for Exchanges, Medicaid and CHIP, and Medicaid Premiums and Cost Sharing” was published in the January 22, 2013 **Federal Register** (78 FR 4594) (Medicaid and Exchange Eligibility Appeals and Notices).

E. Market Reform Rules

A notice of proposed rulemaking relating to market reforms and effective rate review was published in the **Federal Register** on November 26, 2012 (77 FR 70584). The final rule was made available for public inspection at the Office of the Federal Register on February 22, 2013 (Market Reform Rule).

F. Essential Health Benefits and Actuarial Value

A notice of proposed rulemaking relating to essential health benefits and actuarial value was published in the **Federal Register** on November 26, 2012 (77 FR 70644). The final rule was published in the **Federal Register** on February 25, 2013 (78 FR 12834) (EHB/AV Rule).

G. Medical Loss Ratio

HHS published a request for comment on section 2718 of the PHS Act in the April 14, 2010 **Federal Register** (75 FR 19297), and published an interim final rule with 60-day comment period relating to MLR program on December 1, 2010 (75 FR 74864). An interim final rule with 30-day comment period and a final rule with 30-day comment period were published in the **Federal Register** on December 7, 2011 (76 FR 76596 and 76574). A final rule was published in

the **Federal Register** on May 16, 2012 (77 FR 28790).

H. Tribal Consultations

Following publication of the proposed rule, we issued a letter to Tribal leaders seeking input on the provisions of the proposed rule. We also discussed the provisions of the proposed rule in an all-Tribes webinar and conference call and in two meetings with the Tribal Technical Advisory Group. We considered the comments offered during these discussions in developing the provisions in this final rule.

III. Provisions of the Proposed Rule and Responses to Public Comments

We received approximately 420 comments from consumer advocacy groups, health care providers, employers, health insurers, health care associations, and individuals. The comments ranged from general support or opposition to the proposed provisions to very specific questions or comments regarding proposed changes. In this section, we summarize the provisions of the proposed rule and discuss and provide responses to the comments (with the exception of comments on the paperwork burden or the economic impact analysis, which we discuss in those sections of this final rule). We have carefully considered these comments in finalizing this rule.

Comment: We received a number of comments requesting that the comment period be extended to 60 days.

Response: HHS provided a 30-day comment period, which is consistent with the Administrative Procedure Act. We note that HHS previously sought and received significant comment on the Risk Adjustment White Paper, the Risk Adjustment Bulletin, presentations made during the Risk Adjustment Spring Meeting, the Reinsurance Bulletin, the AV/CSR Bulletin, and the Premium Stabilization Rule, which outlined the policy proposed in the proposed rule. HHS believes that interested stakeholders had adequate opportunity to provide comment on the policies established in this final rule.

Comment: One commenter requested that HHS issue a separate final rule containing provisions for each part of the Code of Federal Regulations.

Response: As noted in the Premium Stabilization Rule, the proposed rule, and this final rule, many of the programs covered by this rule are closely linked. To simplify the regulatory process, facilitate public comment, and provide the information needed to meet statutory deadlines, we elected to propose and finalize these regulatory provisions in one rule.

Comment: We received several comments pertaining to the proposed EHB/AV Rule and the proposed Market Reform Rule.

Response: Those comments are addressed in the final EHB/AV Rule and the final Market Reform Rule.

Comment: One commenter suggested that the standards set forth by HHS pertaining to the HHS-operated risk adjustment or reinsurance programs be the minimum requirements for State-operated risk adjustment or reinsurance programs.

Response: HHS aims to provide States with flexibility in implementing these programs while ensuring that the goals of the premium stabilizations programs are being met. Many of the provisions applicable to the risk adjustment and reinsurance programs when operated by a State are also applicable to these programs when operated by HHS on behalf of a State.

Comment: Several commenters asked that HHS monitor and oversee the implementation of the premium stabilization programs.

Response: HHS takes seriously its responsibility to monitor the implementation of these programs to protect consumers, prevent fraud and abuse, and ensure the programs achieve their goals. We will provide further detail on the oversight of these programs in future rulemaking and guidance.

A. Provisions for the State Notice of Benefit and Payment Parameters

In § 153.100(c), we proposed to require that, for benefit year 2014 only, a State must publish a State notice by March 1, 2013, or by the 30th day following publication of the final HHS notice of benefit and payment parameters for 2014, whichever is later. Because the effective date of this rule will be 60 days after its publication, we will not finalize the proposed change to § 153.100(c). Nevertheless, consistent with our proposal, we are finalizing our policy that, for 2014 only, a State must publish a State notice of benefit and payment parameters by the 30th day following publication of this final rule by deeming the March 1 deadline specified in the existing regulation to be extended until the date that is 30 days after publication of this final rule.

Comment: A number of commenters supported the proposed deadline extension for benefit year 2014, while others opposed such an extension. Some suggested that HHS not allow States to operate risk adjustment or reinsurance.

Response: We believe that States should have the flexibility to operate risk adjustment and reinsurance. Because of the publication date of this

final rule, it is clear that a State will not have the notice necessary to publish a State notice of benefit and payment parameters by the deadline specified in the regulation—that is, March 1, 2013 for the 2014 benefit year. Thus, as described above, although we are not finalizing our proposal to amend the regulation, we are setting the deadline for 2014 only as the 30th day after publication of this final rule.

B. Provisions and Parameters for the Permanent Risk Adjustment Program

The risk adjustment program is a permanent program created by Section 1343 of the Affordable Care Act that transfers funds from lower risk, non-grandfathered plans to higher risk, non-grandfathered plans in the individual and small group markets, inside and outside the Exchanges. In subparts D and G of the Premium Stabilization Rule, we established standards for the administration of the risk adjustment program. A State approved or conditionally approved by the Secretary to operate an Exchange may establish a risk adjustment program, or have HHS do so on its behalf. Section 1343 of the Affordable Care Act requires each State to operate a risk adjustment program. In States that have elected not to operate their own risk adjustment program, HHS will operate a program on their behalf. Our authority to operate risk adjustment on the State's behalf arises from sections 1321(c)(1) and 1343 of the Affordable Care Act. Based on HHS's communications with States, as of February 25, 2013, Massachusetts is the only State electing to operate a risk adjustment program for the 2014 benefit year.

In the Premium Stabilization Rule, we established that a risk adjustment program is operated using a risk adjustment methodology. States operating their own risk adjustment program may use a risk adjustment methodology developed by HHS, or may elect to submit an alternate methodology to HHS for approval. In the Premium Stabilization Rule, we also laid out standards for States and issuers with respect to the collection and validation of risk adjustment data.

In section III.B.1. of the proposed rule, we proposed standards for HHS approval of a State-operated risk adjustment program (regardless of whether a State elects to use the HHS-developed methodology or an alternate, Federally certified risk adjustment methodology). In section III.B.2. of the proposed rule, we proposed a small fee to support HHS operation of the risk adjustment program. In section III.B.3. of the proposed rule, we described the

methodology that HHS would use when operating a risk adjustment program on behalf of a State. States operating a risk adjustment program can use this methodology, or submit an alternate methodology, in a process we described in section III.B.4. of the proposed rule. Finally, in section III.B.5. of the proposed rule, we described the data validation process we proposed to use when operating a risk adjustment program on behalf of a State. (These provisions are discussed fully in the proposed rule at 77 FR at 73123–73149).

1. Approval of State-Operated Risk Adjustment

a. Risk Adjustment Approval Process

In the proposed rule, we proposed an approval process for States seeking to operate their own risk adjustment program. Specifically, we proposed a new paragraph (c) in § 153.310, entitled “State responsibility for risk adjustment,” which sets forth a State’s responsibilities with regard to risk adjustment program operations. With this change, we also proposed to redesignate paragraphs (c) and (d) to paragraphs (e) and (f) of § 153.310.

In paragraph § 153.310(c)(1), we proposed that if a State is operating a risk adjustment program for a benefit year, the State administer the program through an entity that meets certain standards. These standards would ensure the entity has the capacity to operate the risk adjustment program throughout the benefit year, and is able to administer the Federally certified risk adjustment methodology the State has chosen to use.

As proposed in § 153.310(c)(1)(i), the entity must be operationally ready to implement the applicable Federally certified risk adjustment methodology and process the resulting payments and charges. We believe that it is important for a State to demonstrate that its risk adjustment entity has the capacity to implement the applicable Federally certified risk adjustment methodology so that issuers may have confidence in the program, and so that the program can effectively mitigate the potential effects of adverse selection. To meet this standard, we proposed that a State demonstrate that the risk adjustment entity: (1) Have systems in place to implement the data collection approach, to calculate individual risk scores, and calculate issuers’ payments and charges in accordance with the applicable Federally certified risk adjustment methodology; and (2) have tested, or have plans to test, the functionality of the system that would be used for risk adjustment operations prior to the start

of the applicable benefit year. We proposed that States also demonstrate that the entity has legal authority to carry out risk adjustment program operations, and has the resources to administer the applicable risk adjustment methodology in its entirety, including the ability to make risk adjustment payments and collect risk adjustment charges.

We proposed in paragraph § 153.310(c)(1)(ii) that the entity have relevant experience to operate a risk adjustment program. To meet this standard, we proposed that a State demonstrate that the entity have on staff, or have contracted with, individuals or firms with experience relevant to the implementation of a risk adjustment methodology. This standard is intended to ensure that the entity has the resources and staffing necessary to successfully operate the risk adjustment program.

We proposed in paragraph § 153.310(c)(2) that a State seeking to operate its own risk adjustment program ensure that the risk adjustment entity complies with all applicable provisions of subpart D of 45 CFR part 153 in the administration of the applicable Federally certified risk adjustment methodology. In particular, we proposed that the State ensure that the entity complies with the privacy and security standards set forth in § 153.340.

We proposed in § 153.310(c)(3) that the State conduct oversight and monitoring of risk adjustment activities in order for HHS to approve the State’s risk adjustment program. Because the integrity of the risk adjustment program has important implications for issuers and enrollees, we proposed to consider the State’s plan to monitor the conduct of the entity.

Finally, we proposed in § 153.310(d) that a State submit to HHS information that establishes that it and its risk adjustment entity meet the criteria set forth in § 153.310(c).

Comment: Commenters generally agreed with our approach to approving State risk adjustment programs beginning in benefit year 2015.

Response: We are finalizing these provisions as proposed.

b. Risk Adjustment Approval Process for Benefit Year 2014

Because of the unique timing issues for approving a State-operated risk adjustment program, we proposed a transitional policy for benefit year 2014. We proposed not to require that a State-operated risk adjustment program receive approval for benefit year 2014. Instead, we proposed a transitional, consultative process that would

commence shortly after the provisions of this final rule are effective. We are finalizing these provisions as proposed.

Comment: One commenter supported the transitional process but urged that the transitional process not be applied to future years. Another commenter requested that HHS require approval in 2014, but make the approval determination on the basis of the proposed consultative process. Other commenters suggested that HHS not allow States to conduct risk adjustment until the agency could formally approve States, beginning in 2015.

Response: We proposed the transitional policy based on the unique circumstances of 2014, and we do not anticipate extending it to future years. Although we are mindful of concerns that States may not be fully ready to operate a complex risk adjustment program for benefit year 2014, we note that each aspect of a State’s operations (including data collection) must be performed in line with one of the Federally certified risk adjustment methodologies published in this final rule. Finally, we note that any State that begins operation of risk adjustment under this transitional process must obtain formal certification for benefit year 2015. We believe this process is sufficiently robust to ensure any State operating risk adjustment in 2014 will be prepared to do so.

2. Risk Adjustment User Fees

In the proposed rule, we noted that, if a State is not approved to operate or chooses to forgo operating its own risk adjustment program, HHS would operate risk adjustment on the State’s behalf. Our authority to operate risk adjustment on the State’s behalf arises from sections 1321(c)(1) and 1343 of the Affordable Care Act. In States where HHS is operating risk adjustment, we proposed that issuers of risk adjustment covered plans remit a user fee to fund HHS’s operation of a Federally operated risk adjustment program. The authority to charge this user fee can be found under sections 1343, 1311(d)(5), and 1321(c)(1) of the statute, and under 31 U.S.C. 9701, which permits a Federal agency to establish a charge for a service provided by the agency. OMB Circular No. A–25R, which establishes Federal policy regarding user fees, specifies that a user charge will be assessed against each identifiable recipient of special benefits derived from Federal activities beyond those received by the general public. The risk adjustment program will provide special benefits as defined in section 6(a)(1)(b) of OMB Circular No. A–25R to an issuer of a risk adjustment covered plan because it will mitigate the

financial instability associated with adverse selection as other market reforms go into effect. The risk adjustment program will also contribute to consumer confidence in the insurance industry by helping to stabilize premiums across the individual and small group health insurance markets.

We further proposed to determine the total amount needed to fund HHS risk adjustment operations by examining the contract costs of operating the program, including development of the model and methodology, collections, payments, account management, data collection, program integrity and audit functions, operational and fraud analytics, stakeholder training, and operational support (not including Federal personnel costs). We proposed to develop a per capita user fee rate by dividing the amount we intend to collect over the course of the benefit year by the expected annual enrollment in risk adjustment covered plans (other than plans not subject to market reforms and student health plans) for that benefit year. We also proposed a standardized schedule for assessment and collection of risk adjustment user fees. Although the user fees would be assessed on a per-enrollee-per-month basis to account for fluctuations in monthly enrollment, we proposed to collect them only once, in June of the year following the benefit year, in order to synchronize user fee collection with risk adjustment payments and charges.

Based on comments received, we are adding § 153.610(f), finalizing our risk adjustment user fee assessment and collection approach as proposed. We clarify that enrollment data for each month will be captured by the servers used in the distributed data collection approach. We are also finalizing our intention to set a per capita user fee rate in the annual HHS notice of benefit and payment parameters using the proposed methodology. The user fee will be determined by dividing HHS's total contract costs for risk adjustment operations in the applicable benefit year by the expected annual enrollment in risk adjustment covered plans for that benefit year. Based on this methodology, for benefit year 2014, we are establishing a per capita annual user fee rate of \$0.96, which we will apply as a per-enrollee-per-month risk adjusted user fee of \$0.08.

Comment: One commenter expressed support for the proposal to collect user fees to fund HHS risk adjustment operations. Other commenters, though not commenting on risk adjustment user fees specifically, urged HHS to minimize or eliminate the fees it

collects from issuers in order to maintain affordable coverage in the post-2014 health insurance market.

Response: We believe that a reliable funding source is necessary to ensure a robust Federal risk adjustment program. We clarify that we are establishing the risk adjustment user fee for the sole purpose of funding HHS's costs for operating the Federal risk adjustment program, and we intend to keep the user fee amount as low as possible.

3. Overview of the Risk Adjustment Methodology HHS Will Implement When Operating Risk Adjustment on Behalf of a State

The goal of the risk adjustment program is to stabilize the premiums in the individual and small group markets as and after insurance market reforms are implemented. The risk adjustment methodology proposed in the proposed rule, which HHS would use when operating risk adjustment on behalf of a State, is based on the premise that premiums should reflect the differences in plan benefits and plan efficiency, not the health status of the enrolled population.

Under § 153.20 of the Premium Stabilization Rule, a risk adjustment methodology is made up of five elements:

- The *risk adjustment model* uses an individual's recorded diagnoses, demographic characteristics, and other variables to determine a risk score, which is a relative measure of how costly that individual is anticipated to be.
- The *calculation of plan average actuarial risk and the calculation of payments and charges* average all individual risk scores in a risk adjustment covered plan, make certain adjustments, and calculate the funds to be transferred between plans. In the proposed rule, these two elements of the methodology were presented together as the payment transfer formula.
- The *data collection approach* describes the program's approach to obtaining data. HHS will do so using the distributed model described in section III.G. of this final rule.
- The *schedule* for the risk adjustment program describes the timeframe for risk adjustment operations.

The risk adjustment methodology addresses three considerations: (1) The newly insured population; (2) plan metal levels and permissible rating variation; and (3) the need for inter-plan transfers that net to zero. Risk adjustment payments or charges are calculated from the payment transfer formula. The key feature of the HHS risk

adjustment methodology is that the risk score alone does not determine whether a plan is assessed charges or receives payments. Transfers depend not only on a plan's average risk score, but also on its plan-specific cost factors relative to the average of these factors within a risk pool within a State.

As discussed in the proposed rule, the risk adjustment methodology developed by HHS:

- Was developed on commercial claims data for a population similar to the expected population to be risk adjusted;
- Uses the HCC grouping logic used in the Medicare population, with HCCs refined and selected to reflect the expected risk adjustment population;
- Calculates risk scores with a concurrent model (current year diagnoses predict current year costs);
- Establishes 15 risk adjustment models, one for each combination of metal level (platinum, gold, silver, bronze, catastrophic) and age group (adults, children, infants);
- Results in "balanced" payment transfers within a risk pool within a market within a State;
- Adjusts payment transfers for plan metal level, geographic rating area, induced demand, and age rating, so that transfers reflect health risk and not other cost differences; and
- Transfers funds between plans within a market within a State.

We are finalizing the methodology HHS will use when operating the risk adjustment program as proposed, with the following modifications: we have included individuals over 64 in the demographic factors; we have updated the cost-sharing reduction (CSR) adjustment factors for zero cost-sharing plan variations to align with the induced demand factors used in the CSR program; we have made technical corrections to the payment transfer formula; we have clarified that geographic cost factors will be calculated for each risk pool in each market in a State; and we have clarified how transfers will be calculated at the plan level.

Comment: We received many comments supporting HHS's general approach to the risk adjustment methodology we will use when operating risk adjustment on behalf of a State.

Response: We are finalizing the methodology as proposed with minor modifications.

Comment: We received one comment suggesting that current risk adjustment methodologies are inadequate because they do not fully account for the sickest patients with the most complex medical

conditions. Another commenter suggested that HHS take an expanded view of risk mitigation by working to ensure a stable risk pool.

Response: The Affordable Care Act establishes a risk adjustment program, and permits the Secretary to base this program on the criteria and methods used in Medicare Parts C and D. While we used criteria and methods from Medicare when appropriate, we also customized this methodology to best mitigate adverse selection based on our projections of the 2014 marketplace. Though we anticipate making future adjustments to the model, we seek to balance stakeholders' desire for a stable model in the initial years with introducing model improvements as additional data becomes available. We look forward to engaging with stakeholders throughout this process. We believe that this program, along with the other 2014 market reforms, will help ensure a stable risk pool.

Comment: We received one comment that HHS should provide issuers information to assess their risk scores and State average risk scores as part of the premium development process for 2014.

Response: As noted in the proposed rule, risk adjustment transfers depend not only on a plan's average risk score, but also on its cost factors compared to the average of these factors within a risk pool within a market within a State. HHS does not currently have the data necessary to calculate the State average risk score to provide to issuers in time for the development of 2014 premiums. HHS contemplates providing technical assistance to States and issuers who are interested in this information.

Comment: We received several comments that HHS should monitor the risk adjustment methodology's performance, with a particular focus on the newly insured population.

Response: We intend to monitor the methodology's performance to determine future adjustments to the model, as data become available.

a. Risk Adjustment Applied to Plans in the Individual and Small Group Markets

In the Premium Stabilization Rule, we defined a "risk adjustment covered plan" in § 153.20 as health insurance coverage offered in the individual or small group markets, excluding plans offering excepted benefits and certain other plans, including "any other plan determined not to be a risk adjustment covered plan in the annual HHS notice of benefit and payment parameters." We proposed to amend this definition by replacing "and any plan determined not to be a risk adjustment covered plan in

the annual HHS notice of benefit and payment parameters" with "and any other plan determined not to be a risk adjustment covered plan in the applicable Federally certified risk adjustment methodology." We noted that, under this revised definition, we would describe any plans not determined to be risk adjustment covered plans under the HHS risk adjustment methodology in the annual HHS notice of benefit and payment parameters, which is subject to notice and comment.

We described our proposed treatment of certain types of plans (specifically, plans not subject to market reforms, student health plans, and catastrophic plans), and our proposed approach to risk pooling for risk adjustment purposes when a State merges markets for the purposes of the single risk pool provision described in section 1312(c) of the Affordable Care Act.

Plans not subject to market reforms: Certain types of plans offering non-grandfathered health insurance coverage in the individual and small group markets would not be subject to the insurance market reforms in the Market Reform Rule and the EHB/AV Rule. In addition, plans providing benefits through health insurance policies that begin in 2013, with renewal dates in 2014, would not be subject to these requirements until renewal in 2014. The statute specifies that the risk adjustment program is to assess charges on non-grandfathered health insurance coverage in the individual and small group markets with less than average actuarial risk and to make payments to non-grandfathered health insurance coverage in these markets with higher than average actuarial risk. We stated that we interpret actuarial risk to mean predictable risk that the issuer has not been able to compensate for through exclusion or pricing. In the current market, plans are generally not subject to the insurance market reforms that begin in 2014 described at § 147.102 (fair health insurance premiums), § 147.104 (guaranteed availability of coverage, subject to the student health insurance provisions at § 147.145), § 147.106 (guaranteed renewability of coverage, subject to the student health insurance provisions at § 147.145), § 156.80 (single risk pool), and subpart B of part 156 (essential health benefits), and so are generally able to minimize actuarial risk by excluding certain conditions (for example, maternity coverage for women of child-bearing age) and denying coverage to those with certain high-risk conditions.

In the proposed rule, we proposed to use the authority in section 1343(b) of

the Affordable Care Act to "establish criteria and methods to be used in carrying out * * * risk adjustment activities" for plans not subject to insurance market reforms at § 147.102 (fair health insurance premiums), § 147.104 (guaranteed availability of coverage, subject to the student health insurance provisions at § 147.145), § 147.106 (guaranteed renewability of coverage, subject to the student health insurance provisions at § 147.145), § 156.80 (single risk pool), and subpart B of part 156 (essential health benefits package). We stated that because plans not subject to these market reform rules are able to effectively minimize actuarial risk, we believe these plans would have uniform and virtually zero actuarial risk. We proposed to treat these plans separately, such that these plans would not be subject to risk adjustment charges and would not receive risk adjustment payments. Also, these plans would not be subject to the issuer requirements described in subparts G and H of part 153. We noted that plans offering coverage through policies issued in 2013 and subject to these requirements upon renewal would become subject to risk adjustment upon renewal, and would comply with the requirements established in subparts G and H of part 153 at that time.

Student health plans: Only individuals attending a particular college or university are eligible to enroll in a student health plan (as described in § 147.145) offered by that college or university. In the proposed rule, we stated our belief that student health plans, because of their unique characteristics, will have relatively uniform actuarial risk. We proposed to use the authority in section 1343(b) of the Affordable Care Act to "establish criteria and methods to be used in carrying out * * * risk adjustment activities" to treat these plans as a separate group that would not be subject to risk adjustment charges and would not receive risk adjustment payments. Therefore, these plans would not be subject to the requirements described in subparts G and H of part 153.

Catastrophic plans: Unlike metal level coverage, only individuals age 30 and under, or individuals for whom insurance is deemed to be unaffordable, as specified in section 1302(e) of the Affordable Care Act, are eligible to enroll in catastrophic plans. Because of the unique characteristics of this population, we proposed to use our authority to establish "criteria and methods" to risk adjust catastrophic plans in a separate risk pool from the general (metal level) risk pool. Catastrophic plans with less than

average actuarial risk compared with other catastrophic plans would be assessed charges, while catastrophic plans with higher than average actuarial risk compared with other catastrophic plans would receive payments. We did not propose to exempt these plans from the requirements in subparts G and H of part 153.

Merger of markets: Section 1312(c) of the Affordable Care Act directs issuers to use a single risk pool for a market—the individual or small group market—when developing rates and premiums. Section 1312(c)(3) of the Affordable Care Act gives States the option to merge the individual and small group market into a single risk pool. To align risk pools for the risk adjustment program and rate development, we proposed to merge markets when operating risk adjustment on behalf of a State if the State elects to do the same for single risk pool purposes. When the individual and small group markets are merged, we proposed that the State average premium described in section III.B.3.c would be the average premium of all applicable individual and small group market plans in the applicable risk pool, and normalization under the transfer equation would occur across all plans in the applicable risk pool in the individual and small group market.

Risk adjustment in State of licensure: Risk adjustment is a State-based program in which funds are transferred within a market within a State, as described above. In general, a risk adjustment methodology will be linked to the rate and benefit requirements applicable under State and Federal law in a particular State. Such requirements may differ from State to State, and apply to policies filed and approved by the department of insurance in a State. However, a plan licensed in a State (and therefore subject to that State's rate and benefit requirements) may enroll individuals in multiple States. To help ensure that policies in the small group market are subject to risk adjustment programs linked to the State rate and benefit requirements applicable to that policy, we proposed in § 153.360 that a risk adjustment covered plan be subject to risk adjustment in the State in which the policy is filed and approved.

We are finalizing these provisions as proposed, with a clarification that risk adjustment covered plans in the small group market will be subject to risk adjustment in the State in which the employer's policy is filed and approved.

Comment: We received a number of comments that expressed support for our proposed approach to student health plans, plans not subject to market reform rules, and catastrophic plans.

Several of these commenters urged HHS to align the single risk pool approach to student health plans with the proposed approach in risk adjustment. Some commenters expressed concern that separately risk adjusting catastrophic plans would prevent the enrollees in these plans from contributing to the general risk pool.

Response: Provisions related to the single risk pool provision were finalized in the Market Reform Rule, which was made available for public inspection at the Office of the Federal Register on February 22, 2013. Non-grandfathered student health insurance coverage is exempt from the single risk pool requirement.

As commenters noted, the risk adjustment program complements the single risk pool provision, which broadens the risk pool by including catastrophic claims experience in the development of the index rate. Because enrollment in catastrophic plans is limited to certain enrollees that are likely to have a different risk profile than enrollees in metal-level plans, we believe it is appropriate to risk adjust these plans in a separate risk pool. For this reason, we are finalizing the treatment of catastrophic plans, student health plans, and plans not subject to the market reform rules as proposed.

Comment: We received comments suggesting several different approaches to our proposal that risk adjustment covered plans be subject to risk adjustment in the State in which the enrollee's policy is filed and approved, including that we modify the requirement to mirror the MLR program's situs of contract requirement, and that we clarify that the employer, not the enrollee, is the policyholder in the small group market.

Response: We are modifying the proposed provision to clarify that risk adjustment covered plans in the small group will be subject to risk adjustment in the State in which the employer's policy is filed and approved.

b. Overview of the HHS Risk Adjustment Model

The proposed HHS risk adjustment models predict plan liability for an enrollee based on that person's age, sex, and diagnoses (risk factors), producing a risk score. We proposed separate models for adults, children, and infants to account for cost differences in each of these age groups. Each HHS risk adjustment model predicts individual-level risk scores, but is designed to predict average group costs to account for risk across plans. This method accords with the Actuarial Standard

Board's Actuarial Standard of Practice for risk classification.

We are finalizing the HHS risk adjustment models as proposed with the following modifications: we have fixed a typographical error to include individuals over 64 in the demographic factors, we have clarified the calculation of age for infants who were born in one benefit year and discharged in the following benefit year, and we have updated the CSR adjustment factors to align with the induced demand factors used in the CSR program.

Comment: We received a number of comments supporting HHS's general approach to establishing risk adjustment models.

Response: We are finalizing the models as proposed with minor modifications.

Comment: One commenter expressed concern that the number of HHS risk adjustment models proposed would create inaccuracies in the model.

Response: The statistical performance of each of the models is well within the published ranges for concurrent models. The HHS risk adjustment models better predict plan liability because they account for age-related clinical and cost differences and differing plan liabilities due to differences in actuarial value across metal levels.

(1) Data Used To Develop the HHS Risk Adjustment Models

In the proposed rule, we described the data used to develop (that is, calibrate) the HHS risk adjustment models. We proposed that the HHS risk adjustment models would be concurrent and not include prescription drug use as a predictor. Finally, we proposed separate risk adjustment models for each metal level because plans at different metal levels would have different liability for enrollees with the same expenditure patterns. We received the following comments about these approaches:

Comment: We received several comments in support of HHS's decision not to include prescription drug data as a predictor in the HHS risk adjustment models. A number of other commenters suggested that HHS include prescription drug data as a predictor in the HHS risk adjustment models to improve each model's predictive accuracy, or consider inclusion of this data as a predictor in the future.

Response: HHS is finalizing its proposal to exclude prescription drugs for the initial HHS risk adjustment models, but will consider how prescription drugs could be included in future HHS risk adjustment models.

Comment: We received a number of comments in support of the concurrent

modeling approach, though a number of these comments suggested that we transition to a prospective model.

Response: In 2014, 2013 diagnostic data for individuals enrolled in risk adjustment covered plans will not be available. We also anticipate that enrollees may move between plans, or between programs. A concurrent model is better able to handle changes in enrollment than a prospective model because individuals newly enrolling in health plans may not have prior data available that can be used in risk adjustment. We are therefore finalizing our approach to use a concurrent model. We plan to investigate the feasibility of transitioning to a prospective approach in the future.

Comment: One commenter asked for further information about the standardized benefit designs used to estimate plan liability in the HHS risk adjustment models.

Response: Plan liabilities were defined by applying standardized benefit design parameters for each given metal level to total expenditures. The standard benefit designs were created using the Actuarial Value Calculator to ensure that each benefit design aligns with the applicable metal level. While an individual plan's design may differ from the standardized benefit, we believe the design is a reasonable approximation for the average plan design at each metal level. The catastrophic plan design was estimated using the estimated maximum annual limitation on cost sharing described in section III.E. of this final rule.

Comment: We received several comments on HHS's approach to account for infant claims if there is no separate infant birth claim from which to gather diagnoses. Some commenters encouraged HHS to require separate claims for mothers and infants. Some commenters recommended that HHS separate these claims in operations. One commenter noted that in the State of Washington there are legal impediments to separating claims for mothers and infants in the first 21 days of life.

Response: HHS calibrated the HHS risk adjustment models by excluding infant claims that were bundled with the mothers, as well as infants without birth codes due to data limitations. In operation, issuers will separate infant and mother claims when possible. If an infant claim cannot be separated, HHS will assign the infant to the lowest severity category and the "term" maturity category. We note that HHS does not intend to unbundle claims in operation.

Comment: We received one comment that data used to calibrate the HHS risk

adjustment models will not reflect the risk adjustment population beginning in 2014. Several commenters suggested that the calibration data set did not reflect benefits that issuers will offer beginning in 2014.

Response: We believe that the commercial data set used for calibration is a reasonable approximation of the population that will be risk adjusted in 2014. The calibration data set was restricted to individuals with prescription drug coverage, mental health coverage, and medical coverage, which are part of the essential health benefits package that issuers will offer starting in 2014.

(2) Principles of Risk Adjustment and the HCC Classification System

We proposed to use a diagnostic classification system. A diagnostic classification system determines which diagnosis codes should be included, how the diagnosis codes should be grouped, and how the diagnostic groupings should interact for risk adjustment purposes. The ten principles that were used to develop the HCC classification system for the Medicare risk adjustment model also guided the creation of the HHS risk adjustment models that we proposed to use when HHS operates risk adjustment on behalf of a State. We selected 127 of the full classification of 264 HHS HCCs for inclusion in the HHS risk adjustment models.

Comment: We received several comments in support of the HHS HCC classification system.

Response: We are finalizing the HHS HCC classification system as proposed.

Comment: Several commenters requested that HHS provide the ICD-9 codes included in each HHS HCC.

Response: We have provided this information for the proposed HHS risk adjustment models on our Web site at: http://cciiio.cms.gov/resources/files/ra_instructions_proposed_1_2013.pdf and http://cciiio.cms.gov/resources/files/ra_tables_proposed_1_2013.xlsx. We intend to provide a final version of these documents to reflect the HHS risk adjustment models in the future.

Comment: Several commenters requested the classification of ICD-10 codes to HHS HCCs.

Response: We are completing the mapping of ICD-10 codes to HHS HCCs and will release this information in future guidance.

Comment: Several commenters suggested that additional HHS HCCs should be included in the HHS risk adjustment models.

Response: In selecting the factors to be included in the HHS risk adjustment

models, we considered the basic criteria below to determine which HCCs should be included in the HHS risk adjustment model:

- Whether the HCC represents clinically significant medical conditions with significant costs for the target population;
- Whether there will be a sufficient sample size to ensure stable results for the HCC;
- Whether excluding the HCC would exclude (or limit the impact of) diagnoses particularly subject to discretionary coding;
- Whether the HCC identifies chronic or systematic conditions that represent insurance risk selection or risk segmentation, rather than random acute events;
- Whether the HCCs represent poor quality of care; and
- Whether the HCC is applicable to the model age group.

We also included a factor to measure increased utilization due to receipt of CSRs. Each model's R-squared and predictive ratios were within published ranges for concurrent models. Thus, we have not included additional HCCs at this time.

Comment: We received a comment in support of our approach to HHS HCC selection.

Response: We are finalizing the HHS HCCs included in the HHS risk adjustment models as proposed.

(3) Factors Included in the HHS Risk Adjustment Models

The proposed HHS risk adjustment models predict annualized plan liability expenditures using age and sex categories, HHS HCCs, and, where applicable, disease interactions. Dollar coefficients were estimated for these factors using weighted least squares regression, where the weight was the fraction of the year enrolled. For each model, the factors were the statistical regression dollar coefficients divided by a weighted average plan liability for the full modeling sample. Due to the inherent clinical and cost differences in the adult (age 21+), child (age 2-20), and infant (age 0-1) populations, HHS proposed separate risk adjustment models for each age group.

Comment: We received a few comments suggesting the weights of specific factors in the HHS risk adjustment models were lower than expected.

Response: The HHS risk adjustment models predict annualized plan liability. The factors were estimated using weighted least squares regression. For each risk adjustment model, the factors were the statistical regression

dollar values for each factor in the model divided by a weighted average plan liability for the full modeling sample. Some factors were grouped or constrained and thus do not exactly represent the statistical regression dollar value. Some factors were grouped or constrained to reduce model complexity, avoid inclusion of HHS HCCs with small sample size, limit upcoding by severity within an HCC hierarchy, reduce additivity within a disease group, and avoid coefficient values in which a lower-ranked HCC in a disease hierarchy had higher coefficient than a higher-ranked HCC.

Comment: A few commenters requested that age be calculated at the time of enrollment. Several commenters asked that age for newborns be defined as date of birth rather than the age as of the last day of enrollment in a risk adjustment covered plan. Another commenter requested that HHS clarify that age determinations be consistent between model calibration and program operation.

Response: The HHS risk adjustment models were calibrated using age as of the last month of enrollment due to data limitations. To align with model calibration, an enrollee's age for risk score calculation will be the age as of the enrollee's last day of enrollment in a risk adjustment covered plan in the applicable benefit year will be used for enrollees in program operation. We are clarifying our approach to calculating the age of infants who are born in a benefit year but are not discharged until the following year. In such a case, the infant will be defined as age 0 for both benefit years. For example, if an infant is born in December of 2014 but has a discharge date of January 2015, the infant would be assigned age 0 for purposes of risk score calculation in benefit year 2014 and for the entire 2015 benefit year.

Comment: We received comments supporting the inclusion of a

demographic factor to account for individuals aged 65 or older. We also received comments requesting that the HHS risk adjustment models include additional factors such as income, receipt of care from an essential community provider, and enrollee language.

Response: In response to comments, we made a typographical correction to re-label the highest adult age factor as 60+. Because data for individuals 65 or older is not captured in the calibration dataset, the estimation of a separate demographic factor for those 65 or older is impractical at this time. Other factors such as income are also not feasible to include due to data limitations. Therefore, we have not modified the HHS risk adjustment models to include such factors. Tables 2, 4, and 5 contain the final factors for the HHS risk adjustment models.

Comment: We received several comments that the HHS risk adjustment models do not appropriately account for short-term enrollment. One commenter suggested that risk scores for individuals that were enrolled for only part of a year would be inaccurate.

Response: Our models were calibrated to account for short-term enrollment in several ways. First, enrollee diagnoses were included from the time of enrollment. Also, in the statistical estimation strategy for the HHS HCCs, average monthly expenditures were defined as the enrollee's expenditures for the enrollment period divided by the number of enrollment months, annualized expenditures (plan liability) were defined as average monthly expenditures multiplied by 12, and regressions were weighted by months of enrollment divided by 12. We believe that this statistical strategy, alongside the minimum enrollment requirement, ensures that monthly expenditures are correctly estimated for all individuals.

(4) Adjustments to Model Discussed in the Risk Adjustment White Paper

We proposed to include an adjustment for the receipt of CSRs in the HHS risk adjustment models, but not to adjust for receipt of reinsurance payments.

Comment: We received comments that were generally supportive of the CSR adjustment to risk scores. One commenter stated that the proposed factors do not adequately account for changes in utilization as enrollees in cost-sharing plan variations may also use more high cost services. Another commenter requested that HHS clarify whether plan liability for increased utilization due to CSR is accounted for by the CSR adjustment factor in the HHS risk adjustment models.

Response: We are finalizing the CSR adjustment factor as proposed, with the modification to the typographical error described in Table 1 below. The CSR adjustment factor for the HHS risk adjustment models is intended to account for the increased plan liability due to increased utilization of health care services by enrollees receiving CSRs.

Comment: We received several comments that noted a typographical error in the zero cost-sharing adjustments.

Response: We have revised the CSR adjustment to align with the CSR adjustment in section III.E. for enrollees in zero cost-sharing plan variations. Table 1 contains the final CSR adjustment factors.

Comment: Several commenters supported our proposal to not adjust the HHS risk adjustment models for reinsurance payments.

Response: We are finalizing our proposal to not adjust the HHS risk adjustment models for reinsurance payments since reinsurance is a temporary program and already offsets adverse selection.

TABLE 1—COST-SHARING REDUCTION ADJUSTMENT

Household income	Plan AV	Induced utilization factor
Silver Plan Variant Recipients		
100–150 percent of FPL	Plan Variation 94 percent	1.12
150–200 percent of FPL	Plan Variation 87 percent	1.12
200–250 percent of FPL	Plan Variation 73 percent	1.00
>250 percent of FPL	Standard Plan 70 percent	1.00
Zero Cost-Sharing Recipients		
<300 percent of FPL	Platinum (90 percent)	1.00
<300 percent of FPL	Gold (80 percent)	1.07
<300 percent of FPL	Silver (70 percent)	1.12
<300 percent of FPL	Bronze (60 percent)	1.15

TABLE 1—COST-SHARING REDUCTION ADJUSTMENT—Continued

Household income	Plan AV	Induced utilization factor
>300 percent of FPL	Limited Cost-Sharing Recipients	1.00

(5) Model Performance Statistics

To evaluate model performance, we examined the R-squared and predictive ratios of the HHS risk adjustment models.

Comment: Several commenters asked for further details on the statistical performance of the HHS risk adjustment models.

Response: HHS analyzed the statistical performance of each model (adult, child, infant at each metal level). The R-squared (the percentage of individual variation explained by the model) for each model was within the range of published estimates for concurrent models.⁹ These values can be found in Table 8. Additionally, the predictive ratios for the overall samples for each of the 15 models were also within the range of published estimates.

(6) Summary of Models

For clarity, we describe here the HHS risk adjustment models that we are finalizing. An individual's risk score will be calculated for adults and children as the sum of the factors in the applicable model for the relevant age and sex categories, HHS HCCs, and, where applicable, disease interactions.

These factors are listed below in Tables 2 and 4. In the adult models, an individual with at least one of the HCCs that comprises the severe illness indicator variable and at least one of the HCCs interacted with the severe illness indicator variable would be assigned a single interaction factor. A hierarchy is imposed on these interaction groups such that an individual with a high cost interaction is excluded from having a medium cost interaction. The high or the medium interaction factor would be added to demographic and diagnosis factors of the individual. The HCCs that comprise the severe illness indicator variable can be found in Table 3. The CSR adjustment factors listed in Table 1 are multiplied by the sum of the applicable demographic, HHS HCCs, and disease interaction factors.

The infant model utilizes a mutually exclusive group approach in which infants are assigned a maturity category (by gestation and birth weight) and a severity category. There are 5 maturity categories: Extremely Immature; Immature; Premature/Multiples; Term; and Age 1. For the maturity category, age 0 infants would be assigned to one of the first four categories and age 1 infants would be assigned to the age 1

category. As discussed previously, infants who are born in a benefit year but are not discharged until the following year will be defined as age 0 for both benefit years. There are 5 severity categories based on the clinical severity and associated costs of the non-maturity HCCs: Severity Level 1 (Lowest Severity) to Severity Level 5 (Highest Severity). All infants (age 0 or 1) are assigned to a severity category based on the highest severity of their non-maturity HCCs. The 5 maturity categories and 5 severity categories would be used to create 25 mutually exclusive interaction terms to which each infant is assigned. An infant who has HCCs in more than one severity category would be assigned to the highest of those severity categories. An infant who has no HCCs or only a newborn maturity HCC would be assigned to Severity Level 1 (Lowest). The male-age factor would be added to the maturity-severity category to which the infant is assigned, and the sum of the factors would be multiplied by the CSR adjustment factor. The maturity-severity factors and the HCCs that comprise these factors can be found in Tables 5–7.

TABLE 2—ADULT RISK ADJUSTMENT MODEL FACTORS

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors					
Age 21–24, Male	0.258	0.208	0.141	0.078	0.062
Age 25–29, Male	0.278	0.223	0.150	0.081	0.064
Age 30–34, Male	0.338	0.274	0.187	0.101	0.079
Age 35–39, Male	0.413	0.339	0.240	0.140	0.113
Age 40–44, Male	0.487	0.404	0.293	0.176	0.145
Age 45–49, Male	0.581	0.487	0.365	0.231	0.195
Age 50–54, Male	0.737	0.626	0.484	0.316	0.269
Age 55–59, Male	0.863	0.736	0.580	0.393	0.339
Age 60+, Male	1.028	0.880	0.704	0.487	0.424
Age 21–24, Female	0.433	0.350	0.221	0.101	0.072
Age 25–29, Female	0.548	0.448	0.301	0.156	0.120
Age 30–34, Female	0.656	0.546	0.396	0.243	0.203
Age 35–39, Female	0.760	0.641	0.490	0.334	0.293
Age 40–44, Female	0.839	0.713	0.554	0.384	0.338
Age 45–49, Female	0.878	0.747	0.583	0.402	0.352
Age 50–54, Female	1.013	0.869	0.695	0.486	0.427
Age 55–59, Female	1.054	0.905	0.726	0.507	0.443
Age 60+, Female	1.156	0.990	0.798	0.559	0.489

⁹ Winkelman, Ross and Syed Mehmud. “A Comparative Analysis of Claims-Based Tools for

Health Risk Assessment.” Society of Actuaries. April 2007.

TABLE 2—ADULT RISK ADJUSTMENT MODEL FACTORS—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Diagnosis Factors					
HIV/AIDS	5.485	4.972	4.740	4.740	4.749
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	13.696	13.506	13.429	13.503	13.529
Central Nervous System Infections, Except Viral Meningitis	7.277	7.140	7.083	7.117	7.129
Viral or Unspecified Meningitis	4.996	4.730	4.621	4.562	4.550
Opportunistic Infections	9.672	9.549	9.501	9.508	9.511
Metastatic Cancer	25.175	24.627	24.376	24.491	24.526
Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	11.791	11.377	11.191	11.224	11.235
Non-Hodgkin's Lymphomas and Other Cancers and Tumors	6.432	6.150	6.018	5.983	5.970
Colorectal, Breast (Age <50), Kidney, and Other Cancers	5.961	5.679	5.544	5.500	5.483
Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors	3.509	3.294	3.194	3.141	3.121
Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors	1.727	1.559	1.466	1.353	1.315
Pancreas Transplant Status/Complications	9.593	9.477	9.411	9.434	9.439
Diabetes with Acute Complications	1.331	1.199	1.120	1.000	0.957
Diabetes with Chronic Complications	1.331	1.199	1.120	1.000	0.957
Diabetes without Complication	1.331	1.199	1.120	1.000	0.957
Protein-Calorie Malnutrition	14.790	14.790	14.786	14.862	14.883
Mucopolysaccharidosis	2.335	2.198	2.130	2.071	2.052
Lipidoses and Glycogenosis	2.335	2.198	2.130	2.071	2.052
Amyloidosis, Porphyria, and Other Metabolic Disorders	2.335	2.198	2.130	2.071	2.052
Adrenal, Pituitary, and Other Significant Endocrine Disorders	2.335	2.198	2.130	2.071	2.052
Liver Transplant Status/Complications	18.445	18.197	18.105	18.165	18.188
End-Stage Liver Disease	6.412	6.102	5.974	6.001	6.012
Cirrhosis of Liver	2.443	2.255	2.177	2.137	2.125
Chronic Hepatitis	1.372	1.228	1.152	1.071	1.046
Acute Liver Failure/Disease, Including Neonatal Hepatitis	4.824	4.634	4.548	4.547	4.550
Intestine Transplant Status/Complications	77.945	78.110	78.175	78.189	78.195
Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	13.144	12.823	12.681	12.743	12.764
Intestinal Obstruction	7.257	6.922	6.789	6.842	6.864
Chronic Pancreatitis	6.682	6.385	6.269	6.309	6.329
Acute Pancreatitis/Other Pancreatic Disorders and Intestinal Malabsorption	3.614	3.380	3.281	3.245	3.234
Inflammatory Bowel Disease	2.894	2.640	2.517	2.398	2.355
Necrotizing Fasciitis	7.878	7.622	7.508	7.545	7.559
Bone/Joint/Muscle Infections/Necrosis	7.878	7.622	7.508	7.545	7.559
Rheumatoid Arthritis and Specified Autoimmune Disorders	3.414	3.135	3.009	2.987	2.982
Systemic Lupus Erythematosus and Other Autoimmune Disorders	1.263	1.124	1.051	0.954	0.921
Osteogenesis Imperfecta and Other Osteodystrophies	3.524	3.300	3.184	3.126	3.107
Congenital/Developmental Skeletal and Connective Tissue Disorders	3.524	3.300	3.184	3.126	3.107
Cleft Lip/Cleft Palate	2.168	1.978	1.891	1.815	1.793
Hemophilia	49.823	49.496	49.321	49.330	49.329
Myelodysplastic Syndromes and Myelofibrosis	15.404	15.253	15.182	15.214	15.224
Aplastic Anemia	15.404	15.253	15.182	15.214	15.224
Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	7.405	7.198	7.099	7.090	7.089
Sickle Cell Anemia (Hb-SS)	7.405	7.198	7.099	7.090	7.089
Thalassemia Major	7.405	7.198	7.099	7.090	7.089
Combined and Other Severe Immunodeficiencies	5.688	5.489	5.402	5.419	5.423
Disorders of the Immune Mechanism	5.688	5.489	5.402	5.419	5.423
Coagulation Defects and Other Specified Hematological Disorders	3.080	2.959	2.899	2.880	2.872
Drug Psychosis	3.776	3.517	3.389	3.302	3.274
Drug Dependence	3.776	3.517	3.389	3.302	3.274
Schizophrenia	3.122	2.854	2.732	2.647	2.624
Major Depressive and Bipolar Disorders	1.870	1.698	1.601	1.476	1.436
Reactive and Unspecified Psychosis, Delusional Disorders	1.870	1.698	1.601	1.476	1.436
Personality Disorders	1.187	1.065	0.974	0.836	0.790
Anorexia/Bulimia Nervosa	3.010	2.829	2.732	2.657	2.631
Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	5.387	5.219	5.141	5.101	5.091

TABLE 2—ADULT RISK ADJUSTMENT MODEL FACTORS—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes	1.264	1.171	1.099	1.015	0.985
Autistic Disorder	1.187	1.065	0.974	0.836	0.790
Pervasive Developmental Disorders, Except Autistic Disorder	1.187	1.065	0.974	0.836	0.790
Traumatic Complete Lesion Cervical Spinal Cord	11.728	11.537	11.444	11.448	11.449
Quadriplegia	11.728	11.537	11.444	11.448	11.449
Traumatic Complete Lesion Dorsal Spinal Cord	10.412	10.205	10.108	10.111	10.111
Paraplegia	10.412	10.205	10.108	10.111	10.111
Spinal Cord Disorders/Injuries	6.213	5.969	5.861	5.843	5.836
Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	3.379	3.094	2.967	2.927	2.919
Quadriplegic Cerebral Palsy	2.057	1.810	1.681	1.610	1.589
Cerebral Palsy, Except Quadriplegic	0.729	0.596	0.521	0.437	0.408
Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies	0.727	0.590	0.522	0.467	0.449
Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	5.174	4.999	4.921	4.900	4.891
Muscular Dystrophy	2.118	1.928	1.848	1.771	1.745
Multiple Sclerosis	7.441	6.971	6.764	6.830	6.850
Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders	2.118	1.928	1.848	1.771	1.745
Seizure Disorders and Convulsions	1.578	1.411	1.321	1.229	1.199
Hydrocephalus	7.688	7.552	7.486	7.492	7.493
Non-Traumatic Coma, and Brain Compression/Anoxic Damage	9.265	9.102	9.022	9.026	9.025
Respirator Dependence/Tracheostomy Status	40.054	40.035	40.022	40.105	40.131
Respiratory Arrest	12.913	12.707	12.612	12.699	12.728
Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes	12.913	12.707	12.612	12.699	12.728
Heart Assistive Device/Artificial Heart	33.372	33.025	32.877	32.978	33.014
Heart Transplant	33.372	33.025	32.877	32.978	33.014
Congestive Heart Failure	3.790	3.648	3.587	3.591	3.594
Acute Myocardial Infarction	11.904	11.451	11.258	11.423	11.478
Unstable Angina and Other Acute Ischemic Heart Disease	6.369	6.001	5.861	5.912	5.935
Heart Infection/Inflammation, Except Rheumatic	6.770	6.611	6.537	6.530	6.528
Specified Heart Arrhythmias	3.363	3.193	3.112	3.063	3.046
Intracranial Hemorrhage	10.420	10.062	9.907	9.943	9.959
Ischemic or Unspecified Stroke	4.548	4.304	4.215	4.242	4.256
Cerebral Aneurysm and Arteriovenous Malformation	5.263	5.000	4.890	4.867	4.859
Hemiplegia/Hemiparesis	5.979	5.846	5.794	5.858	5.881
Monoplegia, Other Paralytic Syndromes	4.176	4.024	3.959	3.938	3.931
Atherosclerosis of the Extremities with Ulceration or Gangrene	11.941	11.801	11.745	11.844	11.876
Vascular Disease with Complications	8.228	7.996	7.896	7.922	7.932
Pulmonary Embolism and Deep Vein Thrombosis	4.853	4.642	4.549	4.539	4.537
Lung Transplant Status/Complications	31.457	31.161	31.030	31.131	31.161
Cystic Fibrosis	10.510	10.142	9.957	9.960	9.962
Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	1.098	0.978	0.904	0.810	0.780
Asthma	1.098	0.978	0.904	0.810	0.780
Fibrosis of Lung and Other Lung Disorders	2.799	2.657	2.596	2.565	2.556
Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	9.052	8.934	8.883	8.913	8.924
Kidney Transplant Status	10.944	10.576	10.432	10.463	10.482
End Stage Renal Disease	37.714	37.356	37.193	37.352	37.403
Chronic Kidney Disease, Stage 5	2.189	2.048	1.995	1.990	1.992
Chronic Kidney Disease, Severe (Stage 4)	2.189	2.048	1.995	1.990	1.992
Ectopic and Molar Pregnancy, Except with Renal Failure, Shock, or Embolism	1.377	1.219	1.120	0.912	0.828
Miscarriage with Complications	1.377	1.219	1.120	0.912	0.828
Miscarriage with No or Minor Complications	1.377	1.219	1.120	0.912	0.828
Completed Pregnancy With Major Complications	3.778	3.285	3.134	2.931	2.906
Completed Pregnancy With Complications	3.778	3.285	3.134	2.931	2.906
Completed Pregnancy with No or Minor Complications	3.778	3.285	3.134	2.931	2.906
Chronic Ulcer of Skin, Except Pressure	2.515	2.371	2.313	2.304	2.304
Hip Fractures and Pathological Vertebral or Humerus Fractures	9.788	9.570	9.480	9.521	9.536
Pathological Fractures, Except of Vertebrae, Hip, or Humerus	1.927	1.805	1.735	1.648	1.620
Sternum Cell, Including Bone Marrow, Transplant Status/Complications	30.944	30.908	30.893	30.917	30.928

TABLE 2—ADULT RISK ADJUSTMENT MODEL FACTORS—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Artificial Openings for Feeding or Elimination	11.093	10.939	10.872	10.943	10.965
Amputation Status, Lower Limb/Amputation Complications	7.277	7.087	7.009	7.056	7.073
Interaction Factors					
Severe illness × Opportunistic Infections	12.094	12.327	12.427	12.527	12.555
Severe illness × Metastatic Cancer	12.094	12.327	12.427	12.527	12.555
Severe illness × Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	12.094	12.327	12.427	12.527	12.555
Severe illness × Non-Hodgkin's Lymphomas and Other Cancers and Tumors	12.094	12.327	12.427	12.527	12.555
Severe illness × Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	12.094	12.327	12.427	12.527	12.555
Severe illness × Heart Infection/Inflammation, Except Rheumatic	12.094	12.327	12.427	12.527	12.555
Severe illness × Intracranial Hemorrhage	12.094	12.327	12.427	12.527	12.555
Severe illness × HCC group G06 (HCC Group 6 includes Myelodysplastic Syndromes and Myelofibrosis, and Aplastic Anemia)	12.094	12.327	12.427	12.527	12.555
Severe illness × HCC group G08 (HCC Group 8 includes Combined and Other Severe Immunodeficiencies, and Disorders of the Immune Mechanism)	12.094	12.327	12.427	12.527	12.555
Severe illness × End-Stage Liver Disease	2.498	2.648	2.714	2.813	2.841
Severe illness × Acute Liver Failure/Disease, Including Neonatal Hepatitis	2.498	2.648	2.714	2.813	2.841
Severe illness × Atherosclerosis of the Extremities with Ulceration or Gangrene	2.498	2.648	2.714	2.813	2.841
Severe illness × Vascular Disease with Complications	2.498	2.648	2.714	2.813	2.841
Severe illness × Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	2.498	2.648	2.714	2.813	2.841
Severe illness × Artificial Openings for Feeding or Elimination	2.498	2.648	2.714	2.813	2.841
Severe illness × HCC group G03 (HCC Group 3 includes Necrotizing Fasciitis and Bone/Joint/Muscle Infections/ Necrosis)	2.498	2.648	2.714	2.813	2.841

TABLE 3—HHS HCCs IN THE SEVERE ILLNESS INDICATOR VARIABLE

Description
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock.
Peritonitis/Gastrointestinal Perforation/Necrotizing Enter colitis.
Seizure Disorders and Convulsions.
Non-Traumatic Coma, Brain Compression/Anoxic Damage.
Respirator Dependence/Tracheostomy Status.
Respiratory Arrest.
Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes.
Pulmonary Embolism and Deep Vein Thrombosis.

TABLE 4—CHILD RISK ADJUSTMENT MODEL FACTORS

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors					
Age 2–4, Male	0.283	0.209	0.106	0.019	0.000
Age 5–9, Male	0.196	0.140	0.064	0.005	0.000
Age 10–14, Male	0.246	0.189	0.110	0.047	0.033
Age 15–20, Male	0.336	0.273	0.191	0.114	0.095
Age 2–4, Female	0.233	0.165	0.071	0.019	0.000
Age 5–9, Female	0.165	0.113	0.048	0.005	0.000
Age 10–14, Female	0.223	0.168	0.095	0.042	0.031
Age 15–20, Female	0.379	0.304	0.198	0.101	0.077
Diagnosis Factors					
HIV/AIDS	2.956	2.613	2.421	2.228	2.166
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/ Shock	17.309	17.142	17.061	17.081	17.088

TABLE 4—CHILD RISK ADJUSTMENT MODEL FACTORS—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Central Nervous System Infections, Except Viral Meningitis	12.636	12.409	12.296	12.313	12.319
Viral or Unspecified Meningitis	3.202	3.004	2.896	2.750	2.702
Opportunistic Infections	20.358	20.262	20.222	20.201	20.189
Metastatic Cancer	34.791	34.477	34.307	34.306	34.300
Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	11.939	11.618	11.436	11.358	11.334
Non-Hodgkin's Lymphomas and Other Cancers and Tumors	9.354	9.071	8.908	8.806	8.774
Colorectal, Breast (Age < 50), Kidney, and Other Cancers	3.689	3.480	3.337	3.188	3.143
Benign/Uncertain Brain Tumors, and Other Cancers and Tumors ¹⁰ ...	3.308	3.084	2.954	2.814	2.769
Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors	1.530	1.368	1.254	1.114	1.066
Pancreas Transplant Status/Complications	18.933	18.476	18.264	18.279	18.289
Diabetes with Acute Complications	2.629	2.354	2.198	1.904	1.799
Diabetes with Chronic Complications	2.629	2.354	2.198	1.904	1.799
Diabetes without Complication	2.629	2.354	2.198	1.904	1.799
Protein-Calorie Malnutrition	13.930	13.794	13.726	13.751	13.759
Mucopolysaccharidosis	6.177	5.867	5.696	5.642	5.625
Lipidoses and Glycogenosis	6.177	5.867	5.696	5.642	5.625
Congenital Metabolic Disorders, Not Elsewhere Classified	6.177	5.867	5.696	5.642	5.625
Amyloidosis, Porphyria, and Other Metabolic Disorders	6.177	5.867	5.696	5.642	5.625
Adrenal, Pituitary, and Other Significant Endocrine Disorders	6.177	5.867	5.696	5.642	5.625
Liver Transplant Status/Complications	18.322	18.048	17.922	17.898	17.888
End-Stage Liver Disease	12.960	12.754	12.650	12.622	12.614
Cirrhosis of Liver	1.177	1.027	0.920	0.871	0.833
Chronic Hepatitis	1.177	1.027	0.920	0.807	0.775
Acute Liver Failure/Disease, Including Neonatal Hepatitis	6.255	6.092	6.003	5.972	5.966
Intestine Transplant Status/Complications	106.169	106.704	106.991	107.180	107.222
Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	16.784	16.360	16.156	16.171	16.179
Intestinal Obstruction	5.715	5.451	5.307	5.210	5.178
Chronic Pancreatitis	16.692	16.315	16.148	16.163	16.166
Acute Pancreatitis/Other Pancreatic Disorders and Intestinal Malabsorption	3.843	3.685	3.584	3.471	3.434
Inflammatory Bowel Disease	5.049	4.673	4.471	4.320	4.271
Necrotizing Fasciitis	5.829	5.551	5.398	5.318	5.292
Bone/Joint/Muscle Infections/Necrosis	5.829	5.551	5.398	5.318	5.292
Rheumatoid Arthritis and Specified Autoimmune Disorders	2.689	2.473	2.327	2.171	2.122
Systemic Lupus Erythematosus and Other Autoimmune Disorders	1.397	1.249	1.139	0.996	0.951
Osteogenesis Imperfecta and Other Osteodystrophies	1.536	1.410	1.311	1.211	1.183
Congenital/Developmental Skeletal and Connective Tissue Disorders	1.536	1.410	1.311	1.211	1.183
Cleft Lip/Cleft Palate	1.785	1.573	1.441	1.281	1.228
Hemophilia	46.388	45.839	45.551	45.541	45.535
Myelodysplastic Syndromes and Myelofibrosis	29.387	29.168	29.063	29.075	29.078
Aplastic Anemia	29.387	29.168	29.063	29.075	29.078
Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	7.791	7.476	7.308	7.229	7.203
Sickle Cell Anemia (Hb-SS)	7.791	7.476	7.308	7.229	7.203
Thalassemia Major	7.791	7.476	7.308	7.229	7.203
Combined and Other Severe Immunodeficiencies	5.690	5.455	5.339	5.270	5.247
Disorders of the Immune Mechanism	5.690	5.455	5.339	5.270	5.247
Coagulation Defects and Other Specified Hematological Disorders	4.909	4.754	4.650	4.543	4.511
Drug Psychosis	4.067	3.816	3.693	3.596	3.566
Drug Dependence	4.067	3.816	3.693	3.596	3.566
Schizophrenia	5.536	5.127	4.916	4.775	4.730
Major Depressive and Bipolar Disorders	1.779	1.591	1.453	1.252	1.188
Reactive and Unspecified Psychosis, Delusional Disorders	1.779	1.591	1.453	1.252	1.188
Personality Disorders	0.935	0.832	0.723	0.511	0.441
Anorexia/Bulimia Nervosa	2.565	2.372	2.252	2.146	2.111
Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	3.606	3.347	3.239	3.201	3.189
Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes	2.403	2.203	2.093	1.982	1.943
Autistic Disorder	1.673	1.500	1.372	1.177	1.112
Pervasive Developmental Disorders, Except Autistic Disorder	0.963	0.850	0.723	0.511	0.441
Traumatic Complete Lesion Cervical Spinal Cord	18.394	18.224	18.156	18.210	18.228
Quadriplegia	18.394	18.224	18.156	18.210	18.228
Traumatic Complete Lesion Dorsal Spinal Cord	18.394	18.224	18.156	18.210	18.228
Paraplegia	18.394	18.224	18.156	18.210	18.228
Spinal Cord Disorders/Injuries	4.668	4.416	4.287	4.181	4.150
Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	14.484	14.155	13.995	13.958	13.954
Quadriplegic Cerebral Palsy	5.717	5.367	5.223	5.251	5.262
Cerebral Palsy, Except Quadriplegic	1.899	1.672	1.557	1.447	1.412
Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies	0.943	0.785	0.686	0.592	0.562

TABLE 4—CHILD RISK ADJUSTMENT MODEL FACTORS—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	5.301	5.071	4.950	4.861	4.832
Muscular Dystrophy	3.122	2.915	2.800	2.698	2.669
Multiple Sclerosis	5.370	4.996	4.806	4.769	4.752
Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders	3.122	2.915	2.800	2.698	2.669
Seizure Disorders and Convulsions	2.188	2.012	1.882	1.702	1.644
Hydrocephalus	6.791	6.630	6.550	6.521	6.513
Non-Traumatic Coma, and Brain Compression/Anoxic Damage	9.073	8.882	8.788	8.753	8.735
Respirator Dependence/Tracheostomy Status	34.717	34.532	34.471	34.623	34.668
Respiratory Arrest	14.998	14.772	14.669	14.691	14.696
Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes	14.998	14.772	14.669	14.691	14.696
Heart Assistive Device/Artificial Heart	25.734	25.262	25.057	25.189	25.225
Heart Transplant	25.734	25.262	25.057	25.189	25.225
Congestive Heart Failure	6.292	6.159	6.073	6.013	5.992
Acute Myocardial Infarction	4.568	4.453	4.410	4.433	4.448
Unstable Angina and Other Acute Ischemic Heart Disease	4.568	4.453	4.410	4.433	4.448
Heart Infection/Inflammation, Except Rheumatic	12.842	12.655	12.573	12.590	12.597
Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders	7.019	6.823	6.668	6.528	6.480
Major Congenital Heart/Circulatory Disorders	2.257	2.143	2.018	1.870	1.828
Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders	1.411	1.319	1.206	1.078	1.047
Specified Heart Arrhythmias	4.483	4.276	4.141	4.052	4.026
Intracranial Hemorrhage	21.057	20.757	20.616	20.617	20.618
Ischemic or Unspecified Stroke	8.498	8.373	8.324	8.360	8.363
Cerebral Aneurysm and Arteriovenous Malformation	4.704	4.464	4.344	4.280	4.250
Hemiplegia/Hemiparesis	5.561	5.404	5.334	5.315	5.310
Monoplegia, Other Paralytic Syndromes	5.561	5.404	5.334	5.315	5.310
Atherosclerosis of the Extremities with Ulceration or Gangrene	10.174	9.937	9.799	9.688	9.641
Vascular Disease with Complications	11.571	11.355	11.257	11.260	11.272
Pulmonary Embolism and Deep Vein Thrombosis	13.894	13.661	13.557	13.591	13.604
Lung Transplant Status/Complications	100.413	100.393	100.412	100.660	100.749
Cystic Fibrosis	13.530	13.006	12.743	12.739	12.742
Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	0.521	0.458	0.354	0.215	0.175
Asthma	0.521	0.458	0.354	0.215	0.175
Fibrosis of Lung and Other Lung Disorders	5.812	5.657	5.555	5.472	5.450
Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	10.730	10.615	10.549	10.566	10.571
Kidney Transplant Status	18.933	18.476	18.264	18.279	18.289
End Stage Renal Disease	43.158	42.816	42.659	42.775	42.808
Chronic Kidney Disease, Stage 5	11.754	11.581	11.472	11.374	11.340
Chronic Kidney Disease, Severe (Stage 4)	11.754	11.581	11.472	11.374	11.340
Ectopic and Molar Pregnancy, Except with Renal Failure, Shock, or Embolism	1.191	1.042	0.917	0.674	0.590
Miscarriage with Complications	1.191	1.042	0.917	0.674	0.590
Miscarriage with No or Minor Complications	1.191	1.042	0.917	0.674	0.590
Completed Pregnancy With Major Complications	3.419	2.956	2.778	2.498	2.437
Completed Pregnancy With Complications	3.419	2.956	2.778	2.498	2.437
Completed Pregnancy with No or Minor Complications	3.419	2.956	2.778	2.498	2.437
Chronic Ulcer of Skin, Except Pressure	1.570	1.479	1.394	1.314	1.289
Hip Fractures and Pathological Vertebral or Humerus Fractures	7.389	7.174	7.022	6.882	6.842
Pathological Fractures, Except of Vertebrae, Hip, or Humerus	2.353	2.244	2.128	1.965	1.912
Stem Cell, Including Bone Marrow, Transplant Status/Complications ..	30.558	30.485	30.466	30.522	30.538
Artificial Openings for Feeding or Elimination	14.410	14.247	14.197	14.340	14.383
Amputation Status, Lower Limb/Amputation Complications	10.174	9.937	9.799	9.688	9.641

¹⁰ This HCC also includes Breast (Age 50+) and Prostate Cancer.

TABLE 5—INFANT RISK ADJUSTMENT MODELS FACTORS

Group	Platinum	Gold	Silver	Bronze	Catastrophic
Extremely Immature * Severity Level 5 (Highest)	393.816	392.281	391.387	391.399	391.407
Extremely Immature * Severity Level 4	225.037	223.380	222.424	222.371	222.365
Extremely Immature * Severity Level 3	60.363	59.232	58.532	58.247	58.181
Extremely Immature * Severity Level 2	60.363	59.232	58.532	58.247	58.181
Extremely Immature * Severity Level 1 (Lowest)	60.363	59.232	58.532	58.247	58.181
Immature * Severity Level 5 (Highest)	207.274	205.589	204.615	204.629	204.644
Immature * Severity Level 4	89.694	88.105	87.188	87.169	87.178
Immature * Severity Level 3	45.715	44.305	43.503	43.394	43.379
Immature * Severity Level 2	33.585	32.247	31.449	31.221	31.163
Immature * Severity Level 1 (Lowest)	33.585	32.247	31.449	31.221	31.163
Premature/Multiples * Severity Level 5 (Highest)	173.696	172.095	171.169	171.111	171.108
Premature/Multiples * Severity Level 4	34.417	32.981	32.155	31.960	31.925
Premature/Multiples * Severity Level 3	18.502	17.382	16.694	16.311	16.200
Premature/Multiples * Severity Level 2	9.362	8.533	7.967	7.411	7.241
Premature/Multiples * Severity Level 1 (Lowest)	6.763	6.144	5.599	4.961	4.771
Term * Severity Level 5 (Highest)	132.588	131.294	130.511	130.346	130.292
Term * Severity Level 4	20.283	19.222	18.560	18.082	17.951
Term * Severity Level 3	6.915	6.286	5.765	5.092	4.866
Term * Severity Level 2	3.825	3.393	2.925	2.189	1.951
Term * Severity Level 1 (Lowest)	1.661	1.449	0.998	0.339	0.188
Age1 * Severity Level 5 (Highest)	62.385	61.657	61.217	61.130	61.108
Age1 * Severity Level 4	10.855	10.334	9.988	9.747	9.686
Age1 * Severity Level 3	3.633	3.299	3.007	2.692	2.608
Age1 * Severity Level 2	2.177	1.930	1.665	1.320	1.223
Age1 * Severity Level 1 (Lowest)	0.631	0.531	0.333	0.171	0.137
Age 0 Male	0.629	0.587	0.574	0.533	0.504
Age 1 Male	0.117	0.102	0.094	0.065	0.054

TABLE 6—HHS HCCs INCLUDED IN INFANT MODEL MATURITY CATEGORIES

Maturity category	HCC/Description
Extremely Immature	Extremely Immature Newborns, Birthweight < 500 Grams.
Extremely Immature	Extremely Immature Newborns, Including Birthweight 500–749 Grams.
Extremely Immature	Extremely Immature Newborns, Including Birthweight 750–999 Grams.
Immature	Premature Newborns, Including Birthweight 1000–1499 Grams.
Immature	Premature Newborns, Including Birthweight 1500–1999 Grams.
Premature/Multiples	Premature Newborns, Including Birthweight 2000–2499 Grams.
Premature/Multiples	Other Premature, Low Birthweight, Malnourished, or Multiple Birth Newborns.
Term	Term or Post-Term Singleton Newborn, Normal or High Birthweight.
Age 1	All age 1 infants.

TABLE 7—HHS HCCs INCLUDED IN INFANT MODEL SEVERITY CATEGORIES

Severity category	HCC
Severity Level 5 (Highest)	Metastatic Cancer.
Severity Level 5	Pancreas Transplant Status/Complications.
Severity Level 5	Liver Transplant Status/Complications.
Severity Level 5	End-Stage Liver Disease.
Severity Level 5	Intestine Transplant Status/Complications.
Severity Level 5	Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis.
Severity Level 5	Respirator Dependence/Tracheostomy Status.
Severity Level 5	Heart Assistive Device/Artificial Heart.
Severity Level 5	Heart Transplant.
Severity Level 5	Congestive Heart Failure.
Severity Level 5	Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders.
Severity Level 5	Lung Transplant Status/Complications.
Severity Level 5	Kidney Transplant Status.
Severity Level 5	End Stage Renal Disease.
Severity Level 5	Stem Cell, Including Bone Marrow, Transplant Status/Complications.
Severity Level 4	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock.
Severity Level 4	Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia.
Severity Level 4	Mucopolysaccharidosis.
Severity Level 4	Major Congenital Anomalies of Diaphragm, Abdominal Wall, and Esophagus, Age < 2.
Severity Level 4	Myelodysplastic Syndromes and Myelofibrosis.
Severity Level 4	Aplastic Anemia.
Severity Level 4	Combined and Other Severe Immunodeficiencies.

TABLE 7—HHS HCCs INCLUDED IN INFANT MODEL SEVERITY CATEGORIES—Continued

Severity category	HCC
Severity Level 4	Traumatic Complete Lesion Cervical Spinal Cord.
Severity Level 4	Quadriplegia.
Severity Level 4	Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease.
Severity Level 4	Quadriplegic Cerebral Palsy.
Severity Level 4	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy.
Severity Level 4	Non-Traumatic Coma, Brain Compression/Anoxic Damage.
Severity Level 4	Respiratory Arrest.
Severity Level 4	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes.
Severity Level 4	Acute Myocardial Infarction.
Severity Level 4	Heart Infection/Inflammation, Except Rheumatic.
Severity Level 4	Major Congenital Heart/Circulatory Disorders.
Severity Level 4	Intracranial Hemorrhage.
Severity Level 4	Ischemic or Unspecified Stroke.
Severity Level 4	Vascular Disease with Complications.
Severity Level 4	Pulmonary Embolism and Deep Vein Thrombosis.
Severity Level 4	Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections.
Severity Level 4	Chronic Kidney Disease, Stage 5.
Severity Level 4	Hip Fractures and Pathological Vertebral or Humerus Fractures.
Severity Level 4	Artificial Openings for Feeding or Elimination.
Severity Level 3	HIV/AIDS.
Severity Level 3	Central Nervous System Infections, Except Viral Meningitis.
Severity Level 3	Opportunistic Infections.
Severity Level 3	Non-Hodgkin's Lymphomas and Other Cancers and Tumors.
Severity Level 3	Colorectal, Breast (Age < 50), Kidney and Other Cancers.
Severity Level 3	Benign/Uncertain Brain Tumors, and Other Cancers and Tumors. ¹¹
Severity Level 3	Lipidoses and Glycogenosis.
Severity Level 3	Adrenal, Pituitary, and Other Significant Endocrine Disorders.
Severity Level 3	Acute Liver Failure/Disease, Including Neonatal Hepatitis.
Severity Level 3	Intestinal Obstruction.
Severity Level 3	Necrotizing Fasciitis.
Severity Level 3	Bone/Joint/Muscle Infections/Necrosis.
Severity Level 3	Osteogenesis Imperfecta and Other Osteodystrophies.
Severity Level 3	Cleft Lip/Cleft Palate.
Severity Level 3	Hemophilia.
Severity Level 3	Disorders of the Immune Mechanism.
Severity Level 3	Coagulation Defects and Other Specified Hematological Disorders.
Severity Level 3	Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes.
Severity Level 3	Traumatic Complete Lesion Dorsal Spinal Cord.
Severity Level 3	Paraplegia.
Severity Level 3	Spinal Cord Disorders/Injuries.
Severity Level 3	Cerebral Palsy, Except Quadriplegic.
Severity Level 3	Muscular Dystrophy.
Severity Level 3	Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders.
Severity Level 3	Hydrocephalus.
Severity Level 3	Unstable Angina and Other Acute Ischemic Heart Disease.
Severity Level 3	Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders.
Severity Level 3	Specified Heart Arrhythmias.
Severity Level 3	Cerebral Aneurysm and Arteriovenous Malformation.
Severity Level 3	Hemiplegia/Hemiparesis.
Severity Level 3	Cystic Fibrosis.
Severity Level 3	Fibrosis of Lung and Other Lung Disorders.
Severity Level 3	Pathological Fractures, Except of Vertebrae, Hip, or Humerus.
Severity Level 2	Viral or Unspecified Meningitis.
Severity Level 2	Thyroid, Melanoma, Neurofibromatosis, and Other Cancers and Tumors.
Severity Level 2	Diabetes with Acute Complications.
Severity Level 2	Diabetes with Chronic Complications.
Severity Level 2	Diabetes without Complication.
Severity Level 2	Protein-Calorie Malnutrition.
Severity Level 2	Congenital Metabolic Disorders, Not Elsewhere Classified.
Severity Level 2	Amyloidosis, Porphyria, and Other Metabolic Disorders.
Severity Level 2	Cirrhosis of Liver.
Severity Level 2	Chronic Pancreatitis.
Severity Level 2	Inflammatory Bowel Disease.
Severity Level 2	Rheumatoid Arthritis and Specified Autoimmune Disorders.
Severity Level 2	Systemic Lupus Erythematosus and Other Autoimmune Disorders.
Severity Level 2	Congenital/Developmental Skeletal and Connective Tissue Disorders.
Severity Level 2	Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn.
Severity Level 2	Sickle Cell Anemia (Hb-SS).

TABLE 7—HHS HCCs INCLUDED IN INFANT MODEL SEVERITY CATEGORIES—Continued

Severity category	HCC
Severity Level 2	Drug Psychosis.
Severity Level 2	Drug Dependence.
Severity Level 2	Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes.
Severity Level 2	Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies.
Severity Level 2	Seizure Disorders and Convulsions.
Severity Level 2	Monoplegia, Other Paralytic Syndromes.
Severity Level 2	Atherosclerosis of the Extremities with Ulceration or Gangrene.
Severity Level 2	Chronic Obstructive Pulmonary Disease, Including Bronchiectasis.
Severity Level 2	Chronic Ulcer of Skin, Except Pressure.
Severity Level 1 (Lowest)	Chronic Hepatitis.
Severity Level 1	Acute Pancreatitis/Other Pancreatic Disorders and Intestinal Malabsorption.
Severity Level 1	Thalassemia Major.
Severity Level 1	Autistic Disorder.
Severity Level 1	Pervasive Developmental Disorders, Except Autistic Disorder.
Severity Level 1	Multiple Sclerosis.
Severity Level 1	Asthma.
Severity Level 1	Chronic Kidney Disease, Severe (Stage 4).
Severity Level 1	Amputation Status, Lower Limb/Amputation Complications.
Severity Level 1	No Severity HCCs.

TABLE 8—R-SQUARED STATISTIC FOR HHS RISK ADJUSTMENT MODELS

Risk adjustment model	R-Squared statistic
Platinum Adult	0.360
Platinum Child	0.307
Platinum Infant	0.292
Gold Adult	0.355
Gold Child	0.302
Gold Infant	0.289
Silver Adult	0.352
Silver Child	0.299
Silver Infant	0.288
Bronze Adult	0.351
Bronze Child	0.296
Bronze Infant	0.289
Catastrophic Adult	0.350
Catastrophic Child	0.295

TABLE 8—R-SQUARED STATISTIC FOR HHS RISK ADJUSTMENT MODELS—Continued

Risk adjustment model	R-Squared statistic
Catastrophic Infant	0.289

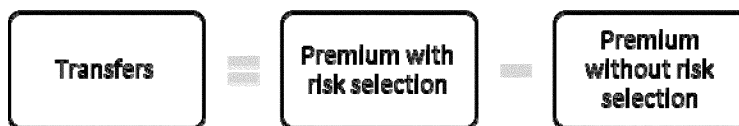
c. Overview of the Payment Transfer Formula

In the proposed rule, we proposed to calculate risk adjustment transfers after the close of the applicable benefit year, following the completion of issuer risk adjustment data reporting.

Transfers are calculated at the geographic rating area level for each plan (HHS would calculate two separate transfer amounts for a plan that operates in two rating areas). In other words, the

payment transfer formula would treat each rating area segment of enrollment as a separate plan for the purposes of calculating transfers. Payment transfer amounts would be aggregated at the issuer level (that is, at the level of the entity licensed by the State) such that each issuer would receive an invoice and a report detailing the basis for the net payment that would be made or the charge that would be owed. The invoice would also include plan-level risk adjustment information.

The payment transfer formula is based on the difference between two plan premium estimates: (1) A premium based on plan-specific risk selection; and (2) a premium without risk selection. Transfers are intended to bridge the gap between these two premium estimates:



Conceptually, the goal of payment transfers is to provide plans with payments to help cover their actual risk exposure beyond the premiums the plans would charge reflecting allowable rating and their applicable cost factors. In other words, payments would help cover excess actuarial risk due to risk selection. Both of these premium estimates are based on the State average premium. The payment transfer formula

includes the following premium adjustment terms:

- Plan average risk score: Multiplying the plan average risk score by the State average premium shows how a plan's premium would differ from the State average premium based on the risk selection experienced by the plan.

- Actuarial value (AV): A particular plan's premium may differ from the State average premium based on the plan's cost-sharing structure, or AV. An

AV adjustment is applied to the State average premium to account for relative differences between a plan's AV and the market average AV.

- Permissible rating variation: Plan rates may differ based on allowable age rating factors. The rating adjustment accounts for the impact of allowable rating factors on the premium that would be realized by the plan.

- Geographic cost differences: Differences in unit costs and utilization

¹¹ This HCC also includes Breast (Age 50+) and Prostate Cancer.

may lead to differences in the average premium between intra-State rating areas, holding other cost factors (for example, benefit design) constant. The geographic cost adjustment accounts for cost differences across rating areas.

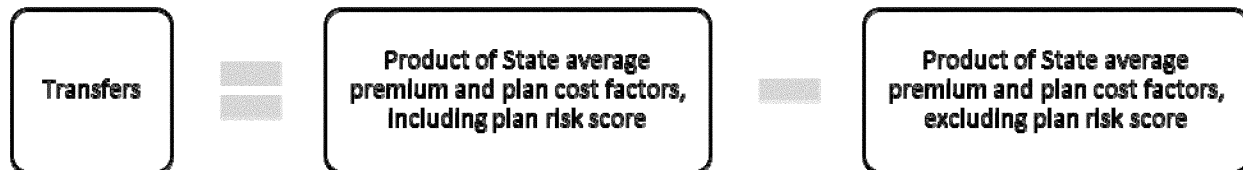
- Induced demand: Enrollee spending patterns may vary based on the generosity of cost sharing. The induced demand adjustment accounts for greater utilization of health care services induced by lower enrollee cost sharing in higher metal level plans.

The State average premium is multiplied by these factors to develop the plan premium estimates used in the payment transfer formula. The factors are relative measures that compare how plans differ from the market average with respect to the cost factors (that is to say, the product of the adjustments is normalized to the market average product of the cost factors).

In the absence of these adjustments, transfers would reflect liability differences attributed to cost factors other than risk selection. For example,

in the absence of the AV adjustment, a low AV plan with lower-risk enrollees would be overcharged because the State average premium would not be scaled down to reflect the fact that the plan's AV is lower than the average AV of plans operating in the market in the State.

The figure below shows how the State average premium, the plan average risk score, and other plan-specific cost factors are used to develop the two plan premium estimates that are used to calculate payment transfers:



We are finalizing the payment transfer formula as proposed, with several technical corrections. We clarify that IDF stands for induced demand factor in

the equations, and modify the denominator of the plan average premium formula within the State average premium and geographic cost

factor calculations to reflect the billable member calculation. Therefore, the 2014 HHS risk adjustment payment transfer formula is:

$$T_i = \left[\frac{PLRS_i \cdot IDF_i \cdot GCF_i}{\sum_i (s_i \cdot PLRS_i \cdot IDF_i \cdot GCF_i)} - \frac{AV_i \cdot ARF_i \cdot IDF_i \cdot GCF_i}{\sum_i (s_i \cdot AV_i \cdot ARF_i \cdot IDF_i \cdot GCF_i)} \right] \bar{P}_s$$

Where:

$\bar{P}_s$ = State average premium;
 $PLRS_i$ = plan i 's plan liability risk score;
 AV_i = plan i 's metal level AV;
 ARF_i = plan i 's allowable rating factor;
 IDF_i = plan i 's induced demand factor;
 GCF_i = plan i 's geographic cost factor;
 s_i = plan i 's share of State enrollment;
 and the denominator is summed across all plans in the risk pool in the market in the State.

Risk adjustment transfers will be calculated at the risk pool level. Each State will have a risk pool for all of its metal-level plans. Catastrophic plans will be treated as a separate risk pool for purposes of risk adjustment. Individual and small group market plans will either be pooled together or treated as separate risk pools, depending on how the State treats these pools under the single risk pool provisions.

The payment transfer formula provides a per member per month (PMPM) transfer amount for a plan within a rating area. The PMPM transfer amount derived from the payment transfer formula (T_{PMPM}) will be

multiplied by each plan's rating area billable member months ($\sum_b M_b$) to calculate the plan's total risk adjustment payment for a given rating area (T_i).

$$T_i = T_{PMPM} * \sum_b M_b$$

Comment: We received a number of comments in support of the general approach to calculating payment transfers, including HHS's approach to adjusting for plan cost factors in the transfer equation.

Response: We are finalizing the payment transfer formula as proposed with minor technical corrections, specified below.

Comment: We received one comment requesting that HHS clarify the calculation of payment transfers at the plan level.

Response: Because we have proposed and are finalizing a geographic cost factor, transfers must be calculated for each rating area in which a plan operates. However, we note that, because the denominator of each term of

the payment transfer equation is the Statewide average of the product of the terms, transfers occur within the risk pool within the market within the State.

Comment: We received one comment requesting that HHS provide detailed examples of the payment transfer formula.

Response: We anticipate working closely with issuers and other stakeholders to provide examples of the payment transfer formula and its application in a market.

(1) State Average Premium

We proposed a payment transfer formula that is based on the State average premium for the applicable market. Plan average premiums will be calculated from the actual premiums charged to their enrollees, weighted by the number of months enrolled. We make a technical correction to the formula to calculate PMPM plan average premiums, as described below. The equations for calculating State average premiums were proposed as:

$$\bar{P}_s = \sum_i s_i^s \bar{P}_i$$

and

$$\bar{P}_i = \frac{\sum_s (M_s \cdot P_s)}{\sum_s M_s}$$

The first equation calculates the State average premium $\bar{P}_s$ as the average of individual plan averages, $\bar{P}_i$ weighted by each plan's share of Statewide enrollment in the risk pool in the market, s_i^s (based on billable member months).

The second equation shows the proposed formula to calculate plan average premiums. The proposed formula, which we are modifying as described below, was the weighted mean over all subscribers s of subscriber premiums P_s , with M_s representing the number of billable member months of enrollment for each subscriber s . Due to a typographical error and to align with the calculation of plan average risk score, we have modified the denominator of the plan average premium equation from the proposed rule. The denominator in the revised formula is equal to the sum of the billable member months for all billable members b enrolled in the plan. The numerator of this formula remains unchanged from the proposed rule. The numerator is equal to the product of each subscriber's billable member months (the billable member months attributed to the individual that is the policy subscriber) and the average monthly premium for the subscriber, summed across all of the subscribers s in the plan. The calculation of each plan's total premium revenue—the numerator of this formula—uses subscriber-level premiums in order to align with the way that premium information will be captured in data on issuers' distributed data environments. The final formula is:

$$\bar{P}_i = \frac{\sum_s (M_s \cdot P_s)}{\sum_b M_b}$$

Billable member months are defined as the number of months during the risk adjustment period billable members are enrolled in the plan (billable members exclude children who do not count towards family rates). In non-community rated States, issuers are required to individually rate each member covered under a family policy and, in the case of large families, issuers are only allowed to include the three

oldest children in the development of family rates. Therefore, for large families, only the three oldest children are counted as billable members in the risk adjustment transfer formula. In community rated States that require family tiering, the number of billable members under a family policy may vary based on the State's tiering structure. For example, if a State's largest family tier is set at two or more children, only the first two children under the family policy would count as billable members. HHS will assess each State's rating requirements and will provide community rated States with additional details on how billable members will be counted in the transfer formula.

Comment: We received a number of comments in support of our proposal to use the State average premium as the basis for risk adjustment transfers. One commenter suggested that use of a plan's own premium may cause unintended distortions in the transfer formula. One commenter suggested that we use net claims, or approximate net claims by using 90 percent of the State average premium, as the basis for risk adjustment transfers.

Response: The goal of the payment transfer formula is, to the extent possible, to promote risk-neutral premiums. We agree with commenters that use of a plan's own premium may cause unintended distortions in transfers. We also believe that both claims and administrative costs include elements of risk selection, and therefore, that transfers should be based on the entire premium. We are finalizing our proposal to base the payment transfer formula on the State average premium.

(2) Plan Average Risk Score

The proposed plan average risk score calculation included an adjustment to account for the family rating rules set forth in the Market Reform Rule, which

limits the number of dependent children in non-community rated States that count toward the build-up of family rates to three. The formula below shows the final plan average risk score calculation including the risk of all members on the policy, including those children not included in the premium.

$$PLRS_i = \frac{\sum_e M_e \cdot PLRS_e}{\sum_b M_b}$$

Where:

$PLRS_i$ is plan i 's average plan liability risk score, the subscript e denotes each enrollee within the plan;

$PLRS_e$ is each enrollee's individual plan liability risk score;

M_e is the number of months during the risk adjustment period the enrollee is enrolled in the plan; and

M_b is the number of months during the risk adjustment period the billable member b is enrolled in the plan (billable members exclude children who do not count towards family rates).

We received the following comments regarding the calculation of the plan average risk score:

Comment: We received comments in support of this approach to calculating plan average risk score. We received one comment that calculating plan average risk score with an adjustment for billable members would be administratively burdensome for issuers.

Response: We are finalizing this term as proposed. We note that, when HHS is operating risk adjustment on behalf of the State, HHS will calculate the plan average risk score and so there will be no additional administrative burden for issuers.

(3) Actuarial Value (AV)

The proposed AV adjustment in the payment transfer formula accounts for relative differences in plan liability due to differences in AV. Table 9 shows the AV adjustment that will be used for

each category of metal level plans. We received no comments on this adjustment, and are finalizing this provision as proposed.

TABLE 9—ACTUARIAL VALUE (AV) ADJUSTMENT USED FOR EACH METAL LEVEL IN THE PAYMENT TRANSFER FORMULA

Metal level	AV Adjustment
Catastrophic	0.57
Bronze	0.60
Silver	0.70

TABLE 9—ACTUARIAL VALUE (AV) ADJUSTMENT USED FOR EACH METAL LEVEL IN THE PAYMENT TRANSFER FORMULA—Continued

Metal level	AV Adjustment
Gold	0.80
Platinum	0.90

(4) Allowable rating variation

We proposed an allowable rating factor adjustment in the payment transfer formula. The Allowable Rating Factor (ARF) adjustment accounts only

for age rating. Tobacco use, wellness discounts, and family rating requirements will not be included in the payment transfer formula. Geographic cost variation is treated as a separate adjustment in the payment transfer formula. We recognize that there may be special rating circumstances in States (for example, community rating) and we intend to clarify how the payment transfer formula will address these circumstances through future rulemaking or guidance. We received comments in support of the allowable rating variation adjustment, and are finalizing this provision as proposed.

TABLE 10—EXAMPLE ALLOWABLE RATING FACTOR CALCULATION

Age band	State age-rating curve	Enrollment percentages (Share of member-months)			
		Plan A	Plan B	Plan C	State
21	1.000	33.30 percent ...	40.00 percent ...	10.00 percent ...	31.70 percent
(Age bands from 22–39 omitted)					
40	1.278	33.30 percent ...	40.00 percent ...	20.00 percent ...	33.30 percent
(Age bands from 41–63 omitted)					
64 and older	3.000	33.30 percent ...	20.00 percent ...	70.00 percent ...	35.00 percent
Total member-months		300,000	200,000	100,000	600,000
Allowable Rating Factor		1.758	1.511	2.456	1.793

(5) Induced demand

We proposed to use the same induced demand factors in the payment transfer formula, shown in Table 11. We received the following comments regarding the induced demand proposed provisions:

Comment: We received comments that, due to a typographical error, the definition of the induced demand factor expressed in the full payment transfer formula in the proposed rule was “plan i’s allowable rating factor” rather than “plan i’s induced demand factor.”

Response: We have made this change in the equation above.

TABLE 11—INDUCED DEMAND ADJUSTMENT USED FOR EACH METAL LEVEL IN THE PAYMENT TRANSFER FORMULA

Metal level	Induced demand adjustment
Catastrophic	1.00
Bronze	1.00
Silver	1.03
Gold	1.08
Platinum	1.15

(6) Geographic Area Cost Variation

The proposed geographic cost factor (GCF) is an adjustment in the payment transfer formula because there are some plan costs—such as input prices or

utilization rates—that vary geographically and are likely to affect plan premiums. GCFs will be calculated for each rating area established by the State under § 147.102(b). These factors will be calculated based on the observed average silver plan premium for the metal-level risk pool (calculated separately for individual and small group if the State does not have a merged market) or catastrophic plan premium for the catastrophic risk pool, in a geographic area relative to the Statewide average silver or catastrophic plan premium. Calculation of the GCF involves three steps. First, the average premium is computed for each silver or catastrophic plan, as applicable, in each rating area (using the same formula that is used to compute plan premiums in the State average premium calculation discussed above). We note that the same modification described above regarding the calculation of the plan average premium also applies to this term. The proposed calculation was:

$$\bar{P}_i = \frac{\sum_s (M_s \cdot P_s)}{\sum_s M_s}$$

Where:

$\bar{P}_i$ is the average premium for plan i ; s indexes all subscribers enrolled in the plan; M_s is the number of billable member months for billable members under the policy of subscriber s ; and P_s is the premium for subscriber s .

The final calculation is:

$$\bar{P}_i = \frac{\sum_s (M_s \cdot P_s)}{\sum_b M_b}$$

Where:

$\bar{P}_i$ is the average premium for plan i ; s indexes all subscribers enrolled in the plan; M_s is the number of billable member months for the subscriber s ; P_s is the premium for subscriber s ; and M_b is the number of billable members b enrolled in the plan.

The second step is to generate a set of plan average premiums that standardizes the premiums for age rating. Plan premiums are standardized for age by dividing the average plan premium by the plan rating factor (calculated at the rating area level), the enrollment-weighted rating factor applied to all billable members (discussed above). This formula is:

$$\bar{P}_i^{AS} = \bar{P}_i / (ARF_i)$$

Where:

$\bar{P}_i^{AS}$ is plan i ’s age standardized average premium; $\bar{P}_i$ is the average premium for plan i ; and ARF_i is the allowable rating factor.

The third and final step is to compute a GCF for each area in each risk pool and assign it to all plans in that area. This is accomplished with the following calculation:

$$GCF_i = \left(\sum_{area} s_i^a \cdot \bar{P}_i^{AS} \right) / \left(\sum_{state} s_i^s \cdot \bar{P}_i^{AS} \right)$$

This equation divides the enrollment-weighted average of standardized silver-level plan premiums in a geographic area by the average of those premiums Statewide.

The numerator's summation is over all silver-level plans within plan *i*'s geographic area,

so $\sum_{area} s_i^a = 1$. Similarly, the summation in the denominator is over all silver-level

plans in the State, so $\sum_{state} s_i^s = 1$.

With the exception of the plan average risk score calculation discussed above, all of the other calculations used in the payment transfer formula are based on billable members (that is, children who do not count toward family policy premiums are excluded). Member months, the State average premium, the allowable rating factor, and the geographic cost factor are all calculated based on billable members.

Comment: We received one comment requesting that HHS include a geographic cost adjustment even if the State elected to use one rating area. Another commenter suggested that HHS include an adjustment in the risk adjustment methodology that accounts for the increased cost of providing care in rural areas.

Response: The purpose of the geographic cost adjustment is to remove differences in premium due to allowable geographic rating variation. We believe that the cost of care in a particular area are reflected in premiums, and therefore captured in the geographic cost factor adjustment. Issuers of plans in a State with a single rating area would not vary rates within the State based on geography, and so it would not be necessary to remove differences in premiums due to allowed rating variation based on geography.

d. Overview of the Data Collection Approach

In § 153.20, we proposed a technical correction to the definition of risk adjustment data collection approach. We proposed to delete “and audited” so that the definition of risk adjustment data collection approach means “the specific procedures by which risk adjustment data is to be stored, collected, accessed, transmitted, validated and the applicable timeframes, data formats, and privacy and security standards.” We received no

comments on the proposed technical correction to the definition of data collection approach, and are finalizing the provision as proposed. Comments regarding the data collection approach for the risk adjustment program are addressed in section III.G. of this final rule.

We also proposed to modify § 153.340(b)(3) by adding the additional restriction that “Use and disclosure of personally identifiable information is limited to those purposes for which the personally identifiable information was collected (including for purposes of data validation).” “Personally identifiable information” is a broadly used term across Federal agencies, and has been defined in the Office of Management and Budget Memorandum M–07–16 (May 22, 2007).¹² This addition will further ensure the privacy and security of potentially sensitive data by limiting the use or disclosure of any personally identifiable information collected as a part of this program. We received no comments on the proposed modification and are finalizing the provision as proposed.

e. Schedule for Risk Adjustment

Under § 153.610(a), issuers of risk adjustment covered plans will provide HHS with risk adjustment data in the form and manner specified by HHS. Under the HHS-operated risk adjustment program, issuers will not send, but must make available to HHS, anonymized claims and enrollment data, as specified in section III.G. of this final rule, for benefit year 2014 beginning January 1, 2014. Enrollee risk scores will be calculated based on enrollee enrollment periods and claims dates of discharge that occur between January 1, 2014 and December 31, 2014.

¹² Available at: <http://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2007/m07-16.pdf>.

Enrollee risk scores for subsequent benefit years will be calculated based on claims and enrollment periods for that same benefit year.

As set forth in the proposed § 153.730, claims to be used in the risk score calculation must be made available to HHS by April 30 of the year following the benefit year. We believe this date provides for ample claims run-out to ensure that diagnoses for the benefit year are captured, while providing HHS sufficient time to run enrollee risk score, plan average risk, and payments and charges calculations and meet the June 30 deadline described at the redesignated § 153.310(e). Comments in response to the proposed § 153.730 are addressed in section III.G of this final rule.

Comment: We received a number of comments that HHS should provide issuers with interim reports of risk scores and other information.

Response: We are committed to implementing the risk adjustment program in a transparent way, and seek to provide issuers with the information necessary for program operations and rate development. We are assessing the feasibility of providing program information prior to the close of the benefit year.

4. State Alternate Methodology

a. Technical Correction

The Premium Stabilization Rule established standards for States that establish their own risk adjustment programs. Under the proposed revision to § 153.310, a State may establish a risk adjustment program if it elects to operate an Exchange and is approved to operate risk adjustment in the State. If a State does not meet the requirements to operate risk adjustment, HHS will carry out all functions of risk adjustment on behalf of the State. In

§ 153.320(a), we established that Federally certified methodologies must be used in the operation of the risk adjustment program, and defined the process by which a methodology may become Federally certified. We proposed to modify § 153.320(a)(1) and (a)(2) to clarify that these methodologies must be published in “the applicable annual” notice of benefit and payment parameters as opposed to “an annual” HHS notice of benefit and payment parameters. This proposed change makes clear that methodologies must be certified for use each year. We did not receive any comments on this proposed change, and will finalize it as proposed.

b. State Alternate Risk Adjustment Methodology Evaluation Criteria

In § 153.330(a), we specified the elements required to be included with the request to HHS for certification of an alternate risk adjustment methodology. Section 153.330(a)(1)(i) states that a request for certification for an alternate methodology must include the elements specified in § 153.320(b), which includes a complete description of: (1) The risk adjustment model; (2) the calculation of plan average actuarial risk; (3) the calculation of payments and charges; (4) the risk adjustment data collection approach; and (5) the schedule for the risk adjustment program. Section 153.330(a)(1)(ii) states that the alternate methodology request must also include the calibration methodology and frequency of calibration, and § 153.330(a)(1)(iii) provides that the request must include statistical performance metrics specified by HHS. Section 153.330(a)(2) requires that the request also include certain descriptive and explanatory information relating to the alternate methodology. We proposed to evaluate risk adjustment methodologies based on the information submitted under § 153.330(a). We proposed additional evaluation criteria to certify alternate risk adjustment methodologies in a new paragraph § 153.330(b).

In the new § 153.330(b)(1), we proposed to consider whether the alternate risk adjustment methodology meets criteria that correspond to the elements of the alternate methodology request described in paragraph § 153.330(a)(1) and (2). Specifically, we stated that we would be evaluating the extent to which an alternate risk adjustment methodology:

- (i) Explains the variation in health care costs of a given population;
- (ii) Links risk factors to daily clinical practices and is clinically meaningful to providers;

- (iii) Encourages favorable behavior among providers and health plans and discourages unfavorable behavior;

- (iv) Uses data that is complete, high in quality, and available in a timely fashion;

- (v) Is easy for stakeholders to understand and implement;

- (vi) Provides stable risk scores over time and across plans; and

- (vii) Minimizes administrative costs.

For example, to determine the extent that an alternate methodology explains the variation in health care costs of a given population, we would consider whether the risk adjustment model was calibrated from data reflecting the applicable market benefits, was calibrated on a sample that is reasonably representative of the anticipated risk adjustment population, and was calibrated using a sufficient sample to ensure stable weights across time and plans. In addition, in evaluating this criterion, we would consider whether the methodology has suitably categorized the types of plans subject or not subject to risk adjustment, given the overall approach taken by the methodology and the goal of the program to account for plan average actuarial risk. States must provide a rationale for the methodology’s approach to the plans subject to risk adjustment. Under this proposed criteria, we would also evaluate the State’s method for calculating payments and charges.

In the proposed § 153.330(b)(2), we would consider whether the alternate methodology complies with the requirements of subpart D, especially § 153.310(e) (as proposed to be renumbered) and § 153.340. Section 153.310(e) requires alternate methodologies to have a schedule that provides annual notification to issuers of risk adjustment covered plans of payments and charges by June 30 of the year following the benefit year. Section 153.340(b)(1) sets forth a number of minimum requirements for data collection under risk adjustment, including standards relating to data privacy and security. While the Federal approach will not directly collect data from issuers, but instead will use a distributed approach that will not include personally identifiable information, the Premium Stabilization Rule gave States the flexibility to design their own data collection approach, provided privacy and security standards are met. The privacy and security of enrollees’ data is of paramount importance to HHS, and the data collection approach in an alternate methodology must protect personally identifiable information, if any, that is

stored, transmitted, or analyzed, to be certified. The application for certification of the alternate methodology should identify which data elements contain personally identifiable information, and should specify how the State would meet these data and privacy security requirements.

In § 153.330(b)(3), we proposed to consider whether the alternate risk adjustment methodology accounts for payment transfers across metal levels. We believe that sharing risk across metal levels is a critical part of a risk adjustment methodology as new market reforms are implemented because of the need to mitigate adverse selection across metal levels, as well as within metal levels. The proposed HHS risk adjustment methodology transfers funds between plans across metal levels, and under this proposal, State alternate methodologies would do so as well.

Under the proposed HHS risk adjustment methodology, we will apply risk adjustment to catastrophic plans in their own risk pool—that is, we will transfer funds between catastrophic plans, but not between catastrophic plans and metal level plans. For a number of plans, such as student health plans and plans not subject to the market reform rules, we will not transfer payments under the HHS risk adjustment methodology. However, as discussed above, we believe that States should have the flexibility to submit a methodology that transfers funds between these types of plans (either in their own risk pool or with the other metal levels).

In § 153.330(b)(4), we proposed to consider whether the elements of the alternate methodology align with each other. For example, the data collected through the data collection approach should align with the data required by the risk adjustment model to calculate individual risk scores.

Comment: A commenter requested further clarity on § 153.330(a)(2)(iii), which requires that a State’s request to operate an alternate methodology must include an assessment of the extent to which the methodology encourages favorable behavior among providers and discourages unfavorable behavior.

Response: We provided examples of favorable and unfavorable behavior in the proposed rule, at 77 FR at 73146. There, we stated that we would consider whether the alternate methodology discriminates against vulnerable populations, as evidenced by unjustified differential treatment on the basis of features like age, disability, or expected length of life. We also stated that alternate methodologies should take into account the health care needs of

diverse segments of the risk adjustment population, including but not limited to women, children, people with disabilities, and other vulnerable groups. We will provide further guidance on these criteria in connection with our evaluation of particular proposed State alternate methodologies.

Comment: A commenter requested that HHS delete the reference to “stakeholders” in the criterion that an alternate methodology be easy to understand and replace it with the term “carriers.”

Response: Risk adjustment affects the overall stability of State insurance markets, with potential impacts on many individuals and entities, including State governments and enrollees. Therefore, we believe the methodology should be reasonably comprehensible to all enrollees and entities, or “stakeholders.” We will maintain our use of “stakeholders” rather than “carriers” because we believe that all affected individuals should be reasonably able to understand the methodology.

Comment: A commenter requested that HHS approve alternate methodologies independent of a State’s factor weights.

Response: An alternate methodology’s factor weights may influence the risk adjustment methodology’s ability to meet the evaluation criteria. The factor weights, therefore, will be included in the evaluation process.

Comment: A commenter generally supported our alternate methodology certification process, but recommended that we additionally require that a State’s proposed alternate methodology must perform similarly to or better than the HHS methodology in that State.

Response: We believe it would be difficult to assess whether a State’s methodology performs “better” than the HHS methodology in light of the various policy goals that different States may have in mind. We believe that States understand their markets well, and that the proposed set of criteria is sufficiently detailed to achieve a high quality risk adjustment methodology. Therefore, we are finalizing these criteria as proposed.

Comment: A commenter recommended that State alternate methodology applications be made available to the public.

Response: HHS is committed to transparency in its process of evaluating and certifying State alternate methodologies. We will publish approved State alternate methodologies in the annual HHS notice of benefit and payment parameters. Because we require that States publish their

alternate methodologies in the State notice of benefit and payment parameters, we believe that this publication is sufficient for public access to the methodology itself and other supporting information.

c. Payment and Charges

In the preamble to the Premium Stabilization Rule, we noted that we plan to establish a national method for calculation of payments and charges. In the proposed rule, we expanded on this approach by designating areas of State flexibility within the general approach to payment transfers. We received no comments on the national method for calculating payments and charges or the State flexibility within this method. We are finalizing this approach as proposed.

5. Risk Adjustment Data Validation

We proposed to add a new subsection, § 153.630, which set forth risk adjustment data validation standards applicable to all issuers of risk adjustment covered plans when HHS is operating risk adjustment. We proposed that, beginning in 2014, HHS will conduct a six-stage data validation program when operating risk adjustment on behalf of a State: (1) Sample selection; (2) initial validation audit; (3) second validation audit; (4) error estimation; (5) appeals; and (6) payment adjustments. We noted that States are not required to adopt this HHS data validation methodology. We are finalizing these provisions as proposed.

Comment: We received a comment asking that the cost of the audits associated with data validation be paid for by the Federal government.

Response: At this time, it is the policy of HHS that costs related to the second validation audit process be borne by the Federal government, while costs associated with initial validation audit process be borne by the applicable issuer. We note that a State may choose to allocate the costs of data validation differently when operating its own risk adjustment program.

Comment: We received a comment requesting that data validation requirements be expressed in § 153.710(c), relating to data collection standards.

Response: We are finalizing the data validation requirements in § 153.630. We believe that the data validation requirements should remain independent of the data collection standards because the data validation requirements are specific to the HHS-operated risk adjustment program and the data collection standards apply to both the risk adjustment and

reinsurance programs when operated by HHS.

Comment: We received a comment expressing concern that the data validation process as described will extend beyond a year, potentially affecting payment transfers.

Response: We appreciate the concerns of the commenter. We intend to complete the data validation process within one year, in time for payment adjustments to be made the following benefit year.

Comment: We received a comment asking that States operating risk adjustment programs be required to follow uniform Federal data validation standards, particularly during the first few years of the program.

Response: The risk adjustment program is intended to be a State-based program. We believe that a State operating its own risk adjustment program should have the flexibility to implement a data validation program that best complements its program design, including the State’s data collection approach and desired level of audit complexity. We note, however, that States and issuers still must abide by the standards for developing a data validation program as described in the Premium Stabilization Rule.

Comment: We received a comment requesting clarification on how issuers that leave a market during the year will affect the Statewide data validation process.

Response: We will provide further detail on this and other data validation issues in future rulemaking and guidance.

a. Data Validation Process When HHS Operates Risk Adjustment

(1) Sample Selection

In § 153.630 of the proposed rule, we discussed some of the guidelines for selecting a statistically valid sample for data validation. We proposed that HHS would choose an adequate sample size of enrollees such that the estimated payment errors would be statistically sound and enrollee-level risk score distributions would reflect enrollee characteristics for each issuer. Additionally, the sample would cover applicable subpopulations for each issuer, such as enrollees with and without risk adjustment diagnoses.

Comment: We received a comment asking for additional information on the statistical validity of the expected sample size of 300, including the confidence interval and expected error rate tolerance. We also received numerous comments requesting the opportunity to comment on a proposed

statistical selection methodology in future guidance.

Response: We anticipate providing more detailed information on the HHS sampling methodology in future rulemaking and guidance, including sample sizes and expected tolerances and confidence intervals.

Comment: We received a comment expressing support for the inclusion of enrollees both with and without risk adjustment diagnoses in the sample. The commenter also suggested that HHS conduct more comprehensive audits for members without any risk adjustment diagnoses, including full medical record review during the second validation audit.

Response: Individuals without risk adjustment diagnoses will be subject to audits of their demographic information as well as medical record reviews during both the initial and second validation audits to determine whether any risk adjustment HCCs should have been assigned that were not. We anticipate revisiting this policy after the first year of the program to assess the utility of performing medical record reviews on enrollees with no HCCs. Over time, we anticipate that issuers will utilize the front-end HHS-operated data submission processes to ensure they are providing all relevant risk adjustment diagnosis for enrollees as opposed to relying on back-end audit processes to reveal this information.

(2) Initial Validation Audit

In § 153.630(b), we proposed that once the audit samples are selected by HHS, issuers would conduct independent audits of the risk adjustment data for their initial validation audit sample enrollees. In § 153.630(b)(1), we proposed that issuers of risk adjustment covered plans engage one or more auditors to conduct these independent initial validation audits. We proposed in § 153.630(b)(2) through (4) that issuers ensure that initial validation auditors are reasonably capable of performing the audit, the audit is completed, the auditor is free from conflicts of interest, and the auditor submits information regarding the initial validation audit to HHS in the manner and timeframe specified by HHS. These proposed requirements would ensure the initial validation audit is conducted according to minimum audit standards, and issuers or auditors transmit necessary information to HHS for use in the second validation audit. We are finalizing these provisions as proposed.

We also proposed that issuers conduct data validation in accordance with audit standards established by HHS. We

described three methods for establishing these audit standards, and requested comment on these approaches.

Comment: We received multiple comments suggesting that auditors conduct interim checks of issuer data during the plan year before the formal validation audit. We received a few comments proposing that auditors report the findings of the interim checks to HHS so that issuers found to have outlier results could be subject to greater audit scrutiny.

Response: We believe that requiring auditors to perform multiple interim checks of issuer data throughout the plan year will be burdensome for issuers. However, an issuer may voluntarily have such checks performed if it believes them to be necessary for appropriate implementation of risk adjustment and compliance.

Comment: We received a comment asking that HHS specify in future guidance the common coding and documentation standards that issuers will be subject to, and provide issuers an opportunity to comment on the standards.

Response: We will clarify in future rulemaking and guidance the uniform audit standards that issuers and auditors will be subject to.

Comment: We received many comments supporting a certification requirement for auditor firms before acting as a validation auditor. A number of commenters supported the development of audit standards. One commenter supported HHS adopting both approaches.

Response: We considered prospectively certifying entities prior to acting as validation auditors. This approach is utilized before performing audits on organizations collecting and reporting performance measures through Health Effectiveness Data and Information Set (HEDIS). While this approach may ensure that entities performing validation audits are capable of conducting the audits in accordance with HHS standards, we believe at this time that issuers will be diligent in selecting audit entities capable of complying with HHS audit standards, and that adequate enforcement remedies exist should an audit entity fail to comply with the standards. We will monitor the performance of validation auditors to determine whether such certification or additional safeguards are necessary in the future.

(3) Second Validation Audit

In § 153.630(c), we proposed that HHS retain an independent second validation auditor to verify the accuracy of the findings of the initial validation audit

using a sub-sample of the initial validation audit sample enrollees for review. Issuers would submit (or ensure their initial validation auditor submits) data validation information, as specified by HHS, from their initial validation audit for each enrollee included in the second validation audit sub-sample. We are finalizing these provisions as proposed.

Comment: We received a comment suggesting that HHS provide, for both the initial and secondary validation audits, a comparison of a plan's diagnosis reporting accuracy to the calibration data set for the risk adjustment models' diagnosis accuracy as reported through MarketScan®.

Response: We do not have access to the underlying medical records necessary to perform such an audit for the calibration data set. We will consider performing similar analyses in future years, as more data becomes available.

Comment: We received a comment seeking clarity on whether the error process would be based exclusively on the second validation audit, and whether the results of the second validation audit would be applied only to the subsample under § 153.630(c).

Response: We anticipate applying any error rate determined by the second validation audit to the error rate calculated by the initial validation audit. This reconciled error rate will be extrapolated to an issuer's entire risk adjusted population, not just the subsample under § 153.630(c). We intend to consult with stakeholders on the details of the methodology for error rate calculation to inform future rulemaking.

Comment: We received a comment asking HHS to permit issuers to submit additional information to the second validation auditor if the initial information provided to the initial validation auditor does not meet the proposed audit standards.

Response: We do not believe that it is appropriate or efficient to permit issuers to submit additional information to the second validation auditor in the event that the initial information provided does not meet the proposed audit standards. We believe that limiting the review of the second validation audit to only that information made available during the initial validation will help to ensure the entire validation process is completed in a timely manner and will provide incentives for making all relevant information available to the initial validation auditor.

(4) Error Estimation

In the preamble to the proposed rule, we stated that we would estimate risk score error rates based on the findings from the data validation process. HHS plans to conduct further analysis to determine the most effective methodology for adjusting plan risk scores for calculating risk adjustment payment transfers. We are finalizing these provisions as proposed.

Comment: We received a few comments regarding the error estimation process generally. One comment proposed a three-tiered approach to extrapolating error rates to overall plan payment. The commenter suggested that sufficiently low error rates within a certain range of model accuracy would receive no extrapolation to plan payment, while high outlier error rates would subject an issuer to an additional round of audits. All other plans would receive an extrapolation of the plan's error rate to its payment rate. Another commenter asked that HHS perform an outlier analysis on risk scores within a State. Another commenter suggested that HHS audit all issuers to determine a mean or expected error rate, then perform appropriate statistical tests to compare issuer error rates to this expected error rate, and then determine the impact on plan payments. We also received a comment requesting that HHS use a dollar adjustment instead of a percent adjustment to the risk score.

Response: Following additional engagement with stakeholders, we expect to provide further detail on our approach to error estimation and payment transfer adjustments in future rulemaking and guidance.

Comment: We received a comment requesting clarification on whether error adjustments apply if an issuer under-reports its risk scores.

Response: Consistent with the approach in Medicare Advantage, we intend to apply error adjustments if an issuer under-reports its risk scores. We will provide further detail on these adjustments in future rulemaking and guidance.

(5) Appeals

Pursuant to § 153.350(d), HHS or a State operating risk adjustment must provide an administrative process to appeal data validation findings. We proposed in § 153.630(d) that issuers may appeal the findings of a second validation audit or the application of a risk score error rate to its risk adjustment payments and charges. We anticipate that appeals would be limited to instances in which the audit was not conducted in accordance with the

second validation audit standards established by HHS.

Comment: We received a few comments expressing support that the appeals process be limited to the application of audit standards, and not the standards themselves.

Response: We are finalizing this provision as proposed.

(6) Payment Adjustments

We proposed that HHS would use a prospective approach when making payment adjustments based on findings from the data validation process. Specifically, we would use an issuer's data validation error estimates from the prior year to adjust the issuer's average risk score in the current transfer year. Additionally, because the credibility of the system is important for the success of the program, we proposed in paragraph § 153.630(e) that HHS may also adjust payments and charges for issuers that do not comply with the initial or second validation audit standards set forth in § 153.630(b) and (c).

Comment: We received a comment requesting further clarity on what impact a prospective approach to payment adjustments will have on plan pricing assumptions, and how actuarial soundness will be maintained if an issuer's risk profile changes substantially from year to year.

Response: We anticipate addressing these issues following stakeholder consultations prior to further rulemaking on data validation.

b. Proposed HHS-Operated Data Validation Process for Benefit Years 2014 and 2015

We proposed that issuers of risk adjustment covered plans adhere to the data validation process beginning with data for the 2014 benefit year. However, due to the complexity of the risk adjustment program and the data validation process, and the uncertainty in the market that will exist in 2014, we are concerned that adjusting payments and charges without first gathering information on the prevalence of error could lead to a costly and potentially ineffective audit program. Therefore, we proposed that issuers conduct an initial validation audit and that we conduct a second validation audit for benefit years 2014 and 2015, but that we would not adjust payments and charges based on validation findings during these first two years of the program. Although we proposed not to adjust payments and charges based on error estimates discovered, we noted that other remedies, such as prosecution under the False Claims Act, may be applicable to

issuers not in compliance with the risk adjustment program requirements.

We requested comments on this approach, particularly with respect to improvements to the data validation process generally, whether there are alternatives to forgoing changes to payments and charges that we should adopt, and what methods we should adopt to ensure data integrity in the first two years of the program.

We also requested comments on the possibility of conducting the second validation audits at the auditor level as opposed to the issuer level in future years. As we anticipate that a small number of audit firms will perform the majority of the initial audits, this would allow us to examine the accuracy of the initial validation audit without having to draw large initial validation audit record samples from each issuer that participates in risk adjustment.

Comment: A number of commenters supported not altering payments and charges based on 2014 and 2015 data validation results. Numerous other commenters requested that HHS apply error rates to payment transfers from the outset of the program, while another commenter supported a one-year observation period before effecting data validation payment transfers.

Response: While we appreciate the concerns of the commenters, we continue to believe that in light of the complexity of the data validation process, two years of observation experience will help HHS refine its data validation process by enabling us to gather sufficient data on issuer and auditor error, and will provide issuers and auditors enough time to adjust to the audit program. Although we are not adjusting payments and charges based on error rates, we note that other remedies, such as prosecution under the False Claims Act, may be applicable to issuers not in compliance with the risk adjustment program requirements when HHS operates risk adjustment on behalf of a State.

Comment: We received multiple comments supporting the publishing of a report on error rates discovered during the first two years of the data validation program. One commenter asked for additional clarification of the overall goal of the report, whether the report will identify issuers and providers, and if the report will disclose error rates attributable to providers.

Response: The intent of the report is to provide issuers and auditors information on the level of error in the commercial market under the HHS-operated risk adjustment program. Additionally, we may study the extent to which errors at the auditor level

contribute to risk score error rate findings during the initial validation audits. We do not anticipate that the report will identify providers, but it may identify issuers. We do anticipate that the report will identify the error rates attributable to auditors.

Comment: We received one comment requesting further clarification on the timeframe in which issuers will be directed to provide sample data for a benefit year. The commenter also asked for further clarification on program integrity efforts if payment transfers are not altered by data validation audit results.

Response: We will issue further guidance and rulemaking on these matters.

c. Data Security and Transmission

In § 153.630(f), we proposed data security and transmission requirements for issuers related to the HHS data validation process. In § 153.630(f)(1), we proposed that issuers submit any risk adjustment data and source documentation specified by HHS for the initial and second validation audits to HHS in the manner and timeframe established by HHS. We proposed in § 153.630(f)(2) that, in connection with the initial validation audit, the second validation audit, and any appeals, an issuer must ensure that it and its initial validation auditor complies with the security standards described at § 164.308, § 164.310, and § 164.312. We did not receive any comments on these provisions, and are finalizing them as proposed.

6. State-Submitted Alternate Risk Adjustment Methodology

HHS received an alternate risk adjustment methodology from one State, the Commonwealth of Massachusetts. We are certifying this methodology as a Federally certified methodology for use in Massachusetts. A summary of that methodology, as prepared by the Commonwealth, is provided below. More detailed information about this methodology can be obtained from the Commonwealth of Massachusetts upon request. In addition, the Commonwealth of Massachusetts must publish a State notice of benefit and payment parameters, which will contain additional detail, within 30 days of the publication date of this final rule. Issuers and other interested parties should consult both of these sources. Additional questions may be addressed to Jean Yang, Executive Director of the Massachusetts Health Connector, at (617) 933-3059.

a. Policy Goals of the Massachusetts 2014 State Alternate Risk Adjustment Methodology

The Commonwealth of Massachusetts shares the same view as the Federal government with respect to the importance of the risk adjustment program and strives to achieve similar policy goals through the State-operated risk adjustment program powered by an alternate methodology. These specific goals include the following:

- The risk adjustment models should accurately explain variation in health care costs;
- The clinical classification used in the Commonwealth's alternate risk adjustment models should link risk factors to daily clinical practice and should be clinically meaningful to providers;
- The design of the clinical classification and the risk weights in the Commonwealth's alternate risk adjustment models should encourage favorable behavior from providers and health plans and discourage unfavorable behavior;
- The design of the Commonwealth's alternate risk adjustment methodology should reflect the Commonwealth's market characteristics, experience with risk adjustment, and be supportive of other health care reform initiatives in the Commonwealth;
- The Commonwealth's alternate risk adjustment methodology should use data that is complete, high quality and available in a timely fashion;
- The Commonwealth's alternate risk adjustment methodology should be easy for stakeholders to understand and implement;
- The methodology should account for risk selection across metal levels;
- The risk adjustment models and additional adjustment factors should provide stable risk scores over time and across plans;
- The operations of the Commonwealth's risk adjustment program should minimize administrative costs; and
- There should be reasonable alignment among different elements of the alternate methodology.

Starting from the same conceptual foundation as the proposed HHS risk adjustment methodology, the proposed Massachusetts alternate methodology is designed to address a number of Massachusetts-specific market characteristics and leverage existing data infrastructures to reduce the administrative burden for health plan issuers as well as for the Health Connector, which will be administering the program.

b. Conceptual Framework for Risk Adjustment Funds Transfer

Massachusetts's conceptual framework for calculating risk adjustment funds transfer is consistent with the proposed Federal risk adjustment methodology in that funds transfer is based on State average premium and should provide plans with payments to help cover excess actuarial risk due to risk selection; that is, risk exposure beyond the premiums issuers can charge reflecting allowable rating and their applicable cost factors.

Massachusetts proposes a single, merged risk adjustment pool for metal level plans in the small group and non-group market to be consistent with Massachusetts's merged market rules. Consistent with the proposed HHS methodology, Massachusetts proposes to keep catastrophic plans in their own risk adjustment pool, separate from the rest of the merged market. Massachusetts believes this will help ensure the accuracy of the risk adjustment calculations as well as the affordability of the catastrophic plans because funds transfer will take place amongst the catastrophic plans only, instead of between the catastrophic plans and the metal level plans if all plans were merged in one risk adjustment pool. It should be noted that under the current regulations in Massachusetts, pricing of the catastrophic plans is subject to the same merged market rules as the small group and non-group plans. Keeping catastrophic plans in a separate risk adjustment pool does not segment the market from a pricing perspective because catastrophic plans are still subject to single risk pool requirements, and risk adjustment is retrospective and applies to all non-grandfathered small group and non-group health plans, including catastrophic plans.

Due to the lack of empirical data, Massachusetts is unable to calibrate a separate risk adjustment model for catastrophic plans. It proposes to use the bronze risk adjustment model and an actuarial value adjustment factor of 0.57 in the funds transfer calculation for catastrophic plans in the initial years, and revisit this approach in future recalibrations when empirical data is available. Massachusetts proposes to treat student health plans and plans that are not subject to the Affordable Care Act Market Reform Rules in the same manner as the Federal methodology.

c. Data Used to Develop Risk Adjustment Methodology

Massachusetts used data from three different sources to develop the risk

adjustment models and additional adjustment factors in the Commonwealth's alternate risk adjustment methodology:

- *For the non-group and small group market, data from the Massachusetts All Payer Claims Database (APCD).* Calendar Year 2010, and 7/1/2011 to 6/30/2012 membership and claims data from the Massachusetts APCD. The Commonwealth obtained data extracts on non-group policy holders and small group members for group size up to 100 with ages 0 to 64 and eligible for medical and pharmacy coverage during the two observation periods. Collectively, Massachusetts thinks they are representative of a significant portion of the population that is subject to the risk adjustment program under the Affordable Care Act. About 700,000 unique individuals were included in the model development sample.

- *For enrollees under 300 percent FPL who are not eligible for Medicaid, data from the Commonwealth Care program.* Fiscal Years 2010 and 2011 Commonwealth Care program's membership and claims. More than 100,000 unique members with ages 0 to 64 from Commonwealth Care met the selection criteria and were included in the model development sample.

Commonwealth Care is a subsidized insurance program created as part of the 2006 Massachusetts health care reform law. It is administered by the Health Connector, and serves individuals with income up to 300 percent FPL who are not eligible for Medicaid and generally do not have access to employer-sponsored health insurance. As of December 2012, there are close to 198,000 members enrolled in the program. Massachusetts anticipates that, effective January 1, 2014, a portion of the current Commonwealth Care members will enroll in the expanded Medicaid program, and the remainder will access QHPs with tax credits through the Exchange.

Most health plan issuers that participate in the current Commonwealth Care program are local Medicaid managed care organizations ("MMCOs") whose provider reimbursement level is typically lower than that of the commercial payers in Massachusetts for the same types of services. To normalize plan paid amount between the APCD data and the Commonwealth Care data, Massachusetts re-priced Commonwealth Care claims using unit prices derived from the APCD data. This was done using the Milliman Health Cost Guidelines® ("HCG") Grouper. The HCG categorizes claims into more than 80 types of services, allowing us to directly

compare unit prices by service type between the Commonwealth Care claims and the APCD claims. There were service types with very few members in either dataset. To obtain robust unit cost estimates, Massachusetts consolidated them with other service types that are similar in nature.

- *For additional sample size for calibration purposes, Calendar Year 2010 Truven Health Analytics MarketScan® Commercial Claims and Encounters database for New England States.* Massachusetts selected members with ages 0 to 64 who were eligible for medical and pharmacy coverage in PPO or Comprehensive plan type, and re-sampled them to match the age/gender distribution of the APCD data. The primary reason for using the MarketScan® data was to obtain a larger sample size which allowed for calibrating more robust risk adjustment models and to strengthen the data quality of the overall model development sample. Massachusetts notes that data from MarketScan® mostly represent large group experience. However, Massachusetts thinks that it is still a useful additional data source. More than 700,000 unique members were included from the MarketScan® New England States.

The consolidated claims data was then processed again through the Milliman Health Cost Guidelines® grouper system. The results from the grouper were compared to regional cost and utilization benchmarks and checked for reasonability. In this process, Massachusetts excluded some commercial payers in the APCD data, as well as certain claim lines in the MarketScan® data.

d. Risk Adjustment Models

(1) HCC Clinical Classification

Using claims from clinically valid sources (for example, laboratory, radiology, durable medical equipment, and transportation are not considered clinically valid), Massachusetts grouped diagnosis codes using the HCC classification system. Massachusetts referenced the HCC classification system in Pope et al. (2000), a Federally funded research study that laid the foundation for the CMS HCC risk adjustment payment system for Medicare Advantage.¹³ The classification system in Pope et al. (2000) contains approximately 780 DxGroups which are then aggregated to

more than 180 condition categories ("CC"s). Clinical hierarchies are then applied on the CCs to create HCCs. Because the HCC classification system was originally designed for the senior population, the designs of the condition categories may not be fully reflective of the characteristics of the commercial population. Through an iterative process using the model development sample, Massachusetts identified 20 DxGroups that were not very well predicted under the original HCC grouping and promoted them into their own HCCs.

When determining acceptable types of claims for grouping the HCCs, Massachusetts modified the approach outlined by Pope et al. (2000) to ensure that risk adjustment does not create unintended consequences with respect to how care is accessed in the current Massachusetts market environment. For example, Massachusetts accepted diagnosis codes from visits/encounters with nurse practitioners and physician assistants, recognizing that in patient-center medical home and ACO care settings, nurse practitioners and physician assistants play active and important roles in preventive care and chronic care management. Massachusetts also accepted diagnosis codes in claims from skilled nursing facilities and ambulatory surgical centers if the claims were coded by a clinician.

In the process of revising the original HCCs to better reflect the characteristics of the commercial population, Massachusetts followed the same 10 principles for designing a risk adjustment classification system as discussed in the proposed Federal risk adjustment methodology.

Compared with the 127 HHS-defined HCCs used by the Federal methodology, Massachusetts's methodology includes 162 Massachusetts-defined HCCs.¹⁴ Below, Massachusetts discusses the key considerations with regard to the Commonwealth's decision to apply a more expansive set of condition categories.

Risk adjustment is a premium redistribution process that equalizes actuarial risks amongst a State's health plan issuers and helps stabilize premiums under modified community rating and individual mandate. Conceptually, risk adjustment models should be as accurate as possible while minimizing the potential for "gaming"

¹³ Available at: <http://www.cms.gov/Research-Statistics-Data-and-Systems/Research/HealthCareFinancingReview/downloads/04summerpgr119.pdf>.

¹⁴ Massachusetts's list of HCCs is available in Table 16 of this alternate methodology, while HHS's list of HCCs is published elsewhere in this rule. Note that the two lists are numbered differently, and different ICD-9 codes are associated with different HCCs and DxGs.

and coding creep. A more accurate model typically requires a higher number of predictive factors, and in the case of the HCCs, more HCCs. However, having more HCCs may also open up more opportunities for coding creep and gaming of the system. Therefore, a careful balance must be achieved. Although Massachusetts acknowledges that its higher number of HCCs may create some added potential for gaming or coding creep, it believes this risk is minimal because it will use only certain claims types and certain provider types, will impose clinical hierarchies, and will exclude certain vague diagnoses and codes subject to discretionary coding. Further, Massachusetts and its issuers have experience with the necessary best practices of risk adjustment and intend to implement an effective data validation process.

The Affordable Care Act risk adjustment program is designed to be a budget-neutral revenue redistribution among issuers. Health insurance issuers expect fair and adequate transfer of funds; that is, member risk profiles should be accurately stratified and correctly ranked.

The complete list of the condition categories included in the Massachusetts models is provided in Table 16. Although Massachusetts includes more HCCs than under the proposed Federal methodology, the Commonwealth notes that most commercial risk adjustment models use almost twice as many condition categories as it includes here.

(2) HCC Models

Similar to the HHS approach, Massachusetts calibrated models for bronze, silver, gold and platinum benefit tiers separately based on actuarial value. Due to the lack of empirical data, Massachusetts is unable to apply a separately-calibrated risk adjustment model for catastrophic plans until a sufficient amount of data becomes available in the future. At the present time, it plans to apply the risk adjustment model developed for bronze plans to catastrophic plans, and proposes to use the actuarial value adjustment factor of 0.57 (as provided by the Federal methodology) to account for benefit design related utilization differences between catastrophic plans and other metal level plans. For calculating funds transfer, Massachusetts plans to keep the catastrophic plans in their own risk adjustment pool in the initial years, which is consistent with the proposed Federal methodology. Please also refer to the conceptual framework for risk adjustment funds transfer above for

more information on Massachusetts's treatment of catastrophic plans in risk adjustment.

The model dependent variable is total plan paid amount, or "plan liability." Factors or explanatory variables included in the risk adjustment models are—1 constant term, 2 age/gender factors, 162 HCCs and 2 disease interaction terms. Unlike the proposed Federal methodology where there are 3 sets of risk weights by age cohort for each metal level, that is, 15 models in total, Massachusetts's models do not contain separate risk weights by age cohort. The Massachusetts methodology has 4 models, one for each metal level. The bronze model will be applicable to both the bronze plans and the catastrophic plans.

In risk adjustment modeling work, partial-year eligibility is typically addressed by annualizing the dependent variable and weighting the least squares regressions by the fraction of eligibility. Massachusetts began modeling using this approach and found that the predictive accuracy for members with short eligibility, especially newborns, was low. Upon further analyses, Massachusetts believes that this was related to annualizing the dependent variable and using eligibility duration as weight in regressions. As a result Massachusetts explored nonlinear modeling techniques and developed a set of factors to adjust for partial-year eligibility. In its risk adjustment models, the minimum eligibility duration requirement is 1 month.

Massachusetts's thinking on this issue reflects the Commonwealth's experience with programs that have high turnover rates, such as the Commonwealth Care program. Massachusetts believes that prediction biases associated with partial-year eligibility could aggravate selection issues if not addressed adequately.

Massachusetts took an iterative approach to developing the risk adjustment models. In each iteration, factors with negative and/or statistically insignificant coefficients and factors without adequate sample size were either excluded or combined with other factors. The unique feature of the HCC risk adjustment models is clinical hierarchy—that is, the coefficient of a less severe condition category should not exceed the coefficient of a more severe condition in the same clinical hierarchy. This ensures clinical validity and preserves healthcare resource for treating more severe medical conditions. Massachusetts ensured that all coefficients follow the clinical hierarchies. Where they did not, it

forced monotonicity in the regression coefficients using restricted regressions.

Because the models are by metal level, one HCC may receive 4 different risk weights in the 4 models. Under the assumption that an HCC treated in a lower metal level plan should not lead to higher plan liability than if it were treated in a higher metal level plan, Massachusetts also forced monotonicity by HCC across metal levels.

In the final models, all factors have nonnegative and statistically significant coefficients, and have met the monotonicity requirements of the HCCs and the monotonicity requirements Massachusetts imposed by metal level. Massachusetts also checked that the member-level total predictions are monotonic across benefit tiers by age/gender groups. Table 17 provides the full set of coefficients.

Below is an example of how to calculate an individual risk score from these HCC models.

Example: Member 001, male, 25 years old, is enrolled in a Gold plan for 6 months, and has three HCCs—HCC005, HCC032, and HCC072.

$$\begin{aligned} \text{Member Risk Score} &= \text{Constant Term} + \\ &\quad \text{Demographic Factor} + \text{Sum (Medical} \\ &\quad \text{Risk Factors)/Duration Adjustment} \\ &\quad \text{Factor} \\ &= 0.108698 + 0 + (4.203378 + 1.093277 + \\ &\quad 4.025404)/0.742262 \\ &= 12.667685 \end{aligned}$$

The Constant Terms, Demographics Factor and Medical Risk Factors are provided in Table 17. The Duration Adjustment Factors are provided in Table 18.

(3) Predictive Accuracy

The final model R-Squared is provided below in Table 12.

TABLE 12—FINAL MODEL R-SQUARED

	Counts of Unique Members	Model R-Squared for Predicting Paid \$PMPY (percent)
Platinum	344,472	48.54
Gold	171,207	52.91
Silver	415,245	46.66
Bronze	193,725	47.58

These are comparable to the R-Squared levels observed in many commercial risk adjustment models. Massachusetts also validated the models using a more recent data extract from the Commonwealth's APCD and obtained similar R-Squared values.

e. Adjusting for Induced Demand

(1) Adjusting for Metallic Tier and Cost-Sharing Reduction

In the proposed rule, a set of induced utilization adjustment factors were provided to account for the expected utilization level differences associated with different benefit levels of plans, as well as those that result from CSRs applied to Silver Variation plans.

Massachusetts proposes to use the HHS proposed induced demand factors to adjust for induced utilization tied to metallic tiers. In terms of adjusting for induced utilization associated with CSR through Silver Variation plans, however, its methodology must appropriately account for Massachusetts's unique circumstance as related to the anticipated cost-sharing wrap above and beyond the Federal CSR.

As a result, from the perspective of induced utilization adjustment, the factors supplied in the HHS methodology (specifically calibrated for target AVs of 73 percent, 87 percent and 94 percent) may not be adequate for Massachusetts. To overcome this limitation, Massachusetts constructed a continuous induced demand curve by fitting a polynomial trend line to the HHS proposed induced utilization factors by metal level, which Massachusetts extended to 100 percent AV and validated as described below.

Using the APCD and Commonwealth Care data sets Massachusetts calculated an average member-month-weighted risk score and an average PMPM claim amount for each metallic tier. It then backed out the average risk score to calculate a risk-neutral PMPM claim amount for each metallic tier. Massachusetts performed this analysis separately for non-group and small group after adjusting the non-group results for the impact of non-group selection. The difference in the risk neutral rate by tier is the impact of benefit design induced utilization. With data from both the APCD and Commonwealth Care, Massachusetts was able to populate the curve with a continuous range of AV values including those that are close to 100 percent.

The sample size for bronze and silver metal levels was too small to be credible but for the gold and platinum metal levels the results were consistent with the HHS factors. Massachusetts determined that this validated its

decision to use the HHS-proposed induced demand factors to adjust for induced utilization tied to metallic tiers.

For plans subject to anticipated cost-sharing wrap subsidies Massachusetts intends to use the same induced demand curve to determine the increased utilization as a result of subsidized cost sharing. In Table 13 below it has listed induced demand factors by actuarial value in 2 percent increments.

TABLE 13—INDUCED DEMAND FACTORS

Plan AV	Induced demand factor
0. 70	1. 000
0. 72	1. 008
0. 74	1. 017
0. 76	1. 027
0. 78	1. 037
0. 80	1. 049
0. 82	1. 061
0. 84	1. 073
0. 86	1. 087
0. 88	1. 101
0. 90	1. 117
0. 92	1. 132
0. 94	1. 149
0. 96	1. 167
0. 98	1. 185

(2) Adjusting for Non-Group Selection

The proposed Market Reform Rule and the proposed HHS notice of benefit and payment parameters for 2014 contemplate separate risk pools for individual and small group policies and modified community rating to be applied separately within each risk pool. The Commonwealth has had a merged small and non-group market since its landmark reform in 2006, where small groups and non-group plans are subject to the same index rate and pricing methodology.

In order to determine if there is an underlying selection dynamic related only to members' group versus non-group status, Massachusetts applied concurrent risk adjustment models developed for the Commonwealth to merged market membership and claims data from the Commonwealth's APCD. The models account for cost variations due to demographics, medical comorbidities and plan benefit design. The risk-adjusted paid amount was calculated at the member level.

Members were grouped by non-group versus small group. Groups of 1 were

treated as non-group policies in its analysis. The average actual annual paid amount and the average risk-predicted annual paid amount were compared in total and by metal level. The ratio of actual paid to the risk-predicted paid for those enrolled in non-group products was compared to the same ratio for those enrolled in small group products. Any meaningful difference between the ratios for these two groups would indicate that there is a cost difference between the types of members—that is, non-group versus small group—that is not explained by the characteristics accounted for in the risk adjustment models.

Massachusetts found a higher average ratio for the non-group market segment. However, it also found that this selection was limited to platinum plans. As such, Massachusetts's methodology includes an induced demand factor that will only be applied to those enrolled in platinum plans. Based on two years' worth of APCD data, Massachusetts found that on average the ratio for platinum plans was 5.7 percent higher for non-group over small group, while for gold plans it was broadly consistent between non-group and small group. The Commonwealth plans to re-calibrate this factor periodically based on up-to-date experience of the market. This factor will be applied to individuals who enrolled in platinum plans and do not receive premium subsidies or CSRs. The individual risk score will be multiplied by this factor.

This adjustment mechanism as part of the risk adjustment methodology is uniquely relevant to the merged market in Massachusetts. In other States where there are separate risk pools for individual plans and small group plans the selection differential is embedded in the underlying claims level of each risk pool.

f. Calculation of Funds Transfer

The funds transfer calculation Massachusetts proposes is structurally the same as the proposed Federal methodology, although some of the adjustment factors included in the Commonwealth's calculation are defined differently and were developed from the Commonwealth's own data.

Massachusetts will use the following formula to calculate risk adjustment funds transfers.

$$T_i = \left[\frac{PLRS_i \cdot IDF_i \cdot GCF_i}{\sum_i (s_i \cdot PLRS_i \cdot IDF_i \cdot GCF_i)} - \frac{AV_i \cdot ARF_i \cdot IDF_i \cdot GCF_i}{\sum_i (s_i \cdot AV_i \cdot ARF_i \cdot IDF_i \cdot GCF_i)} \right] \bar{P}_s$$

(1), where

T_i = plan i 's risk adjustment transfer amount
 $PLRS_i$ = plan i 's plan liability risk score
 P_s = average premium for Massachusetts
 AV_i = plan i 's metal level AV
 ARF_i = allowable rating factor for plan i
 IDF_i = plan i 's induced demand factors for benefit design and non-group selection
 GCF_i = plan i 's geographic cost factor
 s_i = plan i 's share of the Commonwealth's enrollment

The first fraction in formula (1) is premium with risk selection, and the second fraction is premium without risk selection. Each component will average to 1.0 across all plans in the Commonwealth's merged market. Massachusetts will keep catastrophic plans in their own risk adjustment pool. In this case, formula (1) will apply to the catastrophic risk adjustment pool and the metal level plans risk adjustment pool separately.

The calculation of $PLRS_i$, plan i 's plan liability risk score, is the enrolled member month weighted risk scores of plan i using the risk adjustment models and adjusted by billable member months. It is calculated as shown by HHS. See the section above on HCC models and Tables 17 and 18 below for the risk weights and how to calculate member level risk scores. Massachusetts proposes to use this approach for calculating plan liability risk scores under the assumption that the proposed Federal rule for family rating will be replicated by the Commonwealth.

The calculation of the State average premium is as shown by HHS.

Massachusetts will use the Federal adjustment factors for plan AV in the Commonwealth's funds transfer calculations. The AV adjustment factors (AV_i for plan i) are listed in Table 14 below.

TABLE 14—AV ADJUSTMENT FACTORS

Metal level	AV adjustment factor
Catastrophic	0.57
Bronze	0.60
Silver	0.70
Gold	0.80
Platinum	0.90

Massachusetts's methodology includes two separate induced demand factors (IDF_i for plan i), one relates to benefit design and CSR and one for group selection. These two factors are multiplicative, except for individuals who will receive Federal subsidies and additional State subsidies, because their cost-sharing level is prescribed rather than selected.

Allowable rating factors (ARF_i for plan i) will include the State-defined uniform age rating curve. Pending final

State decision on all rating factors applicable to 2014, Massachusetts will provide additional specifications as needed on additional adjustment steps to ensure the accuracy of risk adjustment.

Massachusetts proposes to calculate geographic cost factors consistent with the HHS methodology, except that it plans to use gold plans as the benchmark for the calculations because gold plans are expected to attract the most enrollment in the Massachusetts merged market after 2014, whereas silver plans will likely have relatively low enrollment based on the product market in Massachusetts today. Having a data sample with sufficient enrollment is necessary in order to credibly measure regional cost differences. Massachusetts has not yet made a final decision on the number of rating areas, permissible range of the rates by area, or the schedule for implementing the changes. However, regardless of the specific decisions that determine the actual factors, the calculations will follow the formula shown by HHS.

g. Data Collection Approach

Massachusetts proposes an approach to risk adjustment data collection that leverages the Commonwealth's existing APCD as a resource for data submission to support risk adjustment data collection. This approach facilitates Massachusetts's policy goals of administrative simplicity and minimizing the number and types of data submissions by health plan issuers. Consistent with Federal requirements, it also facilitates the use of data that is complete, high in quality, and available in a timely fashion. Moreover, as elaborated below, use of the APCD ensures that the Commonwealth does not as part of risk adjustment data collection store any personally identifiable information for use as a unique identifier (except as may be required for data validation).

The APCD is maintained by the Massachusetts Center for Health Information and Analysis (CHIA) and requires data submission from the following entities: Public payers, commercial insurance issuers, health maintenance organizations, third-party administrators, and self-insured plans. Data submissions must be filed monthly.

The APCD collects payer data for all members living in Massachusetts. Health plan issuers and other payers submit five files each month: Member eligibility, medical claims, pharmacy claims, dental claims and provider details. Product description files from all of the payers are submitted to the APCD on a quarterly basis. Detailed data

submission requirements are in place and available for review on CHIA's Web site, <http://www.mass.gov/chia/researcher/health-care-delivery/hcf-data-resources/apcd/>. Members of a Massachusetts employer group who live out of State are currently excluded unless the payer also holds a contract with the Commonwealth's employee health administrator to provide data for State-covered non-resident individuals. The Commonwealth is working with CHIA and the affected data submitters actively to have this resolved before 2014 to ensure the accuracy of risk adjustment. It is also working with CHIA and issuers in the Commonwealth to evaluate additional data elements needed to support risk adjustment calculations.

The APCD already collects most of the data elements to support risk adjustment (see discussion of the data extract elements below), and nearly all other elements have to this date been scheduled to be added as part of APCD collection. As part of data intake, automated data quality checks are performed by CHIA. Once data are quality checked the subset required for risk adjustment are processed for purposes of creating an extract for risk adjustment calculations. Creation of the extract signifies the beginning of the risk adjustment data collection process. The extract provides only those data elements that are necessary for risk adjustment and contains no personally identifiable information for use as a unique identifier for an enrollee's data.

Using the data extract from the APCD, the Health Connector will be responsible for performing all risk adjustment calculations as well as facilitating payment and charge transactions. The data extracts will be maintained in a secure environment that meets applicable Federal and State security standards.

Below Massachusetts describes the data elements currently submitted to the APCD that will be used to create the risk adjustment extract. The Commonwealth also reviews the Health Connector's authority to use the APCD to support risk adjustment data collection, and provide additional details on data quality monitoring and control, data privacy and security standards, and the data management plan for risk adjustment operations.

h. Available Data in APCD for Risk Adjustment

As noted, the APCD already collects most of the data elements needed for risk adjustment. Member files include member and subscriber identifiers,

relationships, demographics, information about the payer, product and coverage, and duration of enrollment. Claims files include all paid claims (including encounter data on capitated services) for covered services, including but not limited to institutional and professional services, therapies, durable medical equipment (DME), transportation, laboratory services, imaging, and skilled nursing. Pharmacy files include all prescribed and dispensed medications. Dental claims files include all treatments and services. Provider files support the identification of providers by specialty and location. Product files provide limited information about the different insurance products that correspond to the Member file.

On the Commonwealth of Massachusetts Web site, <http://www.mass.gov/chia/researcher/health-care-delivery/hcf-data-resources/apcd-submitting-data-to-the-apcd.html#regulations>, it has made available a table of a subset of the data elements that are currently collected from payers. It will use the identified elements as inputs for calculating risk adjustment funds transfers and the assignment of a member to the correct plan.

There are data elements required to calculate risk adjustment funds transfer that the APCD currently does not collect, such as monthly premium, employer zip code, household income level, Indian status, and AV or inputs used to calculate AV using the Federal AV calculator. Massachusetts is currently working with CHIA, other State agencies, and the issuers in Massachusetts to add these data elements as part of APCD data collection and is working with plans to have them submitted by June 1, 2013. Some data elements—Indian status and household income—will be submitted to the APCD via the Exchange.

In addition, certain plans may not have sufficient claims experience reported in the APCD. This gap may occur because plans may be exempt from data submission or are new to the Massachusetts market. Current APCD regulations exempt small plans with less than 1,000 covered lives in Massachusetts-based plans from submitting regular data files. This exemption recognizes the administrative cost of programming and providing regular data extracts. Health plan issuers that are new to the Massachusetts market will need to take time to build up the capacity to submit data to the APCD on a regular basis. As such, Massachusetts plans to establish a method for small and new-to-market

plans to submit minimally necessary data for risk adjustment through an alternate mechanism than the APCD. The specifications for this alternate submission, the secure data transfer methodology, and the communication of results to the issuers will be developed as part of risk adjustment operations and will not use any personally identifiable information as a unique identifier.

(1) Legal Authority for the Health Connector To Access APCD Data for Risk Adjustment

Massachusetts General Laws (M. G. L.) Chapter 118G§ 6 authorized the Division of Health Care Finance and Policy (DHCFFP) to collect uniform information from public and private health care payers and to operate the Commonwealth's APCD. The Commonwealth's authority to collect, analyze and report health care cost and utilization was further expanded with the passage and subsequent enactment of Chapter 224 of the Acts of 2012. Section 19 of this law established CHIA with broad responsibility for health care data collection, analysis and reporting, including the APCD. CHIA assumes all of the data collection, management and analysis tasks previously performed by DHCFFP. In addition, the statute enables CHIA to provide government agencies and other parties access to data for the purpose of lowering total medical expenses, coordinating care, benchmarking, quality analysis and other research, for administrative or planning purposes. CHIA may also provide information to and work with other State agencies to "collect and disseminate data concerning the cost, price and functioning of the health care system in the Commonwealth and the health status of individuals."

Massachusetts is currently developing an agreement with CHIA to obtain data management and analytic support to administer the risk adjustment program, consistent with M. G. L. ch. 12C which gives CHIA the authority to enter into interagency service agreements with other Massachusetts agencies "for transfer and use of data."

(2) Data Security and Privacy Protection

As noted, under existing law and regulation, the Commonwealth already collects a range of data through its APCD and protects this information as described below.

Specifically in relation to data collection under risk adjustment and Federal requirements, the risk adjustment extract created through the APCD will not use or store any personally identifiable information for

use as a unique identifier for an enrollee's data. Only those data fields that are reasonably necessary as part of the risk adjustment methodology will be included in the extract.

For background, the APCD data is hosted on servers located at the offices of the Commonwealth of Massachusetts Executive Office of Health and Human Services Center for Health Information and Analysis at Two Boylston Street, Boston, Massachusetts 02116. CMS has approved CHIA's application to receive and hold Medicare data under the newly created APCD category. In fact, CHIA was the first APCD to apply and be approved. CHIA is fully compliant with the CMS Data Use Agreement (See CMS DUA #20937).

CHIA is an experienced custodian of protected health information. Since 1982, CHIA (as DHCFFP) has served as the repository for the State's Hospital Discharge Data, Emergency Room Data and Outpatient Observation Data. CHIA has extensive claims processing experience as the operator of the State's Health Safety Net program. CHIA has passed two independent third party security audits—a HIPAA security audit and a SAS-70 Type 2 audit. In addition, PCI security audits are done quarterly on CHIA's web portal.

As indicated above, the data extract produced by the APCD on behalf of the Health Connector for calculating risk adjustment funds transfer will contain no personally identifiable information for use as a unique identifier for an enrollee's data. All personal identifiers will be replaced with a scrambled Unique Member Identification number that is created independent of any HIPAA Protected Health Information or other personally identifiable information. This number will be a string of letters, numbers and symbols that cannot be "de-encrypted" to yield decipherable data.

The risk adjustment data extract will be securely transmitted into a secure data environment that will be established by the Health Connector. Calculations of plan actuarial risks and funds transfer will take place in this secure environment, with no personally identifiable information being used as a unique identifier. Massachusetts states that it has a fully HIPAA-compliant facility and data infrastructure in active use for operating the risk adjustment program for the Commonwealth Care program, which can be used for administering the Affordable Care Act risk adjustment program. Massachusetts also states that it is in active discussions with CHIA on the possibility of establishing a dedicated secure data

environment for risk adjustment at CHIA's Data Center.

Finally, leveraging funding applied through the Health Connector's Level 2 Exchange Establishment Grant (currently under CCIIO review), CHIA plans to upgrade its disaster recovery program to meet the performance requirement necessary for supporting risk adjustment.

(3) Data Quality Control

The APCD data intake and warehousing operation incorporates data quality evaluation and monitoring processes to ensure the integrity and accuracy of downstream files.

CHIA has published a set of data completeness checks containing nearly 800 unique automated tests that are conducted at intake within the secure processing environment. These checks

are used to assess the file's compliance with minimum standards. A full list of these checks is available on CHIA's Web site: <http://www.mass.gov/chia/researcher/health-care-delivery/hcf-data-resources/apcd/submitting-data-to-the-apcd.html>.

When this evaluation process is complete, a report is generated for the payer's review. The report shows the test results and whether the file "passes" and can move forward into the next phase of processing. If a file does not pass at any point in this process, the APCD does not conduct any further processing and notifies the payer that errors must be corrected and the files resubmitted. Full resubmission of a file is required in order to maintain file integrity.

CHIA will submit further supplemental information detailing its

plans to collect data from any non-compliant issuers, including additional information on alternate data submission procedures.

(4) Data Collection Timeline

Massachusetts plans to provide quarterly funds transfer calculation summaries to each issuer that is subject to risk adjustment and will be working with the issuers to determine the appropriate content and level of detail for the quarterly report summaries. The proposed timeline for processing and analyzing APCD data for Calendar Year 2014 for the purpose of risk adjustment is illustrated below. Massachusetts is in discussions with CHIA and the issuers regarding the timeline and also plan to conduct test runs to ensure the feasibility of the timeline and quality of the data collection process.

TABLE 15—PROPOSED TIMELINE FOR RISK ADJUSTMENT DATA COLLECTION

Time period	Activity
Each quarter: Months 1, 2, 3	Issuers submit data. Data submitters submit on a monthly basis.
Month 3 + 1 month (Month 4)	Claims run-out period.
Month 3 + 2 months (Month 5)	Quality checks at designated points in current APCD process. Member identity resolution and de-identification via removal of personal identifiers. CHIA creates extract with minimally necessary data elements and sends to Connector or Connector's designee to calculate risk adjustment. Quality review by the Connector or its designee. The purpose here is to determine whether data meets quality standards for risk adjustment purposes. Identified issues and recommended action steps will be sent to CHIA and the issuers regarding resubmission.
Month 3 + 3 months (Month 6)	Conducts all calculations relating to risk adjustment. Sends a preliminary report to data submitters for review and discusses results and observations with issuers.
January through March of the following year.	Claims run-out period. The proposed data submission deadline is March 31 of the following year, <i>i.e.</i> , 3 months claims runoff.
April of the following year	Filing deadline for claims paid through March 31 of the following year.
May of the following year	Quality assurance process and creation of the data extract. Grouping and review with data submitters.
June of the following year	Funds transfer settlements calculated and reports generated by June 30 of the following year.

i. Schedule of Calibration and Recalibration

The risk adjustment models and the additional adjustment factors proposed will need to be calibrated and recalibrated periodically to be reflective of current market conditions, the evolving insured population, medical technology and other secular trends in Massachusetts. Massachusetts will evaluate the goodness of fit of the risk adjustment models and the appropriateness of the additional adjustment factors on an ongoing basis and recalibrate every three years if the evaluation justifies. On October 1, 2014, the entire country is expected to

transition to ICD-10-CM coding. Massachusetts expects to update the current clinical classification system such that it can group ICD-10-CM diagnosis codes into the existing HCCs in 2014. However, it does not plan to recalibrate the risk factors in the models due to the lack of claims experience under the new coding system.

j. Data Validation

While not part of the risk adjustment methodology, Massachusetts is considering a range of potential data validation approaches. The Premium Stabilization Rule, § 153.350 requires States operating a risk adjustment

program to conduct data validation and provide an appeals process. The key goal from Massachusetts's perspective is to strike a balance between a data validation process that optimizes the identification of errors while implementing a workable system that is not administratively burdensome and that recognizes the zero sum nature of transfers between health plan issuers. Under the Premium Stabilization Rule, Massachusetts will be developing its approach to data validation and an appeals process, and will provide an overview of current considerations in its State notice of benefit and payment parameters.

TABLE 16—LIST OF HCCs IN MASSACHUSETTS RISK ADJUSTMENT METHODOLOGY FOR 2014

HCC	Description
HCC001	HIV/AIDS.
HCC201	Bacteremia.
HCC002	Septicemia/Shock.
HCC003	Central Nervous System Infection.
HCC004	Tuberculosis.
HCC005	Opportunistic Infections.
HCC202	Secondary Cancer Except Lymph Node.
HCC203	Secondary Cancer of Lymph Node.
HCC204	Cancer of the Brain/Nervous System/Pituitary, Pineal Glands.
HCC205	Acute Leukemia.
HCC008	Lung, Upper Digestive Tract, and Other Severe Cancers.
HCC009	Lymphatic, Head and Neck, Brain, and Other Major Cancers.
HCC010	Breast, Prostate, Colorectal and Other Cancers and Tumors.
HCC011	Other Respiratory and Heart Neoplasms.
HCC012	Other Digestive and Urinary Neoplasms.
HCC013	Other Neoplasms.
HCC015	Diabetes with Renal Manifestation.
HCC016	Diabetes with Neurologic or Peripheral Circulatory Manifestation.
HCC017	Diabetes with Acute Complications.
HCC018	Diabetes with Ophthalmologic Manifestation.
HCC019	Diabetes with No or Unspecified Complications.
HCC020	Type I Diabetes Mellitus.
HCC021	Protein-Calorie Malnutrition.
HCC022	Other Significant Endocrine and Metabolic Disorders.
HCC023	Disorders of Fluid/Electrolyte/Acid-Base Balance.
HCC025	End-Stage Liver Disease.
HCC026	Cirrhosis of Liver.
HCC027	Chronic Hepatitis.
HCC028	Acute Liver Failure/Disease.
HCC029	Other Hepatitis and Liver Disease.
HCC030	Gallbladder and Biliary Tract Disorders.
HCC031	Intestinal Obstruction/Perforation.
HCC032	Pancreatic Disease.
HCC033	Inflammatory Bowel Disease.
HCC034	Peptic Ulcer, Hemorrhage, Other Specified Gastrointestinal Disorders.
HCC035	Appendicitis.
HCC036	Other Gastrointestinal Disorders.
HCC037	Bone/Joint/Muscle Infections/Necrosis.
HCC038	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease.
HCC206	Spinal Stenosis.
HCC039	Disorders of the Vertebrae and Spinal Discs (See HCC206).
HCC040	Osteoarthritis of Hip or Knee.
HCC041	Osteoporosis and Other Bone/Cartilage Disorders.
HCC042	Congenital/Developmental Skeletal and Connective Tissue Disorders.
HCC207	Hemophilia.
HCC044	Severe Hematological Disorders (See HCC207).
HCC045	Disorders of Immunity.
HCC208	Hereditary Hemolytic Anemias and Coagulation Defects.
HCC209	Toxic/Unspecified Encephalopathy.
HCC048	Delirium and Encephalopathy (See HCC209).
HCC049	Dementia.
HCC050	Senility, Nonpsychotic Organic Brain Syndromes/Conditions.
HCC051	Drug/Alcohol Psychosis.
HCC052	Drug/Alcohol Dependence.
HCC054	Schizophrenia.
HCC055	Major Depressive, Bipolar, and Paranoid Disorders.
HCC056	Reactive and Unspecified Psychosis.
HCC057	Personality Disorders.
HCC058	Depression.
HCC059	Anxiety Disorders.
HCC061	Profound Mental Retardation/Developmental Disability.
HCC062	Severe Mental Retardation/Developmental Disability.
HCC063	Moderate Mental Retardation/Developmental Disability.
HCC064	Mild/Unspecified Mental Retardation/Developmental Disability.
HCC065	Other Developmental Disability.
HCC066	Attention Deficit Disorder.
HCC067	Quadriplegia, Other Extensive Paralysis.
HCC068	Paraplegia.
HCC069	Spinal Cord Disorders/Injuries.
HCC070	Muscular Dystrophy.
HCC071	Polyneuropathy.
HCC072	Multiple Sclerosis.

TABLE 16—LIST OF HCCs IN MASSACHUSETTS RISK ADJUSTMENT METHODOLOGY FOR 2014—Continued

HCC	Description
HCC073	Parkinson's and Huntington's Diseases.
HCC074	Seizure Disorders and Convulsions.
HCC075	Coma, Brain Compression/Anoxic Damage.
HCC076	Mononeuropathy, Other Neurological Conditions/Injuries.
HCC077	Respirator Dependence/Tracheostomy Status.
HCC078	Respiratory Arrest.
HCC210	Post Trauma/Surgery Pulmonary Insufficiency, Incl Adult Respir Distress Syndr.
HCC079	Cardio-Respiratory Failure and Shock (See HCC210).
HCC080	Congestive Heart Failure.
HCC081	Acute Myocardial Infarction.
HCC082	Unstable Angina and Other Acute Ischemic Heart Disease.
HCC083	Angina Pectoris/Old Myocardial Infarction.
HCC084	Coronary Atherosclerosis/Other Chronic Ischemic Heart Disease.
HCC085	Heart Infection/Inflammation, Except Rheumatic.
HCC086	Valvular and Rheumatic Heart Disease.
HCC087	Major Congenital Cardiac/Circulatory Defect.
HCC088	Other Congenital Heart/Circulatory Disease.
HCC092	Specified Heart Arrhythmias.
HCC093	Other Heart Rhythm and Conduction Disorders.
HCC095	Cerebral Hemorrhage.
HCC096	Ischemic or Unspecified Stroke.
HCC097	Precerebral Arterial Occlusion and Transient Cerebral Ischemia.
HCC098	Cerebral Atherosclerosis and Aneurysm.
HCC100	Hemiplegia/Hemiparesis.
HCC102	Speech, Language, Cognitive, Perceptual Deficits.
HCC104	Vascular Disease with Complications.
HCC105	Vascular Disease.
HCC106	Other Circulatory Disease.
HCC107	Cystic Fibrosis.
HCC108	Chronic Obstructive Pulmonary Disease.
HCC109	Fibrosis of Lung and Other Chronic Lung Disorders.
HCC110	Asthma.
HCC111	Aspiration and Specified Bacterial Pneumonias.
HCC112	Pneumococcal Pneumonia, Empyema, Lung Abscess.
HCC113	Viral and Unspecified Pneumonia, Pleurisy.
HCC114	Pleural Effusion/Pneumothorax.
HCC115	Other Lung Disorders.
HCC116	Legally Blind.
HCC117	Major Eye Infections/Inflammations.
HCC118	Retinal Detachment.
HCC119	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage.
HCC120	Diabetic and Other Vascular Retinopathies.
HCC122	Glaucoma.
HCC125	Significant Ear, Nose, and Throat Disorders.
HCC126	Hearing Loss.
HCC128	Kidney Transplant Status.
HCC130	Dialysis Status.
HCC211	Acute Renal Failure.
HCC131	Non-Acute Renal Failure (See HCC211).
HCC132	Nephritis.
HCC133	Urinary Obstruction and Retention.
HCC134	Incontinence.
HCC135	Urinary Tract Infection.
HCC136	Other Urinary Tract Disorders.
HCC137	Female Infertility.
HCC138	Pelvic Inflammatory Disease and Other Specified Female Genital Disorders.
HCC141	Ectopic Pregnancy.
HCC142	Miscarriage/Abortion.
HCC143	Completed Pregnancy With Major Complications.
HCC144	Completed Pregnancy With Complications.
HCC145	Completed Pregnancy Without Complications (Normal Delivery).
HCC146	Uncompleted Pregnancy With Complications.
HCC147	Uncompleted Pregnancy With No or Minor Complications.
HCC148	Decubitus Ulcer of Skin.
HCC150	Extensive Third-Degree Burns.
HCC151	Other Third-Degree and Extensive Burns.
HCC152	Cellulitis, Local Skin Infection.
HCC154	Severe Head Injury.
HCC155	Major Head Injury.
HCC156	Concussion or Unspecified Head Injury.
HCC157	Vertebral Fractures.
HCC158	Hip Fracture/Dislocation.

TABLE 16—LIST OF HCCs IN MASSACHUSETTS RISK ADJUSTMENT METHODOLOGY FOR 2014—Continued

HCC	Description
HCC159	Major Fracture, Except of Skull, Vertebrae, or Hip.
HCC160	Internal Injuries.
HCC161	Traumatic Amputation.
HCC164	Major Complications of Medical Care and Trauma.
HCC168	Extremely Low Birthweight Neonates.
HCC169	Very Low Birthweight Neonates.
HCC212	Low Birthweight (1500–2499 grams) or Unspecified.
HCC170	Serious Perinatal Problem Affecting Newborn (See HCC212).
HCC171	Other Perinatal Problems Affecting Newborn.
HCC172	Normal, Single Birth.
HCC213	Bone Marrow Transplant Status/Complications.
HCC174	Major Organ Transplant Status (See HCC213).
HCC175	Other Organ Transplant/Replacement.
HCC176	Artificial Openings for Feeding or Elimination.
HCC177	Amputation Status, Lower Limb/Amputation Complications.
HCC180	Radiation Therapy.
HCC181	Chemotherapy.
HCC182	Rehabilitation

TABLE 17—PROPOSED RISK ADJUSTMENT MODELS FOR MASSACHUSETTS RISK ADJUSTMENT METHODOLOGY FOR 2014

Factor	Platinum	Gold	Silver	Bronze/catastrophic
Constant Term	0. 108698	0. 108698	0. 054613	0. 054613
Female, 0–1	0. 120243	0. 120243	0. 120243	0. 076300
Male, 0–1	0. 430573	0. 252549	0. 252549	0. 130423
HCC001	4. 151453	4. 151453	3. 974417	3. 974417
HCC201	5. 439483	5. 439483	5. 439483	5. 439483
HCC002	4. 911655	4. 911655	4. 911655	4. 911655
HCC003	2. 070673	2. 070673	2. 070673	2. 070673
HCC004	1. 458104	0. 580915	0. 580915	0. 580915
HCC005	4. 203378	4. 203378	4. 203378	4. 203378
HCC202	6. 482786	6. 482786	6. 482786	6. 482786
HCC203	6. 482786	6. 482786	5. 475333	5. 475333
HCC204	6. 047288	4. 581452	4. 147687	2. 272855
HCC205	10. 703344	10. 703344	10. 703344	10. 703344
HCC008	2. 272855	2. 272855	2. 272855	2. 272855
HCC009	1. 075169	1. 075169	1. 075169	1. 075169
HCC010	1. 075169	1. 075169	1. 075169	1. 075169
HCC011	1. 075169	1. 075169	1. 075169	1. 075169
HCC012	0. 375903	0. 373614	0. 373614	0. 373614
HCC013	0. 375903	0. 373614	0. 373614	0. 373614
HCC015	0. 921977	0. 921977	0. 921977	0. 921977
HCC016	0. 395184	0. 395184	0. 395184	0. 395184
HCC017	0. 395184	0. 395184	0. 395184	0. 320869
HCC018	0. 320869	0. 320869	0. 320869	0. 320869
HCC019	0. 320869	0. 320869	0. 320869	0. 320869
HCC020	0. 844671	0. 844671	0. 769198	0. 769198
HCC021	8. 780537	8. 780537	8. 780537	8. 780537
HCC022	0. 976845	0. 976845	0. 976845	0. 976845
HCC023	1. 346099	1. 346099	1. 346099	1. 346099
HCC025	1. 601166	1. 601166	1. 346120	1. 346120
HCC026	0. 986228	0. 986228	0. 408007	0. 408007
HCC027	0. 460726	0. 460726	0. 408007	0. 408007
HCC028	1. 601166	1. 601166	1. 346120	1. 346120
HCC029	0. 408007	0. 408007	0. 408007	0. 408007
HCC030	1. 977590	1. 977590	1. 882379	1. 882379
HCC031	3. 749986	3. 749986	3. 749986	3. 749986
HCC032	1. 093277	1. 093277	1. 093277	1. 093277
HCC033	1. 790188	1. 790188	1. 595541	1. 595541
HCC034	0. 940108	0. 940108	0. 940108	0. 940108
HCC035	2. 683705	2. 683705	2. 683705	2. 011126
HCC036	0. 405518	0. 405518	0. 377057	0. 377057
HCC037	2. 952592	2. 952592	2. 952592	2. 952592
HCC038	1. 094796	1. 094796	1. 094796	1. 094796
HCC206	2. 098343	2. 098343	2. 098343	2. 098343
HCC039	0. 569751	0. 569751	0. 569751	0. 569751
HCC040	1. 094796	1. 094796	1. 094796	1. 094796
HCC041	0. 311993	0. 311993	0. 311993	0. 311993
HCC042	1. 125274	1. 125274	1. 125274	1. 125274

TABLE 17—PROPOSED RISK ADJUSTMENT MODELS FOR MASSACHUSETTS RISK ADJUSTMENT METHODOLOGY FOR 2014—Continued

Factor	Platinum	Gold	Silver	Bronze/catastrophic
HCC207	30. 636640	30. 636640	14. 101544	7. 514115
HCC044	5. 694090	5. 694090	5. 694090	5. 694090
HCC045	1. 011533	1. 011533	1. 011533	1. 011533
HCC208	1. 404092	1. 404092	1. 404092	1. 404092
HCC209	2. 918243	2. 918243	2. 918243	2. 918243
HCC048	1. 345886	1. 345886	1. 182955	1. 182955
HCC049	1. 216549	1. 216549	1. 086774	1. 086774
HCC050	1. 019842	1. 019842	1. 019842	1. 019842
HCC051	1. 343297	1. 343297	1. 343297	1. 343297
HCC052	0. 845301	0. 845301	0. 845301	0. 845301
HCC054	2. 625043	2. 625043	2. 161218	2. 161218
HCC055	0. 848033	0. 848033	0. 772826	0. 772826
HCC056	0. 848033	0. 848033	0. 772826	0. 772826
HCC057	0. 338729	0. 338729	0. 338729	0. 338729
HCC058	0. 338729	0. 338729	0. 338729	0. 338729
HCC059	0. 293976	0. 234661	0. 234661	0. 234661
HCC061	2. 234452	0. 911836	0. 911836	0. 416412
HCC062	0. 551357	0. 551357	0. 416412	0. 416412
HCC063	0. 551357	0. 416412	0. 416412	0. 416412
HCC064	0. 416412	0. 416412	0. 416412	0. 206061
HCC065	0. 315057	0. 315057	0. 315057	0. 206061
HCC066	0. 229744	0. 229744	0. 206061	0. 206061
HCC067	5. 447025	5. 447025	5. 447025	5. 447025
HCC068	2. 224234	2. 224234	2. 224234	2. 224234
HCC069	2. 098343	2. 098343	2. 098343	2. 098343
HCC070	1. 390521	1. 390521	1. 390521	1. 390521
HCC071	1. 209341	1. 209341	1. 209341	1. 209341
HCC072	4. 312296	4. 025404	4. 025404	4. 025404
HCC073	1. 217710	1. 217710	1. 217710	1. 217710
HCC074	1. 302181	0. 980434	0. 980434	0. 980434
HCC075	6. 388482	6. 388482	6. 388482	5. 638247
HCC076	0. 382239	0. 382239	0. 382239	0. 382239
HCC077	30. 588977	30. 588977	17. 179162	17. 179162
HCC078	6. 741034	6. 741034	6. 741034	2. 760821
HCC210	14. 638331	14. 638331	14. 638331	14. 638331
HCC079	4. 963995	4. 963995	2. 922954	2. 760821
HCC080	1. 268543	1. 268543	1. 268543	1. 268543
HCC081	5. 873126	5. 873126	5. 873126	5. 873126
HCC082	3. 409746	3. 409746	3. 409746	3. 170501
HCC083	1. 185868	1. 185868	1. 185868	1. 185868
HCC084	0. 518025	0. 518025	0. 518025	0. 518025
HCC085	3. 358496	3. 358496	3. 358496	3. 358496
HCC086	0. 748725	0. 748725	0. 748725	0. 748725
HCC087	4. 962870	4. 456078	2. 859281	2. 119499
HCC088	0. 748725	0. 748725	0. 748725	0. 748725
HCC092	1. 226834	1. 226834	1. 226834	1. 226834
HCC093	1. 005026	1. 005026	1. 005026	1. 005026
HCC095	6. 224877	6. 224877	4. 744856	4. 744856
HCC096	0. 917154	0. 917154	0. 705810	0. 705810
HCC097	0. 065189	0. 065189	0. 065189	0. 065189
HCC098	0. 065189	0. 065189	0. 065189	0. 065189
HCC100	2. 224234	2. 224234	2. 224234	2. 224234
HCC102	2. 941517	2. 941517	2. 941517	2. 941517
HCC104	2. 598472	2. 598472	2. 598472	2. 598472
HCC105	0. 831150	0. 831150	0. 831150	0. 831150
HCC106	0. 685084	0. 685084	0. 685084	0. 685084
HCC107	8. 318393	7. 678688	4. 188453	3. 417106
HCC108	0. 445827	0. 445827	0. 445827	0. 445827
HCC109	0. 445827	0. 445827	0. 445827	0. 445827
HCC110	0. 327310	0. 327310	0. 298068	0. 298068
HCC111	4. 185448	4. 185448	4. 185448	4. 185448
HCC112	2. 487771	2. 487771	2. 487771	2. 487771
HCC113	0. 459994	0. 459994	0. 459994	0. 459994
HCC114	4. 665050	4. 665050	4. 461861	4. 461861
HCC115	0. 245923	0. 245923	0. 174247	0. 174247
HCC116	1. 846476	1. 846476	1. 846476	1. 846476
HCC117	0. 871167	0. 871167	0. 871167	0. 293138
HCC118	0. 425465	0. 303314	0. 303314	0. 303314
HCC119	0. 975698	0. 975698	0. 975698	0. 975698
HCC120	0. 975698	0. 629335	0. 629335	0. 387584

TABLE 17—PROPOSED RISK ADJUSTMENT MODELS FOR MASSACHUSETTS RISK ADJUSTMENT METHODOLOGY FOR 2014—Continued

Factor	Platinum	Gold	Silver	Bronze/catastrophic
HCC122	0. 156864	0. 156864	0. 156864	0. 156864
HCC125	0. 441244	0. 441244	0. 441244	0. 441244
HCC126	0. 343108	0. 245527	0. 245527	0. 245527
HCC128	3. 935445	3. 086230	3. 086230	3. 086230
HCC130	25. 095071	25. 095071	25. 095071	25. 095071
HCC211	5. 931077	5. 931077	3. 957413	3. 957413
HCC131	0. 609381	0. 609381	0. 609381	0. 548312
HCC132	0. 609381	0. 609381	0. 548312	0. 548312
HCC133	0. 828794	0. 828794	0. 828794	0. 828794
HCC134	0. 333109	0. 333109	0. 179712	0. 179712
HCC135	0. 186132	0. 186132	0. 186132	0. 186132
HCC136	0. 308014	0. 308014	0. 308014	0. 308014
HCC137	2. 229861	2. 019901	1. 191632	1. 191632
HCC138	0. 587042	0. 587042	0. 587042	0. 587042
HCC141	1. 003553	1. 003553	1. 003553	0. 718760
HCC142	0. 557164	0. 557164	0. 480684	0. 431174
HCC143	4. 184966	4. 184966	3. 619387	3. 002414
HCC144	3. 332900	2. 868669	2. 280000	1. 954919
HCC145	1. 171729	0. 774339	0. 774339	0. 216043
HCC146	0. 557164	0. 557164	0. 480684	0. 216043
HCC147	0. 280304	0. 280304	0. 216043	0. 216043
HCC148	12. 543259	12. 543259	6. 014584	6. 014584
HCC150	2. 424426	2. 424426	2. 424426	2. 424426
HCC151	2. 424426	2. 424426	2. 424426	2. 424426
HCC152	0. 333411	0. 322440	0. 322440	0. 322440
HCC154	15. 385354	15. 385354	10. 060566	10. 060566
HCC155	1. 019842	1. 019842	1. 019842	1. 019842
HCC156	0. 378295	0. 378295	0. 378295	0. 378295
HCC157	2. 098343	2. 098343	2. 098343	2. 098343
HCC158	3. 274125	3. 274125	3. 274125	3. 274125
HCC159	0. 995242	0. 995242	0. 995242	0. 995242
HCC160	1. 169886	1. 169886	1. 169886	1. 169886
HCC161	4. 800076	4. 800076	3. 252883	3. 252883
HCC164	4. 416936	4. 416936	4. 416936	4. 416936
HCC168	50. 030035	31. 846702	8. 770478	1. 517088
HCC169	31. 846702	31. 846702	8. 770478	1. 517088
HCC212	5. 348103	4. 531656	2. 869468	1. 517088
HCC170	5. 118321	3. 980982	2. 713315	1. 517088
HCC171	0. 944286	0. 944286	0. 833781	0. 833781
HCC172	0. 766750	0. 282812	0. 282812	0. 282812
HCC213	26. 085463	26. 085463	22. 031148	22. 031148
HCC174	13. 907770	13. 907770	10. 852783	6. 023029
HCC175	0. 417558	0. 391105	0. 391105	0. 145153
HCC176	5. 768476	5. 768476	5. 768476	5. 768476
HCC177	0. 879358	0. 879358	0. 879358	0. 879358
HCC180	4. 989476	4. 989476	4. 989476	4. 989476
HCC181	13. 774728	13. 774728	13. 774728	13. 774728
HCC182	1. 791185	1. 791185	1. 791185	1. 791185
INT01	3. 869565	3. 869565	3. 869565	3. 869565
INT02	1. 608754	1. 608754	1. 608754	1. 608754

Definition of the interaction terms:
 INT01 = CANCER*IMMUNE, and INT02
 = CVD*VD,

Where,
 CANCER = MAX (MAX (of HCC008–
 HCC014), MAX (of HCC202–HCC205));

IMMUNE = HCC045;
 CVD = MAX (of HCC095–HCC103);
 VD = MAX (HCC104, HCC105);

TABLE 18—DURATION ADJUSTMENT IN RISK ADJUSTMENT MODELS IN MASSACHUSETTS RISK ADJUSTMENT METHODOLOGY FOR 2014

Month of eligibility	Platinum	Gold	Silver	Bronze
1	0.225160	0.343520	0.474510	1.000000
2	0.341279	0.462802	0.584191	1.000000
3	0.435275	0.550953	0.659754	1.000000
4	0.517282	0.623502	0.719223	1.000000
5	0.591389	0.686292	0.769018	1.000000
6	0.659754	0.742262	1.000000	1.000000
7	0.723686	0.793130	1.000000	1.000000

TABLE 18—DURATION ADJUSTMENT IN RISK ADJUSTMENT MODELS IN MASSACHUSETTS RISK ADJUSTMENT METHODOLOGY FOR 2014—Continued

Month of eligibility	Platinum	Gold	Silver	Bronze
8	1.000000	0.840003	1.000000	1.000000
9	1.000000	1.000000	1.000000	1.000000
10	1.000000	1.000000	1.000000	1.000000
11	1.000000	1.000000	1.000000	1.000000
12	1.000000	1.000000	1.000000	1.000000

TABLE 19—CLINICAL HIERARCHIES IN MASSACHUSETTS RISK ADJUSTMENT METHODOLOGY FOR 2014

DISEASE HIERARCHIES Hierarchical Condition Category (HCC)	If the Condition Category is Listed in this column . . .	. . . Then drop the HCC(s) listed in this column
Hierarchical Condition Category (HCC) Label		
5	Opportunistic Infections	112, 113, 115
202	Secondary Cancer Except Lymph Node	203, 204, 8, 9, 10, 11, 12, 13
203	Secondary Cancer of Lymph Node	204, 8, 9, 10, 11, 12, 13
204	Cancer of the Brain/Nervous System/Pituitary, Pineal Glands	8, 9, 10, 11, 12, 13
205	Acute Leukemia	8, 9, 10, 11, 12, 13
8	Lung, Upper Digestive Tract, and Other Severe Cancers	9, 10, 11, 12, 13
9	Lymphatic, Head and Neck, Brain, and Other Major Cancers	10, 11, 12, 13
10	Breast, Prostate, Colorectal and Other Cancers and Tumors	11, 12, 13
11	Other Respiratory and Heart Neoplasms	12, 13
12	Other Digestive and Urinary Neoplasms	13
15	Diabetes with Renal Manifestation	16, 17, 18, 19
16	Diabetes with Neurologic or Peripheral Circulatory Manifestation	17, 18, 19
17	Diabetes with Acute Complications	18, 19
18	Diabetes with Ophthalmologic Manifestation	19
25	End-Stage Liver Disease	26, 27, 28, 29, 34, 36
26	Cirrhosis of Liver	27, 29
27	Chronic Hepatitis	29
28	Acute Liver Failure/Disease	29
31	Intestinal Obstruction/Perforation	34, 36
32	Pancreatic Disease	36
33	Inflammatory Bowel Disease	34, 36
34	Peptic Ulcer, Hemorrhage, Other Specified Gastrointestinal Disorders	36
38	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	39, 40
206	Spinal Stenosis	39
207	Hemophilia	44, 208
44	Severe Hematological Disorders	208
209	Toxic/Unspecified Encephalopathy	48, 50
48	Delirium and Encephalopathy	50
49	Dementia	50
51	Drug/Alcohol Psychosis	52
54	Schizophrenia	55, 56, 57, 58, 59
55	Major Depressive, Bipolar, and Paranoid Disorders	56, 57, 58, 59
56	Reactive and Unspecified Psychosis	57, 58, 59
57	Personality Disorders	58, 59
58	Depression	59
61	Profound Mental Retardation/Developmental Disability	62, 63, 64, 65, 66
62	Severe Mental Retardation/Developmental Disability	63, 64, 65, 66
63	Moderate Mental Retardation/Developmental Disability	64, 65, 66
64	Mild/Unspecified Mental Retardation/Developmental Disability	65, 66
65	Other Developmental Disability	66
67	Quadriplegia, Other Extensive Paralysis	68, 69, 76, 100, 157
68	Paraplegia	69, 76, 100, 157
69	Spinal Cord Disorders/Injuries	39, 76, 157
70	Muscular Dystrophy	76
71	Polyneuropathy	76
72	Multiple Sclerosis	76
73	Parkinson's and Huntington's Diseases	76
74	Seizure Disorders and Convulsions	76
75	Coma, Brain Compression/Anoxic Damage	209, 48, 50, 76
77	Respirator Dependence/Tracheostomy Status	78, 210, 79
210	Post Trauma/Surgery Pulmonary Insufficiency, Incl Adult Respir Distress Syndrom.	79
78	Respiratory Arrest	79
81	Acute Myocardial Infarction	82, 83, 84
82	Unstable Angina and Other Acute Ischemic Heart Disease	83, 84
83	Angina Pectoris/Old Myocardial Infarction	84

TABLE 19—CLINICAL HIERARCHIES IN MASSACHUSETTS RISK ADJUSTMENT METHODOLOGY FOR 2014—Continued

DISEASE HIERARCHIES Hierarchical Condition Category (HCC)	If the Condition Category is Listed in this column . . .	. . . Then drop the HCC(s) listed in this column
85	Heart Infection/Inflammation, Except Rheumatic	86, 88
86	Valvular and Rheumatic Heart Disease	88
87	Major Congenital Cardiac/Circulatory Defect	88
92	Specified Heart Arrhythmias	93
95	Cerebral Hemorrhage	96, 97, 98
96	Ischemic or Unspecified Stroke	97, 98
97	Precerebral Arterial Occlusion and Transient Cerebral Ischemia	98
104	Vascular Disease with Complications	105, 106
105	Vascular Disease	106
107	Cystic Fibrosis	108, 109, 110, 115
108	Chronic Obstructive Pulmonary Disease	109, 110, 115
109	Fibrosis of Lung and Other Chronic Lung Disorders	110, 115
110	Asthma	115
111	Aspiration and Specified Bacterial Pneumonias	112, 113, 115
112	Pneumococcal Pneumonia, Empyema, Lung Abscess	113, 115
113	Viral and Unspecified Pneumonia, Pleurisy	115
114	Pleural Effusion/Pneumothorax	115
119	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	120
128	Kidney Transplant Status	130, 131, 132, 136, 175
130	Dialysis Status	211, 131, 132, 136
131	Non-Acute Renal Failure	132, 136
132	Nephritis	136
137	Female Infertility	138
141	Ectopic Pregnancy	142, 146, 147
142	Miscarriage/Abortion	146, 147
143	Completed Pregnancy With Major Complications	144, 145, 146, 147
144	Completed Pregnancy With Complications	145, 146, 147
145	Completed Pregnancy Without Complications (Normal Delivery)	146, 147
146	Uncompleted Pregnancy With Complications	147
150	Extensive Third-Degree Burns	151
154	Severe Head Injury	209, 48, 50, 75, 76, 155, 156
155	Major Head Injury	50, 156
157	Vertebral Fractures	206, 39
161	Traumatic Amputation	177
168	Extremely Low Birthweight Neonates	169, 212, 170, 171, 172
169	Very Low Birthweight Neonates	212, 170, 171, 172
212	Low Birthweight (1500–2499 grams) or Unspecified	171, 172
170	Serious Perinatal Problem Affecting Newborn	171, 172
171	Other Perinatal Problems Affecting Newborn	172
213	Bone Marrow Transplant Status/Complications	175
174	Major Organ Transplant Status	175

k. Caveats and Limitations

In preparing its application Massachusetts relied on data from Massachusetts APCD, Commonwealth Care and Marketscan® New England in developing the risk adjustment models and additional adjustment factors, and as such the results may not apply to other States' risk adjustment programs. Additionally, there are limitations in the datasets which may affect the accuracy and robustness of the models and factors presented here.

C. Provisions and Parameters for the Transitional Reinsurance Program

The Affordable Care Act directs the establishment of a transitional reinsurance program in each State to help stabilize premiums for coverage in the individual market from 2014 through 2016. The reinsurance program is designed to alleviate the need to build

into premiums the risk of enrolling individuals with significant unmet medical needs. By equitably stabilizing premiums in the individual market throughout the United States, the reinsurance program is intended to help millions of Americans purchase affordable health insurance, reduce unreimbursed usage of hospital and other medical facilities by the uninsured, and thereby lower medical expenses and premiums for all people with private health insurance.

In the proposed rule, we aimed to administer the reinsurance program to provide reinsurance payments in an efficient, fair, and accurate manner, where reinsurance assistance is needed most, to effectively stabilize premiums nationally. In addition, we stated our intent to implement the reinsurance program in a manner that minimizes the administrative burden of collecting

contributions and making reinsurance payments. For example, we proposed to collect contributions from health insurance issuers and self-insured group health plans in all States, including States that elect to operate reinsurance. We also stated our intent to simplify collections by using a uniform per capita contribution rate. In addition, in the HHS-operated reinsurance program, we proposed to calculate reinsurance payments using the same distributed approach for data collection that we will use when operating the risk adjustment program on behalf of States.¹⁵ This would permit issuers to receive reinsurance payments using the same systems established for the risk adjustment program, resulting in less administrative burden and lower costs,

¹⁵ See our discussion of this distributed data collection approach in section III.G. of this final rule.

while maintaining the security of identifiable health information.

In the proposed rule, we proposed uniform reinsurance payment parameters to be used across all States, regardless of whether the State, or HHS on behalf of a State, operates reinsurance. In addition, we proposed an annual calendar under which reinsurance contributions would be collected from all contributing entities, and reinsurance payments would be disbursed to issuers of reinsurance-eligible plans. Furthermore, we proposed to distribute reinsurance payments based on the need for reinsurance payments in each State. We believe that allocating contributions in this manner better meets States' individual reinsurance needs and fulfills HHS's obligation to provide equitable allocation of these funds under section 1341(b)(2)(B) of the Affordable Care Act, than does a policy that limits the disbursement of reinsurance payments only to the State in which the contributions are collected.

Comment: One commenter requested that HHS consider extending the reinsurance program past 2016.

Response: Section 1341 of the Affordable Care Act mandates that the transitional reinsurance program operate in the three year period beginning January 1, 2014, which we interpret to mean that the program will operate in benefit years 2014, 2015 and 2016. As a result, we have no statutory authority to extend the program. We note that, under this final rule, reinsurance payments for benefit year 2016 will be made in 2017, and section 1341(a)(4)(B) provides that amounts remaining unexpended as of December 2016 may be used to make payments under any reinsurance program of a State in the individual market in effect in the two-year period beginning on January 1, 2017.

1. State Standards Related to the Reinsurance Program

a. State-Operated Reinsurance Programs, Generally

In the proposed rule, we set forth a reinsurance contribution and payment process, and the uniform contribution rate and reinsurance payment parameters that would apply to all States in the 2014 benefit year. We proposed to amend § 153.100(a)(1) to delete the reference to State modification of data collection frequency as set forth in the Premium Stabilization Rule. That deletion would remove the ability of a State electing to operate reinsurance to modify, via a State notice of benefit and payment

parameters, the data collection frequency for issuers to receive reinsurance payments. Under § 153.100(a)(1), a State establishing a reinsurance program may still modify the data requirements for health insurance issuers to receive reinsurance payments, provided that the State publishes a State notice of benefit and payment parameters that specifies those modifications.

In § 153.100(a)(2), we proposed that a State electing to collect additional reinsurance contributions for purposes of making supplemental reinsurance payments or using additional funds for supplemental reinsurance payments under § 153.220(d) publish supplemental State reinsurance payment parameters in its State notice of benefit and payment parameters. To create the most effective reinsurance program, we proposed to collect reinsurance contributions on behalf of all States from both health insurance issuers and self-insured group health plans in the aggregate, and we proposed to disburse reinsurance payments based on a State's need for reinsurance payments, not based on where the contributions were collected. As a result, HHS would no longer be able to attribute additional funds for administrative expenses back to a State. We therefore proposed to amend § 153.100(a)(3) of the Premium Stabilization Rule to clarify that any additional contributions collected for administrative expenses must be collected by the State operating reinsurance.

Section 1341 of the Affordable Care Act provides that States may elect to operate reinsurance. Based on HHS's communications with States, as of February 25, 2013, Maryland and Connecticut are the only States electing to operate reinsurance for 2014. Pursuant to § 153.100, a State that wishes to collect additional reinsurance funds pursuant to § 153.220(d) must publish the supplemental contribution rate and supplemental State reinsurance payment parameters in a State notice of benefit and payment parameters, which for 2014 must be published by the 30th day following the publication of this final rule.

We are finalizing these provisions as proposed, with a technical amendment to § 153.210(a)(2) in which we clarify that a State's obligation to ensure that each applicable reinsurance entity operates in a distinct geographic area applies regardless of whether the State contracts with or establishes the applicable reinsurance entities. As we also clarify below, governmental entities may serve as applicable reinsurance

entities. We are also amending § 153.100(a)(2) by replacing the cross-reference to § 153.220(d) with § 153.220(d)(1). We are making corresponding revisions in § 153.100(d)(2); and § 153.110(b); 153.400(a).

Comment: One commenter requested that HHS prohibit States operating reinsurance from modifying the data requirements for health insurance issuers to receive reinsurance payments.

Response: Although we recognize the efficiencies to multi-State issuers of having a uniform set of data requirements, we believe that a State should have the flexibility to collect the data it deems necessary, in the manner it deems most appropriate, to calculate reinsurance payments for issuers of non-grandfathered individual market plans in the State. Accordingly, we will permit State flexibility regarding data requirements. As set forth in § 153.100(a)(1), a State modifying the data requirements must describe those requirements in its State notice of benefit and payment parameters.

Comment: One commenter asked that HHS permit a governmental entity to be eligible to serve as an applicable reinsurance entity.

Response: We interpret the definition of an applicable reinsurance entity in section 1341(c)(1) of the Affordable Care Act as a "not-for-profit organization," the purpose of which is to stabilize premiums in the first three years of Exchange operation and the duties of which are to carry out the reinsurance program, to be broad enough to include a governmental entity. Accordingly, we believe that an applicable reinsurance entity is a not-for-profit organization that is exempt from taxation under Chapter 1 of the Internal Revenue Code of 1986, including a governmental entity and a quasi-governmental entity that was not created for and does not operate to make a profit, and carries out reinsurance functions under this part on behalf of the State.

Comment: One commenter requested that HHS permit a State to obtain a waiver from the reinsurance program set forth in section 1341 of the Affordable Care Act.

Response: HHS has no authority to grant such a waiver. As set forth in the Premium Stabilization Rule, if a State does not elect to operate reinsurance, HHS will operate reinsurance on behalf of the State.

Comment: One commenter asked whether HHS will implement an approval process for States choosing to operate reinsurance, similar to the process used to approve States choosing to operate the risk adjustment program.

Response: Unlike the risk adjustment program, there will be no formal approval process for State-operated reinsurance programs. However, HHS will establish a consultative pre-implementation process to ensure that each State operating reinsurance is ready to operate beginning in 2014. HHS intends to work closely with States throughout the duration of the reinsurance program to ensure States' operational readiness.

Comment: One commenter sought clarification on the functions that a State operating reinsurance must perform.

Response: This final rule sets forth a number of functions that a State operating reinsurance must perform, consistent with the functions of the HHS-operated reinsurance program. For example, under § 153.240, a State operating reinsurance must ensure that the State's applicable reinsurance entity collects data required to calculate reinsurance payments, makes reinsurance payments, and provides a process for reinsurance-eligible plans that do not generate individual enrollee claims in the normal course of business to submit claims. In addition, a State operating reinsurance must notify issuers of requests for reinsurance payments made and actual reinsurance payments to be provided. In addition to performing payment functions, a State operating reinsurance may elect to collect additional funds or use State funds under § 153.220(d)(1)(ii) or § 153.220(d)(2) (proposed as (d)(3) in the proposed rule) to fund administrative expenses or set up and fund supplemental reinsurance payment parameters that "wrap around" the uniform reinsurance payment parameters.

b. Reporting to HHS

In § 153.210(e) of the proposed rule, we stated that a State establishing the reinsurance program would be required to provide information to HHS regarding all requests for reinsurance payments received from all reinsurance-eligible plans for each quarter during the benefit year in the State. In § 153.240(b)(2), we proposed that a State, or HHS on behalf of the State, would use the information collected by HHS or submitted under § 153.210(e) to provide issuers of reinsurance-eligible plans with quarterly updates of requests for reinsurance payments for the plan under both the uniform payment parameters and any State supplemental payments parameters set forth under § 153.232, as determined by HHS or the State's applicable reinsurance entity, as applicable. This information could be

used by an individual market issuer in developing rates in subsequent benefit years. We are finalizing these provisions as proposed, with modifications in § 153.240(b)(2) to clarify that a State must provide to an issuer of a reinsurance-eligible plan the calculation of the total reinsurance payments requested under the national reinsurance payment parameters and State supplemental reinsurance payment parameters, on a quarterly basis during the applicable benefit year in a timeframe and manner determined by HHS.

Comment: Several commenters supported the proposal that HHS or States operating reinsurance provide to issuers quarterly updates of requests for reinsurance payments made under the uniform payment parameters and State supplemental payment parameters, as applicable. Several commenters urged HHS not to require a State operating reinsurance to provide these quarterly estimates.

Response: Because the purpose of the reinsurance program is to help stabilize premiums, and because interim information on reinsurance claims will be useful for issuers in setting rates in subsequent benefit years, we are finalizing § 153.240(b) as proposed.

Comment: One commenter requested clarification on whether updates of reinsurance payment requests made would be provided on a rolling basis throughout the benefit year, or only after all reinsurance payment requests have been submitted. Commenters suggested that total payment requests across all issuers be specified so that issuers can estimate whether total payments will exceed total contributions.

Response: A State operating reinsurance or HHS, on behalf of the State, will issue reports on a quarterly basis on the total amount of reinsurance requests submitted. We appreciate the suggestions for the quarterly reporting format, and will take them under consideration. We anticipate issuing guidance for States and issuers regarding quarterly reporting.

c. Additional State Collections

In § 153.220(d), we proposed that a State operating reinsurance may elect to collect more than the amounts based on the national contribution rate set forth in the annual HHS notice of benefit and payment parameters for administrative expenses of the applicable reinsurance entity or for additional reinsurance payments. In addition, under § 153.220(d)(2), we proposed that a State must notify HHS within 30 days after publication of the draft annual HHS notice of benefit and payment

parameters for the applicable benefit year of the additional contribution rate that it elects to collect. We are finalizing these provisions as proposed with the following modification: we are deleting § 153.220(d)(2), which required a State to notify HHS within 30 days after publication of the draft annual HHS notice of benefit and payment parameters for the applicable benefit year of the additional contribution rate that it elects to collect.

Comment: We received several comments asking HHS to eliminate the requirement set forth in § 153.220(d)(2), which provided that a State must notify HHS within 30 days after publication of the draft annual HHS notice of benefit and payment parameters for the applicable benefit year of the additional contribution rate that it elects to collect. However, one commenter encouraged HHS to keep this requirement.

Response: Because HHS will no longer collect additional contributions on behalf of a State, and will not immediately need this information, we are removing § 153.220(d)(2) from this final rule. Any State operating reinsurance and electing to collect additional contributions under § 153.220(d) must set forth any additional contribution rate that it elects to collect in its State notice of benefit and payment parameters.

Comment: One commenter asked HHS to clarify that States may collect additional administrative expenses only when a State is operating reinsurance.

Response: Only a State operating reinsurance is permitted to collect additional administrative expenses under § 153.220(d). The State must set forth any additional contribution rate in its State notice of benefit and payment parameters.

Comment: One commenter asked HHS to prohibit States from collecting additional funds for administrative expenses.

Response: To allow State flexibility in operating reinsurance, a State operating reinsurance will be permitted to collect additional funds for administrative expenses as the State deems necessary.

Comment: Several commenters opposed the collection of additional funds by States from self-insured plans, and urged HHS to specify in regulatory text that States cannot collect from self-insured plans covered by ERISA.

Response: We reiterate that nothing in section 1341 of the Affordable Care Act or 45 CFR part 153 of this final rule gives a State the authority to collect any funds—whether under the national contribution rate or under an additional State contribution rate—from self-

insured group health plans covered by ERISA.

Comment: One commenter requested that HHS specify that the Federal Employees Health Benefit Act prohibits States from imposing additional State reinsurance fund collections on Federal Employees Health Benefits Program (FEHB) plans.

Response: Although § 153.220(d) provides that a State may elect to collect additional reinsurance contributions for administrative expenses or reinsurance payments, we do not interpret section 1341 of the Affordable Care Act or 45 CFR part 153 of this final rule as giving States any additional authority to collect from contributing entities. Any such authority must come from other State or Federal law.

d. State Collections

In § 153.220(a), we proposed that if a State establishes a reinsurance program, HHS will collect all reinsurance contributions from all contributing entities for that State under a national contribution rate. In § 153.220(d)(3) of the proposed rule (which we now renumber as § 153.220(d)(2)), we proposed that States may use additional funds, which were not collected as additional reinsurance contributions, to make supplemental reinsurance payments under the State supplemental reinsurance payment parameters. This would allow States to use other revenue sources, such as funds collected for State high-risk pools. This would also ensure that additional State collections for reinsurance payments and other State funds may be used to reduce premiums. We are finalizing these provisions as proposed.

Comment: Several commenters asked that HHS permit States to collect contributions from health insurance issuers. Other commenters supported the proposed centralized collection of reinsurance contribution under the national contribution rate.

Response: HHS will collect contributions from health insurance issuers and self-insured group health plans in all States, including States that elect to operate reinsurance. This will allow for a centralized and streamlined process for the collection of contributions, and will avoid inefficiencies resulting from the use of different collection processes in different States. Federal collections will also leverage economies of scale, reducing the overall administrative costs of the transitional reinsurance program.

e. High-Risk Pools

Section 1341(d) of the Affordable Care Act and § 153.250 of the Premium Stabilization Rule provide that a State must eliminate or modify its high-risk pool to the extent necessary to carry out the transitional reinsurance program. However, any changes made to a State high-risk pool must comply with the terms and conditions of Grants to States for Operation of Qualified High-Risk Pools (CFDA 93.780), as applicable. Under § 153.400(a)(2)(iii), we proposed that State high-risk pools would be excluded from making reinsurance contributions and would not receive reinsurance payments.

The Affordable Care Act permits a State to coordinate its high-risk pool with the reinsurance program “to the extent not inconsistent”¹⁶ with the statute. We clarify that nothing in the Premium Stabilization Rule or this final rule prevents a State that establishes the reinsurance program from using State money designated for the State’s high-risk pool towards the reinsurance program. However, a State may not use funds collected for the Affordable Care Act reinsurance program for its high-risk pool. Finally, a State could designate its high-risk pool as its applicable reinsurance entity, provided that the high-risk pool meets all the criteria for being an applicable reinsurance entity.

Comment: Several commenters requested that we permit State high-risk pools to be eligible for reinsurance payments for their high-risk enrollees. Commenters stated that the sudden termination of high-risk pools in 2014 would result in high-risk pool enrollees flooding the individual market, potentially resulting in premium increases for all individual market enrollees and a loss of access to providers currently administering care for high-risk pool enrollees.

Response: Under the definition of a reinsurance-eligible plan in § 153.20 of the Premium Stabilization Rule, State high-risk pools are not eligible to receive reinsurance payments for their high-risk enrollees because high-risk pool coverage is not individual market coverage. We note that if a high-risk pool were to be structured as individual market coverage subject to the market reform rules, it would be eligible for reinsurance payments and would also, therefore, be a contributing entity.

Comment: Several commenters asked that HHS clarify that States can continue to operate high-risk pools to complement the reinsurance program

and to provide continuity of coverage to risk pool enrollees.

Response: States have the flexibility to decide whether to maintain, phase-out, or eliminate their high-risk pools. Because State high-risk pools and the reinsurance program both target high-cost enrollees, high-risk pools can operate alongside reinsurance serving a distinct subset of the target population.

Comment: Several commenters asked that the Federal government continue to provide funding for the State High Risk Pool Grant program.

Response: Funding for the State High Risk Pool Grant Program is not addressed in this final rule.

2. Contributing Entities and Excluded Entities

Section 1341 of the Affordable Care Act provides that health insurance issuers and third party administrators on behalf of group health plans must make payments to an applicable reinsurance entity. In the proposed rule, we stated that, with respect to insured coverage, issuers are responsible for making reinsurance contributions. With respect to a self-insured group health plan, the plan is responsible, although a third party administrator (TPA) or administrative services only (ASO) contractor may be utilized to transfer reinsurance contributions on behalf of a plan. A self-insured, self-administered group health plan without a TPA or ASO contractor would make its reinsurance contributions directly. For the reasons described above and in the preamble of the proposed rule, we are modifying the definition of “contributing entity” in § 153.20 to clarify that a “contributing entity” is a health insurance issuer or a self-insured group health plan.

Comment: Several commenters asked that HHS amend the definition of contributing entity, clarifying the liability of TPAs.

Response: We have amended the definition of “contributing entity” in § 153.20 to include the clarification we provided in the proposed rule at 77 FR 73152. This amended definition states that a contributing entity is a health insurance issuer or a self-insured group health plan. Thus, we clarify that a self-insured group health plan is ultimately responsible for the reinsurance contributions, even though it may elect to use a TPA or ASO contractor to transfer the reinsurance contributions.

Comment: Several commenters sought clarification regarding whether self-insured group health plans may remit reinsurance contributions directly to HHS even if the plan otherwise

¹⁶ See section 1341(d) of the Affordable Care Act.

contracts with a TPA or ASO contractor for administration of benefits.

Response: A self-insured group health plan may elect to make its reinsurance contributions directly to HHS or through a TPA or an ASO contractor.

Comment: One commenter suggested that requiring issuers to submit a separate payment for each insured group would add significant administrative burden.

Response: HHS will provide details on the process for submission of reinsurance contributions in future guidance.

Comment: One commenter stated that the proposed rule does not address whether a TPA may charge administrative fees for the additional work it will undertake to collect reinsurance fees and forward them to HHS.

Response: Any fee for such services would be negotiated between the plan and the TPA or ASO contractor. We note that the program is designed to minimize administrative costs, which we expect to be relatively low.

Comment: Several commenters asked that HHS clarify that a plan with several TPAs should determine if and which TPA will calculate the enrollment count and submit reinsurance payments.

Response: The self-insured group health plan is liable for reporting enrollment counts and making reinsurance contributions. It may utilize any TPA or ASO contractor it wishes (or none) to perform these functions.

Under section 1341(b)(3)(B)(i) of the Affordable Care Act, contribution amounts for reinsurance are to reflect, in part, an issuer's "fully insured commercial book of business for all major medical products." We interpret this statutory language to mean that reinsurance contributions are not required for coverage that is not "major medical coverage" or for health insurance coverage that is non-commercial. We also interpret this statutory language to exclude expatriate health coverage, as defined by the Secretary. HHS plans to define expatriate health coverage in the near future.

(1) *Major Medical Coverage:* In § 153.400(a)(1)(i), we proposed that a contributing entity make reinsurance contributions for its health coverage except to the extent that such coverage is not "major medical coverage." Section 1341(b)(3)(B)(i) of the Affordable Care Act refers to "major medical products," but does not define the term. The preamble to the proposed rule at 77 FR 73152 discussed the definition that should apply for

reinsurance purposes. We are finalizing the provisions as proposed.

Comment: One commenter requested that we codify in regulation text the description of major medical coverage that was set forth in preamble.

Response: We reiterate that for purposes of the reinsurance program only, our view is that major medical coverage is health coverage, which may be subject to reasonable enrollee cost sharing, for a broad range of services and treatments including diagnostic and preventive services, as well as medical and surgical conditions provided in various settings, including inpatient, outpatient, and emergency room settings. Coverage that is limited in scope (for example, dread disease coverage, hospital indemnity coverage, or stand-alone vision coverage or stand-alone dental coverage), or extent (for example, coverage that is not subject to section 2711 of the PHS Act and its implementing regulations) would not be major medical coverage.¹⁷

In the proposed rule, we stated that when an individual has both Medicare coverage and employer-provided group health coverage, the Medicare Secondary Payer (MSP) rules under section 1862(b) of the Act would apply, and the group health coverage would be considered major medical coverage only if the group health coverage is the primary payer of medical expenses (and Medicare is the individual's secondary payer) under the MSP rules. For example, a working 68-year-old employee enrolled in a group health plan who, under the MSP rules, is a beneficiary for whom Medicare is the secondary payer would be counted for purposes of reinsurance contributions. However, a 68-year-old retiree enrolled in a group health plan who, under the MSP rules, is a beneficiary for whom Medicare is the primary payer would not be counted for purposes of reinsurance contributions. Similarly, an individual covered under a group health plan with only Medicare Part A (hospitalization) benefits (where Medicare is the primary payer) would not be counted for purposes of reinsurance contributions because the group health coverage would not be considered major medical coverage. We also stated that individuals entitled to Medicare because of disability or end-stage renal disease that have other

primary coverage under the MSP rules would be treated consistently with the working aged, as outlined above.

We are finalizing the proposed provisions with the following revisions, described below: (a) We are modifying the exception in § 153.400(a)(1)(iii) to exclude from reinsurance contributions expatriate health coverage, as defined by the Secretary; (b) we are adding § 153.400(a)(1)(iv) to codify the Medicare coordination rule; and (c) we are adding § 153.400(a)(2)(xiii) to exclude a self-insured group health plan or health insurance coverage that is limited to prescription drug benefits from reinsurance contributions.

Comment: Several commenters supported the proposed treatment of group health coverage that is considered secondary to Medicare under the MSP rules; some requested that the Medicare coordination rule contained in the preamble of the proposed rule appear in regulation text.

Response: We have added paragraph (iv) to § 153.400(a)(1) to codify the rule in regulation text. We have included this rule at § 153.400(a)(1) to clarify that, to the extent a plan or coverage applies to individuals with respect to which benefits under Title XVIII of the Social Security Act (Medicare) are primary under the MSP rules, reinsurance contributions are not required on behalf of those enrollees under that plan or coverage. In order for a contributing entity to determine its enrollment count as required by § 153.405 while taking into account enrollees for which the employer group health coverage is considered secondary to Medicare under the MSP rules, we clarify that the contributing entity may use any reasonable method of estimating the number or percentage of its enrollees. For example, a contributing entity may calculate the percentage of enrollees for which the employer group health coverage is secondary under the MSP rules on the dates it uses when applying the snapshot counting method or actual count method, or on other periodic dates, and reduce the enrollment count calculated using one of the methods in § 153.405 by that percentage. A contributing entity may also calculate the total enrollment of individuals for which the employer group health coverage is secondary under the MSP rules on the last day of the third quarter and reduce the enrollment count that was calculated using one of the methods in § 153.405.

Comment: Several commenters requested that employer-provided retiree coverage be excluded from reinsurance contributions.

¹⁷ See Section 7F of the National Association of Insurance Commissioners (NAIC) Model Regulation to Implement the Accident and Sickness Insurance Minimum Standards Model Act, (MDL-171) for a definition of major medical expense coverage. Available at: http://naic.org/committees_index_model_description_a_c.htm#accident_health.

Response: We have no statutory authority to make the requested change under section 1341 of the Affordable Care Act. We clarify that employer-provided retiree coverage is subject to reinsurance contributions unless one of the general exceptions applies (for example, the coverage is not major medical coverage).

Comment: One commenter requested that we expand the Medicare coordination rule to exclude from reinsurance contributions *any* employer-provided coverage that is secondary to any other coverage.

Response: We decline to make this exclusion because we believe that it would be difficult for an individual sponsor or issuer to determine and verify (and it would be difficult for HHS to confirm) without extensive coordination with other issuers and sponsors which enrollees have another source of coverage, whether that other source of coverage is major medical coverage, and which coverage is primary. We also believe that few individuals will have two sources of primary major medical coverage.

Comment: Two commenters requested additional clarification as to how the MSP rules interact with the reinsurance program when an individual has employer-provided group health coverage and is eligible for Medicare due to end-stage renal disease or disability.

Response: If an individual is eligible for Medicare due to end-stage renal disease or disability, then whether reinsurance contributions would be required on behalf of the individual would depend upon whether the Medicare coverage is primary, as with the working-aged.

Comment: A few commenters requested that the preamble language in the proposed rule clarifying that a separate plan that provides coverage for prescription drugs is excluded from reinsurance contributions be codified in regulation text. One commenter requested clarification that retiree drug plans including employer group waiver plans and other employer-sponsored Part D plans are excluded from reinsurance contributions.

Response: We are amending § 153.400(a)(2) to include a new paragraph (xiii) providing that a self-insured group health plan or health insurance coverage that is limited to prescription drug benefits is excluded from reinsurance contributions. Since they only provide coverage for prescription drug benefits, these plans are not major medical coverage. We also note that § 153.400(a)(2)(ii)(A) contains an exception for coverage provided by

an issuer under contract to provide benefits under Medicare because these private Medicare plans are not part of an issuer's commercial book of business (as discussed in the next section of this preamble).

(2) *Commercial Book of Business:* The second general exception at § 153.400(a)(1)(ii) from the reinsurance contribution requirement applies to health insurance coverage that is not part of an issuer's commercial book of business. Section 1341(b)(3)(B)(i) of the Affordable Care Act refers to a "commercial book of business," which we proposed to interpret to refer to large and small group health insurance policies and individual market health insurance policies. For example, products offered by an issuer under Medicare Part C or D would be part of a "governmental" book of business, not a commercial book of business. Similarly, a plan or coverage offered by a Tribe to Tribal members and their spouses and dependents, and other persons of Indian descent closely affiliated with the Tribe in the capacity of the Tribal members as Tribal members (and not in their capacity as current or former employees of the Tribe or their dependents) would not be part of a commercial book of business. But a plan or coverage offered by the Federal government, a State government, or a Tribe to employees (or retirees or dependents) because of a current or former employment relationship would be part of a commercial book of business.

We are finalizing the provisions as proposed.

Comment: One commenter agreed that coverage offered to Federal, State, or Tribal employees should be subject to reinsurance contributions, and that this coverage would be part of an issuer's commercial book of business. Another commenter stated that since Federal and State employee plans make up a significant share of the market's large group enrollment, these plans should be included in a carrier's book of business for purposes of the reinsurance contribution.

Response: For reinsurance purposes, we agree that insured coverage offered to Federal, State or Tribal employees is part of an issuer's commercial book of business. As discussed in the preamble to the proposed rule, we interpret "commercial book of business" to refer to insured large and small group policies and individual market policies.

(3) *Policy filed and approved by a State:* The third proposed general exception from reinsurance contributions at § 153.400(a)(1)(iii) was for insured coverage not filed or

approved by a State. As noted in the preamble to the proposed rule at 77 FR at 73153, this exception was intended primarily to address group expatriate coverage for individuals whose work requires them to spend a substantial period of time overseas. We are amending § 153.400(a)(1)(iii) so that expatriate health coverage, as defined by the Secretary, is excluded from reinsurance contributions.

Comment: Some commenters requested that all expatriate coverage be excluded from reinsurance contributions, including coverage filed with and approved by a State, as well as self-insured expatriate coverage.

Response: As described above, we are amending this provision so that all expatriate health coverage, as defined by the Secretary, is excluded from reinsurance contributions. We plan to define expatriate health coverage, as well as explain the applicability of the Affordable Care Act to such coverage, in the near future.

Comment: A few commenters noted considerable variation in filing methods for issuers of health insurance coverage in the large group market. The commenters expressed concern that issuers that should make reinsurance contributions may be excluded because of the different filing and approval requirements. For example, some States may not require explicit approval of certain new policy forms, but instead those forms may be deemed approved via issuer certification. One commenter requested clarification as to whether an issuer that is regulated by a State agency other than a department of insurance would be subject to reinsurance contributions under the "filed and approved by a State" language.

Response: We recognize that States can and do use different filing methods to obtain the information from issuers necessary to carry out their regulatory responsibilities. However, we are amending § 153.400(a)(1)(iii) so that the exception from reinsurance contributions applies to all expatriate health coverage, as defined by the Secretary.

We proposed in § 153.400(a)(2) to explicitly exclude the following types of plans and coverage from reinsurance contributions. We are finalizing these provisions as proposed.

(a) *Excepted benefits.* We proposed no change in policy with respect to plans or health insurance coverage that consist solely of excepted benefits as defined by section 2791(c) of the PHS Act, as currently described in § 153.400(a)(2)(i) of the Premium Stabilization Rule.

Comment: A few commenters noted that stand-alone dental or vision coverage is excluded from reinsurance contributions, and requested that other dental or vision coverage should be excluded as well. One commenter suggested that reinsurance contributions should not apply to “carve-out” arrangements that must be offered alongside an employer’s major medical coverage that are similar to prescription drug carve-outs, for example, behavioral health and transplant coverage.

Response: An employer decides whether to offer group health coverage, the scope of the coverage, and its structure. An employer that provides dental or vision coverage may do so on a stand-alone basis, in which case the benefits may qualify as excepted benefits, or may include the coverage with the major medical benefits as part of a group health plan. Excepted benefits are not subject to reinsurance contributions.

(b) *Private Medicare, Medicaid, CHIP, State high-risk pools, and Basic Health Plans:* Both Medicare and Medicaid have fee-for-service or traditional components, as well as managed care components in which private health insurance issuers, under contract with HHS, deliver the requisite benefits. As discussed in the preamble to the Premium Stabilization Rule, these private Medicare or Medicaid plans are excluded from reinsurance contributions because they are not part of a commercial book of business. We also clarified in the proposed rule that for purposes of reinsurance contributions, programs under the CHIP, Federal and State high-risk pools (including the Pre-Existing Condition Insurance Plan Program under section 1101 of the Affordable Care Act), and Basic Health Plans described in section 1331 of the Affordable Care Act are similarly excluded from reinsurance contributions because they are not part of a commercial book of business.

(c) *Health Reimbursement Arrangements (HRAs) integrated with a group health plan.* Section 153.400(a)(2)(v) of the proposed rule excluded HRAs that are integrated with a group health plan offered in conjunction with a major medical plan (integrated HRAs) from reinsurance contributions. The preamble to the proposed rule noted that reinsurance contributions generally would be required for that group health plan.

Comment: Several commenters requested that stand-alone HRAs be excluded from reinsurance contributions. Alternatively, some commenters requested that the “one covered life” rule that the Fees on

Health Insurance Policies and Self-Insured Plans for the Patient-Centered Outcomes Research Trust final rule (the PCORTF Rule)¹⁸ applies to stand-alone HRAs also apply for purposes of reinsurance contributions. Some commenters requested clarification on when an HRA is “integrated” with a traditional group health plan or health insurance coverage, on how to classify arrangements similar to HRAs that do not meet the technical definition of an HRA, and regarding the treatment of specific types of HRAs (for example, an HRA that only may be used to pay premiums under a fully insured plan).

Response: As described above, integrated HRAs are excluded from reinsurance contributions. We note that the Department of Labor, the U.S. Treasury and HHS recently issued guidance on certain HRA-related issues in “Affordable Care Act Implementation FAQs-Set 11,” which can be found at http://cciio.cms.gov/resources/factsheets/aca_implementation_faqs11.html.

(d) *Health saving accounts (HSAs):* Section 153.400(a)(2)(vi) of the proposed rule excluded HSAs from reinsurance contributions. An HSA is an individual arrangement that is offered along with a high deductible health plan. For purposes of reinsurance contributions, we believe that an HSA is not major medical coverage because it consists of a fixed amount of funds that are available for both medical and non-medical purposes, and thus would be excluded from reinsurance contributions. We note that reinsurance contributions generally would be required for the high deductible health plan because it is major medical coverage.

Comment: Some commenters requested clarification on HSAs “integrated with a group health plan” for reinsurance contributions purposes.

Response: HSAs are excluded from reinsurance contributions because they consist of a fixed amount of funds that are available for both medical and non-medical purposes and therefore do not provide major medical coverage.

(e) *Health flexible spending arrangements (FSAs):* Health FSAs are usually funded by an employee’s voluntary salary reduction contributions under section 125 of the Code. Because section 9005 of the Affordable Care Act limits the annual amount that may be contributed by an employee to a health FSA to \$2,500 (indexed for inflation),

we believe that a health FSA is not major medical coverage under this final rule, and therefore is excluded from reinsurance contributions.

(f) *Employee assistance plans, disease management programs, and wellness programs:* Employee assistance plans, disease management programs, and wellness programs typically provide ancillary benefits to employees that in many cases do not constitute major medical coverage. Employers, plan sponsors, and health insurance issuers have flexibility in designing these programs to provide services that are additional benefits to employees, participants, and beneficiaries. If the program (whether self-insured or insured) does not provide major medical coverage, we proposed to exclude it from reinsurance contributions and we are finalizing that provision in the final rule. We also note that employers that provide one or more of these ancillary benefits often sponsor major medical plans which would be subject to reinsurance contributions, absent other excluding circumstances.

(g) *Stop-loss and indemnity reinsurance policies:* For purposes of reinsurance, we proposed to exclude stop-loss insurance and indemnity reinsurance because they do not constitute major medical coverage for the applicable covered lives. Generally, a stop-loss policy is an insurance policy that protects against health insurance claims that are catastrophic or unpredictable in nature and provides coverage to self-insured group health plans once a certain level of risk has been absorbed by the plan. Stop-loss insurance allows an employer to self-insure for a set amount of claims costs, with the stop-loss insurance covering all or most of the remainder of the claims costs that exceed the set amount. An indemnity reinsurance policy is an agreement between two or more insurance companies under which the reinsuring company agrees to accept and to indemnify the issuing company for all or part of the risk of loss under policies specified in the agreement, and the issuing company retains its liability to, and its contractual relationship with, the applicable lives covered. We believe these types of policies were not intended to be subject to the reinsurance program. No inference is intended as to whether stop-loss or reinsurance policies constitute health insurance policies for purposes other than reinsurance contributions.

(h) *Military Health Benefits:* TRICARE is the component of the Military Health System that furnishes health care insurance to active duty and retired personnel of the uniformed services

¹⁸ See the Fees on Health Insurance Policies and Self-Insured Plans for the Patient-Centered Outcomes Research Trust final rule (the PCORTF Rule) published on December 6, 2012 (77 FR 72721).

(and covered dependents) through private issuers under contract. Although TRICARE coverage is provided by private issuers, it is not part of a commercial book of business because the relationship between the uniformed services and service members differs from the traditional employer-employee relationship in certain important respects. For example, service members may not resign from duty during a period of obligated service, may not form unions, and may be subject to discipline for unexcused absences from duty.

In addition to TRICARE, the Military Health System also includes health care services that doctors, dentists, and nurses provide to uniformed services members on military bases and ships. The Veterans Health Administration within the U.S. Department of Veterans Affairs provides health care to qualifying veterans of the uniformed services at its outpatient clinics, hospitals, medical centers, and nursing homes. Because we do not consider these programs to be part of a commercial book of business, such military health programs are excluded from reinsurance contributions.

(i) *Tribal coverage:* Section 153.400(a)(2)(xi) of the proposed rule excluded plans or coverage (whether fully insured or self-insured) offered by a Tribe to Tribal members and their spouses and dependents (and other persons of Indian descent closely affiliated with the Tribe) in their capacity as Tribal members (and not in their capacity as current or former employees of the Tribe or their dependents). Similarly, we proposed that coverage provided to Tribal members through programs operated under the authority of the Indian Health Service (IHS), Tribes or Tribal organizations, or Urban Indian organizations, as defined in section 4 of the Indian Health Care Improvement Act would be excluded from reinsurance contributions because it is not part of a commercial book of business. We note, however, that a plan or coverage offered by a Tribe to its employees (or retirees or dependents) on account of a current or former employment relationship would be required to make reinsurance contributions.

Comment: Some commenters asked that self-insured Tribal plans that cover Tribal employees be excluded from reinsurance contributions, in a manner similar to Tribal plans that cover Tribal members based on their status as Tribal members.

Response: Similar to Federal and State-based employment coverage, these

Tribal plans are based on employment relationships. We do not have the authority to make this exclusion.

We received additional comments which requested exceptions for other types of entities.

Comment: Several commenters requested that plans or coverage provided by a voluntary employee beneficiary association (VEBA) established and maintained under the terms of a class action or bankruptcy settlement ordered by a court (court-ordered VEBA) be excluded from reinsurance contributions. A court-ordered VEBA provides retiree medical benefits to former employees of certain companies. The court order specifies the funding and the eligible individuals, and the former employers have no ongoing financial or administrative responsibility. A significant percentage of existing court-ordered VEBAs are not well funded.

Response: We are unable to categorically exclude court-ordered VEBAs. We note, however, that many VEBAs may be excluded from reinsurance contributions because they do not provide major medical coverage.

Comment: Some commenters requested that certain jointly administered Taft-Hartley plans that provide health coverage to collectively bargained employees be excluded from reinsurance contributions. Generally, many of these plans are self-insured and self-administered, and include multiemployer plans within the meaning of section 3(37) of ERISA.

Response: While we recognize the unique nature of these plans, and their important role in providing coverage to collectively bargained employees and covered dependents, we do not have authority under the statute to exclude them from reinsurance contributions. As clarified in the Premium Stabilization Rule and in this final rule, we do not interpret the application of section 1341 of the Affordable Care Act to be limited to issuers and TPAs on behalf of group health plans. We view the plans' coverage as employment-based, and as a result subject to reinsurance contributions (unless another exclusion applies).

Comment: Several commenters asked for clarification as to whether individuals with group health coverage that elect Consolidated Omnibus Budget Reconciliation Act (COBRA) continuation coverage or similar continuation coverage under State law are covered lives for reinsurance purposes.

Response: Our view is that COBRA or other continuation coverage is a form of employment-based group health

coverage paid for by the former employee. Therefore, to the extent the COBRA coverage qualifies as major medical coverage (and no other exception applies), it is subject to reinsurance contributions.

Comment: A few commenters stated that employer-provided coverage for part-time employees should be excluded from reinsurance contributions.

Response: Unless the coverage for part-time employees is self-insured and is not major medical coverage, or is not part of an issuer's commercial book of business, it is subject to reinsurance contributions (so long as no other exception applies).

3. National Contribution Rate

a. 2014 Rate

As specified in § 153.220(c) of the Premium Stabilization Rule, HHS plans to publish in the annual HHS notice of benefit and payment parameters the national per capita reinsurance contribution rate for the upcoming benefit year. Section 1341(b)(3)(B)(iii) of the Affordable Care Act specifies the total contribution amounts to be collected from contributing entities (reinsurance pool) as \$10 billion for 2014, \$6 billion for 2015, and \$4 billion for 2016, and sections 1341(b)(3)(B)(iv) and 1341(b)(4) of the Affordable Care Act direct the collection of funds for contribution to the U.S. Treasury in the amounts of \$2 billion for 2014, \$2 billion for 2015, and \$1 billion for 2016. We sought comments on whether deferring the collection of the \$2 billion in funds payable to the U.S. Treasury for 2014 until 2016 would be consistent with the statutory requirements described above, and whether there are other steps that could be taken to reduce the burden of these collections on contributing entities. Finally, section 1341(b)(3)(B)(ii) of the Affordable Care Act allows for the collection of additional amounts for administrative expenses. Taken together, these three components make up the total dollar amount to be collected from contributing entities for each of the three years of the reinsurance program under the national per capita contribution rate.

Each year, the national per capita contribution rate will be calculated by dividing the sum of the three amounts (the national reinsurance pool, the U.S. Treasury contribution, and administrative costs) by the estimated number of enrollees in plans that must make reinsurance contributions. As an illustration, under the Affordable Care Act, the 2014 national reinsurance pool is \$10 billion, and the contribution to

the U.S. Treasury is \$2 billion. The amount to be collected for administrative expenses for benefit year 2014 is \$20.3 million (or 0.2 percent of the \$10 billion dispersed), as discussed in greater detail below. The HHS estimate of the number of enrollees in plans that must make reinsurance contributions that total the \$12.02

billion described above yields an annual per capita contribution rate of \$63.00 in benefit year 2014 or \$5.25 per month.

Section 153.220(c) of the proposed rule (previously designated as § 153.220(e) in the Premium Stabilization Rule) stated that HHS plans to set in the annual HHS notice of benefit and payment parameters for the

applicable benefit year the proportion of contributions collected under the national contribution rate to be allocated to reinsurance payments, payments to the U.S. Treasury, and administrative expenses. In Table 20, we specify these proportions (or amounts, as applicable):

TABLE 20—PROPORTION OF CONTRIBUTIONS COLLECTED UNDER THE NATIONAL CONTRIBUTION RATE FOR REINSURANCE PAYMENTS, PAYMENTS TO THE U.S. TREASURY AND ADMINISTRATIVE EXPENSES

Proportion or amount for:	If total contribution collections under the national contribution rate are less than or equal to \$12.02 billion	If total contribution collections under the national contribution rate are more than \$12.02 billion
Reinsurance payments	83.2 percent (\$10 billion/\$12.02 billion)	The difference between total national collections and those contributions allocated to the U.S. Treasury and administrative expenses.
Payments to the U.S. Treasury	16.6 percent (\$2 billion/\$12.02 billion)	\$2 billion.
Administrative expenses	0.2 percent (\$20.3 million/\$12.02 billion)	\$20.3 million.

In light of the comments received, we are finalizing these provisions as proposed.

Comment: Many commenters stated that a national contribution rate would penalize States with lower medical costs, and require those States to subsidize other States with higher medical costs. Some commenters asked that HHS vary the contribution rate using an index of health care costs by State. Conversely, many commenters supported a national per capita contribution rate. One commenter asked that the national contribution rate be calculated based on a percentage of premium and not on a per capita basis.

Response: As stated in the Premium Stabilization Rule (77 FR 17227), we are using a national, per capita contribution rate because it is a simpler approach that minimizes the administrative burden of collections. In addition, varying the contribution rate using an index of health care costs would not capture a State's reinsurance needs, which will also vary based upon the relative sizes of the State's individual, group, self-insured markets, and the uninsured.

Comment: Several commenters expressed concern about the annual per capita national contribution rate of \$63.00 for benefit year 2014, and suggested lowering the rate. Many commenters were concerned with the expense of the reinsurance contribution for employees.

Response: Section 1341 of the Affordable Care Act states that the total contribution amounts to be collected from contributing entities for 2014 is \$12 billion plus administrative expenses. We estimate that the \$63 annual (\$5.25 monthly) per capita

contribution rate for benefit year 2014 will lead to collections in the statutory amount (plus administrative expenses) which we have concluded we have no regulatory authority to change.

Comment: One commenter expressed concern that self-insured group health plans are excluded from receiving reinsurance payments and do not benefit proportionally or directly from their reinsurance contribution. As such, this commenter suggested that HHS prorate the contribution rate for self-insured group health plans, by collecting less than the \$63 annual per capita national contribution rate from those plans.

Response: Section 1341 of the Affordable Care Act directs health insurance issuers and self-insured group health plans to make reinsurance contributions. HHS has set forth a national per capita contribution rate for the 2014 benefit year which applies to all contributing entities, including self-insured group health plans.

Comment: Several commenters asked HHS to defer the collection of the \$2 billion payable to the U.S. Treasury in 2014 until 2016.

Response: We considered the commenters' statutory interpretations for how such a deferral may be permissible under section 1341 of the Affordable Care Act and would support such a deferral, but concluded that we have no statutory authority to defer the collection.

Comment: Several commenters asked HHS to eliminate the \$20.3 million collection for administrative expenses. One commenter stated that HHS has no authority to collect administrative expenses to pay for HHS operating reinsurance on behalf of a State.

Response: We interpret section 1341(b)(3)(B)(ii) of the Affordable Care Act to authorize the collection of additional amounts for administrative expenses, including for HHS when HHS operates reinsurance on behalf of a State. We agree with the commenters on the need to keep these administrative expenses at a minimum, and intend to operate the program efficiently. We note that our estimate of administrative expenses—\$20.3 million—represents approximately 0.2 percent of the reinsurance amounts to be collected for 2014, and the costs of Federal employees are not included in the national contribution rate.

Comment: Several commenters asked for clarification regarding whether an employer may pass the cost of the reinsurance contribution to its enrollees in self-insured group health plans.

Response: This final rule does not address how an employer would meet the reinsurance contribution requirements.

Comment: One commenter asked how the national contribution rate will affect premiums or the affordability of coverage once implemented.

Response: As set forth in the regulatory impact analysis to this final rule, HHS estimates that reinsurance payments to issuers will reduce premiums in the individual market by between 10 to 15 percent. This is an HHS estimate for the 2014 benefit year, based in part on a 2009 analysis of health insurance premiums by the Congressional Budget Office.

Comment: Several commenters asked HHS to explain the methodology used to develop the national contribution rate and the assumptions behind the enrollment estimates that were used to

calculate the national contribution rate for 2014.

Response: As described in the proposed rule, HHS developed the Affordable Care Act Health Insurance Model (ACAHiM), which estimates market enrollment in a manner that incorporates the effects of State and Federal policy choices and accounts for the behavior of individuals and employers. We used the ACAHiM, which was developed with reference to existing models such as those of the Congressional Budget Office and the Office of the Actuary, to characterize medical expenditures and enrollment choices across the 2014 marketplace. The ACAHiM is made up of integrated modules which predict the number and characteristics of market entrants and medical spending. The outputs of the ACAHiM, especially the estimated enrollment and expenditure distributions, were used to analyze estimated enrollment in the 2014 marketplace.

The market enrollment module of the ACAHiM predicts coverage status of individuals in 2014, incorporating the effects of State and Federal policy choices and accounting for the behavior of individuals and employers. Using recent Current Population Survey data with appropriate population adjustments, the ACAHiM assigns individuals to a single health insurance market as their baseline (pre-Affordable Care Act) insurance status. The module estimates transitions from coverage status in the baseline to individuals' projected status in 2014, taking into account factors such as Medicaid eligibility, eligibility for advance payments of the premium tax credit and cost-sharing reductions under the Exchange, and current take-up rates of insurance.

Comment: Several commenters sought clarification on whether the reinsurance contributions may be charged back to an ERISA plan as a reasonable plan expense. Several commenters asked whether IRS had indicated that the reinsurance contribution is tax-deductible as an ordinary and necessary business expenses. Several commenters also asked HHS to clarify that the contribution amount will be considered a "plan cost" for all purposes.

Response: The Department of Labor advised HHS upon its review of this final rule that paying reinsurance contributions would constitute a permissible expense of the plan for purposes of Title I of the ERISA because the payment is required by the plan under the Affordable Care Act (*see*, 77 FR 73198, fn 56). Questions seeking clarification regarding particular

situations should be directed to the Department of Labor. *See generally* Advisory Opinion 2001-01A to Mr. Carl Stoney, Jr., available at www.dol.gov/ebsa (discussing settlor versus plan expenses). For a discussion regarding the tax status of reinsurance contributions pursuant to the Affordable Care Act, see the FAQ issued by the IRS (<http://www.irs.gov/uac/Newsroom/ACA-Section-1341-Transitional-Reinsurance-Program-FAQs>).

b. Federal Administrative Fees

In the proposed rule, we estimated the Federal administrative expenses of operating reinsurance for the 2014 benefit year to be approximately \$20.3 million, or 0.2 percent of the \$10 billion in reinsurance funds to be distributed for the 2014 benefit year. This figure reflects the Federal government's significant economies of scale in operating the program, and results in a national per capita contribution rate of \$0.11 annually for HHS administrative expenses.

In the proposed rule, we set forth the process for apportioning the annual per capita amount of \$0.11 of administrative expenses as follows: \$0.055 of the total amount collected per capita would be allocated to administrative expenses incurred in the collection of contributions from health insurance issuers and self-insured group health plans; and \$0.055 of the total amount collected per capita would be allocated to administrative expenses incurred for activities supporting the administration of payments to issuers of reinsurance-eligible plans. We proposed that if a State operates reinsurance, HHS would retain \$0.055 to offset the costs of contributions collection, and would allocate \$0.055 towards administrative expenses for reinsurance payments. The total amounts allocated towards administrative expenses for reinsurance payments would be distributed to States operating reinsurance (or retained by HHS where HHS is operating reinsurance) in proportion to the State-by-State total requests for reinsurance payments made under the uniform payment parameters. We are finalizing these provisions as proposed.

Comment: Several commenters sought clarification on how administrative expenses will be distributed to States operating reinsurance.

Response: The 2014 allocation for Federal administrative expenses for operating reinsurance totals \$20.3 million. HHS will keep 50 percent to cover the administrative expense of collecting reinsurance contributions from health insurance issuers and self-insured group health plans. The 50

percent allocated for reinsurance payment activities will be distributed in proportion to the State-by-State total requests for reinsurance payments (by total dollars) made under the uniform payment parameters. States operating reinsurance will receive that allocation; HHS will retain the allocation for States not operating reinsurance.

Comment: Several commenters sought clarification on the methodology used to develop the Federal administrative expenses of implementing the reinsurance program in 2014.

Response: We determined HHS's total costs for administering reinsurance on behalf of States by examining HHS's contract costs of operating reinsurance. These contracts cover collections, payments, account management, data collection, program integrity, operational and fraud analytics, stakeholder training, and operational support. We did not include the cost of Federal personnel. We divided HHS's projected total costs for administering reinsurance on behalf of States by the expected enrollment in health insurance plans and self-insured group health plans. We anticipate that the total cost for HHS to operate reinsurance on behalf of States for the 2014 benefit year will be \$20.3 million, or \$0.11 per capita per year.

Comment: One commenter expressed concern that HHS under-estimated the cost to a State of administering reinsurance.

Response: The cost estimates in the proposed rule are estimates of HHS's costs of administering the program. HHS may benefit from economies of scale not available to the States. We understand that States operating reinsurance may need to collect additional funds for administrative expenses.

4. Calculation and Collection of Reinsurance Contributions

a. Calculation of Reinsurance Contribution Amount and Timeframe for Collections

HHS intends to administer the reinsurance program in a manner that minimizes the administrative burden on health insurance issuers and self-insured group health plans, while ensuring that contributions are calculated accurately. Thus, we proposed in § 153.400(a) and § 153.240(b)(1), respectively, to collect and pay out reinsurance funds annually to minimize the costs of administering the reinsurance program and the burden on contributing entities.

In the Premium Stabilization Rule, we stated that we would collect reinsurance contributions through a per capita

assessment on contributing entities. To clarify how this assessment is made, we proposed in § 153.405 that the reinsurance contribution of a contributing entity be calculated by multiplying the average number of covered lives of reinsurance contribution enrollees during the benefit year for all of the contributing entity's plans and coverage that must pay reinsurance contributions, by the national contribution rate for the applicable benefit year.

In § 153.405(b), we proposed that a contributing entity must submit to HHS an annual enrollment count of the average number of covered lives of reinsurance contribution enrollees no later than November 15 of benefit year 2014, 2015, and 2016, as applicable. The count must be determined as specified in proposed § 153.405(d), (e), (f), or (g), as applicable. We proposed to amend § 153.400(a) so that each contributing entity would make annual reinsurance contributions at the national contribution rate, and under any additional applicable State supplemental contribution rate, if a State elects to collect additional contributions for administrative expenses or supplemental reinsurance payments under § 153.220(d). We believe that this annual collection schedule will ensure a more accurate count of a contributing entity's average covered lives, and will avoid the need for any initial estimates and subsequent reconciliation to account for fluctuations in enrollment during the course of the benefit year.

In § 153.405(c)(1), we proposed that within 15 days of submission of the annual enrollment count or by December 15, whichever is later, HHS would notify each contributing entity of the reinsurance contribution amounts to be paid based on the submitted annual enrollment count. We specified in § 153.405(c)(2) that a contributing entity remit contributions to HHS within 30 days after the date of the notification of contributions due for the applicable benefit year. The amount to be paid by the contributing entity would be based upon the notification received under § 153.405(c)(1).

We are finalizing these provisions as proposed, with technical corrections to § 153.400, where we clarify that each contributing entity must make reinsurance contributions annually at the national contribution rate; to § 153.405(c), where we clarify that HHS will notify a contributing entity of reinsurance contributions amounts to be paid for a benefit year by the later of December 15 or 30 days after the submission of the annual enrollment

count; and § 153.405(a)(1), § 153.405(b) and § 153.405(d), where we delete "average" to clarify that reinsurance contributions are calculated by multiplying the number of covered lives of reinsurance contribution enrollees during the applicable benefit year for all contributing entities by the national contribution rate, pursuant to § 153.405(a).

Comment: Several commenters asked HHS to collect contributions after all reinsurance payment requests are submitted and aggregated, emphasizing that the reinsurance contributions should equal the 2014 requests for reinsurance payments.

Response: Under the Affordable Care Act, the total contribution amounts to be collected from contributing entities for reinsurance payments and payments to the U.S. Treasury for 2014 are \$12 billion. We estimate that the \$63.00 (\$5.25 monthly) annual per capita contribution rate for benefit year 2014 will lead to collections in that amount, including the \$20.3 million in administrative expenses. We recognize the possibility that reinsurance payment requests for 2014 may be less than contributions collected for 2014, but section 1341(b)(3)(B)(4)(A) of the Affordable Care Act provides that unused funds after making the 2014 reinsurance payments may be used to stabilize premiums for the three years of the reinsurance program. As set forth in § 153.235(b), any unused funds will be used for reinsurance payments under the uniform reinsurance payment parameters for subsequent benefit years.

Comment: One comment received sought clarification on whether contributing entities are required to make reinsurance contributions once per year.

Response: As set forth in § 153.400(a), a contributing entity makes reinsurance contributions at the national contribution rate annually.

Comment: Several commenters requested that HHS revise the date by which a contributing entity must submit the annual enrollment count date to the end of the benefit year, so that issuers may submit enrollment counts on 12 months of data.

Response: Due to operational time constraints surrounding the collection of reinsurance contributions, HHS must receive annual enrollment counts by November 15 of the applicable benefit year in order to invoice and collect contributions in time to aggregate payment requests and make payments. We do not believe the earlier submission will significantly impair the accuracy of the enrollment count.

Counting Methods for Health Insurance Issuers: In § 153.405(d), we proposed a number of methods that a health insurance issuer may use to determine the average number of covered lives of reinsurance contribution enrollees under a health insurance plan for a benefit year for purposes of the annual enrollment count. These methods promote administrative efficiencies by building on the methods permitted for purposes of the fee to fund the Patient-Centered Outcomes Research Trust Fund (77 FR 72721), modified for applicability to the transitional reinsurance program so that a health insurance issuer may determine an annual enrollment count during the fourth quarter of the benefit year. Thus, under each of these methods, the number of covered lives will be determined based on the first nine months of the benefit year.

(1) *Actual Count Method:* Under the PCORTF Rule, an issuer may use the "actual count method" to determine the number of lives covered under the plan for the plan year by calculating the sum of the lives covered for each day of the plan year and dividing that sum by the number of days in the plan year. We proposed that, for reinsurance contributions purposes, a health insurance issuer would add the total number of lives covered for each day of the first nine months of the benefit year and divide that total by the number of days in those nine months of the benefit year.

(2) *Snapshot Count Method:* Under the PCORTF Rule, a health insurance issuer may use the "snapshot count method" generally by adding the total number of lives covered on a certain date during the same corresponding month in each quarter, or an equal number of dates for each quarter, and dividing the total by the number of dates on which a count was made. For reinsurance contributions purposes, an issuer would add the totals of lives covered on a date (or more dates, if an equal number of dates are used for each quarter) during the same corresponding month in each of the first three quarters of the benefit year (provided that the dates used for the second and third quarters must be within the same week of the quarter as the date used for the first quarter), and divide that total by the number of dates on which a count was made. For this purpose, the same months must be used for each quarter (for example, January, April and July).

(3) *Member Months Method or State Form Method:* Under the PCORTF Rule, a health insurance issuer may use the "Member Months Method" or "State Form Method" by using data from the

NAIC Supplemental Health Exhibit or similar data from other State forms. However, data from these forms may be out of date at the time of the annual enrollment count submission, and we believe that it is important that health insurance issuers achieve an accurate count of covered lives, particularly for individual market plans. We expect that the individual market will be subject to large increases in enrollment between 2014 and 2016. Therefore, we proposed a modified counting method based upon the ratio of covered lives per policy in the NAIC or State form. Specifically, we proposed that health insurance issuers using this method multiply the average number of policies for the first nine months of the applicable benefit year by the ratio of covered lives per policy calculated from the NAIC Supplemental Health Care Exhibit (or from a form filed with the issuer's State of domicile for the most recent time period). Issuers would count the number of policies in the first nine months of the applicable benefit year by adding the total number of policies on one date in each quarter, or an equal number of dates for each quarter (or all dates for each quarter), and dividing the total by the number of dates on which a count was made.¹⁹

Counting Methods for Self-Insured Group Health Plans: In § 153.405(e), we proposed a number of methods that a self-insured group health plan may use to determine the average number of covered lives for purposes of the annual enrollment count. These methods mirror the methods permitted for sponsors of self-insured group health plans under the PCORTF Rule, modified slightly for timing with the reinsurance program, so that enrollment counts may be obtained on a more current basis.

(1) *Actual Count Method or Snapshot Count Method:* We proposed that self-insured plans, like health insurance issuers, may use the actual count method or snapshot count method as described above.

(2) *Snapshot Factor Method:* Under the PCORTF Rule, a plan sponsor generally may use the “snapshot factor method” by adding the total number of lives covered on any date (or more dates if an equal number of dates are used for each quarter) during the same corresponding month in each quarter,

and dividing that total by the number of dates on which a count was made, except that the number of lives covered on a date is calculated by adding the number of participants with self-only coverage on the date to the product of the number of participants with coverage other than self-only coverage on the date and a factor of 2.35.²⁰ For this purpose, the same months must be used for each quarter (for example, January, April, July, and October). For reinsurance contributions purposes, a self-insured group health plan would use this PCORTF counting method over the first three quarters of the benefit year, provided that the corresponding dates for the second and third quarters of the benefit year must be within the same week of the quarter as the date selected for the first quarter.

(3) *Form 5500 Method:* Under the PCORTF Rule, a plan sponsor may use the “Annual Return/Report of Employee Benefit Plan” filed with the Department of Labor (Form 5500) by using data from the Form 5500 for the last applicable plan year. We proposed that, for purposes of reinsurance contributions, a self-insured group health plan may also rely upon such data, even though the data may reflect enrollment in a previous benefit year. Our modeling of the 2014 health insurance marketplace, discussed in section III.C.6. of this final rule, suggests that enrollment in self-insured group health plans is less likely to fluctuate than enrollment in the individual market. Thus, we proposed that a self-insured group health plan may calculate the number of lives covered for a plan that offers only self-only coverage by adding the total participants covered at the beginning and end of the benefit year, as reported on the Form 5500, and dividing by two. Additionally, a self-insured group plan that offers self-only coverage and coverage other than self-only coverage may calculate the number of lives covered by adding the total participants covered at the beginning and the end of the benefit year, as reported on the Form 5500.

Counting Methods for Plans With Self-insured and Insured Options: An employer may sponsor a group health plan that offers one or more coverage

options that are self-insured and one or more other coverage options that are insured. In § 153.405(f), we proposed that to determine the number of covered lives of reinsurance contribution enrollees under a group health plan with both self-insured and insured options for a benefit year, a plan sponsor must use one of the methods specified in either § 153.405(d)(1) or § 153.405(d)(2)—the “actual count” method or “snapshot count” for health insurance issuers.

Aggregation of self-insured group health plans and health insurance plans: We proposed in § 153.405(g)(1) that if a plan sponsor maintains two or more group health plans or health insurance plans that collectively provide major medical coverage for the same covered lives, which we refer to as “multiple plans” for purposes of the reinsurance program, then these multiple plans must be treated as a single self-insured group health plan for purposes of calculating any reinsurance contribution amount due under paragraph (c) of this section. This approach would prevent the double counting of a covered life for major medical coverage offered across multiple plans, and prohibit plan sponsors that provide such major medical coverage from splitting the coverage into separate arrangements to avoid reinsurance contributions on the grounds that it does not offer major medical coverage.

For purposes of § 153.405(g)(1), the plan sponsor is responsible for paying reinsurance contributions. We proposed to define “plan sponsor” in proposed § 153.405(g)(2) based on the definition of the term in the PCORTF Rule as:

- (A) The employer, in the case of a plan established or maintained by a single employer;
- (B) The employee organization, in the case of a plan established or maintained by an employee organization;
- (C) The joint board of trustees, in the case of a multiemployer plan (as defined in section 414(f) of the Code);
- (D) The committee, in the case of a multiple employer welfare arrangement;
- (E) The cooperative or association that establishes or maintains a plan established or maintained by a rural electric cooperative or rural cooperative association (as such terms are defined in section 3(40)(B) of ERISA);
- (F) The trustee, in the case of a plan established or maintained by a voluntary employees' beneficiary association (meaning that the association is not merely serving as a funding vehicle for a plan that is established or maintained by an employer or other person);

¹⁹ For example, if a health insurance issuer indicated on the NAIC form for the most recent time period that it had 2,000 policies covering 4,500 covered lives, it would apply the ratio of 4,500 divided by 2,000, equaling 2.25 to the number of policies it had over the first three quarters of the applicable benefit year. If the issuer had an average of 2,300 policies in the three quarters of the applicable benefit year, it would report 2.25 multiplied by 2,300 as the number of covered lives for the purposes of reinsurance contributions.

²⁰ The preamble to the proposed PCORTF Rule published on April 17, 2012 (77 FR 22691) explains that “the 2.35 dependency factor reflects that all participants with coverage other than self-only have coverage for themselves and some number of dependents. The Treasury Department and the IRS developed the factor, and other similar factors used in the regulations, in consultation with Treasury Department economists and in consultation with plan sponsors regarding the procedures they currently use for estimating the number of covered individuals.”

(G) In the case of a plan, the plan sponsor of which is not described in (A) through (F) above, the person identified or designated by the terms of the document under which the plan is operated as the plan sponsor, provided that designation is made and consented to by no later than the date by which the count of covered lives for that benefit year is required to be provided. After that date, the designation for that benefit year may not be changed or revoked, and a person may be designated as the plan sponsor only if the person is one of the persons maintaining the plan (for example, one of the employers that is maintaining the plan with one or more other employers); or

(H) In the case of a plan the sponsor of which is not described in (A) through (F) above, and for which no identification or designation of a plan sponsor has been made under (G), each employer or employee organization that maintains the plan (with respect to employees of that employer or employee organization), and each board of trustees, cooperative or association that maintains the plan.

Exceptions: We proposed two exceptions to this aggregation rule, in § 153.405(g)(3). A plan sponsor is not required to include as part of a single group health plan as determined under paragraph § 153.405(g)(1): (a) any group health plan that consists solely of excepted benefits within the meaning of section 2791(c) of the PHS Act (such as stand-alone dental or vision benefits); or (b) benefits related to prescription drug coverage. These exceptions were designed to reduce the burden on plan sponsors who have chosen to structure their coverage in that manner.

Multiple Plans: In § 153.405(g)(4), we proposed the counting requirements for multiple plans in which at least one of the plans is an insured plan (§ 153.405(g)(4)(i)), and multiple plans not including an insured plan (§ 153.405(g)(4)(ii)). First, we anticipate that a plan sponsor would generate or obtain a list of the participants in each plan and then analyze the lists to identify those participants that have major medical coverage across all the plans collectively. To calculate the average number of covered lives of reinsurance contribution enrollees across multiple plans, we proposed that a plan sponsor must use one of the methods applicable to health insurance plans or self-insured group health plans under § 153.405(d) and § 153.405(e), respectively, applied across the multiple plans as a whole. We also proposed to require reporting to HHS or the applicable reinsurance entity concerning multiple plans, as discussed

in § 153.405(g)(4). Additionally, it is important to note that the reinsurance program will operate on a benefit year basis, which is defined in § 153.20 of the proposed rule (by reference to § 155.20) as the calendar year. Therefore, the applicable counting methods, whether or not a particular plan operates on a calendar year basis, would not vary.

Multiple Group Health Plans Including an Insured Plan: When one or more of the multiple group health plans is an insured plan, we proposed that the actual count method for health insurance issuers in § 153.405(d)(1) or the snapshot count method for health insurance issuers in § 153.405(d)(2) must be used. We proposed to prohibit the use of the “Member Months Method” or “State Form Method” to count covered lives across multiple insured plans because those methods would not easily permit aggregate counting, since the identities of the covered lives are not available on the applicable forms. We proposed that the plan sponsor must determine and report, in a timeframe and manner established by HHS, to HHS (or the applicable reinsurance entity, if the multiple plans all consist solely of health insurance plans and the applicable reinsurance entity of a State is collecting contributions from health insurance issuers in such State): (1) The average number of covered lives calculated; (2) the counting method used; and (3) the names of the multiple plans being treated as a single group health plan as determined by the plan sponsor and reported to HHS.

Multiple Self-Insured Group Health Plans Not Including an Insured Plan: We described the counting provisions applicable to multiple self-insured group health plans (that is, when none of the plans is an insured plan) in proposed paragraph § 153.405(g)(4)(ii). There are four counting methods available for self-insured plans which are set forth in § 153.405(e)(1) through § 153.405(e)(4). Section 153.405(e)(1) permits a plan sponsor to use the actual count method under § 153.405(d)(1) or the snapshot count method under § 153.405(d)(2) that are also available for insured plans. Paragraph (e)(2) permits an additional method (the snapshot factor method) for self-insured plans. We proposed not to permit a plan sponsor to use the fourth method, the “Form 5500 Method” as described in proposed § 153.405(e)(3) to count covered lives across multiple self-insured plans because that method would not easily permit aggregate counting, since the identities of the covered lives are not available on that

form. Thus, we proposed three possible methods for multiple self-insured plans under paragraph § 153.405(g)(4)(ii). We further proposed that the plan sponsor must report to HHS, in a timeframe and manner established by HHS: (1) The average number of covered lives calculated; (2) the counting method used; and (3) the names of the multiple plans being treated as a single group health plan as determined by the plan sponsor.

Consistency with PCORTF Rule Not Required: We proposed not to require consistency in counting methods between the count calculated under the PCORTF Rule and the count calculated for reinsurance purposes. In other words, we would allow a contributing entity to use, either the counting method corresponding to the method selected for the PCORTF Rule or a different counting method for reinsurance purposes. Because time periods and counting methods may differ, we would not require that a contributing entity submit consistent estimates of its covered lives in the return required in connection with the PCORTF Rule and the annual enrollment count required for reinsurance contributions (although these counts should be performed in accordance with the rules of the counting method chosen). However, when calculating the average number of covered lives across two or more plans under proposed paragraph (g) for purposes of reinsurance, the same counting method would be used across all of the multiple plans, because they would be treated as a single plan for counting purposes.

We are finalizing these provisions as proposed, with the following modifications: we updated the footnotes that referenced the proposed PCORTF Rule with the citation for the final PCORTF Rule; we made a number of technical adjustments to the aggregation rules set forth in § 153.405—we provided plan sponsors with the option to count any coverage options within a single group health plan separately if the coverage options are treated as offering major medical coverage, we provided plan sponsors with the option not to aggregate group health plans for purposes of counting covered lives if each group health plan is treated as offering major medical coverage, and we included HRAs, HSAs, and FSAs in the categories of group health plans that are excluded from the counting rules.

Comment: One commenter asked that HHS confirm that the count of covered lives for purposes of determining reinsurance contributions would be members enrolled in the first nine

months of each year throughout the reinsurance program (and will not be calculated on a twelve-month basis for the second and third years of the reinsurance program).

Response: We intend that the number of covered lives will be determined based on the first nine months of each of the 2014, 2015, and 2016 benefit years.

Comment: Some commenters asked HHS to clarify how the counting methods apply to plans that have a non-calendar plan year.

Response: The reinsurance program will operate on a calendar year basis. As set forth in § 153.405, a contributing entity will determine its enrollment count by counting the average number of covered lives of reinsurance contribution enrollees during the first nine months of the benefit year (that is, calendar year) for all of the contributing entity's plans and coverage that must pay reinsurance contributions.

Comment: Several commenters stated that when a TPA or ASO contractor is submitting reinsurance contributions on behalf of a self-insured group health plan, the TPA or ASO contractor should be permitted to count members consistent with the methodology they use for fully insured lives.

Response: Many of the counting methods available to fully insured plans are also available to self-insured plans. If a self-insured plan's TPA or ASO contractor is an issuer that can easily perform such a count, such a choice may be the most efficient. However, this final rule does not require one specific counting method, and provides a self-insured plan, which is responsible for reporting the enrollment count and ensuring the payment of the reinsurance contribution, with the flexibility to use the counting method that it chooses.

Comment: Several commenters generally appreciated the use of PCORTF counting methods. Some commenters suggested that HHS direct plan sponsors or issuers to count enrollment on the last day of each month and calculate membership based on an average across all months.

Response: In order to relieve the administrative burden of submitting the annual enrollment count, HHS has incorporated, with slight modifications for timing, the counting methods set forth in the PCORTF Rule. Allowing contributing entities to choose from a variety of counting methods gives contributing entities the flexibility to choose a counting method that works best for that plan or coverage.

Comment: Numerous commenters stated that it is unreasonable to believe that employers are unable to identify the

States in which their employees reside or work. Several commenters supported HHS's proposal to eliminate the need for employers to allocate employees by State of residence.

Response: State-based allocation of enrollees in a contributing entity's plans or coverage is not necessary because reinsurance contributions will be collected by HHS and placed into a national pool from which reinsurance payments will be made in an efficient, fair, and accurate manner where they are needed most. We believe that this will be most effective in helping stabilize premiums nationally.

Comment: One commenter asked HHS to revise the snapshot counting methods so that issuers would be permitted to use the same date in the first month in each quarter for counting members, in addition to being able to use any date within the same week of the quarter.

Response: Under the "snapshot count method," a health insurance issuer or self-insured group health plan would add the totals of covered lives on a date (or more dates if an equal number of dates are used for each quarter) during the same corresponding month in each of the first three quarters of the benefit year (provided that the dates used for the second and third quarters must fall within the same week of the quarter as the date used for the first quarter), and divide that total by the number of dates on which a count was made. For this purpose, the same months must be used for each quarter (for example, January, April and July). Under the "snapshot factor method," a self-insured group health plan would use this PCORTF counting method over the first three quarters of the benefit year, provided that for this purpose, the corresponding dates for the second and third quarters of the benefit year must fall within the same week of the quarter as the date selected for the first quarter. We believe that those counting methods provide sufficient flexibility, and intend to keep these methods consistent with the PCORTF Rule.

Comment: One commenter asked that HHS permit contributing entities to submit enrollment counts and contributions electronically. One commenter encouraged HHS to permit contributing entities to submit reinsurance contributions electronically in a manner similar to that used for submissions of collections under the PCORTF Rule.

Response: HHS will provide details on the submission of enrollment counts and contributions in future guidance.

Comment: One commenter asked that HHS give contributing entities

flexibility in correcting errors when making reinsurance contributions.

Response: Given the complexities related to the first year of the reinsurance program, HHS is aware that operational difficulties may arise. We intend to work closely with contributing entities in establishing the operational processes for the submission of enrollment counts and contributions.

Comment: One commenter suggested that HHS clarify that the enrollee counting methods exclude plan participants who do not have major medical coverage.

Response: As set forth in § 153.400(a)(1)(i), reinsurance contributions are not required for a plan or health insurance coverage that is not major medical coverage. Consequently, enrollees in those plans are not required to be included in a count of covered lives for purposes of reinsurance contributions unless required under § 153.405(f) or (g).

Comment: One commenter stated that in order to apply the enrollee counting rules accurately, an employer must be able to determine in what circumstances different health coverage options constitute a single group health plan. The commenter suggested that for the purposes of reinsurance, group health plans be identified by reference to the COBRA rules because they are widely used. Under the COBRA rules, group health arrangements maintained by the same employer generally are treated as a single group health plan unless the instruments governing the arrangements designate them as separate plans and the employer operates them as separate plans.

Response: Section 1301(b)(3) of the Affordable Care Act defines "group health plan" by reference to section 2791(a) of the Public Health Service Act, which states that a group health plan is an employee welfare benefit plan (as defined in section 3(1) of ERISA) to the extent that the plan provides medical care (as defined in section 2791(a)(2)) to employees or their dependents (as defined under the terms of the plan), directly or through insurance, reimbursement, or otherwise.

However, we note that the IRS has promulgated COBRA regulations for determining the number of group health plans an employer maintains. 26 CFR 54.4980B-2, QA 6 (2001)²¹ states, in relevant part, that except as otherwise provided in the regulation, all health care benefits provided by a corporation, partnership or other entity or trade or

²¹ See <http://www.gpo.gov/fdsys/pkg/CFR-2011-title26-vol17/pdf/CFR-2011-title26-vol17-sec54-4980B-2.pdf>.

business shall constitute one group health plan unless it is clear from the instruments governing the arrangement(s) that the benefits are being provided under separate plans, and the arrangement(s) are operated under such instruments as separate plans. The COBRA regulations include an anti-abuse rule which states that if a principal purpose of establishing separate plans is to evade any requirement of law, the separate plans will be considered a single plan to the extent necessary to prevent the evasion. We clarify that for purposes of counting covered lives for reinsurance contributions, an employer may count its group health plans in accordance with these regulations, subject to the anti-abuse rule.

Comment: One commenter suggested that HHS revise proposed § 153.405(f) to permit employers to disaggregate a group health plan that offers both self-insured and insured coverage options to different groups, and to permit an issuer with respect to one group health plan that contains multiple insured options written by more than one issuer to treat the insured options as separate group health plans for purposes of the counting rules. The commenter stated that § 153.405(f) as currently drafted is not consistent with current plan sponsor and issuer practices.

Response: We are amending § 153.405(f) to permit such disaggregation, so long as each coverage option is treated as major medical coverage, except if a coverage option consists solely of excepted benefits as defined by section 2791(c) of the PHS Act, only provides benefits related to prescription drugs, or is an HRA, HSA, or FSA. This amendment is designed to allow contributing entities flexibility in performing enrollment counts, while collecting reinsurance contributions for all enrollees with major medical coverage, without “double-counting.”

Comment: One commenter suggested that the plan aggregation rules be permissive rather than mandatory, and that it should apply only to overlapping simultaneous coverage.

Response: We agree that the plan aggregation rules should only apply to overlapping, simultaneous coverage. For the reasons set forth in the prior response, we are amending § 153.405(f) and (g) to permit disaggregation, so long as each coverage option or separate group health plan is treated as major medical coverage, except if a coverage option or separate group health plan consists solely of excepted benefits as defined by section 2791(c) of the PHS Act, only provides benefits related to

prescription drugs, or is a HRA, HSA, or FSA.

Comment: One commenter suggested that the plan aggregation rules set forth in § 153.405(g) should not apply to any plan or health insurance coverage that is excluded from making reinsurance contributions.

Response: We have clarified that the plan aggregation rules do not apply to a plan or health insurance coverage that consists solely of excepted benefits as defined by section 2791(c) of the PHS Act, only provides benefits related to prescription drugs, or is an HRA, HSA, or FSA. However, we decline to exempt other plans or coverage excluded from making reinsurance contributions from the aggregation rules because the aggregation rules are designed in part to ensure reinsurance contribution collections from arrangements involving multiple plans that collectively provide major medical coverage, even when each component plan does not. Thus, a plan providing only hospital benefits might have to be aggregated with a plan that provides medical coverage other than hospital benefits, even though the hospital benefit plan on its own would be excluded from making reinsurance contributions because it is not major medical coverage.

b. State Use of Contributions Attributed to Administrative Expenses

In the proposed rule, HHS provided guidance on three restrictions that we intend to propose on the use of reinsurance contributions for administrative expenses, to permit States operating the reinsurance program to accurately estimate the cost of administrative expenses. First, we intend to apply the prohibitions described in section 1311(d)(5)(B) of the Affordable Care Act to the reinsurance program which prohibit an Exchange from using funds intended for administrative and operational expenses of the Exchange for such purposes as staff retreats, promotional giveaways, and excessive executive compensation. Second, we intend to propose that reinsurance funds intended for administrative expenses may not be used for any expense not necessary to the operation or administration of the reinsurance program. Third, we intend to propose that an applicable reinsurance entity must allocate any shared, indirect, or overhead costs between reinsurance-related and other State expenses based on generally accepted accounting principles, consistently applied. We received no comments on this guidance. We intend to issue future rulemaking including these provisions.

5. Eligibility for Reinsurance Payments under the Health Insurance Market Reform Rules

We proposed to add § 153.234 to clarify that, under either the uniform reinsurance payment parameters or the State supplemental reinsurance payment parameters, a reinsurance-eligible plan's covered claims costs for an enrollee incurred prior to the application of 2014 market reform rules—§ 147.102 (fair health insurance premiums), § 147.104 (guaranteed availability of coverage, subject to the student health insurance provisions at § 147.145), § 147.106 (guaranteed renewability of coverage, subject to the student health insurance provisions at § 147.145), § 156.80 (single risk pool), and subpart B of part 156 (essential health benefits package)—would not count toward either the uniform or State supplemental attachment points, reinsurance caps, or coinsurance rates. In other words, those claims would not be eligible for reinsurance payments. We noted in the preamble of the proposed rule that, unlike plans subject to the 2014 market reform rules under the Affordable Care Act, plans not subject to these 2014 market reforms may use several mechanisms to avoid claims costs for newly insured individuals. (We also noted that student health plan eligibility would be subject to the modified guaranteed availability and guaranteed issue requirements only, to the extent that they apply, as set forth in § 147.145, and we would require that the student health plans meet those modified requirements to be eligible for reinsurance payments.) The market reform rules will be effective for the individual market for policy years beginning on or after January 1, 2014. As a result, policies that are issued in 2013 will be subject to these rules at the time of renewal in 2014, and therefore, become eligible for reinsurance payments at the time of renewal in 2014.

We believe that providing reinsurance payments only to those reinsurance-eligible plans that are subject to the 2014 market reform rules better reflects the reinsurance program's purpose of mitigating premium adjustments to account for risk from newly insured individuals. We also proposed that State-operated reinsurance programs similarly limit eligibility for reinsurance payments, although we recognize that this policy contrasts with the approach proposed for State-operated risk adjustment programs, under which States are permitted to choose to risk-adjust plans not subject to the 2014 market reform rules. Because some

States may have enacted State-specific rating and market reforms that they believe would justify the inclusion of these plans in risk adjustment before their renewal dates, permitting State flexibility on the applicability of risk adjustment to plans not subject to the 2014 market reform rules furthers the goals of the risk adjustment program. However, we believe that State flexibility for eligibility for reinsurance payments does not further the goal of the reinsurance program. Last, we proposed to operate the reinsurance program on a calendar year basis, which we believe to be most feasible from policy and administrative standpoints. For the reasons described in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 153.234.

Comment: Commenters generally supported the operation of the reinsurance program on a calendar year basis. Commenters also requested that HHS use a calendar year approach versus a plan year approach for administrative simplicity. A commenter also requested that HHS use the term “calendar year” instead of “benefit year” to avoid confusion among issuers.

Response: We use the term “benefit year” throughout this final rule instead of “calendar year” because, under § 155.20 of the Exchange Establishment Rule, “benefit year” is defined as a calendar year for which a health plan provides coverage for health benefits. For consistency, HHS will continue to use the term “benefit year.”

6. Reinsurance Payment Parameters

As described in the Premium Stabilization Rule, reinsurance payments to eligible issuers would be made for a portion of an enrollee’s claims costs paid by the issuer that exceeds an attachment point, subject to a coinsurance rate and a reinsurance cap. The coinsurance rate, attachment point, and reinsurance cap are the reinsurance “payment parameters.” We proposed uniform reinsurance payment parameters that would be applicable to the reinsurance program for each State, whether or not operated by a State. We believe that using uniform payment parameters will result in equitable access to the reinsurance funds across States and will further the goal of premium stabilization across all States by disbursing reinsurance contributions where they are most needed.

We noted in the proposed rule that the primary purpose of the transitional reinsurance program is to stabilize premiums by setting the reinsurance payment parameters to achieve the greatest impact on rate setting, and

therefore, premiums, through reductions in plan risk, while complementing the current commercial reinsurance market. The reinsurance program is designed to protect against issuers’ potential perceived need to raise premiums due to the implementation of the 2014 market reform rules, specifically, guaranteed availability. HHS expects that any potential new high-cost claims from newly insured individuals would be balanced out by low-cost claims from many newly insured individuals who enter the individual market as a result of the availability of premium tax credits, more affordable coverage, the minimum coverage provision, and greater transparency and competition in the market. To that end, the reinsurance program is designed to alleviate the concern of new high-cost claims from newly insured individuals.

We proposed that the 2014 uniform reinsurance payment parameters be established at: (a) An attachment point of \$60,000, when reinsurance payments would begin, (b) a national reinsurance cap of \$250,000, when the reinsurance program stops paying claims for a high-cost individual, and (c) a uniform coinsurance rate of 80 percent, which is the reimbursement percentage applied to the issuer’s aggregated paid claims amounts on behalf of an enrollee while giving issuers an incentive to contain costs between the attachment point and reinsurance cap. These three proposed payment parameters would help offset high-cost enrollees. The parameters would not interfere with traditional commercial reinsurance, which typically has attachment points in the \$250,000 range. We estimate that these uniform payment parameters will result in total requests for reinsurance payments of approximately \$10 billion in the 2014 benefit year. We intend to continue to monitor individual market enrollment and claims patterns to appropriately disburse reinsurance payments throughout each of the benefit years during which the reinsurance program is in effect.

We are finalizing the proposed payment parameters, and the associated payment provisions proposed in § 153.230(a) through § 153.230(c), with a technical revision in § 153.230(a) changing “non-grandfathered individual market plan” to “reinsurance-eligible plan” and clarifying in § 153.230(c) that national reinsurance payments are calculated as the product of the national coinsurance rate multiplied by the health insurance issuer’s claims costs for an individual enrollee’s covered benefits that the health insurance issuer incurs in the applicable benefit year.

Comment: Several commenters supported the use of uniform payment parameters. Many commenters, however, suggested that States should be able to set their own payment parameters using State contributions to better target their local markets. Several commenters sought State flexibility and autonomy, with some commenters stating that they had spent substantial time and money preparing a State-operated program specific to the State. One commenter stated that uniform payment parameters and the national allocation of reinsurance payments will not ensure issuers of the aggregate funding available to pay claims in their respective markets until well after premium setting decisions for the next benefit year must be made.

Response: We believe that these uniform payment parameters best meet the reinsurance program’s goals to promote premium stabilization and market stability in all States while providing plans incentives to continue effective management of enrollee costs. We aim to administer the transitional reinsurance program in an efficient, fair, and accurate manner so that reinsurance funds are allocated equitably and can maximize downward pressure on premiums. To maximize the program’s impact on premiums, uniform reinsurance payment parameters would allow the allocation of reinsurance contributions where they are most needed, to reimburse issuers with high costs in the individual market in 2014, 2015 and 2016. This policy is consistent with the statutory goals of the reinsurance program—to stabilize premiums in the initial years of Exchange implementation and market reform. Additionally, as set forth in § 153.240(b)(2), a State, or HHS on behalf of the State, will provide each reinsurance-eligible plan the expected requests for reinsurance payments made under the national payment parameters and State supplemental parameters, if applicable. These reports can provide the information necessary for issuers to set rates in subsequent benefit years.

Comment: Several commenters requested more detail on the methodology used to calculate the uniform reinsurance payment parameters. One commenter requested that HHS detail the methodology used to determine the \$60,000 attachment point. Another commenter requested that HHS raise the reinsurance cap to \$500,000 to account for attachment points in commercial reinsurance higher than \$250,000. Alternately, one commenter suggested that HHS use a first-dollar approach with no attachment point and a lower coinsurance rate to

better incentivize issuers to control costs from the beginning of an individual's care. Several commenters suggested that the proposed contribution rate is insufficient to fully fund the proposed uniform reinsurance payment parameters, and asked HHS to set the uniform payment parameters such that expected payments would be fully funded.

Response: As described in the proposed rule and earlier in this preamble, we used the ACAHIM, which estimates market enrollment incorporating the effects of State and Federal policy choices and accounting for the behavior of individuals and employers. These assumptions and projections led to our estimate of the 2014 individual and employer-sponsored insurance markets and expenditures, and permitted us to estimate uniform payment parameters that will lead to requests for reinsurance payments of approximately \$10 billion.

Comment: One commenter asked HHS for guidance on how to account for quality improvement costs and attribute those to an individual, though they are not claims costs. Another commenter suggested that HHS use an alternate method for reinsurance payments, such as a fixed fee schedule or a percentage of Medicare reimbursement rates, instead of claims costs.

Response: HHS believes that using claims costs most appropriately reimburses issuers for costs related to higher risk individuals and will most effectively stabilize premiums.

Comment: One commenter suggested that HHS synchronize reinsurance payments with rules governing claims responsibility, such that if a patient changes coverage over the course of a single claim, the issuer paying the claim should be eligible for reinsurance payments.

Response: We believe that using the date of discharge for claims payments effectively synchronizes reinsurance payments with claims responsibility.

7. Uniform Adjustment to Reinsurance Payments

We proposed in § 153.230(d) that HHS would adjust reinsurance payments by a uniform, pro rata adjustment rate if HHS determines that the total requests for reinsurance payments under the reinsurance payment parameters will exceed the reinsurance contributions collected under the national contribution rate during a given benefit year. In the preamble to the proposed rule, we stated that the total amount of contributions considered for this purpose would include any contributions collected but unused

under the national contribution rate during any previous benefit year. We are finalizing § 153.230(d) as proposed.

Comment: Several commenters supported the uniform adjustment to reinsurance payments in the event that total payment requests exceed reinsurance contributions. One commenter objected to the lower coinsurance rate that will effectively result from a uniform adjustment to payments, stating that this could lead to additional uncertainty for issuers.

Response: We developed the national contribution rate and uniform reinsurance payment parameters using enrollment and expenditure estimates for 2014, based on the ACAHIM. We recognize that requests for reinsurance payments may be greater than predicted, or that collections may be lower than predicted. However, we believe that a uniform adjustment to payments is the most equitable approach in these situations.

Comment: We received a comment seeking clarification on when, if necessary, the uniform adjustment to national reinsurance payments set forth in § 153.230(d) would occur, and how HHS will disburse reinsurance funds to States operating reinsurance, in order for the States to make reinsurance payments.

Response: As described in § 153.235, HHS plans to allocate and disburse to each State operating reinsurance (and will distribute directly to issuers if HHS is operating reinsurance on behalf of a State), reinsurance contributions collected from contributing entities under the national contribution rate for reinsurance payments. The disbursed funds would be based on the total requests for reinsurance payments made under the national reinsurance payment parameters by all States and submitted under § 153.410, net of any adjustment under § 153.230(d). Thus, prior to the disbursement, HHS would uniformly adjust reinsurance payments, if applicable, following the collection of contributions and after the receipt of all claims for reinsurance payments, which must be submitted by April 30 of the year following the applicable benefit year. Following that adjustment, HHS will make reinsurance payments in States where HHS is operating reinsurance on behalf of the State, and will distribute funds to States operating reinsurance.

8. Supplemental State Reinsurance Payment Parameters

In § 153.232(a), we proposed that a State establishing the reinsurance program may modify the uniform reinsurance payment parameters only

by establishing State supplemental payment parameters that cover an issuer's claims costs beyond the uniform reinsurance payment parameters. We further proposed that reinsurance payments under these State supplemental payments parameters be made only with the additional funds that the State collects for reinsurance payments under § 153.220(d)(1)(ii) or State funds applied to the reinsurance program under § 153.220(d)(2) (proposed as (d)(3) in the proposed rule). We stated our belief that this approach would not prohibit States from collecting additional amounts for reinsurance payments as provided for under section 1341(b)(3)(B) of the Affordable Care Act, while allowing issuers in all States access to the reinsurance payments from the contributions collected under the national reinsurance contribution rate.

We proposed in § 153.232(a) that a State choosing to establish State supplemental reinsurance payment parameters must set those parameters by adjusting the uniform reinsurance payment parameters in one or more of the following ways: (1) Decreasing the national attachment point; (2) increasing the national reinsurance cap; or (3) increasing the national coinsurance rate. We also proposed that a State may not alter the uniform reinsurance payment parameters in a manner that could result in reduced reinsurance payments.

To provide issuers with greater certainty for premium rate setting purposes, we proposed that a State must ensure that any additional funds for reinsurance payments it collects under § 153.220(d)(1)(ii) or State funds under § 153.220(d)(2) (proposed as (d)(3) in the proposed rule), as applicable, are reasonably calculated to cover additional reinsurance payments projected to be made under the State's supplemental reinsurance payment parameters for a given benefit year. In § 153.232(b), we proposed that contributions collected under § 153.220(d)(1)(ii) or additional funds collected under § 153.220(d)(2) (proposed as (d)(3) in the proposed rule), as applicable, must be applied toward requests for reinsurance payments made under the State supplemental reinsurance payments parameters for each benefit year commencing in 2014 and ending in 2016.

We also proposed in § 153.232(c) that a reinsurance-eligible plan becomes eligible for reinsurance payments under a State's supplemental reinsurance parameters if its incurred claims costs for an individual enrollee's covered benefits during a benefit year exceed: (1)

The supplemental State attachment point; (2) the national reinsurance cap; or (3) the national attachment point, if the State has established a State supplemental coinsurance rate. This would allow reinsurance payments made under the State supplemental payment parameters to “wrap around” the uniform reinsurance payment parameters so that the State could apply any additional contributions it collects under proposed § 153.220(d) towards reinsurance payments beyond the uniform reinsurance payment parameters. We explained in the proposed rule that this approach permits HHS to distribute funds under the uniform payment formula to where they are needed most, while allowing States that elect to operate reinsurance the flexibility to supplement nationally calculated reinsurance payments. As set forth in § 153.240(b), States would be required to separate in their reporting to issuers the reinsurance payments paid under the uniform reinsurance payment parameters and State supplemental reinsurance payment parameters.

To ensure that reinsurance payments under State supplemental payment parameters do not overlap with the uniform reinsurance payment parameters, we proposed the method for calculating State supplemental reinsurance payments. Specifically, we proposed in § 153.232(d) that supplemental reinsurance payments with respect to a health insurance issuer's claims costs for an individual enrollee's covered benefits must be calculated by taking the sum of: (1) The product of such claims costs between the supplemental State attachment point and the national attachment point, multiplied by the national coinsurance rate (or applicable State supplemental coinsurance rate); (2) the product of such claims costs between the national reinsurance cap and the supplemental State reinsurance cap, multiplied by the national coinsurance rate (or applicable State supplemental coinsurance rate); and (3) the product of such claims costs between the national attachment point and the national reinsurance cap, multiplied by the difference between the State supplemental coinsurance rate and the national coinsurance rate.

Similar to payment calculations under the uniform reinsurance payment parameters, we proposed in § 153.232(e) that if all reinsurance payments requests under the State supplemental reinsurance parameters calculated in a State for a benefit year will exceed all the additional funds a State collects for reinsurance payments under § 153.220(d)(1)(ii) or State funds under § 153.220(d)(2) (proposed as (d)(3) in the

proposed rule) as applicable, the State must determine a uniform pro rata adjustment to be applied to all such requests for reinsurance payments in the State. We proposed that each applicable reinsurance entity in the State must reduce all requests for reinsurance payments under the State supplemental reinsurance payment parameters for the applicable benefit year by that adjustment.

Finally, in § 153.232(f), we proposed that a State must ensure that reinsurance payments made to issuers under the State supplemental reinsurance payment parameters do not exceed the issuer's total paid amount for the reinsurance-eligible claims, and any remaining additional funds collected under § 153.220(d)(1)(ii) must be used for reinsurance payments under the State supplemental parameters in subsequent benefit years.

We are finalizing these provisions as proposed, with a technical correction changing “non-grandfathered individual market plan” to “reinsurance-eligible plan” and clarifying that the incurred claims costs for an individual enrollee's covered benefits are those incurred in the applicable benefit year in § 153.232(c). We are clarifying in § 153.232(d) that reinsurance payments will be calculated with respect to an issuer's incurred claims costs for an individual enrollee's covered benefits incurred in the applicable benefit year.

Comment: Several commenters urged HHS to allow additional State flexibility for the State supplemental reinsurance payment parameters under the reinsurance program. In addition, several commenters requested flexibility for a State to design a program that would cover any shortfall in payments under the reinsurance program's uniform parameters.

Response: One of HHS's goals is to provide the greatest amount of flexibility to States while ensuring consistency with the policy goals of the reinsurance program. Therefore, under these final rules, we have provided States with the flexibility to increase the coinsurance rate on reinsurance-eligible claims, which would have the effect of increasing payouts under the uniform parameters. Additionally, nothing in these final rules prevents a State from establishing a separate program that would operate alongside the reinsurance program established under section 1341 of the Affordable Care Act. A State establishing such a program is free to implement the collections methodology and payment formula of its own choosing.

9. Allocation and Distribution of Reinsurance Contributions

Section 153.220(d) of the Premium Stabilization Rule provided that HHS would distribute reinsurance contributions collected for reinsurance payments from a State to the applicable reinsurance entity for that State. In the proposed rule, we proposed to replace this section with § 153.235(a), which provided that HHS would allocate and distribute the reinsurance contributions collected under the national contribution rate based on the need for reinsurance payments, regardless of where the contributions are collected. HHS would disburse all contributions collected under the national contribution rate from all States for the applicable benefit year, based on all available contributions and the aggregate requests for reinsurance payments, net of the pro rata adjustment, if any. We believe that this method of disbursing reinsurance contributions will allow the reinsurance program to equitably stabilize premiums across the nation, and permit HHS to direct reinsurance funds based on the need for reinsurance payments. Consistent with this proposal, we proposed to amend § 153.220(a) to clarify that even if a State establishes the reinsurance program, HHS would directly collect the reinsurance contributions for enrollees who reside in that State from both health insurance issuers and self-insured group health plans.

We are finalizing the provisions as proposed in § 153.220(a). We are revising § 153.235(a) to provide that HHS will allocate and disburse to each State operating reinsurance (and will distribute directly to issuers if HHS is operating reinsurance on behalf of a State), reinsurance contributions collected from contributing entities under the national contribution rate for reinsurance payments. The disbursed funds would be based on the total requests for reinsurance payments made under the national reinsurance payment parameters in all States and submitted under § 153.410, net of any adjustment under § 153.230(d). We are amending § 153.410(a) to clarify that an issuer of a reinsurance-eligible plan may make requests for reinsurance payments when an issuer's claims costs for an enrollee of that reinsurance-eligible plan has met the criteria for reinsurance payments in 45 CFR subpart B and this final rule and where applicable the State notice of benefit and payment parameters.

Comment: Several commenters stated that the proposed allocation of reinsurance payments would penalize

States that effectively and efficiently manage health care costs and have fewer uninsured individuals. Commenters stated that individual markets are largely State-based and that reinsurance works in conjunction with risk adjustment, which is also a State-based program. Commenters also stated that disbursing reinsurance payments under uniform reinsurance payment parameters in all States is contrary to the intent of the statute for a State-based program. We also received comments stating that the implementation of the reinsurance program as proposed would increase the burden for States that wish to supplement the reinsurance program. One commenter suggested that reinsurance payment allocations in accordance with need could discourage issuers from maintaining grandfathered status in order to compete for funds, thereby making it difficult for enrollees to keep their current plan.

Response: To maximize the reinsurance program's impact on premium rates, an allocation of reinsurance payments under uniform payment parameters allows for HHS to disburse reinsurance contributions where they are most needed, to reimburse issuers with high cost claims in the individual market in 2014, 2015 and 2016. This policy is consistent with the statutory goals of the reinsurance program—to stabilize premiums in the initial years of Exchange implementation and market reform. Considering the comments received, we are finalizing these provisions as proposed.

Comment: Several commenters asked that HHS refund any unused contributions collected or use those funds to lower the contribution rate for subsequent benefit years.

Response: The purpose of the reinsurance program is to stabilize premiums in the individual market beginning in 2014. If any funds remain after all requests for reinsurance payments are made for any benefit year, as required by the statute, HHS plans to use those funds for reinsurance payments in subsequent benefit years, furthering the goal of section 1341 of the Affordable Care Act.

Comment: Several commenters supported HHS's proposed annual payments schedule coupled with quarterly reporting estimates. One commenter requested clarification on whether reinsurance payments would be issued on a rolling basis throughout the year, or once annually. Several commenters requested that HHS administer reinsurance payments throughout the year instead of annually

to better accommodate issuers' cash flow.

Response: Because we are seeking to stabilize premiums nationally, an annual disbursement of payments preserves fairness in making reinsurance payments and allows for HHS to appropriately adjust payments, if needed. To better address administrative and operational issues, we proposed to make an annual reinsurance payment for each benefit year. If we were to collect and make reinsurance payments throughout the benefit year, we would likely be required to hold the disbursement of a large portion of the reinsurance payments until the end of the benefit year to ensure an equitable allocation of payments.

Comment: Several commenters sought clarification on the process by which HHS plans to ensure that reinsurance funds will be used to reduce and stabilize premiums in the individual market.

Response: We expect that an issuer that receives reinsurance payments will reduce premiums in the individual market accordingly. We note that a State, or HHS operating reinsurance on behalf of the State, will provide issuers the estimated amount of the reinsurance payments throughout a benefit year so that those issuers can account for reinsurance payments in developing their premiums for subsequent benefit years. We note that under the single risk pool requirement of the final Market Reform Rule (§ 156.80), issuers of non-grandfathered individual market plans must adjust their index rate based on the total expected market-wide payments and charges under the risk adjustment and reinsurance programs in the State, and based on Exchange user fees.

Comment: Several commenters asked HHS how excess reinsurance funds would be distributed after 2016.

Response: HHS will provide details regarding this issue in future rulemaking and guidance.

10. Reinsurance Data Collection Standards

a. Data Collection Standards for Reinsurance Payments

Section 153.240(a) of the Premium Stabilization Rule directs a State's applicable reinsurance entity to collect data needed to determine reinsurance payments as described in § 153.230. We proposed to amend § 153.240(a) by adding subparagraph (1) which would direct a State to ensure that its applicable reinsurance entity either collects or is provided access to the data

necessary to determine reinsurance payments from an issuer of a reinsurance-eligible plan. When HHS operates reinsurance on behalf of a State, HHS would utilize the same distributed data collection approach proposed for risk adjustment. This proposed amendment was meant to clarify that an applicable reinsurance entity may either use a distributed data collection approach for its reinsurance program or directly collect privacy-protected data from issuers to determine an issuer's reinsurance payments. The distributed data collection approach would not involve the direct collection of data; instead, HHS or the State would access data on issuers' secure servers.

We also proposed to amend § 153.240(a) by adding subparagraph (3), directing States to provide a process through which an issuer of a reinsurance-eligible plan that does not generate individual enrollee claims in the normal course of business, such as a capitated plan, may request reinsurance payments or submit data to be considered for reinsurance payments based on estimated costs of encounters for the plan, in accordance with the requirements of § 153.410. We proposed to direct States to ensure that such requests (or a subset of such requests) are subject to, to the extent required by the State, a data validation program. A State would have the flexibility to design a data validation program that meets its adopted methodology and State-specific circumstances. This proposed amendment would enable certain reinsurance-eligible plans, such as staff-model health maintenance organizations, that do not generate claims with associated costs in the normal course of business to provide data to request and receive reinsurance payments.

When HHS operates reinsurance on behalf of a State, issuers of capitated plans would generate claims for encounters, and derive costs for those claims when submitting requests for reinsurance payments (or submitting data to be considered for reinsurance payments). It is our understanding that many capitated plans currently use some form of encounter data pricing methodology to derive claims, often by imputing an amount based upon the Medicare fee-for-service equivalent price or the usual, customary, and reasonable equivalent that would have been paid for the service in the applicable market. As set forth in § 153.710(c), a capitated plan would be required to use its principal internal methodology for pricing encounters for reinsurance purposes, such as the methodology in use for other State or

Federal programs (for example, a methodology used for the Medicare Advantage market). If a capitated plan has no such methodology, or has an incomplete methodology, it would be permitted to implement a methodology or supplement the methodology in a manner that yields derived claims that are reasonable in light of the specific market that the plan is serving. Capitated plans, like all plans that submit reinsurance payment requests (or data to be considered for reinsurance payments) in the HHS-operated reinsurance program, would be subject to validation and audit. Because capitated plans already use pricing methodologies, we believe this proposed policy would permit capitated plans to participate in the reinsurance program with a minimal increase in administrative burden. We have responded to the comments received regarding capitated plans in section III.G. of this final rule, where capitated plans are discussed in § 153.710(c). We are finalizing these provisions as proposed.

b. Notification of Reinsurance Payments

We proposed to add § 153.240(b)(1), which would direct a State, or HHS on behalf of the State, to notify issuers of the total amount of reinsurance payments that will be made no later than June 30 of the year following the applicable benefit year. This corresponds with the date on which a State or HHS must notify issuers of risk adjustment payments and charges. As such, by June 30 of the year following the applicable benefit year, issuers would be notified of reinsurance payments and risk adjustment payments and charges, allowing issuers to account for their total reinsurance payments and risk adjustment payments and charges when submitting data for the risk corridors and MLR programs. To provide issuers in the individual market with information to assist in development of premiums and rates in subsequent benefit years, we also proposed in § 153.240(b)(2) that a State provide quarterly notifications of estimates to each reinsurance-eligible plan of the expected requests for reinsurance payments. HHS intends to collaborate with issuers and States to develop these early notifications. We are finalizing these provisions as proposed.

Comment: Several commenters requested that HHS specify a date by which HHS will make reinsurance payments.

Response: Under § 153.240(b), HHS would notify issuers of reinsurance payments to be made under the uniform payment parameters by June 30 of the

year following the applicable benefit year. We will make every effort to issue payments as quickly as possible. We anticipate issuing further guidance regarding reinsurance payments.

Comment: One commenter requested that, if a State is operates reinsurance in the 2014 benefit year, the deadline for issuers to file rates be moved to April 30 because State supplemental reinsurance payment parameters will affect premium rate setting. The commenter also requested that for the 2015 and 2016 benefit years, HHS require States to publish the State notice of benefit and payments parameters no later than January 31 of the prior year to provide issuers with ample time to calculate and submit rates for filing approval by March 28.

Response: We understand the challenges posed by various State and Federal deadlines, and anticipate that all stakeholders will work together with both States and HHS to meet those deadlines. However, State deadlines for submitting rates are within the authority of the State.

c. Privacy and Security Standards

We proposed in § 153.240(d)(1) that a State establishing the reinsurance program ensure that the applicable reinsurance entity's collection of personally identifiable information²² is limited to information reasonably necessary for use in the calculation of reinsurance payments, and that use and disclosure of personally identifiable information is limited to those purposes for which the personally identifiable information was collected (including for purposes of data validation). In § 153.240(d)(2), we proposed to require that an applicable reinsurance entity implement specific privacy and security standards to ensure enrollee privacy and to protect sensitive information. Specifically, this provision would require an applicable reinsurance entity to provide administrative, physical, and technical safeguards for personally identifiable information that may be used to request reinsurance payments. This provision is meant to ensure that an applicable reinsurance entity complies with the same privacy and security standards that apply to issuers and providers, specifically, the security standards described at § 164.308, § 164.310, and § 164.312. We are finalizing these provisions as proposed.

Comment: We received comments supporting the privacy and security

standards set forth in § 153.240(d) and suggesting audits and other safeguards to protect personal health information from inappropriate disclosure.

Response: HHS takes seriously its responsibility to monitor the implementation of these programs, including the protection of the privacy of consumers. We will provide more information on our approach to these and other oversight matters in future rulemaking.

d. Data Collection

We proposed in § 153.420(a) that an issuer of a reinsurance-eligible plan seeking reinsurance payments submit or make accessible data, in accordance with the reinsurance data collection approach established by the State, or HHS on behalf of the State. In § 153.420(b), we proposed that an issuer of a reinsurance-eligible plan submit data to be considered for reinsurance payments for the applicable benefit year by April 30 of the year following the end of the applicable benefit year. The April 30 deadline would apply to all issuers of reinsurance-eligible plans, regardless of whether HHS or the State is operating reinsurance. Further details surrounding the data collection process when HHS is operating reinsurance on behalf of a State is set forth in subpart H of part 153 and section III.G. of this final rule. We are finalizing these provisions as proposed.

Comment: Several commenters requested clarification on the claims run-out period.

Response: An issuer of a risk adjustment covered plan or reinsurance eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program would submit data for a benefit year by April 30 of the year following the applicable benefit year. For example, claims incurred in the 2014 benefit year must be submitted to HHS by April 30, 2015. The submission deadline (the latest date by which data can be provided for the applicable benefit year) will allow issuers the time necessary to process claims and submit data to their distributed data systems for HHS evaluation. The submission deadline of April 30 of the year following the applicable benefit year also permits HHS an appropriate timeline for payment calculations. However, as described in section III.G. of this final rule, claims submitted for the reinsurance program and encounter data submitted for the risk adjustment program must be for claims and encounters with discharge dates within the applicable benefit year. Use of the discharge date best ensures that services provided across benefit years will be

²² As discussed above, the term "personally identifiable information" is a broadly used term across Federal agencies, and has been defined in the Office of Management and Budget Memorandum M-07-16 (May 22, 2007). Available at:

considered in their entirety rather than being partially or fully excluded from consideration as a result of the data submission timing requirements.

D. Provisions for the Temporary Risk Corridors Program

1. Definitions

In the Premium Stabilization Rule, we stated in response to comments that we intended to propose that taxes and profits be accounted for in the risk corridors calculation, in a manner consistent with the MLR program. Therefore, in the proposed rule, we proposed to amend § 153.500 by defining “taxes” with respect to a QHP as Federal and State licensing and regulatory fees paid with respect to the QHP as described in § 158.161(a), and Federal and State taxes and assessments paid for the QHP as described in § 158.162(a)(1) and § 158.162(b)(1). This definition aligns with the regulatory fees and taxes and assessments deductible from premiums in the MLR calculation. We used this definition to define “after-tax premiums earned,” which we proposed to mean, with respect to a QHP, premiums earned minus “taxes.” We also proposed to revise the definition of “administrative costs” in § 153.500 to mean, with respect to a QHP, the total non-claims costs incurred by the QHP issuer for the QHP, including taxes. We noted that under this broader definition, administrative costs may also include regulatory fees and assessments other than those included in “taxes,” as defined above.

Using the definitions above, we proposed to amend § 153.500 by defining “profits” with respect to a QHP to mean the greater of: (1) 3 percent of after-tax premiums earned; and (2) premiums earned by the QHP minus the sum of allowable costs and administrative costs of the QHP. Thus, we proposed to define profits for a QHP through the use of the risk corridors equation; however, we provided for a 3 percent profit margin so that the risk corridors program would protect a reasonable profit margin (subject to the 20 percent cap on allowable administrative costs as described below).

Finally, using the definition of profits discussed above, we proposed to revise the definition of “allowable administrative costs” in § 153.500 to mean, with respect to a QHP, the sum of administrative costs other than taxes, and profits earned, which sum is limited to 20 percent of after-tax premiums earned (including any premium tax credit under any governmental program), plus taxes. This

definition reflects the inclusion of profits and taxes discussed above, and clarifies that the 20 percent cap on allowable administrative costs applies to taxes, assessments and regulatory fees other than those taxes, assessments and regulatory fees defined as deductible from premium revenue under the MLR rules, a result that is consistent with the way they are accounted for by the MLR rules.

The preamble to our proposed rule contained an example that illustrated the proposed operation of the risk corridors calculation. We have included a minor correction to the calculation of profits in this example:

- *Premiums earned:* Assume a QHP with premiums earned of \$200.

- *Allowable costs:* Assume allowable costs of \$140, including expenses for health care quality and health information technology, and other applicable adjustments.

- *Non-claims costs:* Assume that the QHP has non-claims costs of \$50, of which \$15 are properly allocable to licensing and regulatory fees and taxes and assessments described in § 158.161(a), § 158.162(a)(1), and § 158.162(b)(1) (that is, “taxes”).

The following calculations result:

- *“Taxes”:* Under the proposed definition of taxes, the QHP’s “taxes” will be \$15.

- *Administrative costs* are defined as non-claims costs. In this case, those costs would be \$50. Administrative costs other than “taxes” would be \$35.

- *After-tax premiums earned* are defined as premiums earned minus “taxes,” or in this case $\$200 - \$15 = \$185$.

- *Profits* are proposed to be defined as the greater of: 3 percent of premiums earned, or $3 \text{ percent} * \$185 = \$5.55$; and premiums earned by the QHP minus the sum of allowable costs and administrative costs, or $\$200 - (\$140 + \$50) = \$200 - \$190 = \$10$. Therefore, profits for the QHP would be \$10, which is greater than \$5.55

- *Allowable administrative costs* are defined as the sum of administrative costs, other than “taxes,” plus profits earned by the QHP, which sum is limited to 20 percent of after-tax premiums earned by the QHP (including any premium tax credit under any governmental program), plus “taxes.” $= (\$35 + \$10)$, limited to 20 percent of $\$185$, plus $\$15 = \$45$, limited to $\$37$, plus $\$15 = \$37$, plus $\$15 = \$52$.

- *The target amount* is defined as premiums earned reduced by allowable administrative costs, or $\$200 - \$52 = \$148$.

- *The risk corridors ratio* is the ratio of allowable costs to target amount, or the ratio of $\$140$ to $\$148$, or approximately 94.6 percent (rounded to the nearest one-tenth of one percent), meaning that the QHP issuer would be required to remit to HHS 50 percent of approximately (97 percent – 94.6 percent) = 50 percent of 2.4 percent, or approximately 1.2 percent of the target amount, or approximately $0.012 * \$148$, or approximately \$1.78.

We sought comments on the estimates, data sources, and appropriate profit margin to use in the risk corridors calculation in the proposed rule. We are finalizing these proposed provisions with the following modifications. As discussed below, in order to conform with changes finalized in this rule for the MLR program, and in response to comments, we are deleting § 153.530(b)(1)(ii) to eliminate the adjustment to allowable costs for reinsurance contributions made by an issuer, and are clarifying the treatment of community benefit expenditures within the risk corridors calculation. We are also modifying our proposed definition of “taxes” in § 153.500, by replacing the term “taxes” with “taxes and regulatory fees.”

Comment: A few commenters noted that, while the proposed rule stated that the risk corridors profits calculation was based on after-tax premiums, the example in the preamble to the proposed rule calculated 3 percent of profits based on a pre-tax premium amount (that is, earned premiums).

Response: We are finalizing the definition of “profits” based on after-tax premiums, as proposed. We have corrected the profits calculation example in the preamble.

Comment: Two commenters stated that the risk corridors formula is potentially circular, and asked us to reexamine the treatment of profits and taxes in the risk corridors calculation. Because taxes are a parameter in the risk corridors calculation, if risk corridors payments are taken into account when estimating taxes, the commenters believed that it would result in an iterative effect that could affect the width of the risk corridors. They stated that a similar effect would occur with respect to profits.

Response: In response to these comments, we are clarifying that, similar to the manner in which the MLR is calculated, an issuer should not consider risk corridors payments and charges when estimating taxes under the risk corridors formula. As described in the preamble to the Premium Stabilization Rule, we seek alignment between the MLR and risk corridors

programs when practicable so that similar concepts in the two programs are handled in a similar manner, and similar policy goals are reflected. Consequently, our treatment of taxes for risk corridors purposes follows the approach of the MLR program, as outlined in section 3C of the model MLR regulation published by the National Association of Insurance Commissioners (NAIC).²³ We note that, because of the way profits is defined for the risk corridors calculation, no such circularity will occur with profits.

Comment: One commenter asked whether reinsurance contributions could be considered as “taxes and regulatory fees” when determining “allowable administrative costs” in the denominator of the risk corridors calculation.

Response: We note that other provisions of this final rule amend the MLR calculation so that reinsurance contributions are included in Federal and State licensing and regulatory fees paid with respect to the QHP as described in § 158.161(a), and are deducted from premiums for MLR purposes. Our proposed definition of “taxes” for purposes of the risk corridors program cross-referenced § 158.161(a) and similarly included reinsurance contributions. Thus, in response to these comments, and to maintain consistency with the MLR calculation and our proposed definition, which we are finalizing as proposed, we are making a conforming amendment to § 153.530(b)(1). In this final rule, we are deleting § 153.530(b)(1)(ii) and clarifying that reinsurance contributions are included in Federal and State licensing and regulatory fees paid with respect to the QHP as described in § 158.161(a), and thus are included in allowable administrative costs for risk corridors purposes. We are also making a conforming change to § 153.520(d) to remove the requirement that a QHP issuer must attribute reinsurance contributions to allowable costs for the benefit year. In addition, we are making a conforming modification to the proposed definition of “taxes” in § 153.500, by replacing the term “taxes” with “taxes and regulatory fees.”

Comment: Nearly all those that commented on the risk corridors profit margin agreed with the 3 percent profit

margin set in the proposed rule. One commenter suggested that a 2 percent profit margin would be more appropriate.

Response: Based on the comments received and the policy arguments outlined in our proposed rule, we are finalizing the definition of “profits” in § 153.500 as proposed.

Comment: One commenter expressed concern that an allowance for up to 3 percent profit could disrupt the budget neutrality of the risk corridors program, and asked for clarification on HHS’s plans for funding risk corridors if payments exceed receipts.

Response: The risk corridors program is not statutorily required to be budget neutral. Regardless of the balance of payments and receipts, HHS will remit payments as required under section 1342 of the Affordable Care Act.

Comment: One commenter stated that the risk corridors calculation does not account for the credibility adjustment that is part of the MLR formula, and recommended setting maximum allowable administrative costs at 20 percent plus the allowed credibility adjustment for the carrier’s block of business. The commenter believed that this change would be consistent with the MLR formula and make it more viable for carriers to maintain their smaller blocks of business, given the higher claims volatility that often characterizes these smaller blocks of business.

Response: Although we seek consistency with MLR where the risk corridors and MLR formulas contain similar parameters, we believe that the credibility adjustment is a unique parameter in the MLR formula. The MLR statute provides for a credibility adjustment through “methodologies * * * designed to take into account the special circumstances of smaller plans, different types of plans, and newer plans” at section 2718(c) of the Affordable Care Act. No similar reference appears in section 1342 of the Affordable Care Act.

Comment: One commenter requested clarification on whether community benefit expenses would be included in the taxes of non-profit entities for the purposes of calculating the risk corridors target amount.

Response: We believe that accounting for these expenses as taxes when calculating the target amount would appropriately align the risk corridors formula with the MLR calculation. Our proposed definition of “taxes” in § 153.500 includes Federal and State taxes defined in § 158.162(b), which describes payments made by a tax-exempt issuer for community benefit

expenditures. Consequently, we are clarifying that non-profit entities may account for community benefit expenditures as “taxes and regulatory fees” in a manner consistent with the MLR reporting requirements set forth in § 158.162 for the purposes of calculating the risk corridors target amount.

2. Risk Corridors Establishment and Payment Methodology

We proposed to add paragraph (d) to § 153.510, which would specify the due date for QHP issuers to remit risk corridors charges to HHS. Under this provision, an issuer would be required to remit charges within 30 days after notification of the charges. By June 30 of the year following an applicable benefit year, under § 153.310(e), QHP issuers will have been notified of risk adjustment payments and charges for the applicable benefit year. By that same date, under § 153.240(b)(1), QHP issuers also will have been notified of all reinsurance payments to be made for the applicable benefit year. As such, we proposed in § 153.530(d) that the due date for QHP issuers to submit all information required under § 153.530 of the Premium Stabilization Rule is July 31 of the year following the applicable benefit year. We also proposed that the MLR reporting deadline be revised to align with this schedule. We are finalizing this provision as proposed.

Comment: We received several supportive comments on our proposal to require issuers to submit risk corridors information by July 31 of the year following the applicable benefit year.

Response: We are finalizing § 153.530(d) as proposed, so that the due date for QHP issuers to submit all risk corridors information is July 31 of the year following the applicable benefit year. In section III.I.1. of this final rule, we also finalize our proposal to align the MLR reporting deadline with this schedule.

Comment: One commenter asked how payments made under the State supplemental reinsurance payment parameters are taken into account in the risk corridors calculation. Another commenter requested that HHS clarify the treatment of State “wrap-around” reinsurance payments under the risk corridors calculation, and asked for information on the way in which HHS analyzed the impact of the administrative burden associated with removing these costs.

Response: Under section 1342(c)(1)(B) of the Affordable Care Act, allowable costs are to be reduced by any risk adjustment and reinsurance payments received under sections 1341 and 1343. Supplemental reinsurance payments

²³ Section 3C of the NAIC model regulation, available at http://www.naic.org/documents/committees_ex_mlr_reg_asadopted.pdf states, “[a]ll terms defined in this Regulation, whether in this Section or elsewhere, shall be construed, and all calculations provided for by this Regulation shall be performed, as to exclude the financial impact of any of the rebates provided for in sections 8, 9, and 10 [rebate calculation sections].”

made under State supplemental reinsurance payment parameters are reinsurance payments received under sections 1341 of the Affordable Care Act; thus, allowable costs in the risk corridors formula are to be reduced by the reinsurance payments received both under the uniform payment parameters and any State supplemental reinsurance payment parameters.

We do not believe that adjusting the risk corridors formula to account for this parameter will result in any additional administrative burden on issuers, because issuers will be performing the calculations to account for these adjustments at the same time they adjust for reinsurance payments under the uniform payment parameters.

Comment: One commenter suggested that we align the risk corridors calculation with their suggestions on the MLR calculation, which would entail accounting for risk adjustment transfers and reinsurance contributions as adjustments to premiums, rather than claims. Another commenter similarly recommended that reinsurance payments be treated as an adjustment to premiums in the risk corridors calculation, noting that such an approach would reflect current market practices.

Response: We do not believe we have the statutory authority to accommodate this request, because section 1342(c)(1)(B) of the Affordable Care Act requires reducing allowable costs for reinsurance and risk adjustment payments received.

Comment: A number of commenters indicated that risk corridors should be calculated at the issuer level as opposed to the QHP level. One commenter indicated that the current policy of calculating risk corridors at the plan level is inconsistent with the single risk pool requirement in the proposed Market Reform Rule (77 FR 70584), and other issuers pointed out other policy concerns, such as non-alignment with MLR and lack of statistical credibility.

Response: We agree that a plan-level risk corridors calculation creates an incongruity with the single risk pool requirement set forth at § 156.80. Under the regulation as written, risk corridors would compare allowable costs (adjusted claims), which are currently plan-specific, and target amount (adjusted premiums), which under the single risk pool requirement must be based on market-wide expected claims. After considering comments received on the proposed rule, we are publishing an interim final rule elsewhere in this issue of the **Federal Register** to address alignment of the risk corridors calculations with the single risk pool

requirement. Under the approach implemented in the interim final rule, an issuer could reasonably allocate, in accordance with § 153.520, allowable administrative costs across its business pro rata by premiums earned, leading to an issuer-level risk corridors calculation for its QHP business.

3. Risk Corridors Data Requirements

In § 153.530 of the Premium Stabilization Rule, we stated that to support the risk corridors program calculations, a QHP issuer must submit data related to actual premium amounts collected, including premium amounts paid by parties other than the enrollee in a QHP, specifically, advance premium tax credits. We further specified that risk adjustment and reinsurance payments be regarded as after-the-fact adjustments to allowable costs for purposes of determining risk corridors amounts, and that allowable costs be reduced by the amount of any cost-sharing reductions received from HHS. For example, if a QHP incurred \$200 in allowable costs for a benefit year, but received a risk adjustment payment of \$25, received reinsurance payments of \$35, and received cost-sharing reduction payments of \$15, the QHP issuer's allowable costs would be \$125 (\$200 allowable costs – \$25 risk adjustment payments received – \$35 reinsurance payments received – \$15 cost-sharing reduction payments).

We additionally proposed an approach to reimbursement of cost-sharing reductions that would add an additional reimbursement requirement for cost-sharing reductions by providers with whom the issuer has a fee-for-service compensation arrangement. We proposed that issuers be reimbursed for, in the case of a benefit for which the issuer compensates the provider in whole or in part on a fee-for-service basis, the actual amount of cost-sharing reductions provided to the enrollee for the benefit and reimbursed to the provider by the issuer. However, we clarified that cost-sharing reductions on benefits rendered by providers for which the issuer provides compensation other than on a fee-for-service arrangement (such as a capitated system), would not be held to this standard.

We also proposed to amend § 153.530(b)(2)(iii) so that allowable costs are reduced by any cost-sharing reduction payments received by the issuer for the QHP to the extent not reimbursed to the provider furnishing the item or service. We received no responses to our request for comment on this proposal. Therefore, we are finalizing this provision as proposed.

4. Manner of Risk Corridor Data Collection

We also proposed to amend § 153.530(a), (b), and (c) to specify that we will address the manner of submitting required risk corridors data in future guidance rather than in this HHS notice of benefit and payment parameters. We received no responses to our request for comment on this proposal. Therefore, we are finalizing this provision as proposed.

E. Provisions for the Advance Payment of the Premium Tax Credit and Cost-Sharing Reduction Programs

1. Exchange Responsibilities With Respect to Advance Payments of the Premium Tax Credit and Cost-Sharing Reductions

a. Special Rule for Family Policies

We proposed to amend § 155.305(g)(3), currently entitled “special rule for multiple tax households.” Our proposed amendment renamed this paragraph “special rule for family policies,” added a category for qualified individuals who are not eligible for any cost-sharing reductions, and revised the introductory text to address situations in which Indians (as defined in § 155.300(a)) and non-Indians enroll in a family policy. The proposed amendment also extended the current policy with respect to tax households such that individuals on a family policy would be eligible to be assigned to the most generous plan variation for which all members of the family are eligible. We noted that nothing in this provision precludes qualified individuals with different levels of eligibility for cost-sharing reductions from purchasing separate policies to secure the highest cost-sharing reductions for which they are respectively eligible.

We discuss this policy further with regard to Indians eligible for cost-sharing reductions under section 1402(d) of the Affordable Care Act in section III.E.4.i. of this final rule. We are finalizing these provisions as proposed.

Comment: Several commenters supported the proposed policy, noting that it would be operationally infeasible for QHP issuers to have two family members with different cost-sharing levels enrolled in the same policy. Other commenters stated that families should not need to purchase multiple individual plans so that each family member can receive the full value of the cost-sharing reductions for which they are eligible. Commenters expressed concern that for large families, premiums for multiple individual plans could offset the value of the cost-sharing

reduction, as well as potentially subjecting family members to separate out-of-pocket maximums and separate deductibles. One commenter suggested the option of a family-based plan that offers a weighted actuarial value reflecting the cost-sharing reductions available to individual members. Another commenter was concerned about the ability of Exchanges to explain to consumers the advantages and disadvantages of buying multiple policies versus one family policy.

Response: As deductibles and out-of-pocket limits are calculated at the policy level, we believe it will be operationally difficult to establish separate cost-sharing requirements for different enrollees covered by the same policy at this time. HHS will encourage Exchanges to provide appropriate guidance to consumers on the relative costs and benefits of enrolling in one family policy versus multiple individual policies so that families can best take advantage of cost-sharing reductions.

b. Recalculation of Advance Payments of the Premium Tax Credit and Cost-Sharing Reductions

We proposed to add paragraph (g) to § 155.330 to clarify how an Exchange would redetermine the eligibility of an enrollee during a benefit year if an Exchange receives and verifies new information reported by an enrollee or identifies updated information through data matching that affects eligibility for advance payments of the premium tax credit and cost-sharing reductions. We proposed that when an Exchange recalculates the amount of advance payments of the premium tax credit available after considering such a change, an Exchange must account for any advance payments already made on behalf of the tax filer in that benefit year to minimize, to the extent possible, any projected discrepancies between the advance payments and the tax filer's projected premium tax credit for the benefit year. We specified that this recalculation will only include months for which the tax filer has been determined eligible for advance payments of the premium tax credit. We also proposed that, when redetermining eligibility for cost-sharing reductions during the benefit year, an Exchange must determine an individual to be eligible for the category of cost-sharing reductions that corresponds to the individual's expected annual household income for the benefit year. Further detail and examples of this policy were provided in the proposed rule.

We further noted in the preamble that we considered taking a different approach if an eligibility

redetermination during the benefit year resulted in an increase in advance payments of the premium tax credit—we considered proposing that in such a situation, HHS would make retroactive payments to the QHP issuer for all prior months of the benefit year to reflect the increased advance payment amount, not to exceed the total premium for each month. We solicited comments regarding whether we should adopt this approach, and if so, how QHP issuers should be required to provide the retroactive payments to enrollees. Several commenters raised concerns regarding the operational and administrative challenges associated with such retroactive payments.

We are finalizing the policy substantially as proposed, with modifications to the language in paragraph (g) to increase clarity. We are not implementing the retroactive payment approach.

Comment: A number of commenters expressed their support for the proposed approach, though some sought further clarification regarding the impact of eligibility redeterminations on advance payments of the premium tax credit and cost-sharing reductions. Several commenters also requested that HHS modify the proposed approach, by placing a limit on the number of redeterminations per benefit year to reduce administrative burden, or by providing that when accounting for advance payments of the premium tax credit already received by an enrollee whose income has since increased, an Exchange should never reduce the enrollee's future payments by more than the limits on repayment following the benefit year as specified in 26 CFR 1.36B-4(a). Another commenter urged that HHS require QHP issuers to conduct extensive outreach to enrollees to effectively implement this provision.

Further, although several commenters expressed support for how the alternative proposal could assist enrollees with issues such as past due premium amounts, we also received several comments raising concerns and seeking additional specificity. Commenters mentioned the operational and administrative challenges that the alternative proposal would pose for both QHP issuers as well as HHS, and stated that the potential advantages for enrollees would be minimal.

Response: We provide additional detail on redeterminations during the benefit year and their implications for cost-sharing reductions in § 156.425. We note that redetermining eligibility when changes occur is important to the accuracy of eligibility determinations during the year. We also note that we

expect that QHP issuers will provide guidance to enrollees regarding the importance of reporting changes, and the avenues through which changes can be reported. In finalizing the policy as proposed, we do not specify that the Exchange will consider the statutory limits on repayment, as these limits are separate from the premium tax credit calculation itself, and are intended to be applied at the time of tax filing.

After considering the comments regarding the operational and administrative challenges involved with the alternative proposal, we decided to maintain the approach proposed. We believe that the comments received that questioned the benefits associated with the alternative on which we requested comment, combined with the operational concerns regarding how HHS would provide such retroactive payments to QHP issuers and the process through which QHP issuers would reimburse enrollees, outweigh the potential benefit for enrollees.

c. Administration of Advance Payments of the Premium Tax Credit and Cost-Sharing Reductions

Under our authority to administer the payment of cost-sharing reductions and advance payments of the premium tax credits conferred in section 1412 and the rulemaking authority conferred in section 1321(a) of the Affordable Care Act, we proposed to add two paragraphs to § 155.340. First, we proposed to add paragraph (e) to § 155.340, which would provide that if one or more individuals in a tax household who are eligible for advance payments of the premium tax credit collectively enroll in more than one policy through the Exchange (whether by enrolling in more than one policy under a QHP, enrolling in more than one QHP, or enrolling in one or more QHPs and one or more stand-alone dental plans) for any month in a benefit year, the Exchange would allocate the advance payment of the premium tax credit(s) in accordance with the methodology proposed in § 155.340(e)(1) and (2). Under that methodology, the Exchange must first allocate the portion of the advance payment of the premium tax credit(s) that is less than or equal to the aggregate adjusted monthly premiums for the QHP policies, as defined under 26 CFR 1.36B-3(e), properly allocated to EHB, among the QHP policies in proportion to the respective portions of the premiums for the policies properly allocated to EHB. Any remaining advance payment of the premium tax credit(s) must be allocated among the stand-alone dental policies in proportion to the respective portions of

the adjusted monthly premiums for the stand-alone dental policies properly allocated to the pediatric dental EHB. We provided additional detail on the allocation methodology in the proposed rule and welcomed comments on this proposal.

As discussed in greater detail below, we received a number of comments on the allocation of advance payments of premium tax credits among QHPs and stand-alone dental plans. We also received one comment expressing concern that the proposed allocation methodology was too complicated and may prevent consumers from selecting a plan or the plans that are in the household's best interest. In particular, the proposed pro rata distribution by premium delays the calculation of the allocation of the advance payments until after QHPs have been selected. This delay would prevent an Exchange from displaying the amount of premium that a household would pay out-of-pocket for each plan until all plans have been selected.

We do not want to restrict the way that an Exchange develops the consumer shopping experience, and therefore, considering the comment received on this approach, we are modifying the proposed rule and finalizing a policy to allow Exchanges greater flexibility in allocating the advance payment of the premium tax credit if the individuals in the tax filers' tax household(s) are enrolled in more than one QHP or stand-alone dental plan. Specifically, as finalized in § 155.340(e), if one or more advance payments of the premium tax credit are to be made on behalf of a tax filer (or two tax filers covered by the same plan(s)), and individuals in the tax filers' tax households are enrolled in more than one QHP or stand-alone dental plan, then the advance payment must be allocated as follows: (1) that portion of the advance payment of the premium tax credit that is less than or equal to the aggregate adjusted monthly premiums, as defined in 26 CFR § 1.36B-3(e), for the QHP policies properly allocated to EHB must be allocated among the QHP policies in a reasonable and consistent manner specified by the Exchange; and (2) any remaining advance payment of the premium tax credit must be allocated among the stand-alone dental policies (if any) in a reasonable and consistent manner specified by the Exchange. We do not choose to set specific parameters for the allocation approach; however, the Exchange must apply the same approach to all advance payments of the premium tax credit provided during a benefit year. We are also making some

clarifying modifications to the language of this provision.

For Federally-facilitated Exchanges, we establish a methodology at § 155.340(f) in which the advance payment of the premium tax credit is allocated based on the number of enrollees covered under the QHP or stand-alone dental policy, weighted by the age of the enrollees, using the default uniform age rating curve established by the Secretary of HHS under § 147.102(e) of the final Market Reform Rule.²⁴ If this methodology results in an advance payment of the premium tax credit allocation that exceeds a QHP's adjusted monthly premium properly allocated to EHB, the surplus advance payment of the premium tax credit will be allocated evenly to any of the other QHP policies, up to the applicable adjusted monthly premium properly allocated to EHB. And, in accordance with the general policy, any advance payment of the premium tax credit above the aggregate adjusted monthly premiums for the QHP policies properly allocated to EHB must be allocated among the stand-alone dental policies in a similar manner. We provide the following example:

- A family that is eligible for a premium tax credit and is made up of a child age 18 and two parents age 53 purchases two QHP policies and a stand-alone dental policy on an FFE. One parent and the child are enrolled in QHP A, with an adjusted monthly premium allocable to EHB of \$470. The other parent is enrolled in QHP B, with an adjusted monthly premium allocable to EHB of \$350. The child is enrolled in the stand-alone dental policy, with an adjusted monthly premium of \$20, with all \$20 allocable to EHB. The family receives a monthly advance payment of the premium tax credit equal to \$830. On an FFE, \$820 would be allocated between the two QHPs (that is, the portion of the advance payment of the premium tax credit that is less than or equal to the aggregate premiums for the QHP policies allocable to EHB), and the remainder (\$10) would be allocated to the stand-alone dental plan. Assuming the default uniform age curve requires rates for an individual aged 53 to be adjusted by 2.04, and rates for an individual aged 18 to be adjusted by 0.635, \$465 ($(820/(2.04 + 2.04 + 0.635)) * (2.04 + 0.635)$) would be allocated to

²⁴ We note that to simplify operations, even if a State establishes a uniform age rating curve as allowed under § 147.102(e), we will continue to use the default uniform age rating curve with a 3:1 ratio established by the Secretary of HHS for purposes of allocating advance payments of the premium tax credit.

QHP A and \$355 ($820/(2.04 + 2.04 + 0.635)) * 2.04$) would be allocated to QHP B. However, because \$355 exceeds the portion of QHP A's premium allocable to EHB, the surplus allocation (\$5) is shifted from QHP A to QHP B. Therefore, \$350 will be applied to the premium for QHP A, \$470 for QHP B, and \$10 for the stand-alone dental plan.

This approach will allow an FFE to determine the allocation of the advance payment of the premium tax credit prior to plan selection so that we may display the amount of premium that a household would pay out-of-pocket for each plan during the shopping experience. At the same time, this approach approximates an allocation based on premiums (prioritizing the QHP policies over the stand-alone dental plan coverage as we proposed). State-based Exchanges may choose to adopt the Federal methodology or another reasonable methodology under § 155.340(e) of this final rule.

Comment: We received a comment stating that the methodology proposed in § 155.340(e)(1) and (2) will be too complicated for the average consumer to understand, particularly for complex households. The proposed methodology would prevent an Exchange from displaying the amount of premium that a household would pay out-of-pocket for each plan until all plans have been selected. If out-of-pocket costs cannot be shown at a plan level prior to selection, consumers could be dissuaded from purchasing coverage or might select a single plan for all household members, even if doing so is not in the household's best interest. The commenter proposed that Exchanges allocate the advance payment of the premium tax credit(s) equally to each household member to allow consumers to view the amounts of advance payment of the premium tax credit(s) allocated to each QHP or stand-alone dental plan during the shopping experience, and to permit consumers to compare more effectively different plan options and family member groupings.

Response: We recognize the importance of providing a transparent and consumer-friendly shopping experience, and are modifying our proposal to allow Exchanges the flexibility to choose a reasonable allocation methodology. This policy would allow an Exchange to allocate the portion of the advance payment of the premium tax credit that is less than or equal to the aggregated adjusted monthly premiums for the QHP policies properly allocated to EHB among the QHPs using a per member approach. However, the Exchange must still allocate the remainder to the stand-

alone dental plan(s), though this portion may also be allocated using a per member approach.

The approach that will be used by FFEs to allocate the advance payment of the premium tax credit will allow the FFE to display the amount of premium that a household would pay out-of-pocket for each plan during the shopping experience. In addition, the FFE approach approximates an allocation based on premiums (prioritizing the QHP policies).

Comment: We received several comments regarding the methodology proposed in § 155.340(e)(2). Commenters noted that because we proposed that advance payments of the premium tax credit(s) be allocated first to QHP policies, and any remainder be allocated to stand-alone dental policies, it is unlikely that advance payments of the premium tax credit(s) will be available to offset the cost of the stand-alone dental policies. One commenter stated that advance payments of the premium tax credit(s) should be allocated pro rata among QHP policies and stand-alone dental policies according to premium to assist families with purchasing pediatric dental coverage, which is one of the essential health benefits. Another commenter suggested that advance payments of the premium tax credit(s) should be allocated first to any stand-alone dental policy, and the remainder allocated to the QHP(s). A third commenter stated that the cost to issuers of stand-alone dental policies to develop a process to accept advance payments of the premium tax credit(s) on behalf of enrollees outweighs the potential benefit, and consequently, advance payments of the premium tax credit(s) should only be allocated to QHP policies.

Response: We believe that advance payments of the premium tax credit(s) should first be allocated to QHP policies, and any remainder should be allocated to stand-alone dental policies. This approach will ensure that the majority of the tax credit is allocated to the most costly portion of an individual's coverage. While we understand the burden on stand-alone dental plans of implementing a process to accept the advance payments of the premium tax credit, we believe that consumers should not be required to wait until tax filing in order to receive the full amount of their premium tax credit benefit.

We are finalizing paragraph (e) with the changes from the proposed rule noted above. The second provision we proposed to add to § 155.340 was paragraph (f), now relabeled as

paragraph (g) in this final rule. The standards proposed in this paragraph are discussed below in section III.E.4.g.

2. Exchange Functions: Certification of Qualified Health Plans

We proposed to add § 155.1030 to set forth standards for Exchanges to ensure that QHPs in the individual market on the Exchange meet the requirements related to advance payments of the premium tax credit and cost-sharing reductions, as proposed in § 156.215 and described below. We proposed these standards under section 1311(c) of the Affordable Care Act, which provides for the Secretary to establish criteria for the certification of health plans as QHPs, as well as section 1321(a)(1), which provides general rulemaking authority for title I of the Affordable Care Act, including the establishment of programs for the provision of advance payments of the premium tax credit and cost-sharing reductions.

In § 155.1030(a)(1), we proposed that the Exchange ensure that each issuer that offers or seeks to offer a QHP in the individual market on the Exchange submit the required plan variations, as proposed in § 156.420, for each of its health plans proposed to be offered in the individual market on the Exchange and certify that the submitted plan variations meet the requirements of § 156.420. We expect that an Exchange would collect prior to each benefit year the information necessary to validate that the issuer meets the requirements for silver plan variations, as detailed in § 156.420(a), and collect for certification the information necessary to validate that the issuer meets the requirements for zero and limited cost sharing plan variations, as detailed in § 156.420(b). We proposed in § 155.1030(a)(2) that the Exchange provide the actuarial values of the QHPs and silver plan variations to HHS. As described in proposed § 156.430, HHS would use this information to determine the advance payments to QHP issuers for the value of the cost-sharing reductions.

In § 155.1030(b)(1), we proposed the Exchange collect and review certain information that an issuer must submit under § 156.470 that would allow for the calculation of the advance payments of cost-sharing reductions and the premium tax credit; in addition, the proposal would direct an Exchange to ensure that the allocations provided by the issuer are consistent with the standards identified in § 156.470(c)–(d). Specifically, in § 156.470(a), we proposed that an issuer provide to the Exchange annually for approval, for each metal level health plan (that is, a health plan at any of the four levels of

coverage, as defined in § 156.20) offered, or proposed to be offered, in the individual market on the Exchange, an allocation of the rate and the expected allowed claims costs for the plan, in each case, to: (1) EHB, other than services described in § 156.280(d)(1),²⁵ and (2) any other services or benefits offered by the health plan not described in clause (1). In the preamble to the proposed rule, we explained that the rate allocation information would allow the Exchange to calculate the percentage of the rate attributable to EHB; this percentage could then be multiplied by the adjusted monthly premium, as defined by 26 CFR 1.36B–3(e), and the monthly premium of the QHP in which the taxpayer enrolls, to calculate the premium assistance amount. The allocation of the expected allowed claims costs would be used to validate the rate allocation, and to calculate the advance payments for cost-sharing reductions as described in § 156.430.

In § 156.470(e), we further proposed that an issuer of a metal level health plan offered, or proposed to be offered, in the individual market on the Exchange also submit to the Exchange annually for approval, an actuarial memorandum with a detailed description of the methods and specific bases used to perform the allocations. The Exchange and HHS would use this memorandum to verify that the allocations meet the standards proposed in § 156.470(c). First, the issuer must ensure that the allocation is performed by a member of the American Academy of Actuaries in accordance with generally accepted actuarial principles and methodologies. Second, the rate allocation should reasonably reflect the allocation of the expected allowed claims costs attributable to EHB (excluding those services described in § 156.280(d)(1)). Third, the allocation should be consistent with the allocation of State-required benefits to be submitted by the issuer as proposed and finalized in § 155.170(c) of the final EHB/AV Rule, and the allocation requirements described in § 156.280(e)(4) for certain services. Fourth, the issuer should calculate the allocation as if it were a premium under the fair health insurance premium standards described at § 147.102, the single risk pool standards described at § 156.80, and the same premium rate standards described at § 156.255. We proposed this standard because we

²⁵ 45 CFR 156.280(e)(1)(i) provides that if a QHP provides coverage of services described in paragraph (d)(1) of that section, the QHP issuer must not use Federal funds, including advance payments of the premium tax credit or cost-sharing reductions, to pay for the services.

believe the allocation of rates should be performed consistent with the standards applicable to the setting of rates.

In § 156.470(b), we proposed somewhat similar standards for the allocation of premiums for stand-alone dental plans. Specifically, we proposed that an issuer provide to the Exchange annually for approval, for each stand-alone dental plan offered, or proposed to be offered, in the individual market on the Exchange, a dollar allocation of the expected premium for the plan, to: (1) the pediatric dental essential health benefit, and (2) any benefits offered by the stand-alone dental plan that are not the pediatric essential health benefit. As described in 26 CFR 1.36B-3(k), this allocation will be used to determine the premium tax credit, and thus the advance payment of the premium tax credit, available if an individual enrolls in both a QHP and a stand-alone dental plan. We noted that unlike issuers of metal level health plans, issuers of stand-alone dental plans would be required to submit a dollar allocation of the expected premium for the plan. We specified this because, unlike QHPs, issuers of stand-alone dental plans are not required to finalize premiums prior to the start of the benefit year. However, § 156.470(b) as proposed and finalized here directs stand-alone dental plan issuers to finalize the dollar amount of the premium allocable to the pediatric dental essential health benefit prior to the start of the benefit year to allow for the calculation of advance payments of the premium tax credit.

In § 156.470(e), we also proposed that issuers of stand-alone dental plans submit to the Exchange annually for approval an actuarial memorandum with a detailed description of the methods and specific bases used to perform the allocations, demonstrating that the allocations meet the standards proposed in § 156.470(d). These standards were similar to those proposed for issuers of metal level health plans offered or proposed to be offered as QHPs, with some adaptations specific to stand-alone dental plans. Specifically, in § 156.470(d)(1) and (2) we proposed that the allocation be performed by a member of the American Academy of Actuaries in accordance with generally accepted actuarial principles and methodologies, and be consistent with the allocation applicable to State-required benefits to be submitted by the issuer under § 155.170(c). In addition, in § 156.470(d)(3), we proposed that the allocation be calculated as if it were a premium subject to the fair health insurance premium standards at § 147.102 and the single risk pool

standards at § 156.80, as well as the same premium standard described at § 156.255. However, in § 156.470(d)(4) we provided a specific standard for age-adjustments to account for the fact that the dental essential health benefit only applies to the pediatric population. We also noted that issuers of stand-alone dental plans are not required to submit an allocation of their expected allowed claims costs because these plans are not eligible for cost-sharing reductions, as described in § 156.440(b).

In § 155.1030(b)(1), we proposed that the Exchange collect and review annually the rate or premium allocation, the expected allowed claims cost allocation, and the actuarial memorandum that an issuer submits, to ensure that such allocations meet the standards set forth in § 156.470(c) and (d). To ensure that the allocations are completed appropriately, we explained in the preamble to the proposed rule that we expect that the Exchange will review the allocation information in conjunction with the rate and benefit information that the issuer submits under § 156.210 as finalized in the Exchange Establishment Rule. In addition, an Exchange that coordinates its review of QHP rates and benefits with the State's Effective Rate Review program would be able to also coordinate the allocation review because the revised reporting requirements for issuers seeking to increase rates set forth in the Market Reform Rule at § 154.215(d)(3)-(4), and detailed in the accompanying PRA package, include the rate allocation and expected allowed claims cost allocation information. These reporting requirements will reduce the need for duplicate submissions by issuers and reviews by Exchanges. However, we noted that it is ultimately the responsibility of the Exchange to ensure that the issuer performs the allocations appropriately for each health plan or stand-alone dental plan that the issuer offers, or seeks to offer, on the individual market in the Exchange, including those that are not seeking to increase rates. Therefore, the preamble identified our expectation that Exchanges will collect the allocation information through either securing access to the data submission by QHP issuers for rate increases under § 154.215, or the QHP certification and annual submission process under parts 155 and 156, as appropriate.

In § 155.1030(b)(2), we proposed that the Exchange submit to HHS the approved allocation(s) and actuarial memorandum for each QHP and stand-alone dental plan. In paragraph (b)(4), we proposed authority for the use of this

data by HHS for the approval of the estimates that issuers submit for advance payments of cost-sharing reductions described in § 156.430, and for the oversight of the advance payments of cost-sharing reductions and premium tax credit programs.

In § 155.1030(b)(3), we proposed that the Exchange collect annually any estimates and supporting documentation that a QHP issuer submits to receive advance payments for the value of the cost-sharing reductions under § 156.430(a). The Exchange would then submit the estimates and supporting documentation to HHS for review. We clarified further that the Exchange would not review these estimates, and HHS's review would simply ensure that the estimates were developed in a manner consistent with the methodology established by HHS in the preamble to § 156.430(a) of this final rule, in keeping with HHS's obligation to safeguard Federal funds.

We are finalizing the provisions in § 155.1030 as proposed, with technical corrections to § 155.1030(a) and (b)(2). We replace the phrase, "The Exchange" in the beginning of proposed § 155.1030(a) with "An Exchange," to align with other provisions in part 155. We also replace the phrase "[an issuer] offers or seeks to offer" from the proposed rule with the phrase "[an issuer] offers, or intends to offer" in the final rule, to align with the language in § 156.430(a) requiring issuers to submit information for the advance payment of cost-sharing reductions; the scope of these regulatory requirements is intended to be the same. Similarly, we are making technical corrections to § 156.470(a), (b) and (e) to standardize the phrase describing the issuers who must comply with the rule as those issuers with plans "offered, or intended to be offered" on an Exchange.

We are also adding paragraph (c) to § 155.1030 and paragraph (f) to § 156.470 to clarify the application of these provisions to multi-State plans. Section 1334 of the Affordable Care Act directs OPM to enter into contracts with issuers to offer multi-State plans. Accordingly, OPM is responsible for ensuring that multi-State plans and their issuers comply with various Exchange standards, including standards relating to cost-sharing reductions and advance payments of the premium tax credit.

We are also finalizing the provisions proposed in § 156.470(a), (b), (c), (d)(1), and (e). To allow greater flexibility for stand-alone dental plan issuers in developing the allocation of dental premiums to EHB, we are not finalizing the allocation standards described in paragraphs (d)(2), (3), and (4) of the

proposed rule. We believe the allocation standard previously described in subparagraph (d)(1), which requires that the allocation be performed by a member of the American Academy of Actuaries in accordance with generally accepted actuarial principles and methodologies, is a sufficient standard for ensuring that stand-alone dental plan issuers allocate the premium accordingly. We intend to provide further details on the reporting process for stand-alone dental plan premium allocations for the FFE.

Comment: We received one comment in support of the provisions at § 155.1030 that all QHP issuers provide the plan variations as part of the certification process. We also received a comment requesting that HHS provide to issuers a good-faith compliance safe harbor on the new cost-sharing reductions standards and suggesting that this safe harbor could be revisited prior to the 2016 plan year.

Response: We will take the comment into consideration in future rulemaking on oversight functions.

Comment: In regard to § 156.470, we received a comment asking for one set of guidance on all actuarial data submissions required for QHP certification, rate review, and market stabilization. The commenter suggested that HHS develop a standard template for the annual actuarial memorandum with specific instructions on what data should be included in the actuarial memorandum. In addition, we received a specific comment asking for guidance on how issuers should allocate the cost of prescription drug essential health benefits.

Response: As discussed in the preamble of the proposed rule, we have attempted to streamline actuarial reporting requirements. In the Market Reform Rule, at § 154.215(d)(3)–(4), and detailed in the accompanying PRA package, we revised the reporting requirements for issuers seeking to increase rates to include the rate allocation and expected allowed claims cost allocation information that issuers of metal level health plans would submit to an Exchange under § 156.470(a) finalized here. We created a unified data template for the submission, as well as detailed instructions for completing the actuarial memorandum. We suggest that Exchanges require issuers not seeking rate increases, and stand-alone dental plan issuers who are not subject to the rate review program, to use similar reporting processes in order to submit the rate and claims cost allocation information to the Exchange under § 156.470 as finalized in this final rule.

In response to the specific comment asking for guidance on allocating the cost of prescription drug essential health benefits, we refer readers to § 156.122 of the final EHB/AV Rule, which specifies that for a plan to meet the EHB requirements, it must cover at least the greater of: (1) One drug in every category and class within the United States Pharmacopeia's (USP) classification system; or (2) the same number of drugs in each category and class as the EHB-benchmark plan. We do not specify a maximum number of drugs that a plan may cover. Therefore, when determining the claims costs for EHB, QHP issuers should include all prescription drug claims costs within the USP classification system, except for claims costs associated with drugs for services described in § 156.280(d)(1).

Comment: We received several comments relating to the provisions at § 156.470(b) and (d) on the allocation of premiums for stand-alone dental plans for purposes of calculating advance payments of the premium tax credit. One commenter stated that because stand-alone dental plans are exempt from the rating standards set forth in the final Market Reform Rule, issuers of stand-alone dental plans should not be required to follow such standards when determining the premium allocation. Another commenter supported the proposed policy because it provides equal treatment for the pediatric dental essential health benefit with other essential health benefits. However, the same commenter asked for clarification that this policy permits an issuer of a stand-alone dental plan to offer adult and family dental benefits through an Exchange so long as they are offered and priced separately. The commenter also asked for clarification of the definition of pediatric coverage and the standard proposed at § 156.470(d)(4), given that the final EHB/AV Rule specified that states may set alternative age limits for pediatric coverage.

Response: We agree that stand-alone dental plans, as defined at § 155.1065, are “excepted benefits” under section 2791(c) of the PHS Act, and clarify that issuers of stand-alone dental plans are not required to follow the rating standards set forth in the final Market Reform Rule for purposes of pricing stand-alone dental coverage. In addition, to allow greater flexibility in the implementation of the provisions in § 156.470 related to stand-alone dental plans, we are not finalizing the allocation standards proposed in paragraphs (d)(2), (3), and (4) of § 156.470. We believe the allocation standard proposed at § 156.470(d)(1), which requires that the allocation be

performed by a member of the American Academy of Actuaries in accordance with generally accepted actuarial principles and methodologies, is a sufficient standard for ensuring that issuers allocate the premium accordingly, so we are finalizing that provision in this final rule. We intend to provide further details on the reporting process for stand-alone dental plan premium allocations for the FFE.

3. QHP Minimum Certification Standards Relating to Advance Payments of the Premium Tax Credit and Cost-Sharing Reductions

Under HHS's rulemaking authority under sections 1311(c)(1), 1321(a)(1), 1402 and 1412 of the Affordable Care Act, we proposed to add § 156.215. This section would amend the QHP minimum certification standards and specify that an issuer seeking to offer a health plan on the individual market in the Exchange meet the requirements described in subpart E of part 156 related to the administration of advance payments of the premium tax credit and cost-sharing reductions. We proposed to add this section to clarify that compliance with part 156 subpart E, including the standards and submission requirements proposed at § 156.420 and § 156.470, is a requirement of QHP certification, and therefore, is included in the standard described at § 155.1000(b), under which an Exchange must offer only health plans that meet the minimum certification requirements. Under our proposal, continuing compliance with subpart E requirements by QHPs and QHP issuers is a condition of certification; failure to comply with the requirements could result in decertification of the QHP as well as other enforcement actions. This corresponds to the proposed addition of § 155.1030, which sets forth the Exchange responsibilities on certification with respect to advance payments of the premium tax credit and cost-sharing reductions (described previously). We received no comments on this provision. For the reasons described in the proposed rule, we are finalizing these provisions as proposed.

4. Health Insurance Issuer Responsibilities With Respect to Advance Payments of the Premium Tax Credit and Cost-Sharing Reductions

a. Definitions

Under § 156.400, we proposed definitions for terms that are used throughout subpart E of part 156. These terms apply only to subpart E. Some of these definitions cross-reference definitions elsewhere in parts 155 or

156, including some definitions set forth in the final EHB/AV Rule; the terms “advance payments of the premium tax credit” and “Affordable Care Act” were proposed as defined by reference to § 155.20, and the term “maximum annual limitation on cost sharing” was proposed as defined by reference to § 156.130 of the final EHB/AV Rule. The terms “Federal poverty level or FPL” and “Indian” were proposed to be defined by reference to § 155.300(a). The term “de minimis variation” was proposed to be defined by reference to § 156.140(c)(1) of the final EHB/AV Rule. We also proposed to define “stand-alone dental plan” as a plan offered through an Exchange under § 155.1065.

We proposed to rely on the definitions of “cost sharing” and “cost-sharing reductions” from § 156.20. Finally, we noted in the preamble to the proposed rule that cost-sharing reductions are subject to § 156.280(e)(1)(ii) and do not apply to benefits that are not EHB.

Other definitions were proposed to effectuate the regulations proposed in subpart E. These definitions were described in detail in the proposed rule and listed below for reference:

- We proposed to define “standard plan” as a QHP offered at one of the four levels of coverage, defined at § 156.140, with an annual limitation on cost sharing that conforms to the requirements of § 156.130(a). A standard plan at the bronze, silver, gold, or platinum level of coverage is referred to as a standard bronze plan, a standard silver plan, a standard gold plan, and a standard platinum plan, respectively.

- We proposed to define “silver plan variation” as, with respect to a standard silver plan, any of the variations of that standard silver plan described in § 156.420(a).

- We proposed to define “zero cost sharing plan variation” as, with respect to a QHP at any level of coverage, the variation of such QHP described in § 156.420(b)(1), which provides for the elimination of cost sharing for Indians based on household income level.

- We proposed to define “limited cost sharing variation” as, with respect to a QHP at any level of coverage, the variation of such QHP described in § 156.420(b)(2), which provides for the prohibition on cost sharing applicable to the receipt of benefits from IHS or certain other providers, irrespective of income level.

- We proposed to define “plan variation” as a zero cost sharing plan variation, limited cost sharing plan variation, or silver plan variation. We emphasized that the plan variations of

a QHP are not separate plans, but variations in how the cost sharing required under the QHP is to be shared between the enrollee(s) and the Federal government.

We proposed these definitions to administer and implement the cost-sharing reductions established under section 1402 of the Affordable Care Act. Although an issuer will only offer one actual QHP (for example, a standard silver plan) with one standard cost-sharing structure, we proposed the concept of plan variations to describe how certain eligible individuals will pay only a portion of the total cost sharing required under that QHP, with the Federal government bearing the remaining cost-sharing obligations under section 1402 of the Affordable Care Act.

To reflect how the Affordable Care Act creates different eligibility categories with different associated cost-sharing reductions, we proposed that each plan variation would reflect the enrollee’s portion of the cost sharing requirements for the QHP. We referred to “assigning” enrollees to the applicable plan variation to describe how the enrollees will receive the benefits described in section 1402 of the Affordable Care Act. We reiterated that these variations are not different QHPs and that a change in eligibility for cost-sharing reductions simply changes the enrollee’s responsibility for part of the total cost sharing under the same QHP.

In addition, we also proposed to define “de minimis variation for a silver plan variation” as a single percentage point. That is, we proposed that a 1 percentage point variation in the AV of a silver plan variation would not result in a material difference in the true dollar value of the silver plan variation. We noted that this proposal differed from the 2 percentage point de minimis variation standard for health plans finalized in § 156.140(c) of the final EHB/AV Rule.

We proposed to define “most generous” or “more generous” as, between a QHP (including a standard silver plan) or plan variation and one or more other plan variations of the same QHP, the QHP or plan variation designed for the category of individuals last listed in § 155.305(g)(3).

We proposed to define the “annual limitation on cost sharing” as the annual dollar limit on cost sharing required to be paid by an enrollee that is established by a particular QHP. We noted that this definition refers to the plan-specific cost-sharing parameters, while the defined term “maximum annual limitation on cost sharing” was proposed to refer to the uniform

maximum that would apply to all QHPs (other than QHPs with cost-sharing reductions) for a particular year under standards at § 156.130. Finally, we proposed to define the “reduced maximum annual limitation on cost sharing” as the dollar value of the maximum annual limitation on cost sharing for a silver plan variation that remains after applying the reduction in the maximum annual limitation on cost sharing required by section 1402 of the Affordable Care Act, as announced in the annual HHS notice of benefit and payment parameters. The reduced maximum annual limitation on cost sharing for each silver plan variation for 2014 was proposed in the preamble for § 156.420 of this Payment Notice. The reduced maximum annual limitation applies, as does the maximum annual limitation, only with respect to cost sharing on EHB, and does not apply to cost sharing on services provided by out-of-network providers. *See* § 156.20 (defining cost sharing) and § 156.130(c).

We are finalizing these provisions, with the following modification: we are amending the reference for the definition of the term “de minimis variation” to § 156.140(c) instead of § 156.140(c)(1), in alignment with the final EHB/AV rule. The reduced maximum limitation on cost sharing for each silver plan variation is finalized in section III.E.4.c. below.

Comment: Several commenters recommended that the de minimis variation for silver plan variations be increased to +/-2 percent as proposed in the AV/CSR Bulletin and proposed for standard plans under the final EHB/AV rule. Other commenters supported the +/-1 percent de minimis variation for silver plan variations.

Response: We believe that a narrower de minimis variation for plan variations prevents differences in cost sharing between plan variations and ensures that low- and moderate-income enrollees receive the cost-sharing reductions for which they are eligible. We believe that because cost-sharing reductions are reimbursed by the Federal government, the degree of flexibility afforded to issuers of silver plan variations in their cost-sharing design should be somewhat less. With this standard, we seek to balance the need to ensure that individuals receive the full value of the cost-sharing reductions for which they are eligible, and issuers’ ability to set reasonable cost-sharing requirements.

Comment: One commenter suggested we define “de minimis” variation to mean the allowable variation in the AV of a health plan such that the proportion

of EHB paid by the health plan is within the range established in § 156.140(c).

Response: The definition of *de minimis* variation is incorporated by reference to § 156.140(c) of the final EHB/AV rule. We do not believe that a separate definition of the term “*de minimis*” itself for the purpose of plan variations is warranted.

Comment: We received a number of comments requesting that cost-sharing reductions be limited to in-network services. One commenter opposed excluding out-of-network services from counting towards the annual limitation on cost sharing.

Response: As provided in § 156.130(c) of the final EHB/AV rule, in the case of a plan using a network of providers, cost sharing for services provided out of network do not count toward the annual limitation on cost sharing. We reference this definition and we note that cost-sharing requirements for out-of-network services will similarly not count towards a reduced annual limitation on cost sharing. We note, however, that section 1402(c)(2) of the Affordable Care Act does not specify how any additional reductions should be achieved for individuals eligible for cost-sharing reductions. We therefore clarify that in developing silver plan variations, issuers have the flexibility to reduce cost sharing only for in-network services as long as the required AV levels are achieved and the plan design does not violate the standards set forth in §§ 156.420(c)–(f).

b. Cost-Sharing Reductions for Enrollees

In § 156.410(a), we proposed that a QHP issuer must ensure that an individual eligible for cost-sharing reductions, as demonstrated by assignment to a particular plan variation, pay only the cost sharing required of an eligible individual for the applicable covered service under a plan variation. We also proposed in this paragraph that the enrollee receive this reduction in cost sharing when the cost sharing is collected, which might occur when the enrollee visits the emergency room for care. This proposal would apply to all forms of cost sharing, including copayments, coinsurance, and deductibles. Under our proposal, the QHP issuer would ensure that the enrollee is not charged any type of cost sharing after the applicable annual limitation on cost sharing has been met. Furthermore, we explained in the preamble that for services subject to cost sharing, an individual eligible for cost-sharing reductions would not be eligible for a reduced copayment or coinsurance rate until any applicable (potentially reduced) deductible has been paid. For

the reasons described in the proposed rule and considering the comments received, we are finalizing these provisions as proposed.

Comment: Several commenters supported this policy. One commenter was concerned that the reduced deductible must be applied before an enrollee becomes eligible for the cost-sharing reductions. Another commenter was concerned there could be confusion among providers about the amount of cost sharing to collect and suggested that HHS require QHP issuers to issue membership cards to enrollees that clearly explain the enrollee’s cost-sharing obligations.

Response: We believe it is appropriate for enrollees eligible for cost-sharing reductions to continue to be required to pay any applicable deductibles before taking advantage of other cost-sharing reductions. We recognize that QHP issuers will be required to supply providers with the necessary cost-sharing information to meet the obligation under § 156.410(a) of this final rule to ensure that the cost-sharing reductions are provided when the cost sharing is collected.

In § 156.410(b), we proposed that after a qualified individual makes a plan selection, a QHP issuer would assign the individual to the applicable plan variation based on the eligibility determination sent to the QHP issuer by the Exchange. We noted in preamble that the QHP issuer is entitled to rely upon the eligibility determination sent to the QHP issuer by the Exchange.

In § 156.410(b)(1), we proposed that a QHP issuer assign a qualified individual who chooses to enroll in a silver plan in the individual market in the Exchange to the silver plan variation for which the qualified individual is eligible. Comments on § 156.410(b)(2) and (3) are discussed below in the section of this final rule related to the special cost-sharing reduction rules for Indians. In § 156.410(b)(4), we proposed that a QHP issuer must assign an individual determined ineligible by the Exchange for cost-sharing reductions to the selected QHP with no cost-sharing reductions. We are finalizing these provisions without modification.

Comment: Commenters generally supported requiring QHP issuers to assign enrollees to the plan variation for which they are eligible. One commenter specifically suggested that Exchanges only display the plan variation of each QHP for which the consumer is eligible to avoid confusion.

Response: The standards set forth in § 156.420 ensure that consumers will be best served by being assigned to the most generous plan variation for which

they are eligible. Therefore, we encourage Exchanges to only display the variation of each QHP plan for which the consumer is eligible. As noted in the proposed rule, if an individual does not wish to receive cost-sharing reductions, the individual may elect to decline to apply for cost-sharing reductions.

c. Plan Variations

In § 156.420, we proposed that issuers submit to the Exchange for certification and approval the variations of the health plans that they seek to offer or continue to offer in the individual market on the Exchange as QHPs that include required levels of cost-sharing reductions. We further clarified that under our proposal, multi-State plans, as defined in § 155.1000(a), and CO-OP QHPs, as defined in § 156.505, would be subject to the provisions of this subpart. OPM will certify the plan variations of the multi-State plans and determine the time and manner for submission.

Sections 1402(a) through (c) of the Affordable Care Act direct issuers to reduce cost sharing for EHB for eligible insureds enrolled in a silver health plan with household incomes between 100 and 400 percent of the FPL, such that the plan’s share (before any reimbursement from HHS for cost-sharing reductions) of the total allowed costs of the benefits are a certain percentage (that is, the health plan meets a certain AV level). To achieve these AV levels, the law directs issuers to first reduce the maximum annual limitation on cost sharing. After the issuer reduces the annual limitation on cost sharing to comply with the applicable reduced maximum annual limitation, section 1402(c)(2) of the Affordable Care Act directs the Secretary to establish procedures under which an issuer is to further reduce cost sharing if necessary to achieve the specified AV levels.

For individuals with household incomes of 250 to 400 percent of the FPL, we noted that without any change in other forms of cost sharing, any reduction in the maximum annual limitation on cost sharing will cause an increase in AV. Therefore, we proposed not to reduce the maximum annual limitation on cost sharing for individuals with household incomes between 250 and 400 percent of the FPL. We are finalizing this policy as proposed, with the following modifications. We are adding a new paragraph (g) to clarify that OPM, rather than the Exchange, will determine the time and manner for multi-State plans to submit silver plan variations and zero and limited cost sharing plan variations for the purpose of certification.

Additionally, we note a technical correction with regard to the submission of plan variations under § 156.420(a); we replace the phrase “[an issuer] seeks to offer or to continue to offer” with the phrase “[an issuer] offers, or intends to offer,” to align with the language in § 156.430(a).

Comment: Two commenters recommended that HHS require plans to provide individuals with incomes between 250 percent and 400 percent of FPL the option of enrolling in a plan variation with a lower annual limitation on cost sharing and higher deductibles, copayments, and coinsurance in order to reach the statutorily required AV. Another commenter recommended that HHS rebate excess cost sharing for individuals between 250 percent and 400 percent of the FPL or work with IRS to issue a tax credit.

Response: As noted in the proposed rule, a reduction in the maximum annual limitation on cost sharing could require corresponding increases in other forms of cost sharing to maintain the statutorily required AV levels for individuals between 250–400 percent of FPL. Since we anticipate that most individuals would not be expected to reach the annual limitation on cost sharing, most individuals would be required to pay more up-front costs under such a cost-sharing structure. Furthermore, given the additional administrative burden required in designing and operating additional silver plan variations, we do not modify the proposed policy in this final rule. In addition, we do not believe we have the authority to provide individuals in this income range with an additional tax credit (beyond that provided for in sections 1401 and 1411 of the Affordable Care Act and section 36B of the Code).

For individuals with a household income of 100 to 250 percent of the FPL, we proposed an annual three-step process for the design of cost-sharing structures in the silver plan variations, as follows:

Step 1. In the first step, we identify in the annual HHS notice of benefit and payment parameters the maximum annual limitation on cost sharing applicable to all plans that will offer the EHB package.

Maximum Annual Limitation on Cost Sharing for Benefit Year 2014: As discussed in § 156.130(a) of the final EHB/AV Rule, the maximum annual limitation on cost sharing for 2014 is the dollar limit on cost sharing for high

deductible health plans set by the IRS under section 223(c)(2)(A)(ii) of the Code for 2014. The IRS will publish this dollar limit in the spring of 2013. However, to allow time for HHS to analyze the impact of the reductions in the maximum annual limitation on cost sharing on health plan AV levels, and to allow issuers adequate time to develop the cost-sharing structures of their silver plan variations for submission during the QHP certification process, we proposed to estimate the dollar limit for 2014. Based on the proposed methodology, we estimated that the maximum annual limitation on cost sharing for self-only coverage for 2014 will be approximately \$6,400 (the maximum annual limitation on cost sharing for other than self-only coverage for 2014 would be twice that amount, or \$12,800).²⁶ This estimate was developed and proposed for purposes of setting the reduced maximum annual limitation on cost sharing for silver plan variations. Under section 1302(c)(1)(A) of the Affordable Care Act, cost sharing incurred under plans offering EHB packages, as defined in § 156.20, in 2014 cannot exceed the limit set by the IRS under section 223(c)(2)(A)(ii)(I) and (II) of the Code for the 2014 plan year. For a benefit year beginning after 2014, the maximum annual limitation on cost sharing will equal the dollar limit for 2014 benefit year adjusted by a premium adjustment percentage determined by HHS, under section 1302(c)(4) of the Affordable Care Act. We plan to propose the premium adjustment percentage applicable to the 2015 benefit year in the next HHS notice of benefit and payment parameters.

Step 2. In the second step, we analyze the effect on AV of the reductions in the maximum annual limitation on cost sharing described in section 1402(c)(1)(A) of the Affordable Care Act. Under section 1402(c)(1)(B)(ii), we may adjust the reduction in the maximum annual limitation on cost sharing, if necessary, to ensure that the actuarial values of the applicable silver plan variations do not exceed the actuarial values specified in section 1402(c)(1)(B)(i). We proposed to describe these analyses and the reduced annual limitations on cost sharing for the three income categories in the annual HHS notice of benefit and payment parameters.

Reduced Maximum Annual Limitation on Cost Sharing for Benefit Year 2014.

As described in the proposed rule, for the 2014 benefit year, we analyzed the impact on the actuarial values of three model silver level QHPs of the reductions described in the Affordable Care Act to the estimated maximum annual limitation on cost sharing for self-only coverage for 2014 (\$6,400). These model plans were meant to represent the broad sets of plan designs that we expect issuers to offer at the silver level of coverage through an Exchange. All three model plans meet the actuarial value requirements for silver health plans, and start with an annual limitation on cost sharing equal to the estimated maximum annual limitation on cost sharing (\$6,400). The plan design features of the model QHPs were entered into the AV calculator developed by HHS.

As described in the preamble to the proposed rule, we determined that a reduction in the maximum annual limitation on cost sharing specified in the Affordable Care Act for enrollees with household incomes between 100 and 150 percent of the FPL ($\frac{2}{3}$ reduction), and 150 and 200 percent of the FPL ($\frac{2}{3}$ reduction), would not cause the AVs of any of the model QHPs to exceed the statutorily specified AV levels (94 and 87, respectively). In contrast, the reduction in the maximum annual limitation on cost sharing specified in the Affordable Care Act for enrollees with household incomes between 200 and 250 percent of FPL ($\frac{1}{2}$ reduction), did cause the AVs of the model QHPs to exceed the specified AV level of 73 percent. As a result, we proposed that QHP issuers only be required to reduce their annual limitation on cost sharing for enrollees in the 2014 benefit year with household incomes between 200 and 250 percent of FPL by approximately $\frac{1}{5}$, rather than $\frac{1}{2}$. We further proposed to moderate the reductions in the maximum annual limitation on cost sharing for all three income categories, as shown in Table 21, to account for any potential inaccuracies in our estimate of the maximum annual limitation on cost sharing for 2014, and unique plan designs that may not be captured by our three model QHPs. Based on this analysis, in Table 21, we proposed the following reduced maximum annual limitations on cost sharing for benefit year 2014:

²⁶ The methodology is discussed in detail at 77 FR 73171–73172 of the proposed rule.

TABLE 21—REDUCTIONS IN MAXIMUM ANNUAL LIMITATION ON COST SHARING FOR 2014

Eligibility category	Reduced maximum annual limitation on cost sharing for self-only coverage for 2014	Reduced maximum annual limitation on cost sharing for other than self-only coverage for 2014
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(i) (that is, 100–150 percent of FPL)	\$2,250	\$4,500
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(ii) (that is, 150–200 percent of FPL)	2,250	4,500
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(iii) (that is, 200–250 percent of FPL)	5,200	10,400

We proposed that QHP issuers may rely on the reduced maximum annual limitations on cost sharing published in the final HHS notice of benefit and payment parameters to develop their silver plan variations for the 2014 benefit year.

Step 3. In the proposed third step of the process for structuring cost sharing in the silver plan variations, a QHP issuer offering coverage in the individual market on an Exchange would be required to develop three variations of its standard silver plan—one each for individuals with household incomes between 100 and 150 percent of the FPL, 150 and 200 percent of the FPL, and 200 and 250 percent of the FPL—with each variation having an annual limitation on cost sharing that does not exceed the applicable reduced maximum annual limitation on cost sharing published in the annual HHS notice of benefit and payment parameters. If the application of the reduced annual limitation on cost sharing results in an AV for a particular silver plan variation that differs from the required 73, 87, or 94 percent AV level by more than the permitted amount (that is, the 1 percent de minimis amount for silver plan variations, subject to § 156.420(f), as described below), the QHP issuer would adjust the cost-sharing structure in that silver plan variation to achieve the applicable AV level.

We proposed specifications in § 156.420(a)(1) through (3) for the three silver plan variations, and proposed that they may deviate from the required AV levels by the de minimis variation for silver plan variations that is, 1 percentage point. We further proposed that issuers submit these silver plan variations annually to the Exchange for certification, prior to the benefit year. Under our proposal, silver plan variations would be approved annually even if the standard silver plan does not change, since the reduced maximum annual limitation on cost sharing may change annually due to the premium adjustment percentage. For the reasons

described in the proposed rule and considering the comments received and discussed below, we are finalizing these provisions, including the reductions in the maximum limitation on cost sharing for silver plan variations offered in the 2014, as proposed with certain clarifications.

Comment: One commenter noted that the IRS does not release the dollar limit on cost sharing until late spring and this would be too late for issuers to adjust their product designs to be compliant with the IRS limit and also meet State and Federal filing deadlines. The commenter suggested that HHS develop an estimate of the maximum annual limit on cost sharing that can be used as a safe harbor.

Response: We are finalizing the proposal to permit QHP issuers to rely on the reduced maximum annual limitations on cost sharing published in the final HHS notice of benefit and payment parameters to develop their silver plan variations for the 2014 benefit year. We plan to provide separate guidance on the maximum annual limitation on cost sharing for standard plans to QHP issuers seeking to participate in a Federally-facilitated Exchange consistent with the approach finalized in this Payment Notice.

Comment: One commenter recommended that the maximum annual limitation on cost sharing should be published no later than July 1 of the year prior to open enrollment, with a 45-day comment period.

Response: We understand the need for issuers and stakeholders to have adequate time to consider how the maximum annual limitation on cost-sharing should be applied in the development of plan variations. We note that in later benefit years, the maximum annual limitation on cost sharing will be established under a premium adjustment percentage established by HHS in the annual notice of benefit and payment parameters for the applicable plan year.

Comment: One commenter suggested that HHS should not adjust the

reductions in the maximum annual limitation on cost sharing, as these adjustments could affect other cost-sharing requirements that a State-based Exchange might put in place under its authority to develop certification standards, as described at § 155.1000(c)(2).

Response: We believe it is important to make these adjustments to ensure that issuers have flexibility when developing their plan designs. Without these adjustments, it could be difficult for issuers to achieve the required actuarial value levels for certain plan variations, while complying with other applicable rules on cost-sharing structures, such as the provision at § 156.420(e). Additionally, we anticipate working with States and Exchanges individually to address the interaction between the standards in the Payment Notice and any additional Exchange-specific certification standards.

Comment: One commenter suggested that when silver plan variations cannot be accommodated by the AV calculator, HHS should require that the AV determinations be certified by a member of the American Academy of Actuaries.

Response: We clarify that the definition of and standards for determining actuarial value in § 156.20 and § 156.135 of the final EHB/AV Rule apply to both standard plans and plan variations. Accordingly, if a health plan's design for plan variation is not compatible with the AV calculator, the issuer would be required to follow the processes specified in § 156.135(b) of the final EHB/AV Rule.

Comment: One commenter requested that HHS clarify which “desired metal tier” should be inputted into the AV calculator to determine the AV for the silver plan variations.

Response: We have designed the AV Calculator such that users may select the option to determine whether the plan design satisfies the plan variations standards finalized here. To use the AV Calculator to verify the AV of a plan variation, users should select the indicator that the plan meets the cost-

sharing reduction standard, and select the desired metal tier. In the below table, we provide guidance on which

metal tier should be chosen to align with the expected utilization for each plan variation. Additional information

on the AV Calculator can be found at <http://cciio.cms.gov/resources/regulations/index.html#pm>.

TABLE 22—DESIRED METAL TIER FOR SILVER PLAN VARIATION AV

Household income	Silver plan variation AV	Desired metal tier
100–150 percent of FPL	Plan Variation 94 percent	Platinum.
150–200 percent of FPL	Plan Variation 87 percent	Gold.
200–250 percent of FPL	Plan Variation 73 percent	Silver.

Comment: One commenter asked HHS to clarify how silver plan variations could be designed to be compatible with HSAs.

Response: We are considering this issue and will provide future guidance.

Comment: One commenter asked if HHS could make public its modeling regarding the expected rate of change in cost-sharing reduction eligibility within a plan year.

Response: HHS does not have such an analysis to share at this time.

Comment: Another commenter was concerned about the ability of States to supplement cost-sharing reductions under the proposed policy, and requested HHS give States that wish to supplement cost sharing the flexibility to determine whether issuers must offer all plan variations.

Response: We intend to work with States to assess how the requirements regarding plan variations would interact with any supplemental cost-sharing reductions a State intends to provide.

Comment: Several commenters recommended that HHS establish parameters for deductibles in silver plan variations. One commenter suggested that cost-sharing reductions to reach the required AV levels identified in § 156.420(a) should first be used to lower the deductible and then reduce coinsurance or copayments, and that enrollees should receive negotiated pharmacy prices during the deductible phase. The same commenter suggested waiving or reducing the deductible for outpatient pharmacy for individuals eligible for cost-sharing reductions and making cost-sharing reductions in the forms of lower coinsurance and copayments available to enrollees assigned to plan variations immediately. One commenter asked for allowances to be made to permit issuers to develop innovative plan designs.

Response: We believe that the standards we are finalizing strike the appropriate balance between protecting consumers and preserving QHP issuer flexibility. The standard in § 156.420(e) that cost sharing for a silver plan variation not exceed the corresponding

cost sharing for a standard silver plan or silver plan variation with a lower AV protects low-income populations who are assigned to plan variations. We also clarify that, for purposes of the plan variations, any cost sharing that an enrollee would have been required to pay under the standard plan, but was not required to pay under the plan variation, should not be applied to the annual limitation on cost sharing.

Comment: Several commenters sought clarification on whether issuers must submit a silver plan variation for every plan offered on the individual market.

Response: We clarify that for each silver health plan that an issuer offers, or intends to offer in the individual market on an Exchange, the issuer must submit the three silver plan variations. This policy will ensure that low-income individuals can receive cost-sharing reductions while enrolled in any silver level QHP offered through the Exchange, consistent with section 1402 of the Affordable Care Act.

Sections 156.420(b) and (d) are discussed below in section III.E.4.i. related to the special cost-sharing reduction rules for Indians.

In § 156.420(c) and (e), we proposed additional coverage standards for silver plan variations as part of implementing section 1402. In § 156.420(c), we proposed that silver plan variations cover the same benefits and include the same providers as the standard silver plan. We further proposed that silver plan variations must require the same out-of-pocket spending for benefits other than EHB. Lastly, we proposed that silver plan variations be subject to all requirements applicable to the standard silver plan (except for the requirement that the plan have an AV as set forth in § 156.140(b)(2) of the final EHB/AV Rule). This means, for example, that silver plan variations must meet standards relating to marketing and benefit design of QHPs, network adequacy standards, and essential community providers. Although these requirements are implicit because a plan variation is not a separate plan, we proposed these

requirements explicitly as regulatory standards to ensure that QHP issuers develop appropriate plan variations.

In § 156.420(e), we proposed a standard to govern the design of cost-sharing structures for silver plan variations. Under this approach, the cost sharing for enrollees under any silver plan variation for an EHB from a provider may not exceed the corresponding cost sharing in the standard silver plan or any other silver plan variation of the standard silver plan with a lower AV. This proposed standard would apply to all types of cost-sharing reductions, including reductions to deductibles, coinsurance, and co-payments. An issuer would have the flexibility to vary cost sharing on particular benefits or providers so long as that cost sharing did not increase for a particular benefit or provider in higher AV silver plan variations. For the reasons described in the proposed rule and considering the comments received, we are finalizing these provisions in paragraphs (c) and (e) as proposed.

Comment: A number of commenters supported the requirement that silver plan variations cover the same benefits and include the same providers as the standard silver plan. Several commenters also generally supported the proposal that the cost sharing for enrollees under any silver plan variation for an EHB from a provider may not exceed the corresponding cost sharing in the standard silver plan or any other silver plan variation of the standard silver plan with a lower AV. One commenter supported allowing QHP issuers to have greater flexibility to vary cost-sharing structures across plan variations, and asked for clarification on whether QHP issuers can continue to use medical management policies for silver plan variations. Another commenter asked whether issuers may switch between copayments and coinsurance for silver plan variations as long as the cost sharing in aggregate does not exceed that of plans with lower actuarial values.

Response: We are finalizing the policy as proposed at § 156.420(e). We intend

to interpret and enforce this provision such that a QHP issuer may not switch between copayments and coinsurance for silver plan variations for the same benefit. We believe that allowing this type of substitution could result in an enrollee being subject to greater cost sharing under a plan variation with a higher AV, which § 156.420(e) is intended to prohibit. However, this provision does not limit an issuer's ability to appropriately use reasonable medical management techniques in managing costs consistently in its silver plan variations. We also direct the commenter's attention to § 156.125(c) of the final EHB/AV Rule, which codifies this protection in connection with anti-discrimination requirements, and section 1563(d) of the Affordable Care Act.

In § 156.420(f), we proposed that, notwithstanding the permitted de minimis variation in AV for a health plan or the permitted de minimis variation for a silver plan variation, the AV of the standard silver plan (which must be 70 percent plus or minus 2 percentage points) and the AV of the silver plan variation applicable to individuals with household incomes between 200 and 250 percent of the FPL (which must be 73 percent plus or minus 1 percentage point) must differ by at least 2 percentage points. We are finalizing the provision as proposed.

Comment: Several commenters supported this requirement. Another commenter was concerned about the ability of issuers to create a viable 73 percent plan variation given the number of plan design constraints.

Response: We believe that a 2 percentage point differential will ensure that a difference in cost-sharing reductions provided to each income category is maintained, while providing issuers the flexibility to adjust cost-sharing requirements within these standards.

d. Changes in Eligibility for Cost-Sharing Reductions

In § 156.425(a), we proposed that if the Exchange notifies a QHP issuer of a change in an enrollee's eligibility for cost-sharing reductions (including a change following which the enrollee will not be eligible for cost-sharing reductions), then the QHP issuer must change the individual's assignment so that the individual is assigned to the applicable standard plan or plan variation. We also proposed that the QHP issuer effectuate the change in eligibility in accordance with the effective date of eligibility provided by the Exchange. We explained in preamble that an Exchange would

establish such dates under § 155.330(f). We noted that if an enrollee changes QHPs after the effective date of the eligibility change as the result of a special enrollment period, once the Exchange notifies the issuer of the new QHP of the enrollment, that QHP issuer must assign the enrollee to the applicable standard plan or plan variation of the QHP selected by the enrollee, consistent with § 156.410(b). We are finalizing these provisions as proposed.

Comment: Commenters generally supported the policy, but several stated that a change in an enrollee's eligibility for cost-sharing reductions should only be applied prospectively. One commenter requested that HHS clarify that cost-sharing reductions would not be available until the first day of the following month, to eliminate the need to re-adjudicate claims. Another commenter suggested that if retroactive changes in eligibility for cost-sharing reductions are permitted, only claims the issuer receives after the effective date of the new assignment should be processed under the new cost-sharing requirements.

Response: We are finalizing the policy as proposed. This policy aligns with the eligibility standards and effective dates proposed for the amendment at § 155.330(f) of the proposed Medicaid and Exchange Eligibility Appeals and Notices Rule, which aim to reduce the need for retroactive eligibility changes for cost-sharing reductions, except in certain limited scenarios, discussed in that rule.

Comment: One commenter recommended that HHS ensure that individuals who are not assigned to the applicable plan variation in a timely manner should be refunded any cost sharing they should not have been responsible for after the effective date of the eligibility change.

Response: We believe that it is important that eligible individuals receive the appropriate cost-sharing reductions as of the effective date required by the Exchange. As noted in the proposed rule, an individual would not be penalized based on changes in eligibility for cost-sharing reductions during the benefit year, although he or she would be ineligible for any refund on cost sharing to the extent the newly applicable deductible or annual limitation on cost sharing is exceeded by prior cost sharing.

Comment: We received a comment seeking clarification that the QHP issuer be held harmless for any cost-sharing reductions provided beyond the enrollee's actual eligibility level so long as the QHP issuer makes assignments

and reassignments in accordance with Exchange instructions.

Response: We reiterate that our final rule requires a QHP issuer to follow the eligibility instructions from an Exchange in ensuring the provision of cost-sharing reductions and plan variation assignments under § 156.410(a) and § 156.425. Therefore, a QHP issuer may rely upon the eligibility determination sent by the Exchange. If a QHP issuer does not receive notification of an eligibility redetermination, the QHP issuer would not be permitted to re-assign the enrollee to a different plan variation or standard plan.

In § 156.425(b), we proposed that in the case of a change in assignment to a different plan variation (or standard plan without cost-sharing reductions) of the same QHP in the course of a benefit year (including in the case of a re-enrollment into the QHP following enrollment in a different plan), the QHP issuer must ensure that any cost sharing paid by the applicable individuals under the previous plan variations (or standard plan without cost-sharing reductions) is accounted for in the calculation of deductibles and annual limitations on cost sharing in the individual's newly assigned plan variation (or standard plan without cost sharing) for the remainder of the benefit year. As discussed above, we noted in the preamble that a change from or to an individual or family policy of a QHP due to the addition or removal of a family member does not constitute a change in plan for the family members originally on the individual or family policy. We are finalizing these provisions as proposed.

Comment: One commenter suggested that enrollees not be permitted to switch QHPs as a result of a mid-year change in eligibility for cost-sharing reductions, because an enrollee could mistakenly forfeit credit for previously paid cost sharing. Another commenter suggested that Exchanges be required to explain to consumers the policy relating to continuity of deductibles and annual limitations on cost sharing and the implications of switching QHPs mid-year.

Response: Prohibiting enrollees from switching QHPs would conflict with § 155.420(d)(6) of the Exchange Establishment Rule, which allows an individual who has a change in eligibility for cost-sharing reductions to enroll in or change from one QHP to another during a special enrollment period. We note that enrollees may choose a plan variation of the same QHP in order to ensure that any cost sharing previously paid by the individual is

taken into account. We encourage Exchanges to provide information to consumers on this topic.

Comment: One commenter asked HHS to consider instituting safe harbors if the enrollee already met the annual limit on cost sharing, but due to lags in data the QHP is not informed.

Response: We appreciate the difficulties caused by lags in data, and anticipate consulting with stakeholders to provide guidance on these sorts of operational issues.

Comment: One commenter requested an example to illustrate whether an individual will be required to satisfy the additional deductible amount when moving to a plan with a higher deductible. Another commenter recommended that deductible amounts carried forward to a policy with a lower deductible be counted towards the annual limitation on cost sharing.

Response: In accordance with the rule finalized here at § 156.425(b), as long as the change of assignment is to a different plan variation of the same QHP, any cost sharing paid by the applicable individual under the previous plan variation must be taken into account. This requirement would also apply to Indians who change plan variations within the same QHP as a result of a change in income, such as an Indian who moves from a limited cost sharing plan variation to a zero cost sharing plan variation, and then returns to the limited cost sharing plan variation of the same QHP.

Furthermore, as noted in the proposed rule, an individual eligible for cost-sharing reductions would not be eligible for a reduced copayment or coinsurance until the applicable deductible has been met. For example, if the individual satisfies a \$500 deductible and pays \$100 in co-payments in one plan variation, then moves to a different plan variation of the same QHP with a \$750 deductible as a result of a change in eligibility, the plan would apply \$600 towards the new deductible and the individual would need to satisfy the remaining \$150 of the new deductible to be eligible for the reduced co-payment or coinsurance. Conversely, if an enrollee satisfies a \$900 deductible in a standard plan and then moves to a plan variation of the same QHP with a \$750 deductible as a result of a change in eligibility, the additional \$150 the individual already paid must be applied towards the reduced annual limitation on cost sharing of the new plan variation. However, as we explained in connection with this proposal, the enrollee would not receive a rebate for the amount already paid above the deductible for the new plan variation.

Comment: One commenter sought clarification on how the requirements for continuity of deductibles and the annual limitation on cost sharing would apply if a QHP enrollee becomes eligible for Medicaid, and then later, re-enrolls in the QHP. The same commenter asked how the policy would apply if the individual switches to a different QHP.

Response: As noted in the proposed rule, the requirement regarding the continuity of deductibles and out-of-pocket maximums would apply as long as the change in assignment is to a different plan variation of the same QHP. We interpret this to include re-enrollment into the QHP following enrollment in a different QHP or another type of coverage such as Medicaid within the coverage year. As we also noted in the proposed rule, the QHP issuer is not prohibited from or required to extend the continuity of deductibles and annual limitations on cost sharing policy to situations in which the individual changes QHPs, but is *permitted* to extend this policy, provided that this extension of the policy is applied across all enrollees in a uniform manner.

Comment: One commenter sought clarification on how the proposed policy will affect the reconciliation of advance payments of cost-sharing reductions with actual payments.

Response: Under the reconciliation policy finalized in this rule, cost-sharing reductions properly provided in accordance with this rule will be reimbursed. Thus, if an enrollee changes plan variations mid-year and is properly credited with amounts previously accumulated towards a deductible, then cost-sharing reductions on copayments and coinsurance that are provided because the deductible under the new plan variation is reached more quickly are reimbursable as part of reconciliation.

e. Payment for Cost-Sharing Reductions

We proposed to implement a payment approach under which we would make monthly advance payments to issuers to cover projected cost-sharing reduction amounts, and then reconcile those advance payments at the end of the benefit year to the actual cost-sharing reduction amounts.²⁷ This approach fulfills the Secretary's obligation to make "periodic and timely payments equal to the value of the reductions" under section 1402(c)(3) of the Affordable Care Act. We expect that this

²⁷ We noted that these payments (both advance and reconciled), and the estimated or actual cost-sharing reductions underlying them, are subject to 45 CFR 156.280(e)(1)(ii).

approach would not require issuers to fund the value of any cost-sharing reductions prior to reimbursement. This approach is similar to the one employed for the low-income subsidy under Medicare Part D.

We are finalizing our payment approach as proposed with five specific modifications. The first two modifications relate to reimbursement for cost-sharing reductions for Indians, which are discussed in section III.E.4.i. of this final rule. The third modification is the addition of paragraph § 156.430(a)(4), clarifying that issuers of multi-State plans must provide the estimates described in paragraphs (1) and (2) of § 156.430(a) to OPM, rather than the Exchange, in the time and manner established by OPM. The fourth modification authorizes HHS to adjust the advance payments for cost-sharing reductions during the benefit year. As we acknowledged in the proposed rule, QHP issuers will have access to limited data on its expected enrollees prior to 2014, which could reduce the accuracy of the estimates used to develop the advance payment amounts. Because we wish to use the advance payment process to protect QHP issuers from being required to bear the entire financial burden of providing cost-sharing reductions over the benefit year, we are finalizing a change from the proposed rule to authorize HHS to adjust the advance payments if the QHP issuer provides evidence, certified by a member of the American Academy of Actuaries in accordance with generally accepted actuarial principles and methodologies, that the advance payments for a particular QHP are likely to be substantially different than the cost-sharing reduction amounts provided by the issuer that will be reimbursed by HHS after the end of the year during the reconciliation process. We discuss this policy further below in relation to § 156.430(b).

The fifth modification is to § 156.430(c). As discussed below, we are preserving the intent of the provisions proposed at § 156.430(c)(1) and (2) in finalized paragraphs (c)(1), (2) and (5). This restructuring allows for the addition of paragraphs (c)(3), and (4), which are established in an interim final rule with comment published elsewhere in this issue of the **Federal Register**. In that interim final rule with comment, we describe an approach that would permit a QHP issuer to calculate the value of the cost-sharing reductions provided under the methodology described in this final rule at § 156.430(c)(2), or to use an alternative, simplified methodology, under which the QHP issuer would calculate the

value of the cost-sharing reductions provided using certain summary cost-sharing parameters. As discussed below and in that interim final rule with comment, we believe this flexibility to use an alternative methodology will reduce the administrative burden on QHP issuers.

Comment: We received several comments on our proposed payment approach. One commenter supported our proposal to provide advance payments and then reconcile those advance payments at the end of the benefit year to the actual cost-sharing reduction amounts. Another commenter suggested that the advance payment and reconciliation process would be too cumbersome and instead, HHS should simply reimburse issuers at the end of the year for the actual value of cost-sharing reductions provided. A third commenter agreed that an annual reconciliation process would be burdensome, and suggested that in the initial years the submission of data on the amount of cost-sharing reductions provided and the reconciliation of payments should be optional. These commenters urged that in future years, HHS should reimburse based on monthly estimates of the amount of cost-sharing reductions provided.

Response: We discuss below, in relation to § 156.430(c) and (d), our approach for addressing commenters' concerns regarding the submission of the amount of cost-sharing reductions provided and the reconciliation process.

To implement our proposed payment approach, in § 156.430(a)(1)(i) through (iv), we proposed that for each health plan that an issuer offers, or intends to offer, in the individual market on the Exchange as a QHP, the issuer must provide to the Exchange annually prior to the benefit year, for approval by HHS, an estimate of the dollar value of the

cost-sharing reductions to be provided over the benefit year. If the QHP is a silver health plan, the submission must identify separately the per member per month dollar value of the cost-sharing reductions to be provided under each silver plan variation identified in § 156.420(a)(1), (2), and (3). And for each QHP, regardless of metal level, the submission must identify the per member per month dollar value of the cost-sharing reductions to be provided under the zero cost sharing plan variation. In addition, the estimate should be accompanied by supporting documentation validating the estimate. We expect that Exchanges will collect this information from issuers through the QHP certification process or an annual submission process, and then send the information to HHS for review as required by § 156.1030(b)(3) finalized under this rule. Sections 156.430(a)(1)(ii) and 156.430(a)(2) are further described in section III.E.4.i. of this final rule.

We further proposed that issuers develop the estimates using the methodology specified by HHS in the applicable annual HHS notice of benefit and payment parameters. In § 156.430(a)(3), we proposed that HHS approve estimates that follow this methodology. For the 2014 benefit year, we proposed that issuers use a methodology that utilizes the data that issuers submit under § 156.420 and § 156.470. As a result, issuers would not be required under this proposal to submit any additional data or supporting documentation to receive advance payments in benefit year 2014 for the value of the cost-sharing reductions that would be provided under silver plan variations.

Methodology for Developing Estimate of Value of Cost-Sharing Reductions for

Silver Plan Variations for 2014 Benefit Year.

For the 2014 benefit year, we proposed that advance payments be estimated on a per enrollee per month basis using the following formula:

Per Enrollee Per Month Advance Payment = Monthly Expected Allowed Claims Costs for Silver Plan Variation × (Silver Plan Variation AV – Standard Plan AV)

In this formula, the monthly expected allowed claims cost for a silver plan variation would equal one-twelfth of the annual expected allowed claims costs allocated to EHB, other than services described in § 156.280(d)(1),²⁸ for the standard silver plan, multiplied by a factor to account for the increased utilization that may occur under the specific plan variation due to the reduced cost-sharing requirements. As proposed in § 156.470, the QHP issuer would submit the expected allowed claims cost information to the Exchange annually. The Exchange would then review this estimate, and submit the approved information to HHS, as described in § 155.1030(b)(2) above, for use in the advance payment calculation. HHS would then multiply the monthly expected allowed claims cost by one of the following induced utilization factors, to arrive at the monthly expected allowed claims cost for the particular plan variation. We proposed the following induced utilization factors based on our analysis of the expected difference in expenditures for enrollees in QHPs of different actuarial values. For this analysis, we used the Actuarial Value Calculator, developed by HHS using the Health Intelligence Company, LLC (HIC) database from calendar year 2010.²⁹

TABLE 23—INDUCED UTILIZATION FACTORS FOR PURPOSES OF COST-SHARING REDUCTION ADVANCE PAYMENTS

Household income	Silver plan AV	Induced utilization factor
100–150 percent of FPL	Plan Variation 94 percent	1.12
150–200 percent of FPL	Plan Variation 87 percent	1.12
200–250 percent of FPL	Plan Variation 73 percent	1.00

In the second half of the formula, we proposed the multiplication of the monthly expected allowed claims cost for the particular plan variation by the difference in AV between the standard silver plan and the plan variation. We

proposed to use the actuarial values of the QHPs and silver plan variations that the Exchange will submit to HHS under § 155.1030(a)(2).

We are finalizing the methodology for determining advance payments for the

2014 benefit year as proposed. As noted above, we are also adding paragraph (4) to § 156.430(a), clarifying that issuers of multi-State plans must provide the estimates described in paragraphs (1)

²⁸ Based on the definition of “cost sharing” in 45 CFR 156.20 and limits on cost-sharing reductions in section 1402(c)(4) of the Affordable Care Act, cost-sharing reductions are only provided on EHB. In

addition, § 156.280(e)(1)(i) states that if a QHP provides coverage of services described in paragraph (d)(1) of that section, the QHP issuer

must not use Federal funds, including cost-sharing reductions, to pay for the service.

²⁹ <http://cciio.cms.gov/resources/regulations/index.html#pm>.

and (2) of § 156.430(a) to OPM, in the time and manner established by OPM.

In § 156.430(b), we proposed making periodic advance payments to issuers based on the approved advance estimates provided under § 156.430(a) and the actual enrollment information. We proposed to use the methodology described above to determine the amount of these advance payments. We are finalizing the provisions at § 156.430(a) and (b) relating to the advance payments as proposed, with the following modification. In response to comments discussed below, we are adding subparagraph (b)(2) in the final rule to authorize HHS to adjust the advance payment amount for a particular QHP during the benefit year if the QHP issuer provides evidence, certified by a member of the American Academy of Actuaries in accordance with generally accepted actuarial principles and methodologies, that the advance payments for a particular QHP are likely to be substantially different than the cost-sharing reduction amounts that the QHP provides that will be reimbursed by HHS. Although QHP issuers will be made whole for the value of all cost-sharing reductions provided through the reconciliation process after the close of the benefit year, we recognize that in certain situations, QHP issuers may require adjustments to the advance payments during the benefit year. We do not include in this final rule a formal process for the submission of information for the adjustment of advance payments because we believe the need for an adjustment will be rare, and the circumstances necessitating the adjustment will likely be unique to each QHP issuer. HHS is also considering other mechanisms for mid-year adjustments to advance payments to ensure that QHP issuers are provided sufficient advance payments and to safeguard Federal funds. We anticipate providing further details on such mechanisms in future rulemaking. We also anticipate working closely with QHP issuers in order to monitor whether the advance payments are likely to be significantly greater than or less than the reconciled cost-sharing reduction amounts.

Comment: We received several comments on the methodology for developing estimates of the value of cost-sharing reductions for advance payments. One commenter stated that the formula appeared to be appropriate and will likely result in accurate estimates. However, the commenter was concerned that the formula could produce results that vary based on member rating factors.

Response: As discussed in the proposed Payment Notice in regard to the submission of the expected allowed claims costs under § 156.470(a) and (c), which is the basis of the proposed methodology for estimating the value of cost-sharing reductions, we expect issuers to calculate the expected allowed claims cost for a plan based on the cost of the EHB for all enrollees in all plans in the relevant risk pool under § 156.80 of the final Market Reform Rule, and not across a standardized population or a plan-specific population. This approach should average the effects of the allowable rating factors on plan liability. Therefore, we believe the results of the formula will be appropriately adjusted for the allowable rating factors.

Comment: Although commenters generally supported adjusting the expected allowed claims costs by an induced utilization factor, one commenter stated that the proposed factors do not adequately account for changes in utilization as enrollees in plan variations may also use more high-cost services.

Response: We recognize that additional adjustments are necessary to account for the expected increased utilization of enrollees in plan variations, and as a result created a cost-sharing reduction adjustment for the HHS risk adjustment model. As described in section III.B.3.b. of this final rule, this factor will help compensate QHP issuers with a high number of enrollees that qualify for cost-sharing reductions.

Comment: We received comments asking for additional detail on the process that HHS will use to approve the advance payment amounts. One commenter asked that issuers be permitted to make adjustments to the advance payment amounts to account for enrollment fluctuations or changing demographics of their enrolled population. Another commenter suggested that a process be developed to handle discrepancies in the advance payments on a prospective basis.

Response: Section 156.430(a)(3) as finalized here states that HHS's approval of the advance payment amounts will be based on whether the estimate is made consistent with the methodology specified in the HHS notice of benefit and payment parameters.

In addition, as discussed above, in response to the comments received, we are finalizing an additional provision to allow HHS to adjust the advance payment amount for a particular QHP during the benefit year if the QHP issuer provides evidence that meets certain

standards. The addition of subparagraph (b)(2) aligns with our goal to reduce the financial burden resulting from cost-sharing reductions on QHP issuers during the benefit year, our proposal to perform periodic reconciliations, and the comments received.

In § 156.430(c), we proposed that a QHP issuer report to HHS the actual amount of cost-sharing reductions provided for use by HHS under § 156.430(d) in performing periodic reconciliations of the advance payments to the cost-sharing reductions actually provided. We noted that additional specifications regarding the submission of actual cost-sharing reduction amounts will be provided in future guidance; however, the preamble indicated our expectation that QHP issuers will submit the actual amount of cost-sharing reductions provided after the close of the benefit year. In § 156.430(c)(1) and (c)(2), we proposed specific standards for the reporting of cost-sharing reduction amounts. In § 156.430(c)(1), we proposed that in the case of a benefit for which the QHP issuer compensates the applicable provider in whole or in part on a fee-for-service basis, the QHP issuer submit the total allowed costs for essential health benefits charged for an enrollees' policy for the benefit year, broken down by what the issuer paid, what the enrollee paid, and the amount reimbursed to the provider for the amount that the enrollee would have paid under the standard QHP without cost-sharing reductions. In § 156.430(c)(2), we proposed that in the case of a benefit for which the QHP issuer compensates the applicable provider in any other manner (such as on a capitated basis), the QHP issuer submit the total allowed costs for essential health benefits charged for an enrollees' policy for the benefit year, broken down by what the issuer paid, what the enrollee paid, and the amount that the enrollee would have paid under the standard QHP without cost-sharing reductions. When we referred to compensation made on a capitated basis in this context, we meant a compensation model under which issuers make payments to providers based on a contracted rate for each enrollee, commonly referred to as a "per-member-per-month" rate, regardless of the number or type of services provided. We noted that a non-fee-for-service provider is not required to be reimbursed by the issuer. However, we indicated that we expected that issuers and providers in non-fee-for-service arrangements would make available to providers compensation for

cost-sharing reductions through their negotiated capitation payments. We sought comments on this assumption and other payment approaches for QHPs that use a capitated system to pay providers.

In § 156.430(d), we proposed to periodically reconcile advance payments to issuers against the actual cost-sharing reduction amounts reported under § 156.430(c). Thus, where a QHP issuer compensates a provider in whole or in part on a fee-for-service basis, we would reconcile the advance payments provided to the issuer against the actual amount of cost-sharing reductions reimbursed to providers and provided to enrollees. Where the QHP issuer compensates a provider under another arrangement, such as a capitated arrangement, we would reconcile the advance payments made to issuers against the actual cost-sharing reduction amounts provided to enrollees.

We are finalizing paragraph (d) as proposed. However, as noted before, we are modifying § 156.430(c). We are preserving the intent of the provisions proposed at § 156.430(c)(1) and (2), but restructuring the provisions into finalized paragraphs (c)(1), (2) and (5). This restructuring allows for the addition of paragraphs (c)(3) and (4), which are established in an interim final rule with comment published elsewhere in this issue of the **Federal Register**, and discussed below.

In this final rule, we simplify the language proposed at § 156.430(c)(1) so that it applies to all benefits, including those for which the QHP issuer compensates the applicable provider in a manner other than fee-for-service. Specifically, we establish that a QHP issuer, for each plan variation that it offers on the Exchange, submit to HHS, in the manner and timeframe established by HHS, for each policy, the total allowed costs for EHB charged for the policy for the benefit year, broken down by: (i) The amount the issuer paid; (ii) the amount the enrollee(s) paid; and (iii) the amount the enrollee(s) would have paid under the standard plan without cost-sharing reductions. In paragraph (c)(2), we codify in regulation text the methodology discussed in the preamble of the proposed rule for calculating the amount the enrollee(s) would have paid under the standard plan without cost-sharing reductions. We specify that QHP issuers must apply the actual cost-sharing requirements for the standard plan to the allowed costs for EHB under the enrollee's policy for the benefit year.

Lastly, we establish in paragraph (c)(5) that in the case of a benefit for which the QHP issuer compensates an

applicable provider in whole or in part on a fee-for-service basis, allowed costs associated with the benefit may be included in the calculation of the amount that an enrollee(s) would have paid under the standard plan without cost-sharing reductions only to the extent the amount was either payable by the enrollee(s) as cost sharing under the plan variation or was reimbursed to the provider by the QHP issuer. This provision has the same effect as the language in § 156.430(c)(1) of the proposed rule. Although we do not specify a similar provision for issuers and providers in non-fee-for-service arrangements, we expect that those issuers will compensate providers for cost-sharing reductions through other payment processes.

Comment: We received a number of comments stating that the reporting requirements under § 156.430(c) are too burdensome. Commenters noted that although the reporting and reconciliation process is appropriate for the Medicare Part D Low-Income Subsidy Program, medical benefits are more complex than pharmaceutical benefits and often have a longer lag between submission and adjudication. Commenters stated that to meet the reporting requirements under § 156.430(c), QHP issuers would need to re-adjudicate each claim for enrollees receiving cost-sharing reductions in order to determine the difference in cost sharing between the applicable plan variation and the standard plan. This process could require the development of new information systems in a short period of time. One commenter stated that QHP issuers could provide HHS with access to member-level claims data for enrollees receiving cost-sharing reductions through a distributed data model, similar to the approach used for the risk adjustment program. The commenter stated that this would simplify administrative processes and provide issuers with more time to modify their IT systems. We also received several comments suggesting that HHS should allow QHP issuers to calculate an estimate of the value of cost-sharing reductions at the end of the year using a formula similar to that used for the advance payments, but based on the actual claims experience of the enrollees. These calculated amounts could be used for a reconciliation process, and would place less of a reporting burden on issuers.

Commenters also offered another alternative approach under which issuers would file with the appropriate State department of insurance an adjusted net claims rate for each of their

plan variations. HHS would then reimburse QHP issuers for cost-sharing reductions by multiplying the number of enrollees in each plan variation by the difference in net claims for the plan variation and the standard plan. Commenters also requested additional guidance on the reporting and reconciliation process.

Response: In the initial years of the Exchanges, before adequate data is available on the costs that will be associated with QHPs and their plan variations, we believe it is necessary to balance the need to safeguard Federal funds and the need to minimize burden on issuers. Therefore, as noted above, we are restructuring § 156.430(c) to allow for the addition of paragraphs (c)(3) and (4), which are established in an interim final rule with comment published elsewhere in this issue of the **Federal Register**. Paragraph (c)(3) permits QHP issuers to choose to calculate the amounts that would have been paid under the standard plan without cost-sharing reductions using a simplified methodology. Under this simplified methodology, as described in paragraph (c)(4), a QHP issuer may calculate the value of the cost-sharing reductions provided by using a formula based on certain summary cost-sharing parameters of the standard plan, applied to the total allowed costs for each policy. We believe this amendment will allow QHP issuers to choose the methodology that best aligns with their operational practices, which should reduce the administrative burden on issuers in the initial years of the Exchanges.

Comment: We received several comments stating that both the advance payments and the reconciliation process should account for the full cost of any induced utilization resulting from the cost-sharing reductions.

Response: Section 1402(c)(3) provides for the Secretary of HHS to make payments to QHP issuers equal to the value of the cost-sharing reductions. We interpret this provision to require the Secretary to reimburse QHP issuers for the reduction in cost sharing associated with any induced utilization; however, we do not believe this provision provides for the reimbursement of the remaining plan liability resulting from any induced utilization. Therefore, we finalize the payment methodology as proposed.

Comment: In response to the provisions proposed in § 156.430(c) under which QHP issuers would submit to HHS the portion of the total allowed costs for EHB paid by the enrollee, one commenter noted that issuers cannot report this amount with certainty since

the provider ultimately collects this amount from the enrollee.

Response: We clarify that QHP issuers should report the amount that a provider could charge to an enrollee, accounting for the cost-sharing reduction. We also clarify that the amount reported as paid by the enrollee should include any cost sharing paid by a third party, including a State, on behalf of the enrollee.

Comment: We received several comments that the reporting requirements under § 156.430(c) will be difficult for issuers to meet that do not use fee-for-service reimbursement methods. Commenters suggested that such issuers should receive capitated payments and be exempt from the reconciliation process.

Response: We support the use of such payment methods by issuers to pay providers; therefore, the restriction finalized at § 156.430(c)(5) does not apply to issuers that do not use fee-for-service reimbursement methods. However, we believe that these plans must still reconcile the advance cost-sharing reductions payments they receive from the Federal government.

Comment: Another commenter proposed that QHP issuers make available to providers the amounts reported under § 156.430(c). The commenter stated that this information would allow providers to verify that enrollees received the correct cost-sharing reductions and to identify any inappropriate payments from QHP issuers.

Response: At this time, we are not addressing this issue, but encourage QHP issuers and providers to develop processes to support the provision of cost-sharing reductions.

We proposed in § 156.430(e) that if the actual amounts of cost-sharing reductions exceed the advance payment amounts provided to the issuer, HHS would reimburse the issuer for the shortfall, assuming that the issuer has submitted its actual cost-sharing reduction amounts to HHS in accordance with § 156.430(c). If the actual amounts of cost-sharing reductions are less than the advance payment amounts provided to the issuer, we proposed that the QHP issuer must repay the difference to HHS.

In § 156.430(f), we proposed rules on advance payment and reimbursement of cost-sharing reductions during special transitional periods of coverage where eligibility and enrollment are uncertain, including requirements relating to cost-sharing reductions provided during grace periods following non-payment of premium. In § 156.430(f)(1), we proposed that a QHP issuer will be

eligible for reimbursement of cost-sharing reductions provided prior to a termination of coverage effective date. Furthermore, any advance payments of cost-sharing reductions would be paid to a QHP issuer for coverage prior to a determination of termination, including during any grace period as described in § 155.430(b)(2)(ii)(A) and (B). The determination of termination occurs on the date that the Exchange sends termination information to the QHP issuer and HHS under § 155.430(c)(2). The QHP issuer would be required to repay any advance payments of cost-sharing reductions made with respect to any month after any termination of coverage effective date during a grace period. A QHP issuer generally would not be eligible for reimbursement of cost-sharing reductions provided after the termination of coverage effective date with respect to a grace period. This proposed policy aligns with the approach for advance payments of the premium tax credit described in § 156.270(e).

We proposed in § 156.430(f)(2) and (3) that in the case of any other retroactive termination, if the termination (or late determination thereof) is the fault of the QHP issuer, as reasonably determined by the Exchange, the QHP issuer would not be eligible for advance payments and reimbursement for cost-sharing reductions provided during the period following the termination of coverage effective date and prior to the determination of the termination; and if the termination (or the late determination thereof) is not the fault of the QHP issuer, as reasonably determined by the Exchange, the QHP issuer would be eligible for advance payments and reimbursement for cost-sharing reductions provided during such period.

In § 156.430(f)(4), we proposed that a QHP issuer would be eligible for advance payments and reimbursement of cost-sharing reductions provided during any period for resolution of inconsistencies in information required to determine eligibility for enrollment under § 155.315(f).

We are finalizing these provisions as proposed.

Comment: In general, commenters expressed their support for the policies set forth at § 156.430(f), but asked for clarification on the application of the grace period in relation to cost-sharing reductions. Commenters noted that in many states, issuers are not permitted to pend claims, and that pharmaceutical claims in particular are typically processed at the time and place of service. Other commenters stated that QHP issuers should not be permitted to

pend claims because it shifts the collection burden to health care providers. Commenters also requested clarification on whether QHP issuers may pend cost-sharing reductions during the second and third months of a grace period.

Response: The Exchange Establishment Final Rule, at § 156.270(d), authorizes QHP issuers to pend or pay claims during the second and third month of a grace period in accordance with company policy and State laws. However, as provided in § 156.270(d)(3), QHP issuers must notify providers of the possibility for denied claims when an enrollee is in the second and third months of the grace period. We continue to believe this policy appropriately balances these financial risks, while protecting enrollees. We clarify that we expect QHP issuers to ensure throughout the grace period that cost-sharing reductions are applied at the point of collection for eligible enrollees, as required by § 156.410(a) as finalized here. If an enrollee's coverage is terminated, QHP issuers may deny any claims that were pending, including the reimbursement to the provider for the value of the cost-sharing reductions. Providers could then seek payment directly from the enrollee for any services provided after the termination of coverage, including a refund for the cost-sharing reduction. For a discussion of the standards finalized at § 156.430(b), (d) and (g) in relation to cost-sharing reductions for Indians, please refer to section III.E.4.i below.

f. Plans Eligible for Advance Payments of the Premium Tax Credit and Cost-Sharing Reductions

In § 156.440, we clarified the applicability of advance payments of the premium tax credit and cost-sharing reductions to certain QHPs. We proposed that the provisions of part 156 subpart E generally apply to qualified health plans offered in the individual market on the Exchange.

However, we proposed in § 156.440(a) that the provisions not apply to catastrophic plans because section 36B(c)(3)(A) of the Code defines a QHP to exclude catastrophic plans—a definition that also applies to section 1402 of the Affordable Care Act, by means of section 1402(f)(1) of the Affordable Care Act. Further, eligibility for cost-sharing reductions is tied to a “coverage month with respect to which a premium tax credit is paid,” which would exclude months during which the individual is enrolled in a catastrophic health plan. Therefore, we proposed that enrollment in a

catastrophic plan precludes eligibility for cost-sharing reductions.

We proposed in § 156.440(b) that the provisions of subpart E, to the extent related to cost-sharing reductions, not apply to stand-alone dental plans. Section 1311(d)(2)(B)(ii) of the Affordable Care Act provides that an Exchange must allow a stand-alone dental plan that provides pediatric dental benefits that are EHB to be offered separately from or in conjunction with a QHP. The Exchange Establishment Rule, at § 155.1065, implements these provisions. However, section 1402(c)(5) of the Affordable Care Act states if an individual enrolls in both a QHP and a stand-alone dental plan, the provisions on cost-sharing reductions under sections 1402(a) and (c) of the Affordable Care Act do not apply to that portion of the cost-sharing reductions properly allocable to pediatric dental EHB. Thus, if an individual enrolls in both a QHP and a stand-alone dental plan offered on an Exchange, cost-sharing reductions are not payable with respect to pediatric dental benefits offered by the stand-alone dental plan.

In § 156.440(b), we also proposed that the provisions of subpart E, to the extent relating to advance payments of the premium tax credit, apply to stand-alone dental plans because section 36B(b)(3)(E) of the Code provides for the portion of the premium for such plans that is allocable to EHB coverage be taken into account in calculating the premium tax credit.

We proposed to clarify in § 156.440(c) that the provisions of this subpart E apply to child-only plans. Section 1302(f) of the Affordable Care Act and § 156.200(c)(2) provide that an issuer that offers a QHP at any level of coverage in an Exchange also must offer the plan at the same level of coverage in the Exchange only to individuals that have not attained age 21. Under section 1302(f) of the Affordable Care Act, the child-only plan is to be treated as a QHP, and is therefore subject to the provisions of subpart E. We are finalizing these provisions as proposed with minor technical corrections in paragraphs (a) and (c) to clarify the cross-references.

Comment: One commenter was concerned with the exclusion of stand-alone dental plans from the cost-sharing reduction program. The commenter stated that, because pediatric dental coverage is a required essential health benefit and the statute guarantees cost-sharing reductions for eligible individuals for essential health benefits, cost-sharing reductions should apply to stand-alone dental plans.

Response: We read section 1402(c)(5) of the Affordable Care Act to provide that cost-sharing reductions are not payable with respect to pediatric dental benefits offered by a stand-alone dental plan. Additionally, requiring payment of cost-sharing reductions on pediatric dental benefits offered by a stand-alone dental plan would create significant operational complexities. However, cost-sharing reductions will be provided for pediatric dental benefits if they are offered by a QHP (that is not a stand-alone dental plan).

g. Reduction of Enrollee's Share of Premium To Account for Advance Payments of the Premium Tax Credit

In § 156.460(a), we proposed to codify QHP issuer requirements set forth in section 1412(c)(2)(B) (i)—(iii) of the Affordable Care Act. The law authorizes the payment of advance tax credits to QHP issuers on behalf of certain eligible enrollees. The advance payment must be used to reduce the portion of the premium charged to enrollees. In § 156.460(a)(1), we proposed to codify clause (i) of that subparagraph, which requires that a QHP issuer reduce the portion of the premium charged to the enrollee by the amount of the advance payment of the premium tax credit for the applicable month(s).

In § 156.460(a)(2), we proposed to codify section 1412(c)(2)(B)(ii) of the statute, which requires that the QHP issuer notify the Exchange of any reduction in the portion of the premium charged to the individual. This notification will be sent to the Exchange through the standard enrollment acknowledgment in accordance with § 156.265(g). That information would then be submitted to the Secretary via enrollment information sent from the Exchange to HHS under § 155.340(a)(1).

In § 156.460(a)(3), we proposed to codify section 1412(c)(2)(B)(iii), which requires that a QHP issuer display the amount of the advance payment of the premium tax credit for the applicable month(s) on an enrollee's billing statement. This requirement would ensure that the enrollee is aware of the total cost of the premium and would allow the enrollee to verify that the correct amount for the advance payment of the premium tax credit has been applied to his or her account.

Further, in § 156.460(b), we proposed to prohibit QHP issuers from terminating or refusing to commence coverage on account of any delay in payment of an advance premium tax credit on behalf of an enrollee if the issuer has been notified by the Exchange under § 155.340(a) that it will receive such advance payment. We stated that

we expect that monthly advance payments of the premium tax credit will be paid in the middle of the month, and proposed to prohibit QHP issuers from declining or terminating coverage when the enrollee's payments have been timely but the advance payments of the premium tax credit are not made before the due date for the premium.

We also proposed to add paragraph (f) to § 155.340 (which we designated as § 155.340(g) in this final rule), which sets forth standards for an Exchange when it is facilitating the collection and payment of premiums to QHP issuers and stand-alone dental plans on behalf of enrollees, as permitted under § 155.240(c). Consistent with § 156.460(a), proposed § 155.340(f)(1) would direct the Exchange to reduce the portion of the premium for the policy collected from the enrollee by the amount of the advance payment of the premium tax credit for the applicable month(s). Proposed § 155.340(f)(2) directs an Exchange to display the amount of the advance payment of the premium tax credit for the applicable month(s) on an enrollee's billing statement. Collectively, proposed § 155.340(f) and § 156.460 as proposed ensure that an enrollee is aware of the total cost of the premium so that he or she may verify that the correct advance payment of the premium tax credit has been applied. The goals of these provisions are to promote transparency between Exchanges or QHP issuers and consumers, accurate application of advance payments of the premium tax credit, and continuity of coverage for individuals. For the reasons described in the proposed rule and considering the comments received, we are finalizing § 156.460 as proposed, and are finalizing proposed § 155.340(f) as § 155.340(g).

Comment: A number of commenters stated their support for these provisions directing QHP issuers and Exchanges facilitating the collection and payment of premiums to reduce premiums collected from enrollees by the amount of the advance payments of the premium tax credit. The commenters also supported having QHP issuers and Exchanges display the advance payment of the premium tax credit on enrollees' billing statements. One commenter urged HHS to test the format of the billing statement to ensure it is clear to consumers. Several commenters also supported the proposed prohibition on a QHP issuer terminating coverage following a delay in the issuer's receipt of advance payments of the premium tax credit if the issuer has been notified by the Exchange that it will receive the payment. One commenter stated that

HHS should implement a process to ensure that individuals prematurely terminated in violation of such a provision have coverage reinstated quickly.

Response: Although at this time we do not intend to propose additional requirements related to the format of billing statements, we encourage Exchanges and QHP issuers to test billing statement formats with consumers to ensure that the purpose of the document is clear. We appreciate the comment that we implement a process to quickly correct instances of premature termination. We will take this into consideration in future rulemaking.

h. Allocation of Rates and Claims Costs for Advance Payments of Cost-Sharing Reductions and the Premium Tax Credit

As described in section III.E.2. of this final rule, we proposed in § 156.470 to direct issuers to allocate the rate or expected premium for each metal level health plan and stand-alone dental plan offered, or proposed to be offered, in the individual market on the Exchange, and the expected allowed claims costs for the metal level health plans, among EHB and additional benefits. Under the proposal, issuers would submit these allocations annually to the Exchange, along with an actuarial memorandum with a detailed description of the methods and specific bases used to perform the allocations. The Exchange and HHS would use this memorandum to verify that these allocations meet the standards set forth in paragraphs (c) and (d) of § 156.470.

The comments on the provisions at § 156.470, and our response, are discussed in section III.E.2. of this final rule. We are finalizing the provisions proposed in § 156.470, with a modification to paragraph (d), and technical modifications to § 156.470(a),(b), and (e). We are also adding paragraph (f) to § 156.470 to clarify the application of these provisions to multi-State plans.

i. Special Cost-Sharing Reduction Rules for Indians

In this section, we address certain provisions throughout proposed subpart E governing cost-sharing reductions for Indians.

Interpretation of section 1402(d)(2) of the Affordable Care Act: In the proposed rule, we discussed in detail our interpretation of sections 1402(d)(1), 1402(d)(2), and 1402(f)(2) of the Affordable Care Act. The implication of these interpretations is that cost-sharing reductions under sections 1402(a) and 1402(d)(1) of the Affordable Care Act are

only available to individuals who are eligible for premium tax credits. However, we stated that under our interpretation, cost-sharing reductions under section 1402(d)(2) of the Affordable Care Act would be available to Indians regardless of their eligibility for premium tax credits. This approach aligns with the typical practice today, under which cost sharing is not required with respect to services provided to an Indian by the IHS, an Indian Tribe, Tribal Organization, or Urban Indian Organization.

We also noted that section 1402(d) of the Affordable Care Act specifies that reductions in cost sharing must be provided to Indians who purchase coverage on the Exchange. Although section 1402(d)(1) of the Affordable Care Act applies only to the individual market, section 1402(d)(2) of the Affordable Care Act does not contain this explicit restriction. We proposed to interpret section 1402(d)(2) of the Affordable Care Act to apply only to the individual market because we believe section 1402(d)(2) flows from and builds upon the identification of “any qualified health plans” made in section 1402(d)(1) and because we believe that Congress did not intend for reductions in cost sharing to be available outside the individual market Exchanges. We are finalizing this interpretation of the statute, which underlies the provisions implementing cost-sharing reductions for Indians.

Comment: Several commenters recommended that HHS issue uniform operational guidance on the identification of Indians for use by Exchanges and by the IRS that is consistent with the existing HHS regulations under 42 CFR 447.50. Commenters expressed concern that the lack of uniform operational guidance will impede Exchange, Medicaid, and IRS staff in efficiently making accurate and consistent determinations of eligibility and will result in delayed or denied access for some Indians to specific benefits afforded them under the Affordable Care Act.

Response: The definition proposed for Indian in § 156.400 has the meaning given the term in § 155.330(a). We also note that § 155.350 of the Exchange Establishment Rule currently provides guidance on the verification of Indian status. Further guidance on this issue is outside the scope of this Payment Notice.

Proposed provisions of part 156 relating to Indians: Similar to cost-sharing reductions for non-Indians, we proposed to use the concept of plan variations to describe how Indians would pay only limited, or as

appropriate, none of the total cost sharing required under that QHP, with the Federal government bearing the remaining cost-sharing obligation. Our proposed regulations cross-referenced the eligibility regulations at § 155.305(g), as finalized here, and § 155.350(b), finalized in the Exchange Establishment Rule. In § 156.410(b)(2), we proposed that a QHP issuer assign an Indian determined by the Exchange to have an expected household income that does not exceed 300 percent of the FPL to a zero cost sharing plan variation of the selected QHP (no matter the level of coverage) with no cost sharing, based on the enrollment and eligibility information submitted to the QHP issuer by the Exchange. In § 156.410(b)(3), we proposed that a QHP issuer assign an Indian determined eligible by the Exchange for cost-sharing reductions under section 1402(d)(2) of the Affordable Care Act to a limited cost sharing plan variation of the selected QHP (no matter the level of coverage) with no cost sharing required on benefits received from the IHS and certain other providers.

The assignments to the plan variations would be subject to § 155.305(g)(3), which governs plan variation placement decisions when a single policy covers two or more individuals who are eligible for different levels of cost-sharing reductions. In the preamble, we also discussed an alternative approach to the provision of cost-sharing reductions for Indians. Rather than requiring QHP issuers to assign Indians to zero and limited cost sharing plan variations, QHP issuers would simply assign Indians to the standard plan (or as appropriate, silver plan variation), and waive the cost-sharing requirements, as appropriate. We proposed the approach first described above, but sought comments on which approach HHS should adopt beginning January 1, 2016. For the reasons described in the proposed rule, and considering the comments we received, we are finalizing the policy as proposed, though we continue to welcome comments on what approach HHS should adopt for benefit year beginning on or after January 1, 2016.

Comment: Several commenters expressed their support for the proposed policy at § 155.305(g)(3), noting that the alternative approach would be difficult to administer and would require QHP issuers to make significant changes to their claims systems because issuers today are not able to administer member-based cost-sharing rules. One commenter was concerned that it would be difficult for issuers to waive cost sharing for Indians at or below 300

percent of FPL at the point of service under the alternate approach.

Other commenters, however, expressed concern that the proposed approach would require families with Indian members and non-Indian members to purchase multiple plans in order for each family member to receive the full value of the cost-sharing reductions to which they are entitled. Commenters stated that under this policy, the cost savings available to Indians could be negated by shifting the liability to other non-eligible family members.

A number of commenters recommended a different approach to address the potential increase in costs to be paid by Indian and non-Indian members who elect to enroll in different plans in order to take full advantage of the cost-sharing reductions available to them. These commenters recommended that if family members are enrolled in separate plan variations, the combination of the premiums be required to be no greater than the premium the family would pay if all members were enrolled in the same plan variation. They also recommended that the maximum out-of-pocket liability for the plan variation in which the non-Indians enrolled be set at a proportion of the maximum liability of a single family plan. These commenters also suggested that HHS should implement the alternative approach sooner than 2016.

Response: We will consider adopting the approach recommended by commenters for future benefit years; however, given the current timeframe and operational concerns, we believe that for the 2014 benefit year it is infeasible to require issuers to submit plan variations that take into account cost-sharing obligations for Indian and non-Indian family members covered under a single QHP policy. Therefore, in accordance with the policy in the proposed rule that we are finalizing here, the assignment of Indians to plan variations would be subject to § 155.305(g)(3). If we propose to change the policy for years beginning in 2016, we will provide issuers with sufficient notice and opportunity to comment to effectuate the required operational change.

In § 156.420(b), we proposed that QHP issuers submit to the Exchange the zero cost sharing plan variation and limited cost sharing plan variation for each of the QHPs (at any level of coverage) that it intends to offer on the Exchange. The zero cost sharing plan variation—addressing cost-sharing reductions under section 1402(d)(1) of the Affordable Care Act and available to

Indians with expected household incomes that do not exceed 300 percent of the FPL, as determined under § 155.350(a)—must have all cost sharing eliminated. The limited cost sharing plan variation—addressing cost-sharing reductions under section 1402(d)(2) of the Affordable Care Act and available to all Indians as determined in § 155.350(b)—must have no cost sharing on any item or service furnished directly by the IHS, an Indian Tribe, Tribal Organization, Urban Indian Organization, or through referral under contract health services, as defined in 25 U.S.C. 1603. We noted that unlike silver plan variations, zero cost sharing plan variations and limited cost sharing plan variations must only be submitted for certification when the standard plan is submitted for QHP certification.

In § 156.420(d), we proposed language similar to that proposed in § 156.420(c) for silver plan variations—that the zero cost sharing plan variations and limited cost sharing plan variations cover the same benefits and include the same providers as the standard QHP, and require the same out-of-pocket spending for benefits other than EHB. We also proposed that a limited cost sharing plan variation, which would have no cost sharing on any item or service furnished directly by the IHS, Indian Tribe, Tribal Organization, or Urban Indian Organization, or through referral under contract health services, must have the same cost sharing on items or services not described in § 156.420(b)(2) as the QHP with no cost-sharing reductions.

Lastly, we proposed that zero cost sharing plan variations and limited cost sharing plan variations be subject to all standards applicable to the standard QHP (except for the requirement that the plan have an AV as set forth in § 156.140(b)). We are finalizing these provisions as proposed with two modifications. With regard to the submission of plan variations under § 156.420(b), we are revising the language to align with the language in § 156.420(a), and § 156.470(a) and (b) as finalized. We are also adding paragraph (g) to § 156.420 to clarify the applicability of these provisions to multi-State plans.

Comment: We received a comment stating that QHP issuers should not be required to count the cost sharing that an enrollee in a zero cost sharing plan variation would have paid towards the annual limitation on cost sharing, stating that this would require a manual process which would be resource-intensive and result in errors.

Response: We clarify that for purposes of administering the plan variations and

providing cost-sharing reductions, QHP issuers are not required to apply any cost sharing that an enrollee would have been required to pay under the standard plan but was not required to pay under the plan variation to the annual limitation on cost sharing. However, any cost sharing that an enrollee is required to pay (for example, for those in the limited cost sharing plan variation, cost sharing for services provided by non-IHS or related providers), would count towards the annual limitation on cost sharing. This would also apply to silver health plans when there is no cost sharing for a benefit or service.

Comment: We received a comment in relation to the policy proposed at § 156.410(a), requiring QHP issuers to ensure that an individual eligible for cost-sharing reductions pay only the cost sharing required of an eligible individual when the cost sharing is collected. The commenter suggested that this language might be confusing since in many cases, individuals assigned to a zero cost sharing plan variation or a limited cost sharing plan variation will have no cost sharing. The commenter also suggested that QHP issuers should provide information electronically to providers concerning an individual's cost-sharing protections.

Response: We are finalizing the regulation as proposed without modification, though we clarify that a QHP issuer would be required to ensure that an individual assigned to a zero cost sharing plan variation must not be required to pay any cost sharing at the time when cost sharing would normally be collected. Similarly, a QHP issuer must ensure that an individual assigned to a limited cost sharing plan variation must not be required to pay any cost sharing at the time when cost sharing would normally be collected if the individual receives services or items from IHS or a related provider.

Comment: Several commenters stated that cost-sharing reductions for Indians should not be limited to EHB. Commenters stated that the cost-sharing exemptions for Indians in section 1402(d) of the Affordable Care Act were enacted as distinct, special provisions for Indians and are not subject to the general cost sharing limitation to EHB in section 1402(c)(4) of the Affordable Care Act.

Response: We interpreted and implemented section 1301(c) of the Affordable Care Act to limit the definition of cost sharing to EHB when finalizing § 155.20 of the Exchange Establishment Rule. The regulation defines “cost sharing” as any expenditure required by or on behalf of an enrollee with respect to EHB.

Further, section 1402(c)(4) of the Affordable Care Act provides that all cost-sharing reductions under that section are applicable only to cost-sharing for EHB and not for additional benefits.

Comment: Several commenters raised concerns that providers would be confused regarding the payment they can expect from QHP issuers when an Indian is referred through the contract health services program to an out-of-network provider, or when an Indian is not enrolled in a QHP. Some commenters requested further clarification on the definition of “contract health services.”

Response: We are working to ensure that referrals through the contract health services program are processed in accordance with the standards in this final rule in a manner that is clear to providers and QHP issuers. In addition, we note that “contract health services” is defined under 25 U.S.C. section 1603, and we do not propose to codify this definition in the final rule.

In addition, we note that the proposed Medicaid and Exchange Eligibility Appeals and Notices Rule proposes to codify a prohibition in section 1916(j) of the Social Security Act on imposing premiums or cost sharing on an Indian who is eligible to receive or has received and item or service furnished directly by the Indian Health Service, an Indian Tribe, Tribal Organization, or Urban Indian Organization, or through referral under contract health services. We note the similarity in the statutory language, but note the different income levels and benefits provided under the respective statutes. We intend to continue to review this issue and anticipate issuing guidance to address the operational concerns raised by the commenters.

Comment: Several commenters suggested that issuers should be permitted to submit zero cost sharing plan variations at only one metal level, unless there are significant differences in plan design such as prescription drug formularies, provider networks or covered benefits between metal levels. These commenters noted that it is unlikely that an individual will choose a higher cost plan in that situation because the lower metal level plan will provide the same benefits and networks, at a lower premium and with no cost sharing. One commenter suggested that QHP issuers could administer cost-sharing reductions for Indians regardless of income on a case-by-case basis.

Response: We recognize that there is no practical need to ensure that eligible Indians have access to higher metal level plans if a lower metal level plan

offers identical benefits and networks, at a lower premium and with no cost sharing. We also recognize the burden on QHP issuers of developing plan variations that provide no additional benefit to enrollees. Finally, we do not wish to unnecessarily task Exchanges with certifying such plan variations. Therefore, we clarify that HHS will deem an Exchange to be adequately enforcing the requirements of § 156.420(b)(1) if, within a set of standard plans offered by an issuer that differ only by the cost sharing or premium (that is, the benefits, networks, and all other aspects of the standard plans are exactly the same), the Exchange allows the issuer to submit one zero cost sharing plan variation for only the standard plan within the set with the lowest premium. If an issuer offers standard plans with different benefits or networks, each set of standard plans must have a zero cost sharing plan variation. We do not propose to extend this interpretation to the submission of limited cost sharing plan variations because these variations may still have cost sharing, which could vary among standard plans. We note that for 2014, for operational reasons, the FFE will still require QHP issuers to submit a zero cost sharing plan variation for any level of coverage that the QHP issuer seeks certification. While this operational limitation for 2014 does present additional data inputs, we do not expect it to require additional analysis by issuers because the content of the submissions would be identical except for cost sharing, which would be eliminated for the zero cost sharing plan variation. We will consider changing this approach in later benefit years through future rulemaking.

Section 1402(d)(3) of the Affordable Care Act directs the Secretary to pay a QHP issuer the amount necessary to reflect the increase in AV of a QHP required by reason of the changes in cost sharing for Indians under section 1402(d) of the Affordable Care Act. We proposed to use the same payment approach to reimburse cost-sharing reductions for Indians under section 1402(d) of the Affordable Care Act as we proposed to use for cost-sharing reductions provided to eligible individuals with household incomes between 100 and 250 percent of the FPL under section 1402(a) of the Affordable Care Act. That is, we proposed that QHP issuers submit estimates for the dollar value of the cost-sharing reductions to be provided under the zero cost sharing plan variation and limited cost sharing plan variations in order to receive advance payments, and then reconcile

the advance payments to the actual cost-sharing reduction amounts. This unified approach satisfies both the requirement for “periodic and timely payments equal to the value of the reductions” under section 1402(c)(3) of the Affordable Care Act, and payment of “the amount necessary to reflect the increase in AV of the plan” under section 1402(d)(3) of the Affordable Care Act. We are finalizing the payment approach as proposed, with one amendment at § 156.430(g) relating to compensation for items and services provided directly by the Indian Health Service, an Indian Tribe, Tribal Organization, or Urban Indian Organization, or through referral under contract health services.

In § 156.430(a)(1)(ii), we proposed that for each metal level QHP that an issuer offers, or intends to offer in the individual market on the Exchange, the issuer must provide to the Exchange annually prior to the benefit year, for approval by HHS, estimates, and supporting documentation validating the estimates, of the per member per month dollar value of cost-sharing reductions to be provided under the zero cost sharing plan variation. These estimates must be developed using the methodology specified by HHS in the applicable annual HHS notice of benefit and payment parameters. We proposed that issuers use the same methodology described above for estimating advance payments for the cost-sharing reductions provided under silver plan variations for estimating advance payments for the cost-sharing reductions provided under the zero cost sharing plan variation. This methodology would utilize data that QHP issuers submit for other requirements, such as § 156.420 and § 156.470. As a result, QHP issuers would not be required under the proposal to submit separate estimates or supporting documentation to receive advance payments in benefit year 2014 for the value of the cost-sharing reductions that would be provided under the zero cost sharing plan variation.

As in the case of silver plan variations, the following formula would be used:

$$\begin{aligned} &\text{Per Enrollee Per Month Advance Payment} \\ &= \text{Monthly Expected Allowed Claims Costs for Zero Cost Sharing Plan Variation} \\ &\times (\text{Zero Cost Sharing Plan Variation AV—Standard Plan AV}) \end{aligned}$$

In this formula, the monthly expected allowed claims cost for the zero cost sharing plan variation would equal one-twelfth of the expected allowed claims

costs allocated to EHB, other than services described in § 156.280(d)(1), for the standard plan, multiplied by a factor to account for the increased utilization that may occur under the zero cost sharing plan variation due to the elimination of the cost-sharing requirements. As proposed at § 156.470, the QHP issuer would submit the

expected allowed claims cost information to the Exchange annually. The Exchange would then review this allocation, and submit the approved allocation to HHS, as described in § 155.1030(b)(2), for use in the advance payment calculation. HHS would then multiply the monthly expected allowed claims cost by the induced utilization

factor, to arrive at the monthly expected allowed claims cost for the zero cost sharing plan variation. We proposed the following induced utilization factors for the zero cost sharing plan variation, based on our analysis of the HIC database from calendar year 2010.

TABLE 24—INDUCED UTILIZATION FACTORS FOR ADVANCE PAYMENTS OF COST-SHARING REDUCTIONS FOR INDIANS

Zero cost sharing plan variation	Induced utilization factor
Zero Cost Sharing Plan Variation of Bronze QHP	1.15
Zero Cost Sharing Plan Variation of Silver QHP	1.12
Zero Cost Sharing Plan Variation of Gold QHP	1.07
Zero Cost Sharing Plan Variation of Platinum QHP	1.00

In the second half of the formula, we proposed to multiply the monthly expected allowed claims cost for the zero cost sharing plan variation by the difference in AV between the standard plan and the plan variation. The AV of the zero cost sharing plan variation would be 100, because all cost sharing is eliminated for this plan variation. Lastly, the per enrollee per month estimate will be multiplied by the number of individuals assigned to the zero cost sharing plan variation (based on the most recent confirmed enrollment data) in a given month to arrive at the total advance payment that will be provided to the issuer for each QHP. We are finalizing these provisions as proposed.

Comment: One commenter requested clarification on the induced utilization factors for cost-sharing reductions for Indians, and whether these factors would ensure that QHP issuers are “made whole” for the value of the cost-sharing reductions.

Response: As in the case of the silver plan variations, we incorporated an induced utilization factor into the advance payment formula to ensure that QHP issuers are compensated for the elimination of cost sharing for any increase in utilization resulting from the modification of the cost-sharing requirements. In addition, we developed an induced utilization adjustment for the risk adjustment model, to further offset the higher costs that enrollees eligible for cost-sharing reductions might incur, as described in section III.B.3.b. of this final rule. We believe this approach ensures that issuers are appropriately compensated for the value of the cost-sharing reductions.

In § 156.430(a)(2), we proposed the process for estimating the value of cost-sharing reductions to be provided under the limited cost sharing plan variation open to Indians regardless of household

income. We proposed that QHP issuers have the option to forgo submitting an estimate of the value of these cost-sharing reductions if they believe the operational cost of developing the estimate is not worth the value of the advance payment. If a QHP issuer chooses to not submit an estimate, the issuer would provide the cost-sharing reductions as required, and would be reimbursed by HHS after the close of the benefit year, as proposed in § 156.430(c). If a QHP issuer does seek advance payments for the these cost-sharing reductions, the issuer would provide to the Exchange annually prior to the benefit year, for approval by HHS, an estimate and supporting documentation validating the estimate, of the per member per month dollar value of the cost-sharing reductions to be provided under the limited cost sharing plan variation of the QHP. Under our proposal, the estimate would be developed using the methodology specified by HHS in the applicable annual HHS notice of benefit and payment parameters. For the 2014 benefit year, we simply proposed that issuers submit a reasonable estimate of the value of the reductions, developed by a member of the American Academy of Actuaries in accordance with generally accepted actuarial principles and methodologies, and that the estimate should be no higher than the corresponding estimate for the zero cost sharing plan variation. We did not propose a standardized methodology because, unlike other plan variations, these cost-sharing reductions are to be provided for only a specific subset of providers, and the Affordable Care Act does not prescribe an AV for these reductions. As noted above, because the actuarial value calculator is based on a standard population, it will not have the functionality to generate an accurate AV for these plan variations.

We are finalizing both our proposal for annual rulemaking in the notice of benefits and payment provisions to establish a methodology for advance payments for cost-sharing reductions under the limited cost sharing plan variation, and our proposal of a specific methodology for the 2014 benefit year. As in the case of the other plan variations, we plan to review the methodology for calculating the advance payments once more data is available, and future notices of benefits and payment parameters may include different methodologies. We welcome comments to consider as part of this process. We are also clarifying the language at § 156.430(a)(2) by replacing the phrase “[an issuer] offers or seeks to offer” from the proposed rule with the phrase “[an issuer] offers, or intends to offer” in the final rule, to align with the language in § 156.430(a)(1).

As described above, the Exchange will collect the estimate and supporting documentation, and submit the estimate and supporting documentation to HHS for review, as finalized under § 155.1030. If HHS finds the estimate to be reasonable, HHS will make advance payments to a QHP issuer following the same procedure as for the other plan variations, under § 156.430(b), as finalized in this rule.

In § 156.430(c) through (e), we proposed that QHP issuers submit to HHS the amount of cost-sharing reductions provided under each plan variation. These amounts would then be reconciled against any advance payments. As explained in more detail in section III.E.4.e, we are modifying the reporting provisions described in § 156.430(c), and finalizing as proposed the reconciliation process described in § 156.430(d) and (e). We are also publishing an interim final rule with comment elsewhere in this issue of the **Federal Register** providing an

alternative methodology for reporting the value of the cost-sharing reductions provided. We expect that QHP issuers would be able to use this alternative methodology, if they so choose, for reporting the value of cost-sharing reductions provided under the zero cost sharing plan variation and the limited cost sharing plan variation.

Comment: In general, commenters supported HHS's proposal to use the same payment approach to reimburse cost-sharing reductions for Indians under section 1402(d) as we proposed to use for cost-sharing reductions provided to eligible individuals with household incomes between 100 and 250 percent of the FPL under section 1402(a) of the Affordable Care Act. One commenter, however, stated that due to demographics, very few individuals will be assigned to the limited cost sharing plan variation, and as a result, QHP issuers should simply receive a capitated payment for the value of these cost-sharing reductions, and not be required to submit information for the reconciliation of payments.

Response: At this time, we believe it would be difficult for issuers and HHS to accurately estimate the "increase in AV of the plan" resulting from the cost-sharing reductions provided under section 1402(d)(2) of the Affordable Care Act. Relevant data on Indian populations' cost sharing is not easily available, and issuers would not be able to use the AV calculator to estimate Indian-only cost-sharing features of a plan because the calculator is based on a standard population. Therefore, we finalize the approach set forth in the proposed rule for QHP issuers to submit data on the dollar value of cost-sharing reductions provided to eligible Indians under zero cost sharing and limited cost sharing plan variations, which will be reconciled against any advance payments.

Comment: Another commenter was concerned about the prohibition on cost sharing under the limited cost sharing plan variation for services or items provided through referral under the contract health services program. The commenter suggested that until an accurate, online verification system for contract health services referrals can be established, QHP issuers should be able to rely on the information they receive from providers, and be held harmless for these cost-sharing reductions in the reconciliation process.

Response: We recognize issuers' concerns about this provision, and plan to issue guidance on this topic in the future.

In the proposed rule, we noted that section 1402(d)(2)(B) of the Affordable

Care Act states that QHP issuers cannot reduce payments to the relevant facility or provider for an item or service by the amount of any cost sharing that would be due from an Indian but for the prohibition on cost sharing set forth in section 1402(d)(2) of the Affordable Care Act. We proposed not to codify this provision in regulation because we believed it is clear and self-enforcing, and because we believe that it would also be impermissible for an issuer to reduce payments to a provider for any cost-sharing reductions required under sections 1402(a) or 1402(d)(1) of the Affordable Care Act—particularly because these cost-sharing reductions are to be reimbursed by HHS. We also noted that nothing in this section exempts an issuer from section 206 of the Indian Health Care Improvement Act, which provides that the United States, an Indian Tribe, Tribal organization, or urban Indian organization has the right to recover from third party payers, including QHPs, up to the reasonable charges billed for providing health services, or, if higher, the highest amount an insurer would pay to other providers.

Comment: Commenters asserted that regulation text is needed to ensure there are no reductions in payments to the relevant facility or provider for an item or service by the amount of any cost sharing that would be due from an Indian but for the prohibition on cost sharing set forth in section 1402(d)(2) of the Affordable Care Act.

Response: We have codified this provision by adding § 156.430(g) to the final rule. Regardless of the contracting relationship between a QHP issuer and the Indian health provider, the issuer may not reduce payments to the provider by the amount of any cost sharing that would be due from the Indian under this final rule.

F. Provisions on User Fees for a Federally-Facilitated Exchange (FFE)

Section 1311(d)(5)(A) of the Affordable Care Act contemplates an Exchange charging assessments or user fees to participating health insurance issuers to generate funding to support its operations. If a State does not elect to operate an Exchange or does not have an approved Exchange, section 1321(c)(1) of the statute directs HHS to operate an Exchange within the State. In addition, 31 U.S.C. 9701 permits a Federal agency to establish a charge for a service provided by the agency. Circular No. A-25R establishes Federal policy regarding user fees, and specifies that a user charge will be assessed against each identifiable recipient of special benefits derived from Federal

activities beyond those received by the general public. We proposed to revise § 156.50(b) and to add paragraph (c) to provide for a user fee from participating issuers (as defined in § 156.50(a)) to support the operation of FFEs under these authorities.

Circular No. A-25R states that user charges should generally be set at a level so that they are sufficient to recover the full cost to the Federal government of providing the service when the government is acting in its capacity as sovereign (as is the case when HHS operates a FFE). However, Circular No. A-25R also allows for exceptions to this policy, if approved by OMB. Because we wish to encourage issuers to offer plans on FFEs and to align with the administrative cost structure of State-based Exchanges, and because we believe that growing enrollment is likely to increase user fee receipts in future years, we are seeking an exception to the policy for 2014.

We proposed to revise § 156.50(b) so that it would apply only to user fees to support State-based Exchanges. In § 156.50(c), we proposed that a participating issuer offering a plan through a FFE remit a user fee to HHS each month, in the time and manner established by HHS, equal to the product of the billable members enrolled through the Exchange in the plan offered by the issuer, and the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year. For the 2014 benefit year, we proposed a monthly user fee rate equal to 3.5 percent of the monthly premium charged by the issuer for a particular policy under the plan. We note that this user fee would apply to plans offered through FF-SHOPs, as well as individual market FFEs. We noted that additional guidance on user fee collection processes would be provided in the future. We anticipate collecting user fees by deducting the user fee from Federally-administered Exchange-related program payments. If a QHP issuer does not receive any Exchange-related program payments, the issuer would be invoiced for the user fee on a monthly basis.

In addition, we welcomed comments on a policy that we were considering that would provide for the pooling of Exchange user fees, distribution costs, or all administrative costs across a particular market (in the case of the FFE, however, the user fee would be collected only from issuers participating in the FFE). We note that our proposed rule, "Coverage of Certain Preventive Services under the Affordable Care Act" (78 FR 8457), contemplates a proposal

to reduce the amount of the FFE user fee for QHP issuers that provide coverage for contraceptive services for participants of a self-insured plan that is established or maintained by an eligible organization (or have an affiliated issuer that does so).³⁰ Comments are separately welcome on that proposed regulation on or before April 8, 2013.

Based on the comments we received, we are finalizing the proposal and the regulation text with the following modification: we are clarifying the calculation of the user fee so that the user fee rate is applied directly to the premium set by the issuer for a policy and is charged on each policy with enrollment through the FFE.

Comment: A number commenters expressed concern that our proposed FFE user fee would increase coverage costs for consumers; however, other commenters expressed support for the proposed FFE user fee.

Response: We do not believe that the FFE user fee rate, set at 3.5 percent of premiums, would increase the cost of coverage or discourage consumers from purchasing health insurance through an FFE. We anticipate that the user fee will account for the cost of many of the Exchange-related administrative functions that issuers would otherwise have to perform, such as consumer assistance and enrollment support, and that the cost of the user fee will be outweighed by the many benefits that result from participation in an Exchange. The Exchanges are expected to enhance competition among issuers in the non-group market, which should lower premiums due to the elimination of medical underwriting and the associated issuer administrative costs. Exchanges will also create larger purchasing pools, which should create economies of scale, lowering administrative costs for QHP issuers, and further reducing premiums.

Comment: Several commenters requested that we provide more details regarding our user fee calculations and a breakdown of costs by jurisdiction. Several commenters suggested that we calculate the FFE user fee amount on a per capita basis rather than as a percent of premiums, and a few other commenters supported the percent of premium approach.

Response: We are finalizing our policy to calculate the FFE user fee as a percentage of premium; however, we are modifying the proposed rule to clarify that the FFE user fee amount is set as a percent of premium, without regard to the number of billable members on a policy. This clarification

does not change the value of the user fee. We appreciate commenters' concerns that FFE operating costs be minimized and transparent, and will take those comments into consideration in our approach to FFE operating costs.

Comment: One commenter noted that basing the user fee amount on a percent of premium for a particular policy was confusing.

Response: We are clarifying that an issuer's monthly user fee amount is equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year—which for 2014 is 3.5 percent—and the monthly premium charged by the issuer for *each policy* offered through a Federally-facilitated Exchange.

Comment: One commenter expressed concern about HHS's proposal to align the FFE user fee rate with the user fee rate assessed by State-based Exchanges. Other commenters urged HHS to ensure that the overall amount of the FFE user fee reflected only HHS's actual costs related to FFE operations.

Response: We are clarifying that we are establishing the FFE user fee rate for 2014 only, with the intent of keeping the user fee as low as possible. Independent of final SBE user fee rates, we clarify that we are not considering raising the FFE user fee beyond our operating costs in the future.

Comment: We received several comments on our proposal to pool user fees across all plans in a market within a State. Some commenters suggested that this policy would unfairly increase costs for members that are not enrolled on an Exchange. However, other commenters supported the pooling Exchange user fees. A few commenters requested clarification on how issuers would be permitted to account for user fees on their members' bills, specifically whether issuers would be able to account for user fees in their premium amounts or whether user fees would be billed separately.

Response: We believe that including Exchange user fees in the single risk pool requirement will help prevent adverse selection against QHPs on Exchanges. In the final Market Reform Rule at § 156.80, we require issuers to pool all user fee costs across their applicable market in a State. We refer readers to the discussion associated with § 156.80 of the Market Reform Rule for additional details on this policy.

G. Distributed Data Collection for the HHS-operated Risk Adjustment and Reinsurance Programs

1. Background

In the proposed rule, we proposed to amend 45 CFR part 153 by adding subpart H, entitled "Distributed Data Collection for HHS-Operated Programs," which set forth the data collection process that HHS would use when operating a risk adjustment or reinsurance program on behalf of a State. We proposed to use a distributed approach to data collection for the risk adjustment and reinsurance programs when HHS operates those programs on behalf of a State. In the proposed rule, we described a distributed approach as one in which each issuer formats its own data in a manner consistent with the applicable database, and then passes the relevant information to the entity responsible for making payments and charges for the program. We believe that this approach minimizes issuer burden while protecting enrollees' privacy. We received a number of comments supporting the proposed distributed data approach, and are finalizing the provisions as proposed.

2. Issuer Data Collection and Submission Requirements

Under the HHS-operated risk adjustment and reinsurance programs, we proposed to use a distributed data collection approach to run software on enrollee-level and claims-level data that reside on an issuer's dedicated data environment. This approach requires close technological coordination between issuers and HHS.

a. Distributed Data Environments

In § 153.700(a), we proposed that an issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State where HHS is operating the risk adjustment or reinsurance program on behalf of the State establish a dedicated data environment and provide data access to HHS, in a manner and timeframe specified by HHS, for risk adjustment and reinsurance operations. To accomplish the distributed data collection approach for both the reinsurance and risk adjustment programs, issuers would establish secure, dedicated, electronic server environments to house medical and pharmacy claims, encounter data, and enrollment information. Issuers would be directed to make this data accessible to HHS in HHS-specified electronic formats, and to provide HHS with access to the data environment to install, update, and operate common software and specific reference tables

³⁰ See 78 FR 8474.

for the purpose of executing risk adjustment and reinsurance program operations. Issuers would also be directed to correct submitted files to resolve problems detected by HHS during file processing. Except for purposes of data validation and audit, HHS will not store any personally identifiable enrollee information or individual claim-level information.

We note that HHS will store, in a private and secure HHS computing environment, aggregate plan summary data and reports based on activities performed on each issuer's dedicated server environment.

Comment: Several commenters expressed concern that the distributed approach would have limited use because it would not track the same enrollee across multiple years.

Response: The distributed data approach would not constrain the risk adjustment methodology when HHS operates risk adjustment because the concurrent model does not require tracking of enrollees over multiple years.

Comment: We received a few comments requesting clarification as to what information from the distributed data environments would be shared with States. A few commenters asked for States to have access to data on the distributed data environments.

Response: We are considering ways to provide States with information about HHS-operated programs, and welcome feedback about the types of summary information would be most useful to States. In doing so, we must balance program transparency with protection of potentially sensitive information, including consumer health information. We will provide further information in subsequent guidance, as appropriate.

Comment: A number of commenters requested technical details about the distributed data environment. Several commenters requested the specific requirements for the necessary enrollment, claims and encounter data, applicable software and testing schedule for risk adjustment data submissions. One commenter asked that issuers be permitted to provide two separate data sets on the distributed data environment—one for risk adjustment in the individual and small group markets, and a second for the reinsurance that will only include data for the individual market. One commenter asked for further details on the types of accepted information and recommended that chart reviews be considered acceptable data.

Response: HHS has provided a list of required data for the HHS-operated distributed data approach in the PRA package approved under OMB Control

Number 0938–1155. HHS will make available the data formats, definitions, and technical standards applicable to the HHS-operated distributed data approach in future guidance, including standards relating to data from chart reviews.

Comment: We received comments requesting further clarification about the uses of data collected through the distributed data approach.

Response: We intend to provide further guidance on this issue. We do note that data use will be consistent with HHS's commitment to protecting the privacy and security of enrollees. As a result, we would not store any personally identifiable enrollee information or individual claim-level information in connection with this data collection, except for the purposes of data validation and audit. We believe that this approach minimizes issuer burden while protecting enrollees' privacy.

Comment: One commenter requested that the recalibrations of the risk adjustment models not be based on data from the distributed data environment, but asked that HHS conduct a separate data collection designed specifically for the recalibration of the risk adjustment models.

Response: We are exploring using data from the distributed data environment for future recalibration of the HHS risk adjustment models. We will provide further details on model recalibration in future rulemaking and guidance.

b. Timeline

We proposed in § 153.700(b) that issuers must establish the dedicated data environment (and confirm proper establishment through successfully testing the environment to conform with HHS standards for such testing) three months prior to the first date of full operation.

Comment: A few commenters sought clarification on when HHS would conduct testing of the distributed data environment in order to develop the distributed data environment for full operation.

Response: To ensure accuracy in the application of the distributed data approach, HHS will work with issuers to establish robust systems. Issuers will have the opportunity to submit data files to a test environment. HHS will provide support for issuers who conduct such testing as well as provide ongoing support for the duration of the programs. As testing and implementation will be ongoing, we note that an issuer must establish the dedicated data environment (and

confirm proper establishment through successfully testing the environment to conform with applicable HHS standards for such testing) three months prior to full operation, that is, three months prior to the first date the plan could accrue claims for risk adjustment and reinsurance purposes. Even after an issuer's dedicated data environment is fully operational, further testing and modifications may be necessary. Further details and specifications for such testing will be provided in future guidance.

c. Enrollment, Claims and Encounter Data

In § 153.710(a), we proposed that an issuer of a risk adjustment covered plan or reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, provide to HHS, through the dedicated data environment, access to the enrollee-level plan enrollment data, enrollee claims data, and enrollee encounter data specified by HHS.

Comment: Several commenters sought clarification on whether claims will be dated by the date of admission or the date of discharge. One commentator requested clarification on how claims that straddle the benefit year would be handled. Several commenters requested that claims be dated by date of admission rather than date of discharge, to address the issue of claims that straddle multiple years. Another commenter recommended that risk adjustment scores be based on claims with dates of service from January 1 through December 31.

Response: The proposed rule stated that data should be submitted for the applicable benefit year by April 30 of the year following the end of the applicable benefit year. The discharge date would be used to date claims, because we believe that the discharge date best ensures that services provided across benefit years will be considered in their entirety rather than being partially or fully excluded from consideration as a result of the data submission timing requirements. For example, if an individual is admitted to a hospital in December 2014 and is discharged in January 2015, the incurred costs that occurred in both December 2014 and January 2015 would be considered in the 2015 benefit year for both reinsurance payments and calculation of enrollee risk scores for risk adjustment when HHS operates either of those programs.

Comment: We received several comments requesting clarification on HHS' data storage requirements.

Response: Under § 153.620(b), an issuer that offers risk adjustment covered plans would be required to retain any information requested to support risk adjustment data validation for a period of at least ten years after the date of the report. We will provide further guidance on the data storage requirements for reinsurance-eligible plans and risk adjustment covered plans in forthcoming rulemaking and guidance.

d. Data Requirements

In the proposed rule, we described the types of data that would be acceptable for the reinsurance and risk adjustment programs when HHS operates these programs on behalf of a State.

When HHS is operating reinsurance on behalf of a State, we proposed that medical and pharmacy claims with discharge dates or through dates of service (when no discharge date is applicable, as is often the case for professional services) that fall in the applicable benefit year would be eligible for reinsurance payments for that benefit year.

When HHS is operating risk adjustment on behalf of a State, we proposed that institutional and medical claims and encounter data with discharge dates or through dates of service that fall in the applicable benefit year would be eligible for risk adjustment payments and charges for that benefit year. The data to calculate enrollee risk scores for purposes of risk adjustment would include diagnoses reported on institutional and medical claims that result in final payment action or encounters that result in final accepted status. Only the diagnoses reported on certain hospital inpatient facility, hospital outpatient, and physician provider claims will be acceptable when HHS operates risk adjustment. The risk adjustment model discussed earlier in this preamble provides a description of HHS's criteria for identifying and excluding claims from providers.

Comment: We received a comment requesting clarification on the acceptable provider types.

Response: Diagnoses will only be acceptable for risk adjustment enrollee risk score calculations if they meet criteria that are acceptable for HHS risk adjustment data collection. Generally, for both inpatient and outpatient services, diagnoses are acceptable if from a qualified provider, but only if the procedure code was not for diagnostic laboratory or diagnostic radiology services. HHS will release the full list of acceptable provider types and criteria in forthcoming guidance.

Comment: One commenter recommended that unpaid claims be included in the calculation of enrollee risk scores.

Response: While there may be some advantages to inclusion of unpaid claims, we do not plan to accept claims where services were denied or not covered because HHS risk adjustment models were calibrated on paid claims. However, if services were approved and an issuer incurred no expenses because the claim was fully paid through cost sharing, then those claims would be acceptable for consideration (for example, if the allowable cost of a service provided was \$15 and the enrollee's co-pay was \$15).

e. Claims Data

We proposed in § 153.710(b) that all claims data submitted by an issuer of a risk adjustment covered plan or reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, must have resulted in payment by the issuer (payment of cost sharing by the enrollee). The enrollee-level data must include information from claims and encounter data (including data related to cost-sharing reductions, to permit HHS to calculate enrollee paid claims net of cost-sharing reductions) as sourced from all medical and pharmacy providers, suppliers, physicians, or other practitioners who furnished items or services to the issuer's health plan members for all permitted paid medical and pharmacy services during the benefit period. All data must be provided at the level of aggregation specified by HHS.

Comment: Several commenters asked HHS to notify issuers when HHS identifies errors with data submitted to distributed data environments. One commenter requested that HHS flag claims with derived costs that have not been accepted for payment.

Response: We intend to provide each issuer with a periodic report on data functions performed in each issuer's distributed data environment, and to identify reinsurance-eligible claims. The reports would indicate whether HHS accepted or rejected submitted files and data, and would identify errors detected by HHS. Issuers would need to provide corrected files and data to address errors identified in HHS-provided reports for those files and data to be eligible for reinsurance processing. Timeframes for the processing and reporting of these reports, including for receipt of corrected files and discrepancy resolution, will be provided in future guidance.

Comment: Several commenters requested that HHS provide interim estimates for reinsurance payments and risk adjustment scores. These comments noted that interim estimates will assist issuers in completing financial statements and developing rates for the next calendar year.

Response: We recognize that both the risk adjustment and reinsurance programs are important programs in stabilizing premiums in the individual and small group markets. We will provide further detail on our approach to interim reporting in forthcoming guidance.

f. Claims Data From Capitated Plans

In § 153.710(c), we proposed that an issuer that does not generate claims in the normal course of business must derive costs on all applicable provider encounters using their principal internal methodology for pricing those encounters. If a plan has no such methodology, or has an incomplete methodology, we proposed that the plan be permitted to implement a methodology or supplement the methodology in a manner that yields derived claims that are reasonable in light of the specific market that the plan is serving.

Comment: Commenters generally supported HHS's inclusion of capitated plans' data in the reinsurance and risk adjustment programs. We received many comments asking HHS to provide additional guidance on deriving claims costs or methodological examples of how different types of capitation arrangements would derive their costs, including deriving costs for value-based strategies. Commenters also requested that the State and HHS approve fee schedules to ensure compliance with the reinsurance program.

Response: The proposed approach allows capitated plans the flexibility to use current pricing methodologies, if applicable. Many capitated plans have methods in place for deriving the costs of encounters for participation in other State and Federal programs. If a plan has no such methodology, or has an incomplete methodology, the plan would be permitted to implement a methodology or supplement the methodology in a manner that yields derived claims that are reasonable in light of the specific market that the plan is serving. We believe that permitting flexibility, rather than setting forth specific methodologies or fee schedules, better enables issuers to determine methodologies which are reasonable for the issuer's market.

Comment: One commenter stated that some health plans that sub-capitate

payments to providers may face difficulty in collecting comprehensive and accurate data on a timely basis.

Response: HHS initially considered a claims submission deadline of March 31 but extended the deadline to April 30 to allow issuers more time to submit the necessary enrollment and claim data. The claims submission deadline of April 30 of the year following the applicable benefit year is the latest possible date for HHS to meet our payment processing and reporting obligations codified in the Premium Stabilization Rule. Reinsurance and risk adjustment payment reporting obligations must be completed before the calculations for the risk corridors and MLR programs, and consequently require claims to be submitted by April 30.

Comment: Commenters requested that HHS set forth in regulatory text that capitated plans' derived cost claims will be subject to audit.

Response: Capitated plans, like all plans that submit reinsurance payment requests, or data to be considered for reinsurance payments or risk adjustment, would be subject to validation and audit. We have included data validation language in § 153.240(a)(3) for State-operated reinsurance programs, and in § 153.350 and § 153.630 for State- and HHS-operated risk adjustment programs, respectively. We will issue further rulemaking with regard to HHS-operated reinsurance program oversight for all claims, including those from capitated plans.

g. Establishment and Usage of Masked Enrollee Identification Numbers

We proposed in § 153.720(a) that an issuer of a risk adjustment covered plan or reinsurance-eligible plan in a State in which HHS operates risk adjustment or reinsurance, as applicable, must establish a unique masked enrollee identification number for each enrollee, in accordance with HHS-defined requirements as described in this section, and maintain the same masked enrollee identification number for an enrollee across enrollments or plans within the issuer, within the State, during a benefit year. In § 153.720(b), we proposed that an issuer of a risk adjustment covered plan or reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, may not include an enrollee's personally identifiable information in the masked enrollee identification number or use the same masked enrollee identification number for different enrollees enrolled with the issuer. As discussed in OMB

Memorandum M-07-16, the term "personally identifiable information" is a broadly used term across Federal agencies, and has been defined in the Office of Management and Budget Memorandum M-07-16 (May 22, 2007).³¹

Comment: We received several comments in support of using a masked enrollee number. However one commenter expressed concern that the provisions may not be sufficiently protective.

Response: HHS has taken several steps to ensure robust privacy and security standards. A distributed data approach protects consumer health data in a number of ways. First, a distributed data approach eliminates the need to transmit sensitive data. Data can be particularly vulnerable during transmission, so this approach eliminates this risk. HHS expects that information provided to HHS will be limited to information reasonably necessary for use in the risk adjustment and reinsurance programs. Also, with this approach, we are better able to limit the amount of data needed for program operations. We will be releasing, in forthcoming rulemaking, compliance standards for privacy and security standards, as applicable.

h. Deadline for Submission of Data

We proposed in § 153.730 that an issuer of a risk adjustment covered plan or reinsurance-eligible plan in a State in which HHS operates risk adjustment or reinsurance, as applicable, submit data to be considered for risk adjustment payments and charges and reinsurance payments for the applicable benefit year by April 30 of the year following the end of the applicable benefit year. In order for HHS to provide periodic reports on data functions performed in each issuer's distributed data environment, HHS recommends issuers submit data at least quarterly throughout the benefit year to support the calculation of reinsurance payments and risk adjustment payments and charges.

Comment: We received a comment requesting clarification on the penalty for non-compliant data submission.

Response: Compliance requirements will be forthcoming. We note, however, that one consequence of an issuer failing to timely submit claims and enrollment data would be that the information needed to calculate risk scores and reinsurance allowable amounts would not be available, potentially resulting in

a loss of risk adjustment or reinsurance payments for the issuer.

Comment: Several commenters requested clarification on the claims run out period.

Response: An issuer of a risk adjustment covered plan or reinsurance eligible plan in a State in which HHS operates risk adjustment or reinsurance should submit data by April 30 of the year following the applicable benefit year. For example, claims incurred in the 2014 benefit year must be submitted to HHS by April 30, 2015. The submission deadline will allow issuers time to process claims and submit data to their distributed data systems for HHS evaluation, and will provide HHS adequate time to calculate payments and charges.

H. Small Business Health Options Program

1. Employee Choice in the Federally-Facilitated SHOP (FF-SHOP)

In our proposed rule, we proposed that qualified employers in FF-SHOPs will choose a level of coverage (bronze, silver, gold, or platinum) and a contribution, and employees can then choose any QHP at that level.

In stakeholder consultations following the publication of the Exchange Establishment Rule, some issuers expressed openness to allowing the employee to "buy up" to certain plans at the next higher level of coverage, thereby offering employees a broader range of health plans. We sought comments on whether FF-SHOPs should offer an additional employer option that would allow a qualified employer to make available to employees all QHPs at the level of coverage selected by the employer plus any QHPs at the next higher level of coverage that a QHP issuer agrees to make available under this option. QHP issuers could decide whether or not to make available QHPs at the next higher level of coverage above the level of coverage selected by the employer.

We also sought comments on a transitional policy in which a Federally-facilitated SHOP (FF-SHOP) would allow or direct employers to choose a single QHP from those offered through the FF-SHOP. We received the following comments regarding the proposed provisions of choice in the Federally-facilitated SHOP:

Comment: A few commenters opposed offering employers the single QHP option, suggesting that each SHOP should focus on providing employee choice. Most commenters on this issue supported offering a single QHP option for employers, either as an additional

³¹ Available at: <http://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2007/m07-16.pdf>.

option or as the only option in the initial years of each SHOP. The commenters who supported allowing a qualified employer only the option of offering a single QHP in the initial years of SHOP operation cited several concerns, including whether issuers could complete enrollment and accounting system changes required to interact with the SHOP enrollment and premium aggregation systems required by employee choice; and whether there would be adequate time to educate employers, employees, brokers about the employer and employee choices available in the SHOP. They further suggested that tying Exchange participation to SHOP participation could lead some issuers to participate in neither the Exchange nor the SHOP.

Response: Each SHOP has the option to allow employers to offer employees a single QHP. We have concluded for the reasons identified by the commenters that, as a transition to broader employer adoption of employee choice models, each FF-SHOP should exercise this option, providing employers the option of offering a single QHP to employees, as the small group market customarily does today. This employer option will allow employers who prefer to offer employees a single QHP to participate in an FF-SHOP and retain potential eligibility for the small business tax credit, which is only available through a SHOP Exchange beginning in 2014.

We have also concluded that effective implementation of employee choice in the federally-facilitated SHOP will not be possible in 2014 because of operational challenges noted by the commenters. Therefore, we are proposing in the Small Business Health Options Program proposed rule issued simultaneously with this final rule and published elsewhere in this issue of the **Federal Register** that: (1) The effective date of the employee choice requirements (§ 155.705(b)(2)) and the premium aggregation requirements (§ 155.705(b)(4)) will be January 1, 2015; (2) SHOP Exchanges may offer employee choice and perform premium aggregation for plan years beginning on or after January 1, 2014; and (3) an FF-SHOP will not offer employee choice and premium aggregation until plan years beginning on or after January 1, 2015.

Comment: A few commenters supported a single QHP option but only if linked to the required use of composite premiums.

Response: We believe the decision about the use of calculated composite premiums should remain an employer decision, unless State law requires that premiums be presented to employers as

composite premiums, and have not adopted the linkage suggested by the commenters.

Comment: The employer option of broader, two-level plan choice was supported by a number of commenters, either as proposed or as two-level plan choice among all plans at those levels, without the QHP issuer's choice whether to offer as a buy-up. Several commenters characterized employee choice as a key distinguishing feature of the SHOP, and one suggested considering full employee choice. Many commenters, however, cited the adverse selection that may occur with choices across levels of coverage and recommended restricting employee choice to a single level of coverage chosen by the employer. One commenter noted the operational complexity of a buy-up option.

Response: We are not finalizing the rule with provisions for the FF-SHOPs to accommodate the two-level plan choice because of concerns about adverse selection in the first year of SHOP operation. We note that broader employee choice is a desirable feature of a FF-SHOP that will be explored in subsequent years. Further, the final rule at § 155.705(b)(3)(i) permits each SHOP the flexibility to offer qualified employers choices beyond making one metal level available to employees. Although we are not exercising this flexibility for the FF-SHOPs, we anticipate that some State-based SHOPs may do so.

Comment: One commenter asked that the final notice reflect that employer offerings may also be subject to collective bargaining agreements.

Response: We concur with that comment and note here that employer offers of benefits may be subject to the provisions of collective bargaining agreements.

We are finalizing the rule for the FF-SHOPs with some modifications from the proposal. Under § 155.705(b)(3) as finalized, each FF-SHOP will allow qualified employers the choice of offering employees either all QHPs at a single level of coverage selected by the employer or a single QHP selected by the employer. However, we are proposing elsewhere in this issue of the **Federal Register** that, as a matter of transition, each SHOP have the option to choose whether to implement employee choice and premium aggregation beginning January 1, 2014 or January 1, 2015, with each FF-SHOP exercising the January 1, 2015 implementation option.

2. Methods for Employer Contributions in an FF-SHOP

Employers may elect a variety of ways to contribute toward health coverage that are consistent with Federal law. Because employees in the SHOP may be choosing their own coverage and will need to know the net cost to them after the employer's contribution, each employer will need to choose a contribution method before its employees select their qualified health plans. To facilitate this, we proposed in § 155.705 (b)(11)(i) that each SHOP could define a standard method by which employers would contribute toward the employee coverage. We also proposed in § 155.705 (b)(11)(ii) a specific, standardized method for the FF-SHOPs—a method that reflects a meaningful employer choice and that conforms to existing Federal law.³²

Comment: A broad range of commenters supported our proposal. One commenter expressed concern about the effect on older employees, but recognized the need to match the outside market options. Two commenters suggested requiring a calculated composite premium as the only allowable method.

Response: The choice of contribution method offered in each FF-SHOP reflects a meaningful choice available to employers in 2014, absent a provision in State law to the contrary. We note that the premium differential effect on older employees is limited by the maximum 3:1 ratio for adults. As noted in the proposal, we believe the decision about whether to use a calculated composite premium is best made by the employer so long as that choice is consistent with applicable State law.

Comment: One commenter suggested addressing the contribution method by allowing employers to offer only a single QHP as a transition, which would also give issuers time to adopt SHOP per member rating rules.

Response: Whether an employer offers a single QHP or all QHPs at a given level of coverage, an FF-SHOP will still need to adopt an approach to employer contributions. The approach proposed in the draft Notice and finalized in this rule will allow employers options regarding how they and their employees contribute toward coverage that applies to both single QHP and single level of coverage offers.

Comment: One commenter stated that an issuer should not be involved in employer decisions about allocation of premium between employer and employee.

³² See 77 FR 73184–85.

Response: We do not believe that either the proposed rule or the final rule involves the QHP issuer in employer decisions about the employer contribution toward the premium. The FF-SHOP standard contribution method, as proposed and finalized, does establish a method by which the employer can contribute in a standardized, non-discriminatory way. The QHP issuer is not involved in the FF-SHOP policy nor is the issuer involved in employer decisions about the allocation of premium between employer and employee.

Comment: One commenter asked for clarification about how mid-year turnover would be handled with a calculated composite premium method.

Response: In future guidance, we will discuss mid-year changes in group composition and how a SHOP might address the resulting changes in the average premium for the group.

We proposed at § 155.705(b)(11)(ii)(D) to permit a qualified employer participating in an FF-SHOP to establish, to the extent allowed by Federal and State law, different contribution percentages for different employee categories. We have concluded that this provision is inconsistent with the uniformity provisions established in Internal Revenue Service Notice 2010-82, which require employers to contribute a uniform percentage to all employees in order to claim a small business tax credit for health insurance premiums paid. Although the provisions in Notice 2010-82 apply only to employers claiming the tax credit in tax years through December 31, 2013, the use of a uniform percentage for all employees helps assure that the employer contributions do not violate other anti-discrimination provisions. We therefore are not finalizing the proposal at § 155.705(b)(11)(ii)(D) and the final rule redesignates the proposed paragraphs (b)(11)(ii)(E) and (F) as paragraphs (b)(11)(ii)(D) and (E). We are otherwise finalizing the rule as proposed.

3. Linking Issuer Participation in an FFE to Participation in an FF-SHOP

We proposed standards that we believe will help ensure that qualified employers and qualified employees enrolling through an FF-SHOP are offered a robust set of QHP choices in a competitive small group marketplace. We believe that a competitive marketplace offering qualified individuals, qualified employers, and qualified employees a choice of issuers and QHPs is a central goal of the Affordable Care Act, and that the SHOP can provide an effective way for small

employers to offer their employees a choice of issuers and QHPs. We proposed in § 156.200(g) to leverage issuers' participation in an FFE to ensure participation in the corresponding FF-SHOP, provided that no issuer would be required to begin offering small group market products as a result of this provision. We sought comments on this issue and whether or not the policy meets three intended goals: Enhancing employer and employee choice, assuring similar effects on single issuers and issuer groups, and not requiring any issuer to begin offering coverage in the small group market in order to meet this provision.

Comment: A substantial number of commenters supported the tying provision and the issuer group definition, concluding that the provision would enhance consumer choice in FF-SHOPs.

Many commenters opposed the tying provision, arguing that plans should have full choice about participation and that requiring participation may make it harder to meet the timeline for QHP submission in the individual market FFE. Several commenters specifically suggested that the tying provision might result in decreased issuer participation in the individual market FFE in some states. Several commenters noted the extensive efforts that would be required to offer plans in the SHOP, even if the issuer were already participating in the State's small group market.

Response: We have considered the concerns about the tying provision and conclude that adopting the provision will help assure that small group market QHPs are available to employers and employees. We have also considered comments that tying would lead to issuers declining participation in both the FFE and the FF-SHOP, and concluded that it is more likely to result in that outcome among issuers with relatively low market shares for whom the administrative costs to modify systems to enable SHOP participation may outweigh the value of increased enrollment. Finally, we considered how these issuer concerns about tying might relate to issuer concerns about the effects of employee choice, and whether those concerns might be reduced by our concurrent proposal to allow SHOPs to delay the implementation of employee choice by a year.

Adoption of a tying standard that applies only to issuers with more than a threshold market share will serve the goal of assuring that QHPs are available in each FF-SHOP in 2014 without unduly burdening issuers. We examined small group market share data based on

earned premiums reported to HHS in conjunction with evaluations of issuer minimum loss ratios and have concluded that using a 20 percent market share to determine whether a small group market issuer is subject to the tying provision will result in sufficient competition and the ability to offer a robust set of QHPs in the FF-SHOPs, while minimizing the burden on small issuers. We are finalizing the rule accordingly.

Comment: One commenter objected because OPM does not require multi-State plans to offer SHOP products until 2017, and CO-OPs are not subject to a similar provision.

Response: In a final rule published elsewhere in this issue of the **Federal Register**, OPM establishes a similar tying provision for multi-State plans based on market share. CO-OPs operate under a different tying provision. We direct the commenter's attention to § 156.515(c)(2), which requires CO-OPs to comply with a strict tying provision with no market share exception. If a CO-OP participates in a State's small group market, it must offer silver and gold plans on the SHOP.

Comment: One commenter suggested implementing the tying provision but reevaluating the policy in two years. A second commenter suggested the possibility of delaying introduction of the tying provision.

Response: We will be evaluating on an ongoing basis the effectiveness of the tying provision in enhancing employer and employee choice in FF-SHOPs without adversely affecting participation in the FFEs.

We are finalizing these provisions as proposed, with a modification to limit the tying rule to at the applicant issuer itself or an issuer member of the same issuer group that has a 20 percent share of the small group market in the State, based on the most recent earned premium data reported under § 158.110 to fulfill minimum loss ratio reporting requirements.

4. Broker Compensation for Coverage Sold Through an FFE or FF-SHOP

In a new paragraph § 156.200(f), we proposed that QHP certification by an FFE and an FF-SHOP be conditioned on the QHP issuer paying similar broker compensation for QHPs offered through an FFE or FF-SHOP that it would pay for similar health plans offered outside an FFE and an FF-SHOP. We requested comments on whether "similar health plans" is a sufficient standard and if not, which factors should be considered in identifying "similar health plans." We also requested comments on how this standard might apply when small

group market product commissions are calculated on a basis other than an amount per employee or covered life or a percentage of premium.

Comment: Multiple commenters representing both consumer groups and issuers supported the compensation proposal, with several recommending that “similar” be more clearly defined. One commenter proposed that “similar” be defined by the issuer. One commenter opposed the proposal, recommending that the issuer be allowed to set different compensation on and off the Exchange.

Response: For the reasons outlined in the preamble to the proposed rule, we are finalizing these provisions as proposed. We do not at this time propose a specific definition of “similar.” We expect to issue further guidance at a later date.

5. Minimum Participation Rate in FF–SHOPS

As discussed the preamble to the proposed rule, we aim to minimize the potential for risk selection in the small group market and in SHOPS. In the final Market Reform Rule, we discussed this issue in connection with section 2702 of the PHS Act, which requires issuers in the individual and group markets to accept every employer and individual that applies for such coverage but permits issuers to limit enrollment in coverage to only open and special enrollment periods. That final rule implements this provision by permitting an issuer offering health insurance coverage in the small group market to limit its offering of coverage to the limited open enrollment periods described in § 147.104(b)(1) in the case of an employer that fails to meet contribution or minimum participation requirements. In connection with the SHOP, the Exchange Establishment final rule permits a SHOP to authorize minimum participation requirements for qualified employers participating in the SHOP so long as the participation is measured at the SHOP level and not based on enrollment in a single QHP.

We proposed a minimum participation rate for an FF–SHOP of 70 percent, calculated at the level of the participation of the employees of the qualified employer in the FF–SHOP and not enrollment in a single QHP. We based the proposed rate on consultations with issuer organizations and regulators about customary minimum participation rates and proposed that it apply to all qualified employers in the FF–SHOP serving a given State. Because State law, regulation, and market practices vary from State to State, we also proposed an

option for an FF–SHOP to adopt a different uniform minimum participation rate in a State with a FF–SHOP if there is evidence that:

- (1) A State law sets the rate; or
- (2) A higher or lower rate is customarily used by the majority of QHP issuers in that State for products in the State’s small group market outside the SHOP. In addition, we proposed to exclude employees with certain types of alternative coverage from the calculation of the minimum participation rate:

- (1) A group health plan offered by another employer; or
- (2) A governmental program such as Medicare, Medicaid, or TRICARE. The preamble, and the proposed regulation text, also acknowledged that imposition of any minimum participation rate would have to be subject to the exception to the guaranteed issue requirements of section 2702 of the PHS Act and the then-pending proposed rule implementing guaranteed issue.

We sought comments on the default minimum participation rate and the exceptions that will help ensure alignment with current State practice and standards inside and outside the SHOP.

Comment: Many commenters were supportive of both setting a default and allowing flexibility to adapt to different states.

Response: We are retaining both the default and the flexibility, as proposed.

Comment: One commenter questioned the necessity of a minimum participation rate given market reforms and suggested using minimum contribution instead.

Response: While the degree of risk segmentation is substantially reduced by market reform, we conclude that a minimum participation rate should be applied, at least in the early years of an FF–SHOP. We have no authority under the Exchange Establishment Rule to set a minimum contribution rate for an FF–SHOP. We note, however, that a minimum participation rate encourages employers to set their contributions toward coverage high enough that the minimum participation rate is achieved.

We are finalizing the provisions as proposed, with minor revisions to the text consistent with the discussion in the preamble. The introductory text at § 155.705(b)(10), as well as the text at subparagraph (b)(10)(i), is amended to include the phrase “Subject to § 147.104 of this title” to clarify when and how a minimum participation rate may be imposed under applicable law. Under this final rule, when an FF–SHOP makes the employee choice model available to qualified employers, it will

use a consistent minimum participation rate across issuers.

6. Determining Employer Size for Purposes of SHOP Participation

We proposed to amend the definitions of “small employer” and “large employer” in § 155.20 to specify the method for determining employer size for Exchange purposes and to add the definition of large employer to § 157.20. In determining whether an employer is a small employer for purposes related to the SHOP, we proposed that the full-time equivalent method used in section 4980H(c)(2)(e) of the Code, as added by section 1513 of the Affordable Care Act, be used. We sought comments on the proposed definition.

Comment: Some commenters suggested that each SHOP, including FF–SHOPS, should use State counting methods permanently. Other commenters supported an immediate move to a federal standard counting method that takes all employees into account. One commenter noted that the more comprehensive reference for the counting method used in the IRC would be Section 4980H(c)(2), which includes a provision to exclude certain seasonal employees when determining whether an employer is subject to the shared responsibility provisions.

Response: We believe that the Affordable Care Act requires the use of a counting method that takes part time employees into account, and that the full-time equivalent method used in section 4980H(c)(2)(e) of the IRC is a reasonable method to apply with regard to Exchanges. We have changed the IRC reference from section 4980H(c)(2)(e) to 4980H(c)(2) in response to the comment. We believe that the broader cross-reference is appropriate because it brings here the limit in § 4980H(c)(2)(B) on how certain seasonal employees are counted. We believe that excluding certain seasonal employees when determining whether an employer has more than 50 employees would be closer to counting provisions used in many states and that employers should be able to use the same method to determine SHOP eligibility that they will use to determine whether they will be subject to section 4980H. This method of determining SHOP eligibility will be reevaluated before 2016, when the small group market in all states will consist of employers with from 1 to 100 employees rather than 1 to 50 employees.

Comment: Several commenters recommended that any counting method used to define employer size and thus the corresponding group market should

apply for all ACA purposes, not just for purposes relating to Exchanges.

Response: Based on the scope of the proposed regulations, we are unable to adopt definitions in this Notice that apply beyond the Exchange regulations.

We are finalizing the provisions as proposed, changing the reference to section 4980H(c)(2) of the IRC.

7. Definition of a Full-Time Employee for Purposes of Exchanges and SHOPS

We proposed to add to § 155.20 a definition of full-time employee that cross-references section 4980H(c)(4) of the Code, which provides that a full-time employee with respect to any month is generally an employee who is employed an average at least 30 hours of service per week, subject to the transitional policies discussed in the next paragraph. Under our proposal, this definition would control for purposes of the section 1312(f)(2)(A) requirement that qualified employers offer coverage to all full-time employees.

Comment: Only one commenter addressed the definition of full time employee, suggested that full-time employee be defined as an employee working more than 1300 hours in the past year.

Response: We find no rationale for adopting that definition of a full time employee, and retain instead the definition based on 30 hours a week used elsewhere in the Affordable Care Act.

We are finalizing the definition as proposed.

8. Transitional Policies

With our proposed definitions of large and small employer and full-time employee, for purposes of Exchange and SHOP administration, we proposed policies to provide for a transition from different, existing State law. With respect to State-operated SHOPS for 2014 and 2015 only, we proposed that HHS will not take any enforcement actions against a State-operated SHOP for including a group in the small group market based on a State definition that does not include part-time employees when the group should have been classified as part of the large group market based on the Federal definition. Our proposal did not address application of State-specific definitions or counting rules that would exclude a small group health plan from protections provided under federal law. Similarly, during 2014 and 2015, an employer and a State-operated SHOP may adopt a reasonable basis for their determination of whether they have met the SHOP requirement to offer coverage

to all full-time employees, such as the definition of full-time employee from the State's small group market definition or the Federal definition from section 4980H of Chapter 43 of the Code.

Under our proposal, however, each FF-SHOP would use a counting method that takes part-time employees into account. We proposed that these definitions will be effective October 1, 2013 for each FF-SHOP. We requested comments on the proposed definitions and on the proposed transition policies.

Comment: Most commenters supported using State methods, either long term or as a transitional method in 2014–2015. Two commenters supported an immediate move to a federal standard counting method that takes all employees into account.

Response: We conclude that, for purposes relating to the Exchange regulations, the definition of “full-time employee” and the definitions of “small employer” and “large employer” and their associated counting methods using a full-time equivalent (FTE) methodology should be effective for plan years beginning on or after January 1, 2016. During 2014 and 2015, when states have the discretion to choose whether the upper limit of small employer size is 50 or 100, we will exercise enforcement discretion, relying on State methods of determining group size and status as a full-time employee. However, in operating the FF-SHOPS, we do not have the same discretion; for plan years beginning on or after January 1, 2014 and in connection with open enrollment activities beginning October 1, 2013, we will use definitions of full-time employee, small employer, and large employer based on the FTE method of determining group size. Thus, prior to 2016, an FF-SHOP will use the State's choice of 50 or 100 employees, but will count those employees using the full-time equivalent method referenced in the definitions.

We are finalizing the effective dates of the definitions of “full-time employee,” “small employer,” and “large employer” as proposed, with a minor modification to clarify that the definitions will apply to plan years beginning on or after January 1, 2014 and in connection with open enrollment activities beginning October 1, 2013. As the SHOP, including FF-SHOPS, will not provide access to coverage until January 1, 2014, we believe the proposed text may have been subject to unintended ambiguity and are finalizing revised text to eliminate that concern.

9. Web Site Disclosures Relating to Agents and Brokers

We proposed modifications to the Web site disclosure standards relating to brokers in § 155.220(b). Specifically, we proposed a new paragraph (b)(1) that would allow an Exchange or SHOP to limit the display of agent and broker information to include only those licensed agents and brokers who are registered with the Exchange or SHOP and a new paragraph (b)(2) that would specifically adopt this provision for an FFE and an FF-SHOP. We believed that listing only brokers who have registered with the Exchange is in the best interest of the consumer, both because the registration and training helps assure that the agent or broker is familiar with the Exchange policies and application process and because the proposed listing will not contain large numbers of licensed brokers who are not active in the market. We welcomed comments on these proposals.

Comment: Several commenters expressed strong support for the authority to list only registered brokers. One suggested the broader authority to list only those actually selling exchange QHPs. None opposed the proposal.

Response: We are finalizing the regulation as proposed. At this time, we do not propose further limiting the listing based on actual sales.

10. QHP Issuer Standards Specific to SHOP

We proposed modifications to the QHP issuer standards specific to SHOP for enrollment in § 156.285. Specifically, we proposed a technical correction in paragraph (c)(7) such that QHP issuers participating in the SHOP must enroll qualified employees if they are eligible for coverage. This correction aligns SHOP enrollment standards to Exchange enrollment standards.

Comment: One commenter supported the proposed regulation. No other comments were received.

Response: We are finalizing the regulation as proposed.

I. Medical Loss Ratio Requirements Under the Patient Protection and Affordable Care Act

1. Treatment of Premium Stabilization Payments, and Timing of Annual MLR Reports and Distribution of Rebates

In the December 2012 HHS Notice of Benefit and Payment Parameters for 2014 proposed rule (77 FR 73187), we proposed to modify the definition of premium revenue in § 158.130, the formula in § 158.221(c) for calculating an issuer's MLR, and the formula in § 158.240(c) for calculating an issuer's

rebate if the MLR standard is not met, in the current MLR regulation to account for payments and receipts related to the premium stabilization programs. Specifically, we proposed to account for all premium stabilization amounts in a way that would not have a net impact on the adjusted earned premium used in calculating the MLR denominator and rebates. Additionally, we proposed to amend § 158.140(b) to include all premium stabilization amounts (positive or negative) as adjustments to incurred claims in calculating the MLR numerator as provided in § 158.221. We invited comment on this approach. We also indicated in the proposed rule that we considered adopting a methodology under which premium stabilization amounts would have a net impact on the MLR denominator, and invited public comment on that approach as well.

In addition, as discussed in the proposed rule, we proposed to amend § 158.110(b), § 158.240(d), and § 158.241(a)(2) to change the MLR reporting and rebate deadlines, beginning with the 2014 MLR reporting year, to coordinate them with the reporting cycles of the premium stabilization programs. Comments on the proposed timeline were welcomed.

Comment: Most commenters supported our proposal to include risk corridors amounts and reinsurance payments as adjustments to the MLR numerator, but many commenters suggested a change in our proposed approach with respect to reinsurance contributions and all risk adjustment amounts, which these commenters recommended be applied as adjustments to the MLR denominator. With respect to the reinsurance contributions, most commenters expressed the view that these are assessments on issuers that are more properly regarded as assessments or regulatory fees, and consequently should be deducted from premium in MLR and rebate calculations. With respect to risk adjustment, several commenters asserted that because State average premium is used to calculate risk adjustment amounts, MLR and rebate calculations should treat these transfer amounts as adjustments to premium. Two commenters expressed concern that including any premium stabilization amounts in the MLR numerator would reduce rebates. One commenter also suggested that we clarify the rebate calculation example in § 158.240(c)(2) to make it clear that the rebate calculations account for premium stabilization amounts at the aggregation

level, rather than at an individual enrollee level.

Response: We recognize commenters' concerns regarding inclusion of risk adjustment amounts in the MLR numerator. However, as noted in the proposed rule, while PHS Act section 2718 provides that premium revenue should "account for" collections or receipts for the premium stabilization programs, section 1342(c) of the Affordable Care Act requires that risk corridors calculations treat reinsurance and risk adjustment payments as adjustments to allowable cost. Because the MLR and the risk corridors programs are closely related and rely on the same definitions, there should be consistency between these two programs. Proper functioning of the MLR and premium stabilization programs will be especially important in 2014–2016, the initial years the health insurance market will undergo significant changes. Thus, with respect to premium stabilization amounts other than reinsurance contributions (that is, risk adjustment amounts, risk corridors amounts, and reinsurance payments), we are adopting our proposed approach that these adjustments have a net impact on the MLR numerator. However, we agree with those commenters that stated that reinsurance contributions could reasonably be characterized as fees or assessments deductible from premium in MLR and rebate calculations, and this final rule amends § 158.161(a) accordingly. Additionally, we are making clarifying changes to the rebate calculation example in § 158.240(c)(2) in response to comments.

In sum, this final rule amends the formula for calculating the MLR as follows:

$$\text{MLR} = \frac{[(i + q - s + n - r) / \{(p + s - n + r) - t - f - (s - n + r)\}] + c}{c}$$

Where,

i = incurred claims

q = expenditures on quality improving activities

p = earned premiums

t = Federal and State taxes and assessments

f = licensing and regulatory fees, including transitional reinsurance contributions

s = issuer's transitional reinsurance receipts

n = issuer's risk corridors and risk

adjustment related payments

r = issuer's risk corridors and risk adjustment related receipts

c = credibility adjustment, if any.

Issuers must provide rebates to enrollees if their MLRs fall short of the applicable MLR standard for the reporting year. Rebates for a company whose MLR falls below the minimum MLR standard in a given State market

will be calculated using the following amended formula:

$$\text{Rebates} = (m - a) * [(p + s - n + r) - t - f - (s - n + r)]$$

Where,

m = the applicable minimum MLR standard for a particular State and market

a = issuer's MLR for a particular State and market.

The amendments made by this final rule will be effective for MLR reporting years beginning in 2014.

Comment: Three commenters recommended that HHS include the Federally-facilitated Exchange user fees and user fees assessed on issuers participating in the HHS-operated risk adjustment programs as regulatory fees deductible from premium in MLR and rebate calculations. Two commenters recommended that issuer costs associated with operating risk adjustment data validation systems also be deducted for MLR purposes, either as an addition or offset to the payments or receipts related to the premium stabilization programs, or as regulatory fees or assessments deducted from premium. Three commenters further suggested that fees and/or operational costs related to the premium stabilization programs and Exchanges, that are priced into premium for policy years spanning 2013–2014, and consequently will be partially reflected in 2013 premium, be either deducted or excluded from 2013 premium.

Response: We have previously addressed the deductibility of State and Federal Exchange user fees in sub-regulatory guidance issued on April 20, 2012.³³ We agree with the commenters' suggestion regarding the deductibility of the risk adjustment user fees, and we interpret § 158.161(a) as allowing these user fees to be deducted from premium in MLR and rebate calculations. However, we do not agree with commenters that issuer expenditures on risk adjustment data validation systems, or any other operational costs related to the premium stabilization programs, constitute a regulatory fee or assessment or a transfer under the premium stabilization programs. We do not think that these types of expenditures can be distinguished from issuers' other administrative costs involved in compliance with laws and regulations. We also do not agree with comments suggesting that it would be appropriate to reduce rebates to 2013 enrollees by applying estimated 2014 regulatory fees

³³ CCIIO Technical Guidance (CCIIO 2012–002): Questions and Answers Regarding the Medical Loss Ratio Regulation, Q&A #34 (Apr. 20, 2012), available at <http://ccio.cms.gov/resources/files/mlr-qna-04202012.pdf>.

priced into 2013 premium to 2013 MLR and rebate calculations. PHS Act section 2718 does not provide for estimated regulatory fees for future years to be deducted from premium used in MLR and rebate calculations for the reporting year.

Comment: We received several comments supporting our proposal to extend the MLR and rebate deadlines. Two commenters opposed extending the rebate deadline.

Response: We appreciate the comments regarding the proposed deadlines. As noted in the proposed rule, we recognize both consumers' and policyholders' interests in maintaining the dates for MLR reporting and rebates as close to the June 1 and August 1 dates as possible, as well as issuers' interests in having the necessary data to submit their annual MLR reports and having sufficient time to disburse any rebates. We believe that the proposed deadlines strike a balance between these competing interests. Therefore, this final rule extends the MLR and rebate deadlines in § 158.110(b), § 158.240(d), and § 158.241(a)(2) as proposed in the December 2012 HHS Notice of Benefit and Payment Parameters for 2014 proposed rule (77 FR 73187).

2. Deduction of Community Benefit Expenditures

In the December 2012 HHS Notice of Benefit and Payment Parameters for 2014 proposed rule (77 FR 73187), we proposed to amend § 158.162(b)(1)(vii) to allow an issuer exempt from Federal income tax to deduct both State premium taxes and community benefit expenditures from earned premium in MLR and rebate calculations. The proposal limited the community benefit expenditure deduction available to a tax exempt issuer to the higher of (1) the highest premium tax rate in the State; or (2) 3 percent of premium, ensuring a level playing field. The proposed amendment would not change the treatment of State premium taxes and community benefit expenditures for those issuers that are not exempt from paying Federal income tax.

Comment: Several commenters suggested that the proposed treatment is unnecessary and would give Federal income tax exempt entities a competitive advantage. These commenters suggested that tax-exempt entities have sufficient advantages stemming from their favored tax treatment. These commenters further asserted that the deduction of community benefit expenditures should not depend on an issuer's tax status because such funds are not available to be used on subscribers' claims. The

commenters proposed either allowing any issuer to deduct all taxes and community benefit expenditures, or eliminating the community benefit expenditure deduction.

In contrast, most other commenters agreed that a Federal income tax exempt issuer is required to make community benefit expenditures to maintain its Federal income tax exempt status and supported the deduction of both State premium taxes and community benefit expenditures from earned premium for such issuers. These commenters agreed that the proposed treatment levels the MLR playing field and would allow a Federal income tax exempt issuer to deduct its community benefit expenditures in the same manner that a for-profit issuer is allowed to deduct its Federal income taxes.

Response: We agree that, because an issuer that is exempt from Federal income taxes must make community benefit expenditures, such an issuer should be allowed to deduct community benefit expenditures and State premium taxes. This final rule allows a Federal income tax exempt issuer to deduct its community benefit expenditures in the same manner that another issuer is allowed to deduct its Federal income taxes. This rule does not alter the community benefit expenditure deduction currently available to an issuer that is not exempt from Federal income taxes. Such issuers are allowed to deduct the higher of (1) their State premium taxes or (2) their community benefit expenditures limited to the highest premium tax rate charged to an issuer in the State. This final rule accordingly amends § 158.162(b)(1)(vii) as proposed in the December 2012 HHS Notice of Benefit and Payment Parameters for 2014 proposed rule (77 FR 73187). We note that the amount of community benefit expenditures deducted is not allowed to exceed the amount of actual community benefit expenditures in the reporting year.

Comment: One commenter suggested that the proposed community benefit expenditure deduction could lead to abuse, while another suggested that the deduction limit was speculative. However, most commenters agreed with the proposed community benefit expenditure limit.

Response: In its MLR model rule, the National Association of Insurance Commissioners (NAIC) adopted and limited the community benefit deduction to the State premium tax rate. We adopted the NAIC methodology in the December 1, 2010 interim final rule (75 FR 74864, as amended), and comments in response to it noted that some States do not subject every type of

issuer to State premium taxes and the community benefit deduction might not be available to those tax exempt issuers. In balancing the availability of the deduction and the potential for abuse, this final rule implements the community benefit expenditure deduction cap of the highest of (1) 3 percent of premium, or (2) the highest premium tax rate charged in the State, as proposed in the December 2012 HHS Notice of Benefit and Payment Parameters for 2014 proposed rule (77 FR 73187).

3. Summary of Errors in the MLR Regulation

In the December 2012 HHS Notice of Benefit and Payment Parameters for 2014 proposed rule (77 FR 73187), we proposed to correct three errors in the December 1, 2010 interim final rule (75 FR 74864, as amended): the date by which issuers must define the formula they use for the blended rate adjustment, described in § 158.140(b)(5)(i); the date after which partially-credible issuers that consistently fail to meet the MLR standard will not be allowed to use a credibility adjustment, described in § 158.232(d); and the calculation of the per-person deductible described in § 158.232(c)(1)(i).

Comment: We received one comment regarding our proposed correction to § 158.232(d). The commenter recommended that an issuer that fails to meet the MLR standard for four or more consecutive years be penalized only once every three years. The commenter stated that after an issuer fails to meet the MLR standard for three consecutive years (the statistical probability of which is generally 50 percent x 50 percent x 50 percent, or 12.5 percent), the probability of it failing to meet the MLR standard for the fourth consecutive year is 50 percent.

Response: We disagree with the commenter's calculation. The commenter is correct that the statistical probability of an issuer failing to meet the MLR standard in any given year may be 50 percent. However, the probability of an issuer failing to meet the MLR standard for a number of consecutive years is 50 percent – n, where n is the number of years. Consequently, the probability of an issuer failing to meet the MLR standard for four consecutive years is 6.25 percent, and for five consecutive years it is 3.125 percent. With each additional year, the probability of an issuer failing to meet the MLR standard due to statistical fluctuations continues to shrink, increasingly indicating an intentional pricing below the MLR standard.

This final rule therefore implements the technical corrections to § 158.140(b)(5)(i), § 158.232(d), and § 158.232(c)(1)(i) as proposed in the December 2012 HHS Notice of Benefit and Payment Parameters for 2014 proposed rule (77 FR 73187).

Comment: We received several comments suggesting that HHS clarify the MLR treatment of State high-risk pool assessments, events occurring after MLR reporting deadlines, and cost-sharing reductions. We also received one comment suggesting a larger adjustment for fraud prevention activities, an extension of allowable ICD-10 costs to the 2013 reporting year, and inclusion of all-payer claims databases in quality improving activities.

Response: The matters discussed in these comments are not within the scope of this final rule. However, we will continue to consider the need to issue clarifying guidance regarding the various accounting and actuarial elements affecting MLR and rebate calculations.

IV. Provisions of the Final Regulations

For the most part, this final rule incorporates the provisions of the proposed rule. Those provisions of this final rule that differ from the proposed rule are as follows:

A. Provisions for the State Notice of Benefit and Payment Parameters

- We are not amending § 153.100(c) to provide that, if a State is required to publish an annual State notice of benefit and payment parameters for benefit year 2014, it must do so by the 30th day following the publication of the final HHS notice of benefit and payment parameters.

B. Provisions and Parameters for the Permanent Risk Adjustment Program

- We are modifying the requirement at § 153.360 to clarify that small group market plans will be risk adjusted in the State in which the employer's policy was filed and approved.
- We are adding § 153.610(f) to describe the risk adjustment user fees.

C. Provisions and Parameters for the Transitional Reinsurance Program

- We are amending the definition of "contributing entity" in § 153.20 to include clarifying language that a contributing entity is a health insurance issuer or a self-insured group health plan.
- We are amending § 153.100(a)(2) by replacing the cross-reference to § 153.220(d) with § 153.220(d)(1). We are making corresponding revisions in

§ 153.100(d)(2); and § 153.110(b); § 153.400(a).

- We are deleting § 153.220(d)(2), which required a State to notify HHS within 30 days after publication of the draft annual HHS notice of benefit and payment parameters for the applicable benefit year of the additional contribution rate that it elects to collect.

- We are revising § 153.230(a) by replacing non-grandfathered individual market plan with reinsurance-eligible plan.

- We are revising § 153.230(c) to clarify that national reinsurance payments are calculated as the product of the national coinsurance rate multiplied by the health insurance issuer's claims costs for an individual enrollee's covered benefits that the health insurance issuer incurs in the applicable benefit year.

- We are revising § 153.232(c) by replacing non-grandfathered individual market plan with reinsurance-eligible plan and clarifying that the incurred claims costs for an individual enrollee's covered benefits are those incurred in the applicable benefit year.

- We are revising § 153.232(d) by clarifying that reinsurance payments will be calculated with respect to an issuer's incurred claims costs for an individual enrollee's covered benefits incurred in the applicable benefit year.

- We are revising § 153.235(a) to provide that HHS will allocate and disburse to each State operating reinsurance (and will distribute directly to issuers if HHS is operating reinsurance on behalf of a State), reinsurance contributions collected from contributing entities under the national contribution rate for reinsurance payments. The disbursed funds would be based on the total requests for reinsurance payments made under the national reinsurance payment parameters in all States and submitted under § 153.410, net of any adjustment under § 153.230(d).

- We are amending § 153.240(b)(2) to clarify that a State must provide to an issuer of a reinsurance-eligible plan the calculation of the total reinsurance payments requested, on a quarterly basis during the applicable benefit year in a timeframe and manner determined by HHS, made under the national reinsurance payment parameters and State supplemental reinsurance payment parameters.

- We are amending § 153.400 to clarify that each contributing entity must make reinsurance contributions annually at the national contribution rate for all reinsurance contribution enrollees, in a manner specified by HHS.

- We are amending § 153.400(a)(1)(iii) to exclude from reinsurance contributions expatriate health coverage, as defined by the Secretary.

- We are amending § 153.400(a)(1) by adding paragraph (iv) to exempt employer-provided health coverage, when such coverage applies to individuals with respect to which benefits under Title XVIII of the Social Security Act (Medicare) are primary under the Medicare Secondary Payor rules under section 1862(b) of the Social Security Act.

- We are amending § 153.400(a)(2) by adding paragraph (xiii) to exempt a self-insured group health plan or health insurance coverage that is limited to prescription drug benefits from reinsurance contributions.

- We are revising § 153.405(a)(1), § 153.405(b) and § 153.405(d) by deleting "average" to clarify that reinsurance contributions are calculated by multiplying the number of covered lives of reinsurance contribution enrollees during the applicable benefit year for all contributing entities by the national contribution rate, pursuant to § 153.405(a).

- We are amending § 153.405(c) to provide that HHS will notify contributing entities of the reinsurance contribution amount to be paid for the applicable benefit year within 30 days of submission of the annual enrollment count.

- We are amending § 153.405(f) to revise the procedures for counting covered lives for group health plans with a self-insured coverage option and an insured coverage option.

- We are amending § 153.405(g) to revise the aggregation of multiple group health plans maintained by the same plan sponsor.

- We are amending § 153.405(g)(3) to clarify that a plan sponsor is not required to include as part of a single group health plan any group health plan that consists solely of excepted benefits, that only provide prescription drugs benefits, or that is an HRA, HSA, or FSA.

- We are amending § 153.410(a) to clarify that an issuer of a reinsurance-eligible plan may make requests for reinsurance payments when an issuer's claims costs for an enrollee of that reinsurance-eligible plan has met the criteria for reinsurance payments in 45 CFR subpart B and this final rule and where applicable the State notice of benefit and payment parameters.

D. Provisions for the Temporary Risk Corridors Program

- We are modifying our proposed definition of "taxes" in § 153.500, by

replacing the term “taxes” with the term “taxes and regulatory fees.” We are clarifying that reinsurance contributions are included within the definition of “taxes and regulatory fees” in § 153.500.

- We are amending § 153.520 to remove references to reinsurance contributions in paragraph (d).

- We are also deleting § 153.530(b)(1)(ii) and amending § 153.530(b)(1) to eliminate the adjustment to allowable costs for reinsurance contributions made by an issuer, and are clarifying the treatment of community benefit expenditures within the risk corridors calculation.

E. Provisions for the Advance Payment of the Premium Tax Credit and Cost-Sharing Reduction Programs

- We are finalizing the provisions in § 155.330(g) substantially as proposed, with modifications to the language to increase clarity.

- We are adding additional language at § 155.340(e) to allow Exchanges greater flexibility in allocating the advance payment of the premium tax credit if one or more individuals in a tax household enroll in more than one policy through the Exchange. We also clarify our language in regard to tax filers covered by the same plan(s). In addition, we are adding paragraph (f) in which we specify the methodology that will be used for allocating advance payments of the premium tax credit provided through Federally-facilitated Exchanges.

- We are relabeling § 155.340(f) as § 155.340(g).

- We are making a minor technical correction at § 155.1030(a).

- We are making clarifying revisions to the provisions at § 155.1030(a) and (b)(2), § 156.420(a) and (b), § 156.430(a)(2), and 156.470(a), (b), and (e) to standardize language across the final rule.

- We are adding paragraph (c) to § 155.1030, paragraph (g) to § 156.420, paragraph (a)(4) to § 156.430, and paragraph (f) to § 156.470 to clarify the application of these provisions to issuers of multi-State plans.

- We are substituting § 156.140(c) for § 156.140(c)(1) as the cross-reference for the term “de minimis variation” in § 156.400.

- We are making a clarifying revision to the provision at § 156.410(a).

- We are modifying the provisions at § 156.430(b) to permit HHS to adjust the cost-sharing reduction advance payments if the QHP issuer demonstrates that the cost-sharing reductions provided are likely to differ significantly from the advance payment amounts.

- We are modifying paragraph (c)(1) and (2) of § 156.430, reserving paragraphs (c)(3) and (4), and adding paragraph (c)(5). The modified structure of § 156.430(c) will allow for the amendments established in the interim final rule with comment published elsewhere in this issue of the **Federal Register**.

- We are adding paragraph (g) to § 156.430 to provide that if an Indian is enrolled in a QHP in the individual market through an Exchange and is furnished an item or service directly by the Indian Health Service, an Indian Tribe, Tribal Organization, or Urban Indian Organization, or through referral under contract health services, the QHP issuer may not reduce the payment to any such entity for such item or service by the amount of any cost sharing that would be due from the Indian but for the prohibitions on cost sharing set forth in § 156.410(b)(2) and (3).

- We are making minor technical corrections to paragraphs (a) and (c) of § 156.440 to clarify the cross-references.

- We are deleting paragraphs (d)(2) through (4) of § 156.470, relating to certain allocation standards for stand-alone dental plans.

F. Provisions on User Fees for a Federally-Facilitated Exchange (FFE)

- We are removing the reference to billable enrollees, so that the user fee rate is applied directly to the premium set by the issuer.

G. Distributed Data Collection for the HHS-Operated Risk Adjustment and Reinsurance Programs

- We are finalizing the proposed provisions.

H. Small Business Health Options Program

- In § 155.20, the definitions of “full-time employee,” “small employer,” and “large employer,” we are clarifying the effective date for use of these definitions. In addition, in the definition of “large employer,” we are correcting the word “larger” to “large.”

- In § 155.705(b)(3)(ii), we are adding a provision requiring each FF–SHOP to allow qualified employers the choice of offering employees either all QHPs at a single level of coverage selected by the employer or, as a transition policy, a single QHP selected by the employer.

- We are revising § 155.705(b)(10) to include language limiting authority to impose a minimum participation rate subject to 45 CFR 147.104.

- In § 155.705(b)(11)(ii), we are deleting a provision at subparagraph (D) requiring each FF–SHOP to allow employers to define different

contribution percentages for different employee categories and relabeling the remaining subparagraphs accordingly.

- We are finalizing § 156.200(g) with modifications in new subparagraph (g)(3) so that the QHP certification standard relating to participation in the FFE and FF–SHOP does not apply if neither the issuer nor any other issuer in the issuer group has a market share of the State’s small group market greater than 20 percent, as determined using information submitted pursuant to 45 CFR 158.110.

I. Medical Loss Ratio Requirements Under the Patient Protection and Affordable Care Act

- We are amending the MLR formula to subtract reinsurance contributions from earned premium as regulatory fees, instead of treating them as an addition to incurred claims.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

The following sections of this document contain estimates of paperwork burden; however, not all of these estimates are subject to the information collection requirements (ICRs) under the PRA for the reasons noted.

A. Collections Related to State Operation of Reinsurance & Risk Adjustment Programs (§ 153.210 Through § 153.240, § 153.310)

In sections § 153.210 through § 153.240 and § 153.310 of the proposed rule, we estimated the cost of collecting data for State-operated reinsurance and risk adjustment. Fewer than 10 States have told HHS that they will operate reinsurance or risk adjustment for the

2014 benefit year. Since collections from fewer than 10 persons are exempt from the PRA under 44 U.S.C. 3502(3)(A)(i), we are not seeking PRA approval for these information collection requirements. However, if more than nine States elect to operate risk adjustment in the future, we will seek PRA approval for these information collections.

Comment: One commenter stated that our administrative cost estimates for these provisions were too low to be credible. Another commenter stated that we underestimated the cost to States of administering supplemental reinsurance payment parameters and monitoring fund balances. In particular, the commenter stated that establishing a governing board, engaging with stakeholders, and hiring independent actuaries would be expensive. One commenter believed that the cost to submit a report should include the State's costs for executive-level review to determine whether to operate reinsurance, and that HHS was confusing regulatory cost with the PRA's information collection burden.

Response: We limited our estimates in the proposed rule to the incremental information collection associated with the requirements of these provisions. In the "Supporting Statement for Paperwork Reduction Act submissions: Standards related to Reinsurance, Risk Corridors, and Risk Adjustment" (Premium Stabilization Rule Supporting Statement), we estimated a baseline cost for the development of the State notice of benefit and payment. Therefore, we believe that there will only be a small incremental cost to States as a result of the reporting requirements at § 153.210 through § 153.240, § 153.310. However, for reasons described earlier in this Collection of Information section, we are not seeking PRA approval for these collections. We have moved our discussion of the administrative costs associated with these provisions to the Regulatory Impact Analysis section of this final rule.

B. ICRs Regarding Calculation of Reinsurance Contributions (§ 153.405)

In § 153.405, we finalize the rules related to an annual enrollment count of covered lives by contributing entities using counting methods derived from the PCORTF Rule. We are requiring contributing entities to provide annual counts of their enrollment and remit reinsurance contributions to HHS based on that enrollment count. The work associated with this requirement is the time and effort required by an issuer or self-insured group health plan to derive an annual enrollment count. Because

issuers or self-insured group health plans will already be obligated to determine a count of covered lives using a PCORTF counting method, the cost associated with this requirement is conducting these counts using the slightly modified counting methods specified in this final rule. In this final rule, we are modifying our estimate of the number of contributing entities from the proposed rule. We estimate that 22,900 contributing entities will be subject to this requirement, based on the Department of Labor's estimated count of self-insured plans and the number of fully insured issuers that we estimate will make reinsurance contributions.³⁴ On average, we estimate it will take each issuer or self-insured group health plan 1 hour (at a wage rate of \$55 for an operations analyst) to calculate and submit final enrollment counts to HHS. Therefore, we estimate an aggregate cost of \$1,259,500 for 22,900 reinsurance contributing entities as a result of this requirement. We will revise the Premium Stabilization Rule Supporting Statement to include the required data elements that issuers or self-insured group health plans will need to submit their annual enrollment counts in accordance with the counting methodology established in this final rule.

C. Requests for Reinsurance Payment (§ 153.410)

As described in § 153.410, issuers of reinsurance-eligible plans seeking reinsurance payments must make requests in accordance with the requirements of this final rule or the State notice of benefit and payment parameters, as applicable. To be eligible for reinsurance payments, issuers of reinsurance-eligible plans must submit or make accessible to HHS or the State, as applicable, all necessary data to be considered for reinsurance payments for the applicable benefit year.

To minimize burden on issuers, HHS intends to collect data in an identical manner for HHS-operated reinsurance programs and HHS-operated risk adjustment. Although we clarified the data elements issuers would be required to submit as part of the reinsurance payment request process, the burden associated with this requirement is already accounted for under the Premium Stabilization Rule Supporting

Statement with an October 31, 2015 expiration date, and we will update it to reflect these clarified data elements.

D. Upload of Risk Adjustment and Reinsurance Data (§ 153.420, § 153.700, § 153.710, § 153.720)

Under the HHS-operated risk adjustment and reinsurance programs, HHS will use a distributed data collection approach for enrollee-level enrollment, claims and encounter data that reside on an issuer's dedicated data environment. Under § 153.710(a), an issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State where HHS is operating the risk adjustment or reinsurance on behalf of the State, as applicable, must provide HHS, through the dedicated data environment, access to enrollee-level plan enrollment data, enrollee claims data, and enrollee encounter data, as specified by HHS. Under § 153.710(b), all claims data submitted by an issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating risk adjustment or reinsurance, as applicable, must have resulted in payment by the issuer. Under § 153.710(c), an issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating risk adjustment or reinsurance, as applicable, that does not generate individual enrollee claims in the normal course of business must derive costs on all applicable provider encounters using its principal internal methodology for pricing those encounters.

Issuers will be directed to make risk adjustment and reinsurance data accessible to HHS in a way that conforms to HHS-established guidelines and applicable standards for electronic data collection and submission, storage, privacy and security, and processing. In § 153.720(a), we require these issuers to establish a unique masked enrollee identification number for each enrollee, in accordance with HHS-defined requirements and maintain the same masked enrollee identification number for enrollees that enroll in different plans within the issuer, within the State, during a benefit year. Issuers must provide all data to HHS in the specified formats, and must correct submitted files to resolve problems detected by HHS during file processing. The cost associated with this requirement is the time and effort to ensure that information in the dedicated data environment complies with HHS requirements. We estimate this will affect 1,800 issuers and will cost each issuer approximately \$178 per year, reflecting three hours of work by a

³⁴ We use an estimate of self-insured entities published by the Department of Labor in the April 2012 "Report to Congress: Annual Report of Self-insured Group Health Plans," which reflects only those self-insured health plans (including 14,800 self-insured plans and 6,300 plans that mixed self-insurance and insurance) that are required to file a Form 5500 with the Department of Labor.

technical employee at \$59.39 per hour. Therefore, we estimate an aggregate cost of \$320,706 for all issuers as a result of these provisions.

In addition, we discussed in the proposed rule an updating amendment to the Premium Stabilization Rule Supporting Statement that was approved with an October 31, 2015 expiration date reflecting updated cost estimates for implementing the distributed data approach. We are making a slight modification to the labor estimate we assumed in our proposed rule by assuming Federal holidays and two weeks of vacation time for full time employees. In this final rule, we estimate that this data submission requirement will affect 1,800 issuers, and will cost each issuer approximately \$342,086 in total labor costs. This cost reflects an estimate of three full-time equivalent employees (5,760 hours per year) at an average hourly rate of \$59.39 per hour. We anticipate that approximately 400 data processing servers will be established across the market in 2014 (at an average cost of \$15,000), and these servers will process approximately 9 billion claims and enrollment files. Therefore, we estimate an aggregate cost that includes labor and capital of \$621,754,800 for all issuers as a result of these provisions. Although we had previously accounted for this estimate as a new administrative cost to issuers in the proposed rule, we are not doing so in this final rule because it is not an incremental cost that issuers will incur as a result of the provisions in this final rule. We had previously estimated the costs associated with these risk adjustment and reinsurance enrollment data submission requirements in the Premium Stabilization Rule Supporting Statement that was approved with an October 31, 2015 expiration date. We will revise that supporting statement to reflect our updated estimate. We are also amending the tables in the Collection of Information section and Regulatory Impact Analysis section of this final rule so that the tables reflect only those incremental costs that result from provisions of this final rule.

Comment: One commenter stated that there was no basis for the proposed estimate and that the values seemed low considering the importance and complexity of the tasks involved. The commenter also believed that the estimate did not account for costs associated with overhead, administrative tasks, and employee benefits.

Response: We believe that our proposed estimate is reasonable for first year operations. The estimate reflects average labor and capital costs

associated with standing up a dedicated data environment, as well as average claims volume. Some issuers will have appropriate staff and infrastructure in place to support the data collection and other issuers will need to acquire resources. While we anticipate an initial concentrated effort for set-up of the dedicated data environment, we believe that three full-time equivalents would cover the number of hours needed (on average) for set-up and maintenance in the first year of operations. The average hourly rate of \$59.39 is based on the Bureau of Labor Statistics, U.S. Department of Labor, *National Compensation Survey: Occupational Earnings in the United States, 2011*. We note that it approximates the lower range of hourly wages, \$60, estimated by respondents to a recent industry survey,³⁵ and that industry respondents' cost estimates ranged widely to reflect different pricing and conditions. Our aggregate cost estimate also includes costs associated with capital purchases, overhead, and fringe benefits.

E. ICR Regarding User Fee When HHS Operates Risk Adjustment (§ 153.610)

Under § 153.610(f), we establish a user fee to support Federal operation of risk adjustment. This per capita monthly fee will be charged to issuers of risk adjustment covered plans based on enrollment estimates provided to HHS in the distributed data environment. HHS will calculate user fees owed, and issuers will remit the fee owed only once, in June of the year following the benefit year, in connection with processing of payments and charges for risk adjustment.

We estimate that 1,800 issuers will be required to pay risk adjustment user fees, and the additional cost associated with this requirement is the time and effort for an issuer to provide monthly enrollment data and remit fees. Because HHS will utilize existing data collection and payments and charges processing, we do not anticipate that this provision will alter the collection cost that is already approved in the Premium Stabilization Rule Supporting Statement under OMB control number 0938–1155 with an October 31, 2015 expiration date.

F. ICRs Regarding Data Validation Requirements When HHS Operates Risk Adjustment (§ 153.630)

Under § 153.630(b), an issuer that offers at least one risk adjustment

covered plan in a State where HHS is operating risk adjustment on behalf of the State for the applicable benefit year must have an initial validation audit performed on its risk adjustment data. The cost associated with this requirement is the issuer's time and effort to provide HHS with source claims, records, and enrollment information to validate enrollee demographic information for initial and second validation audits and the issuer's cost to employ an independent auditor to perform the initial validation audit on a statistically valid sample of enrollees.

The statistically valid sample of enrollees provided to each issuer will consist of enrollees both with and without HCCs. We estimate that each issuer sample will consist of approximately 300 enrollees, with approximately two-thirds of the sample consisting of enrollees with HCCs. We anticipate that this audit will affect approximately 1,800 issuers.

Based on Truven Health Analytics 2010 MarketScan® data, we have determined that for enrollees with HCCs, the average number of HCCs to be reviewed by an auditor per enrollee is approximately two. Additionally, based on HHS audit experience, we estimate that it will cost approximately \$180 (\$90 per hour for two hours) for an auditor to review the medical record documentation for one enrollee with two HCCs. In the proposed rule, we did not estimate the cost of reviewing medical records for enrollees without HCCs. HHS intends to require the review of medical records for all sample enrollees in the initial validation audit. Therefore, we are revising our estimate to align with the policy finalized in this rule. We expect that it may cost approximately \$60 per enrollee (\$90 per hour for 40 minutes) to validate demographic information and review medical records for all enrollees in the audit sample, totaling approximately \$210 per enrollee with HCCs (\$90 per hour for two hours and 20 minutes) and \$60 per enrollee with no HCCs. We assume that an initial validation audit will be performed on 180,000 enrollees without HCCs, and 360,000 enrollees with HCCs. Based on the information above, we estimate that the total cost per issuer to retain initial validation auditors to perform the initial validation would cost approximately \$48,000. Therefore, for 1,800 issuers, the total cost of conducting initial validation audits will be \$86.4 million. We will revise the information collection currently approved OMB Control Number 0938–1155 with an October 31,

³⁵ “Health Plans’ Estimated Costs of Compliance with Expanded Federal Rate Review and with Data Collection for Risk Adjustment and Reinsurance,” Center for Policy Research, America’s Health Insurance Plans, December 2012.

2015 expiration date to account for this additional burden.

Under § 153.630(d), issuers will have the opportunity to appeal errors identified through the second validation audit process. Because we intend to provide further detail on this process in later guidance and rulemaking, we currently cannot estimate the number of issuers that will appeal HCC findings, or the cost per issuer for doing so. Therefore, we will seek OMB approval and solicit public comment on the information collection requirements established under § 153.630(d) at a future date.

G. ICRs Regarding QHP Certification Standards Related to Advance Payments of the Premium Tax Credit and Cost-Sharing Reductions (§ 155.1030)

In § 155.1030(a)(1) of this final rule, we establish that the Exchange must ensure that each issuer that offers or intends to offer a QHP in the individual market on the Exchange submit the required plan variations, as set forth in § 156.420, for each of its health plans proposed to be offered as a QHP in the individual market on the Exchange. Further, the Exchange must certify that the plan variations meet the requirements detailed in § 156.420. We expect that an Exchange will collect prior to each benefit year the information necessary to validate that the issuer meets the requirements for silver plan variations, as detailed in § 156.420(a), and collect as part of QHP certification the information necessary to validate that the issuer meets the requirements for zero and limited cost sharing plan variations, as detailed in § 156.420(b). We expect that this data collection would include the cost-sharing requirements for the plan variations, such as the annual limitation on cost sharing, and any reductions in deductibles, copayments or coinsurance. In addition, the Exchange will collect or calculate the actuarial values of each QHP and silver plan variation, calculated under § 156.135 of the final EHB/AV Rule. We proposed in § 155.1030(a)(2) that the Exchange provide the actuarial values of the QHPs and silver plan variations to HHS. As set forth in § 155.1030(b)(4), HHS may use this information in connection with approving estimates for advance payment of cost-sharing reductions submitted by issuers under § 156.430 finalized here. Because HHS will already have this information for Federally-facilitated Exchanges, the burden associated with this requirement is the time and effort for a State participating in each State Partnership

and for a State-based Exchange to submit this information to HHS. We estimate that the submission from each of these entities will take approximately 3.5 hours to collect, validate, and submit to HHS (3 hours by a database administrator at \$47.70 per hour, and 0.5 hours by a manager at \$75.15 per hour). We estimate that this will cost each submitting entity approximately \$181 per year. We plan to revise the supporting statement published under CMS form number 10433, which is pending OMB approval, to account for this additional burden.

In paragraph (b)(1) and (2), we established that the Exchange collect, review, and submit the rate or expected premium allocation, the expected allowed claims cost allocation, and the actuarial memorandum that a metal level health plan or stand-alone dental plan issuer submits under § 156.470. This collection will allow for the calculation of the advance payments of cost-sharing reductions and the premium tax credit. The Exchange must ensure that such allocations meet the standards set forth in § 156.470(c) and (d). This allocation information must be collected and approved before a health plan or stand-alone dental plan can be certified for participation in the Exchange. We expect that the Exchange will collect the allocation information in conjunction with the rate and benefit information that the issuer submits under § 156.210 or the rate information that the QHP issuers submit through the Effective Rate Review program. Therefore, we believe that the cost for Partnership Exchanges or State-based Exchanges to submit to HHS this information collected from QHPs is generally part of the cost that is accounted for in the PRA approved under OMB Control Number 0938-1141 or the cost that is accounted for in the supporting statement published under CMS form number 10433, which is pending OMB approval. We estimate that Partnership and State-based Exchanges will incur additional cost to submit allocation information to HHS for stand-alone dental plans. We estimate that it will take each Exchange 30 minutes to submit this information for each stand-alone dental plan, and assume that this submission will be performed at the hourly wage rate of \$38.49 for an insurance analyst. Assuming 20 stand-alone dental plans across the market, we estimate an aggregate cost of approximately \$385 for all Partnership or State-based Exchanges to submit this information to HHS. We plan to revise the supporting statement published under CMS form number

10433, which is pending OMB approval, to account for this additional burden.

In subparagraph (b)(3), we establish that the Exchange must collect any estimates and supporting documentation that a QHP issuer submits to receive advance payments of certain cost-sharing reductions, as described in § 156.430(a), and submit, in the manner and timeframe established by HHS, the estimates and supporting documentation to HHS for review. Because HHS will already have this information for Federally-facilitated Exchanges, the burden associated with this requirement is the time and effort for each Partnership or State-based Exchange to submit this information. We believe that this provision will impose minimal burden, and that it will take an insurance analyst five minutes (at an hourly wage rate of \$38.49), to collect and submit this information to HHS for each Partnership or State-based Exchange. Therefore, we estimate a cost of \$3.21 for each Partnership or State-based Exchange as a result of this requirement.

H. ICRs Regarding Plan Variations (§ 156.420)

In § 156.420, we set forth standards for issuers to submit to the Exchange for certification the variations of the health plans that they offer or propose to offer in the individual market on the Exchange that include the required levels of cost-sharing reductions. We provide an overview of the submission process associated with this requirement in this final rule. In paragraph (a), we establish that, for each silver health plan that an issuer offers or intends to offer in the individual market on the Exchange, the QHP issuer must submit to the Exchange for certification the standard silver plan and three variations of the standard silver plan. In paragraph (b), we further establish that a QHP issuer must, for each of its health plans at any metal level of coverage, submit a zero cost sharing plan variation and a limited cost sharing plan variation of each health plan offered or proposed to be offered in the individual market on the Exchange. However, in this final rule, we clarify that an Exchange is adequately enforcing this requirement if, within a set of standard plans offered by an issuer that differ only by the cost sharing or premium, it allows an issuer to submit one zero cost sharing plan variation for only the standard plan with the lowest premium within the set. Although this approach will likely reduce the burden on issuers and Exchanges, it is unclear how many Exchanges will adopt this approach, and

as a result, we have not adjusted our burden estimates below.

We estimate that 1,200 issuers will participate in an Exchange nationally, and that each issuer will offer one QHP per metal level with four zero cost sharing plan variations and four limited cost sharing plan variations (one per metal level QHP) and three plan variations for low-income populations, for a total of four standard plans and eleven plan variations. Our estimate assumes that each issuer will submit these plan variations as part of their electronic QHP application, which is described in further detail in the “Supporting Statement for Initial Plan Data Collection to Support QHP Certification and other Financial Management and Exchange Operations,” which was provided for public comment on November 21, 2012 (77 FR 69846). We estimate that it will take approximately 1.5 hours to submit the requisite information for a plan variation (0.75 hours by an actuary at a wage rate of \$56.89, 0.5 hours by an insurance analyst at a wage rate of \$38.49, and 0.25 hours by an insurance manager at a wage rate of \$67.44). Based on the figures above, we estimate it will cost each issuer approximately \$866 to submit 11 plan variations annually, for an aggregate cost of \$1,039,698 for all issuers participating in the Exchanges. We plan to revise the supporting statement published under CMS form number 10433, which is pending final OMB approval, to account for this additional burden.

I. ICRs Regarding Payment of Cost-Sharing Reductions (§ 156.430)

In § 156.430(a)(1), we establish that for each silver plan variation and zero cost sharing plan variation that an issuer offers or proposes to offer in the individual market on the Exchange, the QHP issuer must provide to the Exchange, for approval by HHS, estimates, and supporting documentation validating the estimates, of the dollar value of cost-sharing reductions to be provided. However, as described in the preamble to this final rule, we are finalizing a simplified methodology for calculating the advance payments for the initial years of the cost-sharing reduction program. This methodology will utilize data that QHP issuers submit for other requirements, such as § 156.420 and § 156.470. As a result, there will be no additional burden associated with this requirement for QHP issuers.

In § 156.430(a)(2), we discuss the process for estimating the value of cost-sharing reductions to be provided under the limited cost sharing plan variation

open to Indians with a household income above 300 percent of the FPL, described in § 156.420(b)(2). If a QHP issuer seeks advance payments for these cost-sharing reductions, the issuer must provide to the Exchange, for approval by HHS, an estimate, and supporting documentation validating the estimate, of the dollar value of the cost-sharing reductions to be provided under the limited cost sharing plan variation of the QHP. We estimate that 1,200 issuers will participate in Exchanges nationally, and that each issuer will offer one QHP per metal level, with one limited cost sharing plan variation for each metal level. For each plan variation, the issuer may submit an estimate and supporting documentation of the dollar value of the cost-sharing reductions. We expect estimates and supporting documentation will be submitted as part of the electronic QHP application, which is described in further detail in the “Supporting Statement for Initial Plan Data Collection to Support QHP Certification and other Financial Management and Exchange Operations,” which was provided for public comment on November 21, 2012 (77 FR 69846). We estimate that it will take approximately one hour to submit each response for a plan variation (0.5 hours by an actuary at a wage rate of \$56.89 and 0.5 hours by an insurance analyst at a wage rate of \$38.49.) We estimate that each response for a plan variation will cost an issuer \$47.69, for an estimated total issuer cost to submit responses for four plan variations of \$228,912 for the year. We plan to revise the supporting statement published under CMS form number 10433, which is pending final OMB approval, to account for this additional burden.

In § 156.430(c)(1), (c)(2), and (c)(5), we finalize a standard that directs a QHP issuer to submit to HHS, in the manner and timeframes established by HHS, the actual amount of cost-sharing reductions provided to each enrollee. This information is necessary so that HHS can reconcile advance payments made throughout the year to the actual cost-sharing reduction amounts. Based upon preliminary discussions with the issuer and vendor community regarding the costs associated with implementing the standard methodology, we assume that the information technology necessary to implement the standard methodology will be developed by three vendors at a cost of approximately \$6 million per vendor, for total costs of approximately \$18 million. We also expect that each issuer will need to spend approximately \$100,000 to customize the vendor solution

technology and/or modify their claims system. Therefore, we estimate total administrative costs of approximately \$138 million. While these information collection requirements are subject to the Paperwork Reduction Act, the information collection process and instruments associated with this requirement are currently under development. We will seek OMB approval and solicit public comments upon their completion. We note that we have not included our initial cost estimate of this approach in Table 25 or Table 26.

As discussed in section III.E.4.e, we are issuing an interim final rule with comment elsewhere in this issue of the **Federal Register** to provide QHP issuers with the option to submit data about the actual amount of cost-sharing reductions using an alternate methodology for purposes of payment reconciliation. We address the burden associated with this alternate approach in the Collection of Information section of the interim final rule with comment.

J. ICRs Regarding Reduction of an Enrollee's Share of Premium To Account for Advance Payment of the Premium Tax Credit (§ 156.460)

Under § 156.460(a)(2), if a QHP issuer receives an advance payment of the premium tax credit on behalf of an individual, the QHP issuer must notify the Exchange of any reduction in premium through the standard enrollment acknowledgment in accordance with § 156.265(g). Because this notification will occur through the enrollment acknowledgment process that already exists under the final Exchange Establishment Rule (77 FR 18310), at § 156.265(g), we believe that this requirement will impose minimal burden on QHP issuers, and that it will take an insurance analyst five minutes (at an hourly wage of \$38.49), to collect and submit this information to each Exchange. Therefore, we estimate a cost of approximately \$3.21 for each QHP issuer, and an aggregate cost of approximately \$3,849 for all 1,200 QHP issuers, as a result of this requirement.

K. ICRs Regarding Allocation of Rates and Claims Costs for Advance Payments of the Premium Tax Credit and Cost-Sharing Reductions (§ 156.470)

In § 156.470(a), we establish that an issuer provide to the Exchange annually for approval, for each metal level health plan offered or intended to be offered in the individual market on the Exchange, an allocation of the rate and the expected allowed claims costs for the plan, for EHB, other than services described in § 156.280(d)(1), and any

other services or benefits offered by a health plan that do not meet the definition of EHB. In § 156.470(b), we establish that an issuer of a stand-alone dental plan provide to the Exchange for approval a dollar allocation required by the expected premium for the plan to the pediatric dental essential health benefit. In § 156.470(c), we are finalizing standards for QHP issuers for calculating the allocation required by paragraph (a). As discussed above, we are modifying § 156.470(d) and finalizing one standard for issuers of stand-alone dental plans for calculating the allocation in paragraph (b). Lastly, in § 156.470(e), we are finalizing the requirement that an issuer of a metal level health plan or stand-alone dental plan offered, or intended to be offered, in the individual market on the Exchange, submit an actuarial memorandum with a detailed description of the methods and specific bases used to perform the allocations that would be required under paragraphs (a) and (b) of that section, demonstrating that the allocations meet the standards set forth in paragraphs (c) and (d).

QHP issuers will submit these allocations and justifications through the Effective Rate Review program (as finalized in the Market Reform Rule at § 154.215(d)(3)–(4), and detailed in the accompanying PRA package with OMB Control Number 0938–1141) or directly to the Exchange if the issuer is not required to submit rates to the Effective Rate Review program. The Rate Increase Disclosure and Review Rule establishes a process to ensure the public disclosure of all information and justifications relating to unreasonable rate increases. To that end, the regulation establishes various reporting requirements for health insurance issuers, including a Preliminary Justification for a proposed rate increase, a Final Justification for any rate increase determined by a State or HHS to be unreasonable, and a notification requirement for unreasonable rate increases that will not be implemented. The Preliminary

Justification includes data supporting the potential rate increase as well as a written explanation of the rate increase. For those rates HHS will be reviewing, issuers' submissions also will include data and information that HHS will need to make a valid actuarial determination regarding whether a rate increase is unreasonable. Therefore, there will be no additional burden on QHP issuers that submit their rates through the Effective Rate Review program. The burden for the Effective Rate Review submission is already accounted for in OMB Control Number 0938–1141. We are also revising the supporting statement of the information collection approved under OMB Control Number 0938–1141 to clarify that we will be collecting this allocation information from metal plans to be offered on an Exchange, whether they are new or existing.

This requirement will result in additional burden for stand-alone dental plans. We estimate that it will take each stand-alone dental plan five hours to prepare and submit this information to the Exchange. We assumed that this requirement will require three hours of labor by an insurance analyst (at an hourly wage rate of \$38.49) and two hours of labor by an actuary (at an hourly wage rate of \$56.89). Assuming 20 stand-alone dental plans across the market, we estimate an aggregate cost of approximately \$4,585 for all stand-alone dental plans to submit these allocations and justifications to the Exchange. We plan to revise the supporting statement published under HHS form number 10433, which is pending final OMB approval, to account for this additional burden.

L. ICRs Regarding QHP Participation Standards in SHOP (§ 156.200)

In § 156.200(g)(1), we establish a QHP certification standard for the FFE. If the issuer of a QHP in an FFE also participates in the State's small group market, the QHP certification standard would be met if the issuer offers at least one small group market QHP at the

silver level of coverage and one QHP at the gold level of coverage in a FF–SHOP serving that State. We also propose that, if neither the issuer nor any issuer in the same issuer group has a share of the State's small group market greater than 20 percent, the standard would be met. Therefore, no issuer would be required to begin offering small group market plans to meet this requirement. The burden associated with this requirement is the time and effort for an issuer to prepare a QHP certification application for a SHOP for at least one silver level and one gold level plan design. This burden would be incurred by issuers who, absent this requirement, would otherwise not have participated in a SHOP. We describe the burden associated with this requirement in the 30-day **Federal Register** Notice for the Initial Plan Data Collection published on November 21, 2012 (77 FR 69846). The market share determination is based on earned premiums already submitted by all issuers in the State's small group market under § 158.110, and thus poses no additional reporting burden.

M. ICRs Regarding Medical Loss Ratio Reporting (§ 158.130, § 158.140, § 158.162, § 158.221, § 158.240)

This final rule directs issuers to include all payments and receipt amounts related to the reinsurance, risk corridors and risk adjustment programs in the annual MLR report.

The existing information collection requirement is approved under OMB Control Number 0938–1164. This includes the annual reporting form that is currently used by issuers to submit MLR information to HHS. Prior to the deadline for the submission of the annual MLR report for the 2014 MLR reporting year, and in accordance with the PRA, HHS plans to solicit public comment and seek OMB approval for an updated annual form that will include reporting of the premium stabilization payments and will reflect the changes in deduction for community benefit expenditures for Federal income tax exempt not-for-profit issuers.

TABLE 25—ESTIMATED FISCAL YEAR REPORTING RECORDKEEPING AND COST BURDENS

Regulation sections	OMB Control No./CMS Form No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ³⁶ (\$)	Total labor cost (\$)	Total capital/maintenance costs (\$)	Total cost (\$)
§ 153.405	0938–1155	22,900	22,900	1.00	22,900	55.00	1,259,500	0	1,259,500
§ 153.630(b)	0938–1155	1,800	540,000	1.78	960,000	90.00	86,400,000	0	86,400,000
§ 153.720(a)	0938–1155	1,800	1,800	3.00	5,400	59.39	320,706	0	320,706
§ 155.1030(a)	0938–NEW/CMS–10433	51	51	3.50	179	51.62	9,240	0	9,240
§ 155.1030(b)(2)	0938–NEW/CMS–10433	20	20	0.50	10	38.49	385	0	385
§ 155.1030(b)(3)	0938–NEW/CMS–10433	51	51	0.08	4.25	38.49	164	0	164
§ 156.420	0938–NEW/CMS–10433	1,200	13,200	1.50	19,800	52.51	1,039,698	0	1,039,698
§ 156.430(a)(2)	0938–NEW/CMS–10433	1,200	4,800	1.00	4,800	47.69	228,912	0	228,912
§ 156.460(a)(2)	0938–NEW/CMS–10433	1,200	1,200	0.08	100	38.49	3,849	0	3,849
§ 156.470	0938–NEW/CMS–10433	20	20	5	100	45.85	4,585	0	4,585

TABLE 25—ESTIMATED FISCAL YEAR REPORTING RECORDKEEPING AND COST BURDENS—Continued

Regulation sections	OMB Control No./CMS Form No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ³⁶ (\$)	Total labor cost (\$)	Total capital/maintenance costs (\$)	Total cost (\$)
Total		24,171					89,267,039	0	89,267,039

VI. Regulatory Impact Statement (or Analysis)

A. Statement of Need

This final rule implements standards related to premium stabilization programs (reinsurance, risk adjustment, and risk corridors), consistent with the Affordable Care Act. This final rule also includes provisions governing the cost-sharing reductions program, the advance payment of the premium tax credit program, the medical loss ratio program, the SHOP Exchange, and user fees for Federally-facilitated Exchanges. The purpose of the three premium stabilization programs is to prevent adverse selection and to protect consumers from increases in premiums due to issuer uncertainty. The Premium Stabilization Rule explained that further details on the implementation of these programs, including the specific parameters applicable to these programs, would be included in this rule.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of

reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects (\$100 million or more in any 1 year).

OMB has determined that this Payment Notice is “economically significant” within the meaning of section 3(f)(1) of Executive Order 12866, because it is likely to have an annual effect of \$100 million in at least one year. Accordingly, we have prepared a regulatory impact analysis that presents the costs and benefits of this final rule.

The overarching goal of the premium stabilization and Exchange-related provisions and policies in the Affordable Care Act is to make affordable health insurance available to individuals who do not have access to affordable employer-sponsored coverage. The provisions within this final rule are integral to the goal of expanding coverage. For example, the premium stabilization programs (risk adjustment, reinsurance, and risk corridors) decrease the risk of financial loss that health insurance issuers might otherwise expect in 2014. The cost-sharing reductions program and advance payments of the premium tax credit assist low- and moderate-income consumers in purchasing health insurance. The combined impacts of these provisions affect the private sector, issuers, and consumers, through increased access to health care services including preventive services, decreased uncompensated care, lower premiums, and increased plan (and thereby cost) transparency. Through the reduction of financial uncertainty for issuers and increased affordability for consumers, the provisions are expected to increase access to health coverage.

Recent research³⁷ analyzed the effects of increased insurance coverage. The analysis studied the health effects of expanded Medicaid eligibility in three States (New York, Maine, and Arizona) with comparable States that did not expand Medicaid over a multiyear time

period. The study found that increased coverage resulted in:

- Significant reduction in mortality (19.6 deaths per 100,000) during the period of study;
- Increased rate of self-reported health status (by three percent); and
- Reduction in cost-related delays in care (by 21 percent).

While these results may not be entirely generalizable given the population and coverage type, they do replicate other research findings³⁸ of the importance of health coverage in improving health and delaying mortality.

There are administrative costs to States to administer these programs, although Federal grants are available through 2014 for States seeking to establish State-based Exchanges, and to support certain State activities related to the establishment of FFEs or State Partnership Exchanges.

Issuers making reinsurance contributions but not receiving reinsurance payments may receive indirect benefits in the form of lower uncompensated care costs. There are also reporting costs for issuers to submit data and financial information. This regulatory impact analysis discusses the benefits and costs of the provisions in this final rule.

In this analysis, we discuss programs and standards newly implemented by the final rule, such as certain provisions related to the cost-sharing reductions program, the advance payment of the premium tax credit program, the medical loss ratio program, the SHOP Exchange, and user fees for a Federally-facilitated Exchange, as well as new regulatory provisions for the three premium stabilization programs (reinsurance, risk adjustment, and risk corridors) which were introduced in the Premium Stabilization Rule (77 FR 17220). In addition to building on the regulatory impact analysis for that earlier rule, we are able, for the analysis of much of the final rule, to use the Congressional Budget Office’s estimates of the Affordable Care Act’s impact on Federal spending, revenue collection, and insurance enrollment.

³⁶ Bureau of Labor Statistics, U.S. Department of Labor, *National Compensation Survey: Occupational Earnings in the United States, 2011*. United States Government Printing Office. May 2011. Retrieved from <http://www.bls.gov/ncs/ncswage2010.htm>.

³⁷ Sommers, Ben et al “Mortality and Access to Care among Adults after State Medicaid Expansions” *New England Journal of Medicine* No: 367 20121025–1034.

³⁸ Finkelstein, A et al. “The Oregon Health Insurance Experiment: Evidence from the First Year.” NBER Working Paper No. 17190, July 2011.

Comment: Two commenters urged further analysis of the costs and benefits of the rule. Specifically, one commenter asked HHS to provide analysis showing how this rule would affect consumer premiums, employer costs, and taxpayer subsidies. The commenter asked HHS to project how increased use of health care would impact employers and wages for lower-income workers.

Response: While we cannot precisely predict the price of insurance, the premium stabilization programs are designed to mitigate premium increases for all consumers. In the individual and small group markets, the advance payment of the premium tax credit and cost-sharing reduction programs are intended to make health insurance affordable for low-income individuals. CBO's estimates remain the most comprehensive accounting of all the interacting provisions pertaining to the Affordable Care Act, and contain Federal budget impact estimates of some provisions that have not been independently estimated by CMS. Table 26 shows accounting projections on the costs and transfers of this rule. We are unable to project either the potential economic and social benefit from a more productive workforce that could result from access to health care or the

potential economic and social cost when more people use health care. HHS relied on the Bureau of Labor Statistics, U.S. Department of Labor, *National Compensation Survey Occupational Earnings in the United States, 2011*, for estimates of most job descriptions and wages. We believe that our analysis reflects our best estimate of the costs associated with the proposed rule. Therefore, we are not modifying the proposed estimates of regulatory impact in this final rule.

C. Impact Estimates of the Payment Notice Provisions and Accounting Table

In accordance with OMB Circular A–4, Table 26 below depicts an accounting statement summarizing HHS's assessment of the benefits, costs, and transfers associated with this rule.

This final rule implements standards for programs that will have numerous effects, including providing consumers with affordable health insurance coverage, reducing the impact of adverse selection, and stabilizing premiums in the individual and small group health insurance markets and in an Exchange. We are unable to quantify the benefits of the final rule, such as improved health, longevity, and national productivity due to increased insurance enrollment, and some of its

costs, such as the cost of providing additional medical services to newly-enrolled individuals. Direct costs in the Table 26 below reflect administrative costs to States (including those costs associated with operating risk adjustment and reinsurance), health insurance issuers, and Exchanges, but do not include administrative costs incurred by the Federal government. As discussed earlier, we estimate costs associated with establishing a dedicated data environment in the Premium Stabilization Rule Supporting Statement, and do not include those costs in Table 26. The effects in Table 26 reflect estimated cost-sharing reduction payments, which are transfers from the General Fund of the U.S. Treasury to consumers who qualify for cost-sharing reductions. These transfer estimates are based on the Congressional Budget Office's March 2012 baseline estimates, and have been annualized over the five-year period from fiscal years (FYs) 2013 through 2017. Estimated transfers do not reflect any user fees paid by insurance issuers for the Federally-facilitated Exchange. Estimated transfers from health insurance issuers resulting from risk adjustment user fees are included in the table below.

TABLE 26—ACCOUNTING TABLE

Category	Estimates	Units		
		Year dollar	Discount rate (per- cent)	Period covered
Benefits				
Annualized Monetized (\$millions/year)	Not Estimated Not Estimated			
Costs				
Annualized Monetized (\$millions/year)	\$68.95	2013	7	2013–2017
	\$70.37	2013	3	2013–2017
Transfers				
Federal Annualized Monetized (\$millions/year)	\$6,529.29	2013	7	2013–2017
	\$6,803.02	2013	3	2013–2017

This impact analysis for the premium stabilization programs references estimates from CBO and CMS. CBO's estimates remain the most comprehensive accounting of all the interacting provisions pertaining to the Affordable Care Act, and contain Federal budget impact estimates of some provisions that have not been independently estimated by CMS. Based on our review, we expect that the provisions of this final rule will not

significantly alter CBO's estimates of the budget impact of the reinsurance, risk corridors, and risk adjustment programs. The requirements of these programs are well within the parameters used by CBO in the modeling of the Affordable Care Act. Our review and analysis of the requirements indicate that the impacts are likely within the model's margin of error.

For this regulatory impact analysis, we are shifting the estimates for the

reinsurance and risk adjustment programs to reflect the four-year period from FYs 2014 through 2017. Table 27 includes the CBO estimates for outlays and receipts for the reinsurance and risk adjustment programs from FYs 2014 through 2017. These estimates for reinsurance and risk adjustment reflect CBO's scoring of these provisions. CBO assumed risk adjustment payments and charges would begin to be made in 2014, when in fact these payments and

charges will begin in 2015, as discussed in section III.B. of this final rule; therefore, the estimates are assigned one year later in Table 27 than they were in the original CBO report.

CBO did not separately estimate the program costs of risk corridors, but assumed aggregate collections from

some issuers would offset payments made to other issuers. Table 27 summarizes the effects of the risk adjustment and reinsurance programs on the Federal budget, with the additional, societal effects of this rule discussed in this regulatory impact

analysis. We note that transfers associated with risk adjustment and reinsurance were previously estimated in the Premium Stabilization Rule; therefore, to avoid double-counting, we do not include them in the accounting statement for this rule (Table 26).

TABLE 27—ESTIMATED FEDERAL GOVERNMENT OUTLAYS AND RECEIPTS FOR THE REINSURANCE AND RISK ADJUSTMENT PROGRAMS FROM FYS 2014–2017

[In billions of dollars]

Year	2014	2015	2016	2017	2014–2017
Reinsurance and Risk Adjustment Program Payments *		11	18	18	47
Reinsurance and Risk Adjustment Program Receipts *		12	16	18	46

* Risk adjustment program payments and receipts lag by one quarter. Receipt will fully offset payments over time. The CBO estimates do not reflect the \$5 billion in reinsurance contributions that are submitted to the U.S. Treasury.

Source: Congressional Budget Office. 2011. *Letter to Hon. Nancy Pelosi*. March 20, 2010.

Risk Adjustment

Risk adjustment is a permanent program that may be administrated by States that operate an HHS-approved Exchange. States have the option of proposing alternative methodologies. Risk adjustment is generally applied to non-grandfathered health plans offered in the individual and small group markets, both inside and outside of the Exchange. The Exchange may operate risk adjustment, although a State may also elect to have an entity other than the Exchange perform the risk adjustment functions, provided that the State is approved by HHS to operate risk adjustment. Similar to the approach for reinsurance, multiple States may contract with a single entity to administer risk adjustment, provided that transfers do not occur between States and that each State is approved to operate their risk adjustment program. Having a single entity administer risk adjustment in multiple States may provide administrative efficiencies. In this final rule, we establish a risk adjustment State approval process. We estimate it will take each State approximately 180 hours to complete the initial risk adjustment entity approval process. We estimate it will take an operations analyst 72 hours (at \$55 an hour), a contract administrator 72 hours (at \$40 per hour), a senior manager 24 hours (at \$77 an hour), and an attorney 12 hours (at \$77 an hour) to meet the initial approval requirements. Therefore, we estimate administrative costs of approximately \$9,612 for each entity, as a result of these approval requirements.³⁹

The details of the HHS-developed risk adjustment methodology are specified in this final rule. The HHS-developed risk adjustment methodology is based on a model that is concurrent and uses demographic and diagnosis information in a benefit year to predict total plan liability in the benefit year. The national payment transfer methodology is based on the State average premium to ensure that payments and charges net to zero.

States may use this methodology or develop and propose alternate risk adjustment methodologies that meet Federal standards. Once HHS approves an alternate risk adjustment methodology, it will be considered a Federally certified risk adjustment methodology that any State may elect to use. In this final rule, we lay out the criteria that HHS will use to evaluate alternate risk adjustment methodologies. Approved Federally certified risk adjustment methodologies will be published annually in the HHS notice of benefit and payment parameters.

States that elect to develop their own risk adjustment methodologies are likely to have increased administrative costs. Developing a risk adjustment methodology requires complex data analysis, including population simulation, predictive modeling, and model calibration. States that elect to use the HHS-developed methodology would likely reduce administrative costs. We describe these administrative costs in the Collection of Information Requirements section of this final rule.

In the Premium Stabilization Rule, we defined a risk adjustment covered plan as any health insurance coverage offered in the individual or small group market with the exception of grandfathered health plans, group health insurance coverage described in § 146.145(c) of

this subchapter, individual health insurance coverage described in § 148.220 of this subchapter, and any other plan determined not to be a risk adjustment covered plan in the annual HHS notice of benefit and payment parameters. In this final rule, we clarify that plans not subject to certain market reforms and student health plans will not be subject to the issuer requirements in subparts G and H of 45 CFR part 153. Under Section 1312(c)(3) of the Affordable Care Act, States have the flexibility to merge the individual and small group markets into a single risk pool, or keep them separate. In this final rule, we clarify that HHS will merge markets when operating risk adjustment on behalf of a State if the State elects to do the same for single risk pool purposes.

Developing the technology infrastructure required for data submission will likely require an administrative investment. The risk adjustment process will require significant amounts of demographic and diagnostic data to run through a risk assessment model to determine individual risk scores that form the basis for plan and State averages. The Premium Stabilization Rule requires States to collect or calculate individual risk scores at a minimum. States may vary the amount and type of data collected, provided that States meet specified data collection standards.

Administrative costs will vary across States and health insurance issuers depending on the type of data collection approach used in the State. In States opting to operate risk adjustment using a distributed model of data collection, the costs associated with mapping and storing the required data and, in some cases, the costs associated with running

³⁹ For purposes of Table 26, we assume that one State will operate risk adjustment.

the risk adjustment software will likely be borne by the issuer.

States and issuers that already have systems in place for data collection and reporting will have reduced administrative costs. For example, issuers that already report data for Medicare Advantage (MA) or Medicaid Managed Care may see minimal additional administrative cost for risk adjustment. Additionally, some States risk-adjust their Medicaid Managed Care programs. States with all-payer or multi-payer claims databases may need to modify their systems to meet the requirements of risk adjustment. However, these costs of modification will be less than the costs of establishing these systems. States and issuers that do not have existing technical capabilities will have larger administrative costs related to developing necessary infrastructure.

Issuer characteristics, such as size and payment methodology, will also affect administrative costs. In general, national issuers will likely be better prepared for the requirements of risk adjustment than small issuers.

In this final rule, we provide more details on the data collection approach when we operate risk adjustment on behalf of a State. The Premium Stabilization Rule established that when HHS operates risk adjustment on behalf of a State, it will use a distributed approach. We believe that this approach minimizes issuer burden while protecting enrollee privacy. Under a distributed approach, issuers will need to format risk adjustment data, and maintain that data in compliance with HHS-established guidelines and applicable standards. We describe these administrative costs in the Collection of Information Requirements section of this final rule.

The Premium Stabilization Rule directs States to audit a sample of data from each issuer and to ensure proper implementation of risk adjustment software by all issuers that participate in risk adjustment. States may extrapolate results from the sample to adjust the average actuarial risk for the plan. This approach is consistent with the approach now used in Medicare Advantage, where audit sample error rates will be extrapolated to contract-level payments to recoup overpayment amounts.

In this final rule, we establish data validation standards for when HHS operates risk adjustment on behalf of a State. HHS will conduct a data validation program consisting of six stages: (1) Sample selection; (2) initial validation audit; (3) second validation audit; (4) error estimation; (5) appeals;

and (6) payment adjustments. Issuers will engage independent initial auditors to conduct an initial audit of an HHS-selected sample of risk adjustment data. HHS will retain a second validation auditor to verify the findings of the initial validation audit and provide error estimates. However, in this final rule we note that there will be no adjustments to payments and charges based on the error estimates for benefit years 2014 and 2015. We describe these administrative costs in the Collection of Information Requirements section of this final rule. We also describe a process to appeal data validation findings. Issuers will have an opportunity to appeal findings from both the initial validation audit and second validation audit. In addition, HHS will collect approximately \$20 million in user fees to support the Federally operated risk adjustment program.

Risk adjustment transfers dollars from health plans with lower-risk enrollees to health plans with higher-risk enrollees. We are updating the cost estimates for this RIA to include 2017, using CBO estimates.⁴⁰ From 2014 through 2017, we estimated that there will be \$45 billion transferred among issuers.

Risk adjustment protects against adverse selection by allowing insurers to set premiums according to the average actuarial risk in the individual and small group market without respect to the type of risk selection the insurer would otherwise expect to experience with a specific product offering in the market. This should lower the risk premium and allow issuers to price their products closer to the average actuarial risk in the market. In addition, it mitigates the incentive for health plans to avoid unhealthy members.

The risk adjustment program also serves to level the playing field inside and outside of the Exchange, as payments and charges are applied to non-grandfathered individual and small group plans inside and outside of the Exchange. This mitigates the potential for excessive premium growth within the Exchange due to anticipated adverse selection.

Comment: One commenter disagreed with the \$600 million in aggregate administrative costs estimated in the Collection of Information section of the proposed rule, and reflected in this regulatory impact analysis. The commenter stated that the cost associated with this rule would be much

higher than the \$600 million estimated in the proposed rule.

Response: The cost to States of developing their own risk adjustment and reinsurance programs was addressed in the Premium Stabilization Rule, Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment, published March 23, 2012. We recognize States may require significant analysis to assess whether to operate risk adjustment or reinsurance programs. Many states received grants available under the Affordable Care Act to underwrite such analyses (although we note that these grants would affect who bears the cost of the rule, not the amount incurred by society as a whole). States choosing in the future to operate risk adjustment may benefit from methodologies developed by other States and approved by HHS. The cost of reporting data to HHS should decline once systems are in place.

We have limited our estimate to the incremental information collection associated with the requirements of the proposed rule. HHS relied on the Bureau of Labor Statistics, U.S. Department of Labor, *National Compensation Survey Occupational Earnings in the United States, 2011*, for estimates of most job descriptions and wages. We believe that our analysis reflects our best estimate of the costs associated with the proposed rule. We also note we have modified some estimates from our proposed rule to better reflect the most current agency estimates.

Reinsurance

The Affordable Care Act creates a transitional reinsurance program for benefit years 2014, 2015, and 2016. Each State is eligible to operate reinsurance. If a State operates reinsurance, the State must enter into a contract with an applicable reinsurance entity to carry out the program. If a State does not elect to operate reinsurance, HHS will carry out reinsurance for that State.

The Affordable Care Act requires a reinsurance pool of \$10 billion in 2014, \$6 billion in 2015, and \$4 billion in 2016. It also requires annual contributions payable to the U.S. Treasury of \$2 billion, \$2 billion, and \$1 billion for those years, respectively. These contributions are funded by health insurance issuers and self-insured group health plans. Section 1341(b)(3) of the Affordable Care Act directs the Secretary of HHS to establish the method for determining contribution levels for the program. In this final rule, HHS establishes a national per capita contribution rate designed to collect the \$12.02 billion in 2014 to cover the

⁴⁰ Congressional Budget Office. 2011. *Letter to Hon. Nancy Pelosi*. March 20, 2010. We note that these estimates include only risk adjustment transfers whereas Table 27 shows transfer estimates for risk adjustment and reinsurance.

required \$10 billion in reinsurance payments, the \$2 billion contribution to the U.S. Treasury, and the additional \$20.3 million to cover the Federal administrative expenses of operating reinsurance in 2014. We estimate that we will collect these authorized amounts from 2014 through 2016.

HHS will collect the required contributions under the national contribution rate from health insurance issuers and self-insured group health plans.⁴¹ States operating reinsurance may collect additional contributions for administrative costs, reinsurance payments, or both. Section 1341(a)(3)(B) of the Affordable Care Act requires that the reinsurance contribution amount for each issuer reflect each issuer's fully insured commercial book of business for all major medical products. In this final rule, we clarify which types of health insurance coverage and self-insured group health plans are to make reinsurance contributions, and which are not. This clarification does not affect the amounts authorized to be collected for reinsurance.

A State that establishes the reinsurance program may elect to collect additional contributions to provide funding for administrative expenses or supplemental reinsurance payments. Additional contributions for administrative expenses may be collected by the State's applicable reinsurance entity, at the State's election. Any additional contributions for reinsurance payments must be collected by the State's applicable reinsurance entity. In this final rule, we establish that HHS will collect administrative expenses for HHS-operated reinsurance programs. A State that operates the reinsurance program bears the administrative costs of the applicable reinsurance entity, and must ensure that the applicable reinsurance entity complies with program requirements. HHS will share some of its collections for administrative costs with States that run the program. If a State operates reinsurance, HHS would retain \$0.055 per capita per year to offset the costs of contributions collection, and would allocate \$0.055 per capita per year towards administrative expenses for reinsurance payments. The total amounts allocated towards administrative expenses for

reinsurance payments would be distributed to States operating reinsurance (or retained by HHS where HHS is operating the reinsurance program) in proportion to the State-by-State total requests for reinsurance payments made under the uniform payment parameters. A State may have more than one applicable reinsurance entity, and two or more States may jointly enter into an agreement with the same applicable reinsurance entity to carry out reinsurance functions in their State. Administrative costs will likely increase if multiple applicable reinsurance entities are established within a State, whereas administrative efficiencies may be found if multiple States contract with one applicable reinsurance entity.

We also finalize an annual collections and payment cycle in this final rule. We considered a quarterly collections and payment cycle, as envisioned by the Premium Stabilization Rule. However, a quarterly cycle would impose significant costs on contributing entities. Additionally, because HHS and States operating reinsurance would likely need to hold back a significant portion of reinsurance funds until the end of the year to ensure equitable payment of requests for reinsurance payments, issuers would receive only limited benefits from a quarterly payment cycle.

Under § 153.100(a), a State operating reinsurance must issue an annual notice of benefit and payment parameters specific to that State if it elects to: (i) Modify the data requirements from the HHS-operated reinsurance program; (ii) collect additional reinsurance contributions, under § 153.220(d); or (iii) use more than one applicable reinsurance entity.

States that establish the reinsurance program will also maintain any records associated with the reinsurance program, as set forth in § 153.240(c) of the Premium Stabilization Rule. The Premium Stabilization Rule established that reinsurance contributions will be based on a per capita amount. The per capita approach will be less complex to administer in comparison to the percent of premium approach that HHS considered but ultimately decided not to pursue. Further, the per capita approach will better enable HHS to maintain the goals of the reinsurance program by providing issuers with a more straightforward approach to reinsurance contributions. States will be permitted to collect additional contributions towards supplemental reinsurance payments. We estimate that it will take an operations analyst 8 hours (at \$55 an hour) and a senior

manager 2 hours (at \$77 an hour) to ensure that reinsurance contributions collected and funds used are reasonably calculated to cover additional reinsurance payments that are projected to be made only under the supplemental reinsurance payment parameters. We believe that it will cost each State choosing to collect additional contributions approximately \$594 to comply with this requirement. Additionally, under § 153.232(e), if all requested reinsurance payments under the State supplemental reinsurance parameters exceed all reinsurance contributions collected under the additional State contribution rate for the benefit year, the State must determine a uniform pro rata adjustment to be applied to all requests for supplemental reinsurance payments. The State or the applicable reinsurance entity must reduce all such requests for supplemental reinsurance payments for the applicable benefit year by that adjustment. We estimate it will take an operations analyst 40 hours (at \$55 an hour) and a senior manager 12 hours (at \$77 an hour) to determine appropriate payment calculations and, if necessary, a pro rata adjustment. Therefore, we estimate that it will cost each State choosing to collect additional contributions approximately \$3,124 to comply with this requirement.⁴²

In this final rule, we establish the methodology to be used for counting covered lives for purposes of calculating reinsurance contributions. This methodology offers contributing entities a choice similar to counting methods permitted under the PCORTF Rule. We believe that relying on a previously established process set forth in the PCORTF Rule for counting enrollees will minimize issuer burden for conducting these counts. In the Collection of Information Requirements section of this final rule, we describe the administrative costs for issuers associated with the data requirements in § 153.400(b) for all contributing entities both inside and outside the Exchange. The contributing entities will provide enrollment data to HHS to substantiate contribution amounts.

Reinsurance payments will be made to issuers of individual market insurance coverage for high claims costs for enrollees. In this final rule, we establish a national attachment point, national reinsurance cap, and national coinsurance rate. In the Premium Stabilization Rule, we established that payments will be made on a portion of claims costs for enrollees in reinsurance

⁴¹ The Department of Labor has reviewed this rule and advised that paying required reinsurance contributions would constitute a permissible expense of the plan for purposes of Title I of the Employee Retirement Income Security Act (ERISA) because the payment is required by the plan under the Affordable Care Act as interpreted in this rule. (See generally, Advisory Opinion 2001-01A to Mr. Carl Stoney, Jr., available at www.dol.gov/ebsa discussing settlor versus plan expenses.)

⁴² For purposes of Table 26, we assume that two States will operate reinsurance.

eligible plans incurred above an attachment point, subject to a reinsurance cap.

Use of a reinsurance cap, as well as the requirement for health insurance issuer cost sharing above the attachment point and below the cap, is designed to incentivize health insurance issuers to control costs. This approach based on claims costs is simpler to implement and more familiar to health insurance issuers, and therefore will likely result in savings in administrative costs as compared to a condition-based reinsurance approach.

A State operating reinsurance may supplement the reinsurance payment parameters proposed by HHS only if the State elects to collect additional contributions for supplemental reinsurance payments or use additional State funds for supplemental reinsurance payments, and must specify these supplemental payment parameters in its State notice of benefit and payment parameters. We estimate that it will take an operations analyst 2 hours (at \$55 an hour) to gather the relevant information, for a total burden of \$110 per State electing to run reinsurance. Note that a State may develop a separate reinsurance program using entirely its own design.

In this final rule, we require States to provide a process through which a reinsurance-eligible plan that does not generate individual enrollee claims in its normal course of business may derive costs to request reinsurance payments. In addition, we clarify that when HHS operates the reinsurance program on behalf of a State that these plans may price encounters in accordance with their existing principal, internal encounter pricing methodology. Additionally, in § 153.240(b) of this final rule, States operating the reinsurance program must notify issuers annually of reinsurance payments to be made, as well as provide reinsurance-eligible plans quarterly estimates of requests for reinsurance payments. Moreover, we establish that for both State- and HHS-operated reinsurance programs, only plans subject to the 2014 market reform rules are eligible for reinsurance payment.

We estimate it will take an operations analyst 40 hours (at \$55 an hour), 10 hours per quarter, and a senior manager 12 hours (at \$77 an hour), 3 hours per quarter, to determine appropriate quarterly estimates of expected reinsurance payments and to notify plans. Additionally, we expect it will take an operations analyst 40 hours (at \$55 an hour) and a senior manager 12 hours (at \$77 an hour) to determine the total amount of reinsurance payments

for each reinsurance-eligible plan. Therefore, we estimate that it will cost each State choosing to run reinsurance approximately \$6,248 to comply with this requirement.

We also believe that these provisions will result in a small administrative cost to States associated with determining a format for submission of reinsurance payment data and notifying capitated plans of the acceptable method and format of data collection. We anticipate that a State will only need to establish this process once. On average, we estimate that it will take each State approximately 50 hours to comply with this requirement. We estimate it will take an operations analyst 40 hours (at \$55 an hour) and a senior manager 10 hours (at \$77 an hour) to determine an appropriate format for submission of reinsurance payment data for capitated plans and to notify plans of the acceptable method and format for data collection. Therefore, we estimate that it will cost each State choosing to run reinsurance approximately \$2,970 to comply with these requirements.

In this final rule, we also provide more details on the data collection approach for HHS-operated reinsurance programs. HHS plans to use the same distributed data collection approach used for risk adjustment; however, only data elements necessary for reinsurance claim selection will be considered for the purpose of determining reinsurance payments. In the Collection of Information Requirements section, we describe the administrative costs required in § 153.410 for issuers of reinsurance-eligible plans in States where HHS is operating reinsurance to receive reinsurance payments. We believe details on the reinsurance data collection approach finalized in this rule are reflected in these cost estimates.

A wide range of health insurance issuers and self-insured group health plans contribute to the reinsurance pool because successful implementation of this rule, in combination with the range of Affordable Care Act reforms starting in 2014, benefit all of their enrollees; for example, those reforms should lead to fewer unreimbursed health costs, lowering the costs for issuers and group health plans. Providing reinsurance payments to health insurance issuers with plans in the individual market serves to stabilize premiums in the individual market. Reinsurance will put downward pressure on individual market rates as new enrollees with unknown risk join the market. It will also help prevent insurers from building in risk premiums to their rates given the unknown health of their new enrollees. It is expected that the cost of

reinsurance contributions will be roughly equal to 1 percent of premiums in the total market in 2014, less in 2015 and 2016, and will end in 2017. In contrast, it is anticipated that reinsurance payments will result in premium decreases in the individual market of between 10 and 15 percent.

Evidence from the Healthy New York (Healthy NY) program⁴³ supports the magnitude of these estimates. In 2001, the State of New York began operating Healthy NY and required all HMOs in the State to offer policies for which small businesses and low-income individuals would be eligible. The program contained a “stop-loss” reinsurance provision designed to lower premiums for enrollees. Under the program, if any enrollee incurred \$30,000 in annual claims, his or her insurer was reimbursed for 90 percent of the next \$70,000 in claims. Premiums for Healthy NY policies were about 15 percent to 30 percent less than those for comparable HMO policies in the small group market.

Comment: One commenter asked how HHS derived the estimate that reinsurance contributions would increase total market premiums paid by 1 percent, and that reinsurance payments to issuers would reduce premiums in the individual market by between 10 percent and 15 percent.

Response: This is an HHS estimate for the effects of reinsurance in 2014 that relied in part on a 2009 analysis of health insurance premiums by the Congressional Budget Office.

Risk Corridors

The Affordable Care Act creates a temporary risk corridors program for the years 2014, 2015, and 2016 that applies to QHPs. The risk corridors program creates a mechanism for sharing risk for allowable costs between the Federal government and QHP issuers. The Affordable Care Act establishes the risk corridors program as a Federal program; consequently, HHS will operate the risk corridors program under Federal rules with no State variation. The risk corridors program will help protect against inaccurate rate setting in the early years of the Exchanges by limiting the extent of issuer losses and gains.

QHP issuers must submit to HHS data on premiums earned, allowable claims and quality costs, and allowable administrative costs, reflecting data categories required under the Medical Loss Ratio Interim Final Rule (75 FR

⁴³ Swartz, K. “Health New York: Making Insurance More Affordable for Low-Income Workers.” *The Commonwealth Fund*. November 2001.

74918). In designing the program, HHS has sought to leverage existing data reporting for Medical Loss Ratio purposes as much as possible.

As noted above, the risk corridors program is intended to protect QHP issuers in the individual and small group markets against inaccurate rate setting. Due to uncertainty about the population during the first years of Exchange operation, issuers may not be able to predict their risk accurately, and their premiums may reflect costs that are ultimately lower or higher than predicted. To determine whether an issuer pays into, or receives payments from, the risk corridors program, HHS will compare allowable costs (essentially, claims costs subject to adjustments for health care quality, health IT, risk adjustment payments and charges and reinsurance payments) and the target amount—the difference between a plan's earned premiums and allowable administrative costs. In this final rule, we have provided for adjustments to the risk corridors calculation to account for taxes and profits within its allowable administrative costs. The threshold for risk corridor payments and charges is reached when a QHP issuer's allowable costs exceed, or fall short of, the target amount by at least three percent. A QHP with allowable costs that are at least three percent less than its target amount will pay into the risk corridors program. Conversely, a QHP with allowable costs that exceed its target amount by at least 3 percent will receive payments. Risk corridor payments and charges are a percentage of the difference between allowable costs and target amount and therefore are not on a "first dollar" basis.

In this final rule, HHS also specifies the annual schedule for the risk corridors program, including dates for claims run-out, data submission, and notification of risk corridors payments and charges.

We believe the proposals on the risk corridors program in this final rule have a negligible effect on the impact of the program established by and described in the Premium Stabilization Rule.

Advance Payments of the Premium Tax Credit and Cost-Sharing Reductions

The impact analysis for Payment Notice provisions relating to advance payments of the premium tax credit and cost-sharing reductions references estimates from the CBO's March 2012 baseline projections. Based on our review, we expect that those provisions will not alter CBO's March 2012 baseline estimates of the budget impact of those two programs. The

requirements are well within the parameters used in the modeling of the Affordable Care Act. Our review and analysis of the requirements indicate that the impacts are likely within the model's margin of error. The Affordable Care Act provides for premium tax credits and the reduction or elimination of cost sharing for certain individuals enrolled in QHPs offered through the Exchanges. This assistance will help many low- and moderate-income individuals and families obtain health insurance—for many people, cost sharing is a barrier to obtaining needed health care.⁴⁴

Section 1402(a)–(c) of the Affordable Care Act directs issuers to reduce cost sharing for essential health benefits for individuals with household incomes between 100 and 400 percent of the FPL who are enrolled in a QHP offered at the silver level of coverage in the individual market on the Exchange and are eligible for a premium tax credit or advance payment of premium tax credits. The Affordable Care Act, at section 1402(d), also directs issuers to eliminate cost sharing for Indians (as defined in § 155.300) with a household income at or below 300 percent of the FPL who are enrolled in a QHP of any metal level in the individual market on the Exchange, and prohibits issuers from requiring cost sharing for Indians, regardless of household income, for items or services furnished directly by the IHS, an Indian Tribe, a Tribal Organization, or an Urban Indian Organization or through referral under contracted health services. Finally, the Affordable Care Act, at section 1412, provides for the advance payments of the premium tax credit and cost-sharing reductions.

A subset of the persons who enroll in QHPs in the individual market through the Exchanges beginning in 2014 will be affected by the provisions relating to advance payments of premium tax credit and cost-sharing reductions (those with household incomes below 400 percent of the FPL and Indians enrolled in QHPs). In March 2012, CBO estimated that there will be approximately 20 million enrollees in Exchange coverage by 2016, including approximately 16 million Exchange enrollees who will be receiving subsidies.⁴⁵ Participation rates are expected to be lower in the first few years of Exchange availability as employers and individuals adjust to the features of the Exchanges.⁴⁶

⁴⁴ Brook, *et al.*

⁴⁵ "Updated Estimates for the Insurance Coverage Provisions of the Affordable Care Act," Congressional Budget Office, March 2012.

⁴⁶ Congressional Budget Office, "Letter to the Honorable Evan Bayh: An Analysis of Health

In this final rule, we provide additional details for Exchanges and QHP issuers on the administration of advance payments of premium tax credit and cost-sharing reductions for individuals and families. We clarify the approach to providing for cost-sharing reductions to eligible individuals who purchase a family policy. We also establish standards applicable to Exchanges when collecting premiums from enrollees and administering advance payments of cost-sharing reductions and the premium tax credit. We describe these administrative costs in the Collection of Information Requirements section of this final rule.

Finally, we direct QHP issuers to enroll individuals in the plan variation with the correct cost-sharing structure, and to provide those individuals with the cost-sharing reductions for which they are eligible. QHP issuers are responsible for submitting plan variations containing the cost-sharing structures proposed by HHS as required by the Affordable Care Act. We also clarify which plans are eligible for cost-sharing reductions, and we set forth standards relating to advance payments of cost-sharing reductions and reconciliation of those advance payments against actual cost-sharing reduction provided. In addition, we establish standards for QHP issuers to reduce an enrollee's share of premium to account for advance payments of the premium tax credit, and submit allocations of rates and claims costs to allow for the calculation of advance payments of cost-sharing reductions and the premium tax credit. We describe these administrative costs in the Collection of Information Requirements section of this final rule.

The cost-sharing reductions and advance payments of the premium tax credit policies will apply to all issuers that choose to seek certification to offer QHPs through the Exchanges for the individual market. QHP issuers will experience costs related to preparing and submitting to HHS data to support the administration of cost-sharing reductions and advance payments of the premium tax credit. We anticipate that the provisions for advance payments of the premium tax credit and cost-sharing reductions will result in transfers from the General Fund of the Treasury to those individuals who qualify for those programs.

User Fees

To support certain Federal operations of Federally-facilitated Exchanges, we

Insurance Premiums under the Patient Protection and Affordable Care Act," Washington, DC, 2009.

establish in this final rule, under section 1311(d)(5)(A) of the Affordable Care and 31 U.S.C. 9701, that a participating issuer offering a plan through a Federally-facilitated Exchange must remit a user fee to HHS each month equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year and the monthly premium charged by the issuer for each policy under the plan offered through a Federally-facilitated Exchange. For the 2014 benefit year, we establish a monthly user fee rate equal to 3.5 percent.

SHOP

The SHOP facilitates the enrollment of small businesses into small group health insurance plans. A qualitative analysis of the costs and benefits of establishing a SHOP was included in the regulatory impact analysis published in conjunction with the Exchange Establishment Rule.⁴⁷ This impact analysis addresses the additional costs and benefits of the proposed modifications in this rule to the SHOP sections of the Exchange Establishment Rule.

In this final rule, we implement policies for FF-SHOPS designed to prevent significant adverse selection while promoting QHP choice for employees. These policies include methods a qualified employer may use to make QHPs available to its employees, rules to ensure parity with a market's group participation requirements, rules to permit the display of agent and broker information on FF-SHOP Web sites, alignment of market definitions with other applicable rules, and incentives for issuers to participate in FF-SHOPS. Many of these proposed policies are expected to create no significant new costs.

Section 1312 of the Affordable Care Act permits a qualified employer participating in a SHOP to select a metal level of coverage and make all plans in that level of coverage available to its employees. Permitting employers to choose a single level of coverage reduces potential adverse selection within the group and therefore any additional cost due to expanded choice. In the Exchanges Establishment final rule, we provided each SHOP the flexibility to choose additional means by which a qualified employer could make QHPs available to qualified employees. In this final rule, we add an FF-SHOP option to allow qualified employers to offer qualified employees

only a single QHP. This employer option is designed to further reduce adverse selection, although it may reduce the benefit to the employee resulting from broader choice. In the Exchange Establishment Rule, we did not quantify either the small risk premium or the modest additional consumer benefit resulting from employee choice at a single level of coverage, and we do not quantify the reduction in risk premium or consumer benefit resulting from this change.

The Exchange Final Rule permits a SHOP to set a minimum participation rate; such authority is limited to the extent a minimum participation rate is permissible under the PHS Act and applicable State law. Minimum participation rates require participation in the health plan by a substantial portion of the employer's group, thereby assuring a more representative risk pool and reducing adverse selection. Setting a minimum participation rate that is too low would make it ineffective, while setting it too high would reduce the number of employers offering coverage. This final rule establishes, subject to permissibility under the PHS Act, that FF-SHOPS use a default participation rate of 70 percent that may be modified if there is evidence that a higher or lower rate is either customary in the State or required by State statute. Because this policy results in no change in market dynamics, it places no additional costs on employers or issuers.

This final rule establishes that health insurance issuers with shares of a State's small group market greater than 20 percent will participate in the FF-SHOP if they also seek to participate in the FFE in the State. This policy promotes robust issuer participation in the FF-SHOP which will help qualified employers offer their employees a broad choice of health plan. The benefits of broad plan choice are quite significant. One study suggests expanding plan choice while holding premiums constant for employees results in a median increase in value to consumers ("consumer surplus") of 20 percent of the premium cost of coverage.⁴⁸ Some of this benefit is due to expanded choice in plan type and health insurance issuer. There are two additional impacts associated with this policy. The first is the cost for the QHP issuer of submitting plans for certification in the FF-SHOP, which is described in the 30-day **Federal Register** Notice for the Initial

Plan Data Collection published on November 21, 2012 (77 FR 69846). The second is the transfer associated with user fees for additional enrollees in QHPs in the FF-SHOP.

Medical Loss Ratio

This final rule amends the MLR and rebate calculation methodologies to include payments and receipts related to the premium stabilization programs. The definition of premium revenue is modified to account for these payments and receipts. When the MLR annual reporting form is updated for the reporting year 2014 and later, premium stabilization payment and receipt amounts will be considered a part of gross earned premium reported to the Secretary, similar to other elements involved in the derivation of earned premium. Gross earned premium will not be reduced by the amount of contributions under the transitional reinsurance program. The MLR annual reporting form will then account for premium stabilization payment and receipt amounts other than the reinsurance contributions by removing them from adjusted earned premium, so that these amounts do not have a net impact on the adjusted earned premium used in calculating the MLR denominator and rebates. Contributions under the transitional reinsurance program will be included with the Federal assessments that are deducted from earned premium in MLR and rebate calculations. Additionally, this final rule amends the MLR calculation methodology to add or subtract premium stabilization payment and receipt amounts, other than reinsurance contributions, in the MLR numerator, consistent with the way the statute prescribes the calculation methodology for risk corridors. These adjustments will reduce or increase issuers' MLRs, and may increase or reduce issuers' rebates, respectively. The amended methodology will result in a more accurate calculation of MLR and rebate amounts, since it will reflect issuers' actual claims-related expenditures. This approach will also support the effectiveness of both the MLR and the premium stabilization programs by correctly offsetting the premium stabilization payment and receipt amounts against rebates, consistently with the risk corridors calculation methodology adopted in § 153.530.

Based on HHS's experience with the 2011 MLR reporting year, there are 466 health insurance issuers⁴⁹ offering

⁴⁷ Available at: <http://ccio.cms.gov/resources/files/Files2/03162012/hie3r-ria-032012.pdf>.

⁴⁸ Dafny, L., Ho, K., & Varela, M. (2010). *Let them have choice: Gains from shifting away from employer-sponsored health insurance and toward an individual exchange* (No. w15687). National Bureau of Economic Research.

⁴⁹ Issuers represent companies (for example, NAIC company code). These estimates do not

coverage in the individual and group markets to almost 80 million enrollees that will be affected by the proposed amendment to account for premium stabilization payments in MLR and rebate calculations. In 2012, an estimated 54 issuers paid \$396 million in rebates for the 2011 MLR reporting year to approximately 4 million enrollees in the individual markets, while 59 issuers in the small group market provided approximately \$289 million in rebates to policyholders and subscribers on behalf of over 3 million enrollees, and 47 issuers in the large group market provided approximately \$403 million in rebates to policyholders and subscribers on behalf of almost 6 million enrollees. Lack of data makes it difficult to predict how high-risk enrollees will be distributed among issuers and, therefore, how MLRs and total rebates would be affected. Issuers with relatively low-risk enrollees are likely to have positive net premium stabilization payments (that is, payments would be greater than receipts) and, if so, their MLRs will increase as a result of the amended MLR calculation methodology. If any of these issuers fail to meet the MLR standard, taking the premium stabilization payments and receipts into account in the MLR calculations will result in lower rebate payments. Issuers with relatively high-risk enrollees are likely to have positive net receipts (that is, receipts would be greater than payments) and, if so, their MLRs would decrease as a result. If any such issuer fails to meet the MLR standard, its rebate amount will increase. Since such issuers are likely to have high claims expenditures and therefore, high MLRs, they would be less likely to owe rebates. So we do not anticipate that rebates will go up for such issuers.

This final rule also changes the deadlines for MLR report submission and rebate payments so that the deadlines occur after all the premium stabilization payment and receipt amounts are determined. The change in the deadlines will allow issuers to calculate the MLR and rebate amounts based on actual calculated payments and receipts rather than estimated amounts and will improve the accuracy of the rebate payments and reports. This will also reinforce the effectiveness of the premium stabilization programs, since issuers are less likely to pay higher or lower rebates based on inaccurate payment and receipt estimations. Accordingly, this final rule

changes the date of MLR reporting to the Secretary from June 1 to July 31, and the rebate due date from August 1 to September 30.

Issuers will also have to report their payments and receipts related to the premium stabilization programs in the annual MLR report beginning in the 2014 MLR reporting year. Once issuers calculate these amounts, which they will be required to do regardless of the MLR reporting requirements, the administrative cost of including these amounts in the report will be minimal.

The previous MLR calculation methodology allowed an issuer to deduct from premiums in the calculation of an issuer's MLR and rebates either the amount it paid in State premium taxes, or the amount of its community benefit expenditures up to a maximum of the highest premium tax rate in the State, whichever is greater, as provided in the final rule with comment period (76 FR 76574) published on December 7, 2011. This final rule amends the MLR methodology to allow a Federal income tax exempt not-for-profit issuer to deduct from premium both community benefit expenditures and State premium taxes, limited to the higher of the State's highest premium tax rate or 3 percent of premium. Other issuers will continue to use the previous methodology. This will create a level playing field for Federal income tax exempt not-for-profit issuers, who are required to make community benefit expenditures to maintain their Federal income tax exempt status and will not discourage community benefit expenditures. This is likely to increase the MLRs for tax exempt not-for-profit issuers. If any of these issuers fail to meet the MLR standard, then this will result in lower rebate payments.

Based on MLR annual reports submitted by issuers for the 2011 MLR reporting year, we estimate that there are 132 not-for-profit issuers that will be affected by this amendment. In the absence of data on tax exempt not-for-profit issuers, we use the estimates for not-for-profit issuers in our analysis. Therefore, the actual impact is likely to be lower. For the 20 not-for-profit issuers that submitted data on community benefit expenditures, such expenditures as a percentage of earned premiums ranged from 0.04 percent to 4.11 percent with an average of 1.57 percent, which is likely to be less than the current limit for most of the issuers and is less than the proposed limit as well. We assume that in 2012 issuers will maintain the level of community benefit expenditures as reported in their MLR annual reports for the 2011 MLR

reporting year. Therefore, we estimate that under the current policy, in the 2012 MLR reporting year, 17 not-for-profit issuers will owe approximately \$182 million in rebates to approximately 1.5 million enrollees, which is the same as the experience in the 2011 MLR reporting year. The adopted change in treatment of community benefit expenditures for such issuers will have minimal effect on their MLRs and rebates under this assumption, since their current expenditures are below the current deduction limits.

Issuers with lower rebate payments as a result of these adjustments will need to send fewer rebate notices, and therefore, will have lower administrative costs related to rebates and rebate notices.

D. Alternatives Considered

Risk Adjustment

We considered State flexibility for risk adjustment. This option would have allowed States to develop State-specific characteristics but it would have resulted in few Federal standards by which to compensate for risk. This final rule describes a HHS risk adjustment methodology but allows States to seek HHS approval for alternate methodologies based on criteria established in this final rule. This compromise gives States some flexibility but also reduces the burden on multi-State issuers and the Federal government.

Reinsurance

We proposed State flexibility to establish the reinsurance program in the Premium Stabilization Rule. This option would have allowed for State innovation, but it would have greatly increased the administrative burden on self-insured group health plans, multi-State issuers and the Federal government. A national approach is more efficient and less expensive. Moreover, we believe that uniform reinsurance payment parameters deliver payments where they are most needed—to issuers with high cost claims in the individual market. Centralized collection of contributions, an annual contribution and payment schedule, as well as a national contribution rate provide a more effective approach to stabilize premiums, while decreasing administrative burden.

Risk Corridors

Elsewhere in this issue of the **Federal Register**, we are implementing an alternative to our current policy, under which the risk corridor calculation

include issuers of plans with total annual limits of \$250,000 or less (sometimes referred to as "mini-med" plans) or expatriate plans.

methodology compares plan-specific allowable costs (adjusted claims) to a target amount (adjusted premiums). In order to align the risk corridor calculation methodology with the single risk pool requirements finalized at § 156.80, we are modifying the definition of “allowable costs” for the risk corridors calculation at § 153.500 such that “allowable costs” are calculated in a manner consistent with the single risk pool requirement for premiums. We believe that this approach will better align risk sharing under the program with how issuers will be required to set rates. We address the burden associated with this approach in the Collection of Information Section of the interim final rule with comment “Amendments to the HHS Notice of Benefit and Payment Parameters for 2014”, published elsewhere in this issue of the **Federal Register**.

Advance Payments of the Premium Tax Credit and Cost-Sharing Reductions

As discussed in section III.E.4.i, we considered requiring QHP issuers to provide cost-sharing reductions to Indians by waiving the cost sharing as appropriate, rather than assigning the eligible Indian to a particular plan variation. However, we believe this alternative approach would be too burdensome for issuers to implement in the short term. As discussed in section III.E.4.e, we are issuing an interim final rule with comment to provide QHP issuers with the option to submit data about the actual amount of cost-sharing reductions using an alternate methodology for purposes of payment reconciliation. This alternative will provide greater flexibility to issuers and may reduce the reporting burden for some issuers. We describe the burden associated with this alternative in the Collection of Information Section of the interim final rule with comment “Amendments to the HHS Notice of Benefit and Payment Parameters for 2014”, published elsewhere in this issue of the **Federal Register**.

User Fees

We considered calculating user fees on a per capita basis, but that approach fails to adjust for premium variation and geographic wage differences, and commenters suggest that most issuers and stakeholders prefer that such costs be calculated as a percentage of premium.

SHOP

We considered making no change to the employer options in the FF-SHOP, but concluded that allowing employers

the option of offering a single QHP to employees would simplify the transition from current market practices to the SHOP. We will be proposing further rulemaking to ease the transition from the current market to the SHOP.

We considered a range of threshold values for determining which issuers would be subject to the QHP certification requirement linking FFE and FF-SHOP participation and chose a threshold (20 percent market share) that minimized the number of issuers affected by the certification requirement while still ensuring that at least one large issuer in each State would offer QHPs in the FF-SHOP.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) requires agencies to prepare a final regulatory flexibility analysis to describe the impact of the final rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The RFA generally defines a “small entity” as (1) A proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of “small entity.” HHS uses a change in revenues of more than three to five percent as its measure of significant economic impact on a substantial number of small entities.

This final rule contains rules for premium stabilization programs required of health plan issuers and self-insured group health plans. These programs include the risk adjustment program, the transitional reinsurance program and the temporary risk corridors programs. Because we believe that few insurance firms offering comprehensive health insurance policies fall below the size thresholds for “small entities” established by the SBA, we do not believe that a final regulatory flexibility analysis is required with respect to such firms.

For purposes of the RFA, we expect the following types of entities to be affected by this final rule: (1) Health insurance issuers; (2) health insurance plan sponsors; (3) applicable reinsurance entities; (4) risk adjustment entities; (5) self-insured group health plans and (6) third-party administrators. We believe that health insurance issuers and plan sponsors would be classified under the North American Industry Classification System (NAICS) code

524114 (Direct Health and Medical Insurance Carriers); applicable reinsurance entities, risk adjustment entities and third party administrators would be classified under NAICS codes 524130 (Reinsurance Carriers), 524298 (Actuarial Services) and 524292 (Third Party Administration of Insurance). According to SBA size standards, entities with average annual receipts of \$7 million or less would be considered small entities for these NAICS codes. Issuers could possibly be classified in 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard would be \$10 million or less.

Based on data from Medical Loss Ratio annual report submissions for the 2011 MLR reporting year, there are 22 small entities (companies), each with less than \$7 million in earned premiums, that offer individual or group health insurance coverage and would therefore be subject to the provisions related to MLR. Thirty six percent of these small issuers belong to holding groups, and many if not all of these small issuers are likely to have other lines of business that would result in their revenues exceeding \$7 million.

We believe that a number of sponsors of self-insured group health plans could qualify as “small entities.” This final rule specifies that third-party administrators may incur the operational costs associated with submitting reinsurance contributions to HHS. We do not believe that the reinsurance contribution amount or the operational cost associated with submitting the contribution are likely to result in a change in revenues of more than 3 to 5 percent for a substantial number of self-insured group health plans or third-party administrators that meet the definition of a small entity. We requested comment on whether the small entities affected by the proposed rule have been fully identified. We also requested comment and information on potential costs for these entities and on any alternatives that we should consider.

Comment: We received no comments on whether the small entities described in this rule have been fully identified or on potential costs to them. However, one State expressed concern that the number of small self-insured entities is expected to grow and could cause an uneven playing field if not included in reinsurance contribution assessments. The State said maintaining a level playing field is desirable so as not to provide additional incentive to self-insure and thereby deny employees the consumer protection applicable to insured products on the Exchange.

Response: We are aware that a growing number of small entities may consider self-insuring since self-insured groups are exempt from community ratings and minimum health care benefits. HHS will collect reinsurance contributions on a per enrollee basis from all self-insured group health plans regardless of their size. This will help ensure that entities are not incentivized to self-insure in order to avoid making reinsurance contributions. Because these contributions will be calculated on a per capita basis, we believe that it is unlikely that the amount of these contributions (or the operational costs associated with making these contributions) will result in a significant change in revenue for a substantial number of small entities.

In this final rule, we establish requirements on employers that choose to participate in a SHOP Exchange. As discussed above, the SHOP is limited by statute to employers with at least one but not more than 100 employees. For this reason, we expect that many employers would meet the SBA standard for small entities. We do not believe that the regulation imposes requirements on employers offering health insurance through SHOP that are more restrictive than the current requirements on small employers offering employer-sponsored coverage. For example, the FF-SHOP will generally match existing minimum participation rates in the outside market. Additionally, as discussed in the regulatory impact analysis, we believe the employee choice option will ultimately provide greater choice for the employee among QHPs and issuers, benefitting both employer and employee and simplifying the process for the employer of administering multiple health benefit plans while allowing a SHOP to let an employer choose one plan eases the transition from the current marketplace. We believe the processes that we have established constitute the minimum amount of requirements necessary to implement statutory mandates and accomplish our policy goals, and that no appropriate regulatory alternatives could be developed to further lessen the compliance burden.

F. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a State, local, or Tribal governments, in the aggregate, or by the private sector,

of \$100 million in 1995 dollars, updated annually for inflation. In 2013, that threshold is approximately \$141 million. Although we have not been able to quantify the user fees that will be associated with this rule, the combined administrative cost and user fee impact on State, local, or Tribal governments and the private sector may be above the threshold. Earlier portions of this RIA constitute our UMRA analysis.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct costs on State and local governments, pre-empts State law, or otherwise has Federalism implications. Because States have flexibility in designing their risk adjustment, reinsurance, and Exchange-related programs, State decisions will ultimately influence both administrative expenses and overall premiums. States are not required to establish a risk adjustment or reinsurance program, or an Exchange.

In HHS's view, while this final rule does not impose substantial direct requirement costs on State and local governments, this regulation has Federalism implications due to direct effects on the distribution of power and responsibilities among the State and Federal governments relating to determining standards relating to health insurance that is offered in the individual and small group markets. Each State electing to establish a risk adjustment or reinsurance program or an Exchange must adopt the Federal standards contained in the Affordable Care Act and in this final rule, or have in effect a State law or regulation that implements these Federal standards. However, HHS anticipates that the Federalism implications (if any) are substantially mitigated because under the statute, States have choices regarding the structure and governance of these programs. Additionally, the Affordable Care Act does not require States to establish these programs; if a State elects not to establish these programs (or the State's risk adjustment program or Exchange is not approved), HHS must establish and operate these programs in that State.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have Federalism implications or limit the policy making discretion of the States, HHS has engaged in efforts to consult with and work cooperatively with affected States, including participating in conference calls with

and attending conferences of the National Association of Insurance Commissioners, and consulting with State insurance officials on an individual basis.

Throughout the process of developing this final rule, HHS has attempted to balance the States' interests in regulating health insurance issuers, and Congress' intent to provide access to Affordable Insurance Exchanges for consumers in every State. By doing so, it is HHS's view that we have complied with the requirements of Executive Order 13132.

List of Subjects

45 CFR Part 153

Administrative practice and procedure, Adverse selection, Health care, Health insurance, Health records, Organization and functions (Government agencies), Premium stabilization, Reporting and recordkeeping requirements, Reinsurance, Risk adjustment, Risk corridors, Risk mitigation, State and local governments.

45 CFR Part 155

Administrative practice and procedure, Health care access, Health insurance, Reporting and recordkeeping requirements, State and local governments, Cost-sharing reductions, Advance payments of premium tax credit, Administration and calculation of advance payments of the premium tax credit, Plan variations, Actuarial value.

45 CFR Part 156

Administrative practice and procedure, Advertising, Advisory Committees, Brokers, Conflict of interest, Consumer protection, Grant programs-health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, American Indian/Alaska Natives, Individuals with disabilities, Loan programs-health, Organization and functions (Government agencies), Medicaid, Public assistance programs, Reporting and recordkeeping requirements, State and local governments, Sunshine Act, Technical assistance, Women, and Youth.

45 CFR Part 157

Employee benefit plans, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Organization and functions (Government agencies), Medicaid, Public assistance programs, Reporting and recordkeeping requirements, Safety,

State and local governments, Sunshine Act, Technical Assistance, Women, and Youth.

45 CFR Part 158

Administrative practice and procedure, Claims, Health care, Health insurance, Health plans, penalties, Reporting and recordkeeping requirements, Premium revenues, Medical loss ratio, Rebating.

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR parts 153, 155, 156, 157 and 158 as set forth below:

PART 153—STANDARDS RELATED TO REINSURANCE, RISK CORRIDORS, AND RISK ADJUSTMENT UNDER THE AFFORDABLE CARE ACT

- 1. The authority citation for part 153 continues to read as follows:

Authority: Secs. 1311, 1321, 1341–1343, Pub. L. 111–148, 24 Stat. 119.

- 2. Section 153.20 is amended by revising the definitions of “Contributing entity”, “Risk adjustment covered plan” and “Risk adjustment data collection approach” to read as follows:

§ 153.20 Definitions.

* * * * *

Contributing entity means a health insurance issuer or self-insured group health plan. A self-insured group health plan is responsible for the reinsurance contributions, though it may elect to use a third party administrator or administrative services only contractor for transfer of the reinsurance contributions.

* * * * *

Risk adjustment covered plan means, for the purpose of the risk adjustment program, any health insurance coverage offered in the individual or small group market with the exception of grandfathered health plans, group health insurance coverage described in § 146.145(c) of this subchapter, individual health insurance coverage described in § 148.220 of this subchapter, and any plan determined not to be a risk adjustment covered plan in the applicable Federally certified risk adjustment methodology.

* * * * *

Risk adjustment data collection approach means the specific procedures by which risk adjustment data is to be stored, collected, accessed, transmitted, and validated and the applicable timeframes, data formats, and privacy and security standards.

* * * * *

- 3. Section 153.100 is amended by—

- A. Revising paragraph (a)(1).
- B. Removing paragraph (a)(2).
- C. Redesignating paragraphs (a)(3) and (4) as paragraphs (a)(2) and (3).
- D. Revising newly designated paragraph (a)(2).
- E. Removing paragraph (a)(5).
- F. Revising paragraph (d)(1).
- G. Removing paragraph (d)(2).
- H. Redesignating paragraphs (d)(3) and (4) as paragraphs (d)(2) and (3).
- I. Revising newly designated paragraph (d)(2).
- J. Removing paragraph (d)(5).
- K. Redesignating paragraph (d)(6) as paragraph (d)(4).
- The revisions read as follows:

§ 153.100 State notice of benefit and payment parameters.

(a) * * *

(1) Modify the data requirements for health insurance issuers to receive reinsurance payments from those specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year;

(2) Collect additional reinsurance contributions under § 153.220(d)(1) or use additional funds for reinsurance payments under § 153.220(d)(2); or

* * * * *

(d) * * *

(1) Adhere to the data requirements for health insurance issuers to receive reinsurance payments that are specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year;

(2) Forgo the collection of additional reinsurance contributions under § 153.220(d)(1) and the use of additional funds for reinsurance payments under § 153.220(d)(2);

* * * * *

- 4. Section 153.110 is amended by:

- A. Revising paragraph (a).
- B. Removing paragraph (b).
- C. Redesignating paragraph (c) as paragraph (b) and revising newly designated paragraph (b).
- D. Redesignating paragraph (d) as paragraph (c).
- E. Removing newly designated paragraph (c)(2).
- F. Redesignating paragraph (c)(3) as paragraph (c)(2).
- G. Removing newly designated paragraph (c)(4).
- H. Removing newly designated paragraph (c)(5).
- I. Redesignating paragraph (c)(6) as paragraph (c)(3).
- J. Removing paragraph (e).
- K. Redesignating paragraph (f) as paragraph (d).

The revisions read as follows:

§ 153.110 Standards for the State notice of benefit and payment parameters.

(a) *Data requirements.* If a State that establishes a reinsurance program elects to modify the data requirements for health insurance issuers to receive reinsurance payments from those specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year, the State notice of benefit and payment parameters must specify those modifications.

(b) *Additional collections.* If a State that establishes a reinsurance program elects to collect additional funds under § 153.220(d)(1) or use additional funds for reinsurance payments under § 153.220(d)(2), the State must publish in the State notice of benefit and payment parameters the following:

(1) A description of the purpose of the additional collection, including whether it will be used to cover reinsurance payments made under § 153.232, administrative costs, or both;

(2) The additional contribution rate at which the funds will be collected; and

(3) If the purpose of the additional collection includes reinsurance payments (or if the State is using additional funds for reinsurance payments under § 153.220(d)(2)), the State supplemental reinsurance payment parameters required under § 153.232.

* * * * *

- 5. Section 153.210 is amended by revising paragraph (a)(2) and adding paragraph (e) to read as follows:

§ 153.210 State establishment of a reinsurance program.

(a) * * *

(2) If a State contracts with or establishes more than one applicable reinsurance entity, the State must ensure that each applicable reinsurance entity operates in a distinct geographic area with no overlap of jurisdiction with any other applicable reinsurance entity.

* * * * *

(e) *Reporting to HHS.* Each State that establishes a reinsurance program must ensure that each applicable reinsurance entity provides information regarding requests for reinsurance payments under the national contribution rate made under § 153.410 for all reinsurance-eligible plans for each quarter during the applicable benefit year in a manner and timeframe established by HHS.

- 6. Section 153.220 is amended by—

- A. Revising paragraph (a).
- B. Removing paragraph (b).
- C. Redesignating paragraph (c) as paragraph (b).
- D. Removing paragraph (d).

- E. Redesignating paragraph (e) as paragraph (c).
- F. Revising newly designated paragraph (c)(2).
- G. Removing paragraph (f).
- H. Redesignating paragraph (g) as paragraph (d).
- I. Revising newly designated paragraph (d).
- J. Removing paragraph (h).

The revisions read as follows:

§ 153.220 Collection of reinsurance contribution funds.

(a) *Collections.* If a State establishes a reinsurance program, HHS will collect all reinsurance contributions from all contributing entities for that State under the national contribution rate.

* * * * *

(c) * * *

(2) Payments to the U.S. Treasury as described in paragraph (b)(2) if this section; and

* * * * *

(d) *Additional State collections.* If a State establishes a reinsurance program:

(1) The State may elect to collect more than the amounts that would be collected based on the national contribution rate set forth in the annual HHS notice of benefit and payment parameters for the applicable benefit year to provide:

(i) Funding for administrative expenses of the applicable reinsurance entity; or

(ii) Additional funds for reinsurance payments.

(2) A State may use additional funds which were not collected as additional reinsurance contributions under this part for reinsurance payments under the State supplemental payment parameters under § 153.232.

* * * * *

■ 7. Section 153.230 is revised to read as follows:

§ 153.230 Calculation of reinsurance payments made under the national contribution rate.

(a) *Eligibility for reinsurance payments under the national reinsurance parameters.* A health insurance issuer of a reinsurance-eligible plan becomes eligible for reinsurance payments from contributions under the national contribution rate when its claims costs for an individual enrollee's covered benefits in a benefit year exceed the national attachment point.

(b) *National reinsurance payment parameters.* The national reinsurance payment parameters for each benefit year commencing in 2014 and ending in 2016 set forth in the annual HHS notice of benefit and payment parameters for

each applicable benefit year will apply with respect to reinsurance payments made from contributions received under the national contribution rate.

(c) *National reinsurance payments.* Each reinsurance payment made from contributions received under the national contribution rate will be calculated as the product of the national coinsurance rate multiplied by the health insurance issuer's claims costs for an individual enrollee's covered benefits that the health insurance issuer incurs in the applicable benefit year between the national attachment point and the national reinsurance cap.

(d) *Uniform adjustment to national reinsurance payments.* If HHS determines that all reinsurance payments requested under the national payment parameters from all reinsurance-eligible plans in all States for a benefit year will exceed all reinsurance contributions collected under the national contribution rate in all States for an applicable benefit year, HHS will determine a uniform pro rata adjustment to be applied to all such requests for reinsurance payments for all States. Each applicable reinsurance entity, or HHS on behalf of a State, must reduce all requests for reinsurance payments for the applicable benefit year by any adjustment required under this paragraph (d).

■ 8. Section 153.232 is added to read as follows:

§ 153.232 Calculation of reinsurance payments made under a State additional contribution rate.

(a) *State supplemental reinsurance payment parameters.* (1) If a State establishes a reinsurance program and elects to collect additional contributions under § 153.220(d)(1)(ii) or use additional funds for reinsurance payments under § 153.220(d)(2), the State must set supplemental reinsurance payment parameters using one or more of the following methods:

(i) Decreasing the national attachment point;

(ii) Increasing the national reinsurance cap; or

(iii) Increasing the national coinsurance rate.

(2) The State must ensure that additional reinsurance contributions and funds projected to be received under § 153.220(d)(1)(ii) and § 153.220(d)(2), as applicable, for any applicable benefit year are reasonably calculated to cover additional reinsurance payments that are projected to be made only under the State supplemental reinsurance payment parameters (that will not be paid under

the national payment parameters) for the given benefit year.

(3) All applicable reinsurance entities in a State collecting additional reinsurance contributions must apply the State supplemental reinsurance payment parameters established under paragraph (a)(1) of this section when calculating reinsurance payments.

(b) *General requirement for payments under State supplemental reinsurance parameters.* Contributions collected under § 153.220(d)(1)(ii) or funds under § 153.220(d)(2), as applicable, must be applied towards requests for reinsurance payments made under the State supplemental reinsurance payments parameters for each benefit year commencing in 2014 and ending in 2016.

(c) *Eligibility for reinsurance payments under State supplemental reinsurance parameters.* If a State establishes State supplemental reinsurance payment parameters under § 153.232(a)(1), a reinsurance-eligible plan becomes eligible for reinsurance payments from contributions under § 153.220(d)(1)(ii) or funds under § 153.220(d)(2), as applicable, if its incurred claims costs for an individual enrollee's covered benefits in the applicable benefit year:

(1) Exceed the State supplemental attachment point set forth in the State notice of benefit and payment parameters for the applicable benefit year if a State has established such a supplemental attachment point under § 153.232(a)(1)(i);

(2) Exceed the national reinsurance cap set forth in the annual HHS notice of benefit and payment parameters for the applicable benefit year if a State has established a State supplemental reinsurance cap under § 153.232(a)(1)(ii); or

(3) Exceed the national attachment point set forth in the annual HHS notice of benefit and payment parameters for the applicable benefit year if a State has established a supplemental coinsurance rate under § 153.232(a)(1)(iii).

(d) *Payments under State supplemental reinsurance parameters.* Each reinsurance payment made from contributions received under § 153.220(d)(1)(ii) or funds under § 153.220(d)(2), as applicable, will be calculated with respect to an issuer's incurred claims costs for an individual enrollee's covered benefits in the applicable benefit year as the sum of the following:

(1) If the State has established a State supplemental attachment point, to the extent the issuer's incurred claims costs for such benefits in the applicable benefit year exceed the State

supplemental attachment point but do not exceed the national attachment point, the product of such claims costs between the State supplemental attachment point and the national attachment point multiplied by the national coinsurance rate (or, if the State has established a State supplemental coinsurance rate, the State supplemental coinsurance rate);

(2) If the State has established a State supplemental reinsurance cap, to the extent the issuer's incurred claims costs for such benefits in the applicable benefit year exceed the national reinsurance cap but do not exceed the State supplemental reinsurance cap, the product of such claims costs between the national reinsurance cap and the State supplemental reinsurance cap multiplied by the national coinsurance rate (or, if the State has established a State supplemental coinsurance rate, the State supplemental coinsurance rate); and

(3) If the State has established a State supplemental coinsurance rate, the product of the issuer's incurred claims costs for such benefits in the applicable benefit year between the national attachment point and the national reinsurance cap multiplied by the difference between the State supplemental coinsurance rate and the national coinsurance rate.

(e) *Uniform adjustment to payments under State supplemental reinsurance payment parameters.* If all requested reinsurance payments under the State supplemental reinsurance parameters calculated in accordance with paragraph (a)(1) of this section from all reinsurance-eligible plans in a State for a benefit year will exceed all reinsurance contributions collected under § 153.220(d)(1)(ii) or funds under § 153.220(d)(2) for the applicable benefit year, the State must determine a uniform pro rata adjustment to be applied to all such requests for reinsurance payments. Each applicable reinsurance entity in the State must reduce all such requests for reinsurance payments for the applicable benefit year by that adjustment.

(f) *Limitations on payments under State supplemental reinsurance parameters.* A State must ensure that:

(1) The payments made to issuers must not exceed the issuer's total paid amount for the reinsurance-eligible claim(s); and

(2) Any remaining additional funds for reinsurance payments collected under § 153.220(d)(1)(ii) must be used for reinsurance payments under the State supplemental reinsurance payment parameters in subsequent benefit years.

■ 9. Section 153.234 is added to read as follows:

§ 153.234 Eligibility under health insurance market rules.

A reinsurance-eligible plan's covered claims costs for an enrollee incurred prior to the application of the following provisions do not count towards either the national reinsurance payment parameters or the State supplemental reinsurance payment parameters: 45 CFR 147.102, 147.104 (subject to 147.145), 147.106 (subject to 147.145), 156.80, and subpart B of part 156.

■ 10. Section 153.235 is added to read as follows:

§ 153.235 Allocation and distribution of reinsurance contributions

(a) *Allocation of reinsurance contributions.* HHS will allocate and disburse to each State operating reinsurance (and will distribute directly to issuers if HHS is operating reinsurance on behalf of a State), reinsurance contributions collected from contributing entities under the national contribution rate for reinsurance payments. The disbursed funds would be based on the total requests for reinsurance payments made under the national reinsurance payment parameters in all States and submitted under § 153.410, net of any adjustment under § 153.230(d).

(b) *Excess reinsurance contributions.* Any reinsurance contributions collected from contributing entities under the national contribution rate for reinsurance payments for any benefit year but unused for the applicable benefit year will be used for reinsurance payments under the national reinsurance payment parameters for subsequent benefit years.

■ 11. Section 153.240 is amended by revising paragraphs (a) and (b) and by adding a new paragraph (d) to read as follows:

§ 153.240 Disbursement of reinsurance payments.

(a) *Data collection.* If a State establishes a reinsurance program, the State must ensure that the applicable reinsurance entity:

(1) Collects data required to determine reinsurance payments as described in § 153.230 and § 153.232, as applicable, from an issuer of reinsurance-eligible plans or is provided access to such data, according to the data requirements specified by the State in the State notice of benefit and payment parameters described in subpart B of this part.

(2) Makes reinsurance payments to the issuer of a reinsurance-eligible plan after receiving a valid claim for payment

from that health insurance issuer in accordance with the requirements of § 153.410.

(3) Provides a process through which an issuer of a reinsurance-eligible plan that does not generate individual enrollee claims in the normal course of business may use estimated claims costs to make a request for payment (or to submit data to be considered for reinsurance payments) in accordance with the requirements of § 153.410. The State must ensure that such requests for reinsurance payment (or a subset of such requests) are subject to validation.

(b) *Notification of reinsurance payments.* For each applicable benefit year,

(1) A State, or HHS on behalf of the State, must notify issuers annually of:

(i) Reinsurance payments under the national payment parameters, and

(ii) Reinsurance payments under the State supplemental payment parameters if applicable, to be made for the applicable benefit year no later than June 30 of the year following the applicable benefit year.

(2) A State must provide to each issuer of a reinsurance-eligible plan the calculation of total reinsurance payment requests, on a quarterly basis during the applicable benefit year in a timeframe and manner specified by HHS, made under:

(i) The national reinsurance payment parameters, and

(ii) State supplemental reinsurance payments parameters if applicable.

* * * * *

(d) *Privacy and security.* (1) If a State establishes a reinsurance program, the State must ensure that the applicable reinsurance entity's collection of personally identifiable information is limited to information reasonably necessary for use in the calculation of reinsurance payments, and that use and disclosure of personally identifiable information is limited to those purposes for which the personally identifiable information was collected (including for purposes of data validation).

(2) If a State establishes a reinsurance program, the State must ensure that the applicable reinsurance entity implements security standards that provide administrative, physical, and technical safeguards for the personally identifiable information consistent with the security standards described at 45 CFR 164.308, 164.310, and 164.312.

■ 12. Section 153.310 is amended by:

■ A. Redesignating paragraphs (c) and (d) as paragraphs (e) and (f), respectively.

■ B. Adding new paragraphs (a)(4), (c) and (d).

The additions read as follows:

§ 153.310 Risk adjustment administration.

(a) * * *

(4) Beginning in 2015, any State that is approved to operate an Exchange and elects to operate risk adjustment but has not been approved by HHS to operate risk adjustment prior to publication of its State notice of benefit and payment parameters for the applicable benefit year, will forgo implementation of all State functions in this subpart, and HHS will carry out all of the provisions of this subpart on behalf of the State.

* * * * *

(c) *State responsibility for risk adjustment.* (1) A State operating a risk adjustment program for a benefit year must administer the applicable Federally certified risk adjustment methodology through an entity that—

(i) Is operationally ready to implement the applicable Federally certified risk adjustment methodology and process the resulting payments and charges; and

(ii) Has experience relevant to operating the risk adjustment program.

(2) The State must ensure that the risk adjustment entity complies with all applicable provisions of subpart D of this part in the administration of the applicable Federally certified risk adjustment methodology.

(3) The State must conduct oversight and monitoring of its risk adjustment program.

(d) *Certification for a State to operate risk adjustment.* (1) To be approved by HHS to operate risk adjustment under a particular Federally certified risk adjustment methodology for a benefit year, a State must establish that it and its risk adjustment entity meet the standards set forth in paragraph (c) of this section.

(2) To obtain such approval, the State must submit to HHS, in a form and manner specified by HHS, evidence that its risk adjustment entity meets these standards.

* * * * *

■ 13. Section 153.320 is amended by revising paragraphs (a)(1) and (a)(2) to read as follows:

§ 153.320 Federally certified risk adjustment methodology.

(a) * * *

(1) The risk adjustment methodology is developed by HHS and published in the applicable annual HHS notice of benefit and payment parameters; or

(2) An alternate risk adjustment methodology is submitted by a State in accordance with § 153.330, reviewed and certified by HHS, and published in

the applicable annual HHS notice of benefit and payment parameters.

* * * * *

■ 14. Section 153.330 is amended by—
■ A. Redesignating paragraph (b) as paragraph (c).

■ B. Adding new paragraph (b).

The additions read as follows:

§ 153.330 State alternate risk adjustment methodology.

* * * * *

(b) *Evaluation criteria for alternate risk adjustment methodology.* An alternate risk adjustment methodology will be certified by HHS as a Federally certified risk adjustment methodology based on the following criteria:

(1) The criteria listed in paragraph (a)(2) of this section;

(2) Whether the methodology complies with the requirements of this subpart D;

(3) Whether the methodology accounts for risk selection across metal levels; and

(4) Whether each of the elements of the methodology are aligned.

* * * * *

■ 15. Section 153.340 is amended by revising paragraph (b)(3) to read as follows:

§ 153.340 Data collection under risk adjustment.

* * * * *

(b) * * *

(3) If a State is operating a risk adjustment program, the State must ensure that any collection of personally identifiable information is limited to information reasonably necessary for use in the applicable risk adjustment model, calculation of plan average actuarial risk, or calculation of payments and charges. Except for purposes of data validation, the State may not collect or store any personally identifiable information for use as a unique identifier for an enrollee's data, unless such information is masked or encrypted by the issuer, with the key to that masking or encryption withheld from the State. Use and disclosure of personally identifiable information is limited to those purposes for which the personally identifiable information was collected (including for purposes of data validation).

* * * * *

■ 16. Section 153.360 is added to subpart D to read as follows:

§ 153.360 Application of risk adjustment to the small group market.

Enrollees in a risk adjustment covered plan must be assigned to the applicable risk pool in the State in which the

employer's policy was filed and approved.

■ 17. Section 153.400 is revised to read as follows:

§ 153.400 Reinsurance contribution funds.

(a) *General requirement.* Each contributing entity must make reinsurance contributions annually; at the national contribution rate for all reinsurance contribution enrollees, in a manner specified by HHS; and at the additional State supplemental contribution rate if the State has elected to collect additional contributions under § 153.220(d)(1), in a manner specified by the State.

(1) A contributing entity must make reinsurance contributions for its self-insured group health plans and health insurance coverage except to the extent that:

(i) Such plan or coverage is not major medical coverage;

(ii) In the case of health insurance coverage, such coverage is not considered to be part of an issuer's commercial book of business;

(iii) Such plan or coverage is expatriate health coverage, as defined by the Secretary; or

(iv) In the case of employer-provided health coverage, such coverage applies to individuals with respect to which benefits under Title XVIII of the Act (Medicare) are primary under the Medicare Secondary Payor rules under section 1862(b) of the Act and the regulations issued thereunder.

(2) Accordingly, as specified in paragraph (a)(1) of this section, a contributing entity is not required to make contributions on behalf of the following:

(i) A self-insured group health plan or health insurance coverage that consists solely of excepted benefits as defined by section 2791(c) of the PHS Act;

(ii) Coverage offered by an issuer under contract to provide benefits under any of the following titles of the Act:

(A) Title XVIII (Medicare);

(B) Title XIX (Medicaid); or

(C) Title XXI (Children's Health Insurance Program);

(iii) A Federal or State high-risk pool, including the Pre-Existing Condition Insurance Plan Program;

(iv) Basic health plan coverage offered by issuers under contract with a State as described in section 1331 of the Affordable Care Act;

(v) A health reimbursement arrangement within the meaning of IRS Notice 2002-45 (2002-2 CB 93) or any subsequent applicable guidance, that is integrated with a self-insured group health plan or health insurance coverage;

(vi) A health savings account within the meaning of section 223(d) of the Code;

(vii) A health flexible spending arrangement within the meaning of section 125 of the Code;

(viii) An employee assistance plan, disease management program, or wellness program that does not provide major medical coverage;

(ix) A stop-loss policy or an indemnity reinsurance policy;

(x) TRICARE and other military health benefits for active and retired uniformed services personnel and their dependents;

(xi) A plan or coverage provided by an Indian Tribe to Tribal members and their spouses and dependents (and other persons of Indian descent closely affiliated with the Tribe), in the capacity of the Tribal members as Tribal members (and not in their capacity as current or former employees of the Tribe or their dependents);

(xii) Health programs operated under the authority of the Indian Health Service; or

(xiii) A self-insured group health plan or health insurance coverage that consists solely of benefits for prescription drugs.

(b) *Data requirements.* Each contributing entity must submit to HHS data required to substantiate the contribution amounts for the contributing entity, in the manner and timeframe specified by HHS.

■ 18. Section 153.405 is added to read as follows:

§ 153.405 Calculation of reinsurance contributions.

(a) *In general.* The reinsurance contribution required from a contributing entity for its reinsurance contribution enrollees during a benefit year is calculated by multiplying:

(1) The number of covered lives of reinsurance contribution enrollees during the applicable benefit year for all plans and coverage described in § 153.400(a)(1) of the contributing entity; by

(2) The contribution rate for the applicable benefit year.

(b) *Annual enrollment count.* No later than November 15 of benefit year 2014, 2015, or 2016, as applicable, a contributing entity must submit an annual enrollment count of the number of covered lives of reinsurance contribution enrollees for the applicable benefit year to HHS. The count must be determined as specified in paragraphs (d) or (e) of this section, as applicable.

(c) *Notification and payment.* (1) Within 30 days of the submission of the annual enrollment count described in

paragraph (b) of this section or by December 15 of the applicable benefit year, whichever is later, HHS will notify the contributing entity of the reinsurance contribution amount to be paid for the applicable benefit year.

(2) A contributing entity must remit reinsurance contributions to HHS within 30 days after the date of the notification.

(d) *Procedures for counting covered lives for health insurance issuers.* To determine the number of covered lives of reinsurance contribution enrollees under a health insurance plan for a benefit year, a health insurance issuer must use one of the following methods:

(1) Adding the total number of lives covered for each day of the first nine months of the benefit year and dividing that total by the number of days in the first nine months;

(2) Adding the total number of lives covered on any date (or more dates, if an equal number of dates are used for each quarter) during the same corresponding month in each of the first three quarters of the benefit year, and dividing that total by the number of dates on which a count was made. For this purpose, the same months must be used for each quarter (for example January, April and July) and the date used for the second and third quarter must fall within the same week of the quarter as the corresponding date used for the first quarter; or

(3) Multiplying the average number of policies in effect for the first nine months of the benefit year by the ratio of covered lives per policy in effect, calculated using the prior National Association of Insurance Commissioners (NAIC) Supplemental Health Care Exhibit (or a form filed with the issuer's State of domicile for the most recent time period).

(e) *Procedures for counting covered lives for self-insured group health plans.* To determine the number of covered lives of reinsurance contribution enrollees under a self-insured group health plan for a benefit year, a plan must use one of the following methods:

(1) One of the methods specified in either paragraph (d)(1) or paragraph (d)(2) of this section;

(2) Adding the total number of lives covered on any date (or more dates, if an equal number of dates are used for each quarter) during the same corresponding month in each of the first three quarters of the benefit year (provided that the date used for the second and third quarters must fall within the same week of the quarter as the corresponding date used for the first quarter), and dividing that total by the number of dates on which a count was

made, except that the number of lives covered on a date is calculated by adding the number of participants with self-only coverage on the date to the product of the number of participants with coverage other than self-only coverage on the date and a factor of 2.35. For this purpose, the same months must be used for each quarter (for example, January, April, and July); or

(3) Using the number of lives covered for the benefit year calculated based upon the "Annual Return/Report of Employee Benefit Plan" filed with the Department of Labor (Form 5500) for the last applicable time period. For purposes of this paragraph (e)(3), the number of lives covered for the benefit year for a plan offering only self-only coverage equals the sum of the total participants covered at the beginning and end of the benefit year, as reported on the Form 5500, divided by 2, and the number of lives covered for the benefit year for a plan offering self-only coverage and coverage other than self-only coverage equals the sum of the total participants covered at the beginning and the end of the benefit year, as reported on the Form 5500.

(f) *Procedures for counting covered lives for group health plans with a self-insured coverage option and an insured coverage option.*

(1) To determine the number of covered lives of reinsurance contribution enrollees under a group health plan with a self-insured coverage option and an insured coverage option for a benefit year, a plan must use one of the methods specified in either paragraph (d)(1) or paragraph (d)(2) of this section.

(2) Notwithstanding paragraph (f)(1), a plan with multiple coverage options may use any of the counting methods specified for self-insured coverage or insured coverage, as applicable to each option, if it determines the number of covered lives under each option separately as if each coverage option provided major medical coverage (not including any coverage option that consists solely of excepted benefits as defined by section 2791(c) of the PHS Act, that only provides benefits related to prescription drugs, or that is a health reimbursement arrangement, health savings account, or health flexible spending arrangement).

(g) *Multiple group health plans maintained by the same plan sponsor.*

(1) *General rule.* If a plan sponsor maintains two or more group health plans (including one or more group health plans that provide health insurance coverage) that collectively provide major medical coverage for the same covered lives simultaneously, then

those multiple plans must be treated as a single group health plan for purposes of calculating any reinsurance contribution amount due under this section. However, a plan sponsor may treat the multiple plans as separate group health plans for purposes of calculating any reinsurance contribution due under this section if it determines the number of covered lives under each separate group health plan as if the separate group health plan provided major medical coverage.

(2) *Plan sponsor.* For purposes of this paragraph (g), the term “plan sponsor” means:

(i) The employer, in the case of a plan established or maintained by a single employer;

(ii) The employee organization, in the case of a plan established or maintained by an employee organization;

(iii) The joint board of trustees, in the case of a multiemployer plan (as defined in section 414(f) of the Code);

(iv) The committee, in the case of a multiple employer welfare arrangement;

(v) The cooperative or association that establishes or maintains a plan established or maintained by a rural electric cooperative or rural cooperative association (as such terms are defined in section 3(40)(B) of ERISA);

(vi) The trustee, in the case of a plan established or maintained by a voluntary employees’ beneficiary association (meaning that the association is not merely serving as a funding vehicle for a plan that is established or maintained by an employer or other person);

(vii) In the case of a plan, the sponsor of which is not described in paragraph (g)(2)(i) through (g)(2)(vi) of this section, the person identified by the terms of the document under which the plan is operated as the plan sponsor, or the person designated by the terms of the document under which the plan is operated as the plan sponsor, provided that designation is made, and that person has consented to the designation, by no later than the date by which the count of covered lives for that benefit year is required to be provided, after which date that designation for that benefit year may not be changed or revoked, and provided further that a person may be designated as the plan sponsor only if the person is one of the persons maintaining the plan (for example, one of the employers that is maintaining the plan with one or more other employers or employee organizations); or

(viii) In the case of a plan, the sponsor of which is not described in paragraph (g)(2)(i) through (g)(2)(vi) of this section, and for which no identification or

designation of a plan sponsor has been made under paragraph (g)(2)(i)(vii) of this section, each employer that maintains the plan (with respect to employees of that employer), each employee organization that maintains the plan (with respect to members of that employee organization), and each board of trustees, cooperative or association that maintains the plan.

(3) *Exception.* A plan sponsor is not required to include as part of a single group health plan as determined under paragraph (g)(1) of this section any group health plan that consists solely of excepted benefits as defined by section 2791(c) of the PHS Act, that only provides benefits related to prescription drugs, or that is a health reimbursement arrangement, health savings account, or health flexible spending arrangement.

(4) *Procedures for counting covered lives for multiple group health plans treated as a single group health plan.* The rules in this paragraph (g)(4) govern the determination of the average number of covered lives in a benefit year for any set of multiple self-insured group health plans or health insurance plans (or a combination of one or more self-insured group health plans and one or more health insurance plans) that are treated as a single group health plan under paragraph (g)(1) of this section.

(i) *Multiple group health plans including an insured plan.* If at least one of the multiple plans is an insured plan, the average number of covered lives of reinsurance contribution enrollees must be calculated using one of the methods specified in either paragraph (d)(1) or paragraph (d)(2) of this section, applied across the multiple plans as a whole. The following information must be determined by the plan sponsor and reported to HHS, in a manner and timeframe specified by HHS:

(A) The average number of covered lives calculated;

(B) The counting method used; and

(C) The names of the multiple plans being treated as a single group health plan as determined by the plan sponsor and reported to HHS.

(ii) *Multiple group health plans not including an insured plan.* If each of the multiple plans is a self-insured group health plan, the average number of covered lives of reinsurance contribution enrollees must be calculated using one of the methods specified either in paragraph (e)(1) or paragraph (e)(2) of this section, applied across the multiple plans as a whole. The following information must be determined by the plan sponsor and reported to HHS, in a manner and timeframe specified by HHS:

(A) The average number of covered lives calculated;

(B) The counting method used; and

(C) The names of the multiple plans being treated as a single group health plan as determined by the plan sponsor.

■ 19. Section 153.410 is amended by revising paragraph (a) as follows:

§ 153.410 Requests for reinsurance payments.

(a) *General requirement.* An issuer of a reinsurance-eligible plan may make a request for payment when that issuer’s claims costs for an enrollee of that reinsurance-eligible plan has met the criteria for reinsurance payment set forth in subpart B of this part and the HHS notice of benefit and payment parameters and State notice of benefit and payment parameters for the applicable benefit year, if applicable.

* * * * *

■ 20. Section 153.420 is added to subpart E to read as follows:

§ 153.420 Data collection.

(a) *Data requirement.* To be eligible for reinsurance payments, an issuer of a reinsurance-eligible plan must submit or make accessible all required reinsurance data in accordance with the reinsurance data collection approach established by the State, or by HHS on behalf of the State.

(b) *Deadline for submission of data.* An issuer of a reinsurance-eligible plan must submit or make accessible data to be considered for reinsurance payments for the applicable benefit year by April 30 of the year following the end of the applicable benefit year.

■ 21. Section 153.500 is amended by—

■ A. Revising the definitions of “Administrative costs” and “Allowable administrative costs.”

■ B. Adding the definitions of “After-tax premiums earned,” “Profits,” and “Taxes and regulatory fees” in alphabetical order.

The revisions and additions read as follows:

§ 153.500 Definitions.

* * * * *

Administrative costs mean, with respect to a QHP, total non-claims costs incurred by the QHP issuer for the QHP, including taxes and regulatory fees.

After-tax premiums earned mean, with respect to a QHP, premiums earned with respect to the QHP minus taxes and regulatory fees.

Allowable administrative costs mean, with respect to a QHP, the sum of administrative costs of the QHP, other than taxes and regulatory fees, plus profits earned by the QHP, which sum is limited to 20 percent of after-tax

premiums earned with respect to the QHP (including any premium tax credit under any governmental program), plus taxes and regulatory fees.

* * * * *

Profits mean, with respect to a QHP, the greater of:

(1) Three percent of after-tax premiums earned, and

(2) Premiums earned of the QHP minus the sum of allowable costs and administrative costs of the QHP.

* * * * *

Taxes and regulatory fees mean, with respect to a QHP, Federal and State licensing and regulatory fees paid with respect to the QHP as described in § 158.161(a) of this subchapter, and Federal and State taxes and assessments paid with respect to the QHP as described in § 158.162(a)(1) and (b)(1) of this subchapter.

* * * * *

■ 22. Section 153.510 is amended by adding new paragraph (d) to read as follows:

§ 153.510 Risk corridors establishment and payment methodology.

* * * * *

(d) *Charge submission deadline.* A QHP issuer must remit charges to HHS within 30 days after notification of such charges.

■ 23. Section 153.520 is amended by revising paragraph (d) to read as follows:

§ 153.520 Attribution and allocation of revenue and expense items.

* * * * *

(d) *Attribution of reinsurance and risk adjustment to benefit year.* A QHP issuer must attribute reinsurance payments and risk adjustment payments and charges to allowable costs for the benefit year with respect to which the reinsurance payments or risk adjustment calculations apply.

* * * * *

■ 24. Section 153.530 is amended by—
■ A. Revising paragraphs (a), (b) introductory text, (b)(1), (b)(2)(iii), and (c).

■ B. Adding new paragraph (d).

The revisions and additions read as follows:

§ 153.530 Risk corridors data requirements.

(a) *Premium data.* A QHP issuer must submit to HHS data on the premiums earned with respect to each QHP that the issuer offers in a manner specified by HHS.

(b) *Allowable costs.* A QHP issuer must submit to HHS data on the allowable costs incurred with respect to

each QHP that the QHP issuer offers in a manner specified by HHS. For purposes of this subpart, allowable costs must be—

(1) Increased by any risk adjustment charges paid by the issuer for the QHP under the risk adjustment program established under subpart D of this part.

(2) * * *

(iii) Any cost-sharing reduction payments received by the issuer for the QHP to the extent not reimbursed to the provider furnishing the item or service.

(c) *Allowable administrative costs.* A QHP issuer must submit to HHS data on the allowable administrative costs incurred with respect to each QHP that the QHP issuer offers in a manner specified by HHS.

(d) *Timeframes.* For each benefit year, a QHP issuer must submit all information required under this section by July 31 of the year following the benefit year.

■ 25. Section 153.610 is amended by adding paragraph (f) to read as follows:

§ 153.610 Risk adjustment issuer requirements.

* * * * *

(f) *Assessment and collection of user fees for HHS risk adjustment operations.* Where HHS is operating risk adjustment on behalf of a State, an issuer of a risk adjustment covered plan (other than a student health plan or a plan not subject to 45 CFR 147.102, 147.104, 147.106, 156.80, and subpart B of part 156) must, for each benefit year—

(1) Submit or make accessible to HHS its monthly enrollment for the risk adjustment covered plan for the benefit year through the risk adjustment data collection approach established at § 153.610(a), in a manner and timeframe specified by HHS; and

(2) Remit to HHS an amount equal to the product of its monthly enrollment in the risk adjustment covered plan multiplied by the per-enrollee-per-month risk adjustment user fee specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year.

■ 26. Section 153.630 is added to subpart G to read as follows:

§ 153.630 Data validation requirements when HHS operates risk adjustment.

(a) *General requirement.* An issuer of a risk adjustment covered plan in a State where HHS is operating risk adjustment on behalf of the State for the applicable benefit year must have an initial and second validation audit performed on its risk adjustment data as described in this section.

(b) *Initial validation audit.* (1) An issuer of a risk adjustment covered plan

must engage one or more independent auditors to perform an initial validation audit of a sample of its risk adjustment data selected by HHS.

(2) The issuer must ensure that the initial validation auditors are reasonably capable of performing an initial data validation audit according to the standards established by HHS for such audit, and must ensure that the audit is so performed.

(3) The issuer must ensure that each initial validation auditor is reasonably free of conflicts of interest, such that it is able to conduct the initial validation audit in an impartial manner and its impartiality is not reasonably open to question.

(4) The issuer must ensure validation of the accuracy of risk adjustment data for a sample of enrollees selected by HHS. The issuer must ensure that the initial validation audit findings are submitted to HHS in a manner and timeframe specified by HHS.

(c) *Second validation audit.* HHS will select a subsample of the risk adjustment data validated by the initial validation audit for a second validation audit. The issuer must comply with, and must ensure the initial validation auditor complies with, standards for such audit established by HHS, and must cooperate with, and must ensure that the initial validation auditor cooperates with, HHS and the second validation auditor in connection with such audit.

(d) *Data validation appeals.* An issuer may appeal the findings of a second validation audit or the application of a risk score error rate to its risk adjustment payments and charges.

(e) *Adjustment of payments and charges.* HHS may adjust payments and charges for issuers that do not comply with audit requirements and standards, as specified in paragraphs (b) and (c) of this section.

(f) *Data security and transmission.* (1) An issuer must submit the risk adjustment data and source documentation for the initial and second validation audits specified by HHS to HHS or its designee in the manner and timeframe specified by HHS.

(2) An issuer must ensure that it and its initial validation auditor comply with the security standards described at 45 CFR 164.308, 164.310, and 164.312 in connection with the initial validation audit, the second validation audit, and any appeal.

■ 27. Subpart H is added to read as follows:

Subpart H—Distributed Data Collection for HHS-Operated Programs

Sec.

- 153.700 Distributed data environment.
 153.710 Data requirements.
 153.720 Establishment and usage of
 masked enrollee identification numbers.
 153.730 Deadline for submission of data.

Subpart H—Distributed Data Collection for HHS-Operated Programs**§ 153.700 Distributed data environment.**

(a) *Dedicated distributed data environments.* For each benefit year in which HHS operates the risk adjustment or reinsurance program on behalf of a State, an issuer of a risk adjustment covered plan or a reinsurance-eligible plan in the State, as applicable, must establish a dedicated data environment and provide data access to HHS, in a manner and timeframe specified by HHS, for any HHS-operated risk adjustment and reinsurance program.

(b) *Timeline.* An issuer must establish the dedicated data environment (and confirm proper establishment through successfully testing the environment to conform with applicable HHS standards for such testing) three months prior to the first date of full operation.

§ 153.710 Data requirements.

(a) *Enrollment, claims, and encounter data.* An issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, must provide to HHS, through the dedicated data environment, access to enrollee-level plan enrollment data, enrollee claims data, and enrollee encounter data as specified by HHS.

(b) *Claims data.* All claims data submitted by an issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, must have resulted in payment by the issuer (or payment of cost sharing by the enrollee).

(c) *Claims data from capitated plans.* An issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, that does not generate individual enrollee claims in the normal course of business must derive the costs of all applicable provider encounters using its principal internal methodology for pricing those encounters. If the issuer does not have such a methodology, or has an incomplete methodology, it must supplement the methodology in a manner that yields

derived claims that are reasonable in light of the specific service and insurance market that the plan is serving.

§ 153.720 Establishment and usage of masked enrollee identification numbers.

(a) *Enrollee identification numbers.* An issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, must—

(1) Establish a unique masked enrollee identification number for each enrollee; and

(2) Maintain the same masked enrollee identification number for an enrollee across enrollments or plans within the issuer, within the State, during a benefit year.

(b) *Prohibition on personally identifiable information.* An issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program on behalf of the State, as applicable, may not—

(1) Include enrollee's personally identifiable information in the masked enrollee identification number; or

(2) Use the same masked enrollee identification number for different enrollees enrolled with the issuer.

§ 153.730 Deadline for submission of data.

A risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, must submit data to be considered for risk adjustment payments and charges and reinsurance payments for the applicable benefit year by April 30 of the year following the applicable benefit year.

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

■ 28. The authority citation for part 155 continues to read as follows:

Authority: Secs. 1301, 1302, 1303, 1304, 1311, 1312, 1313, 1321, 1322, 1331, 1334, 1401, 1402, 1411, 1412, 1413.

■ 29. Section 155.20 is amended by—

■ A. Revising the definitions of “Large employer” and “Small employer.”

■ B. Adding definitions of “Federally-facilitated Exchange,” “Federally-facilitated SHOP,” and “Full-time employee” in alphabetical order.

The revisions and additions read as follows:

§ 155.20 Definitions.

* * * * *

Federally-facilitated Exchange means an Exchange established and operated within a State by the Secretary under section 1321(c)(1) of the Affordable Care Act.

Federally-facilitated SHOP means a Small Business Health Options Program established and operated within a State by the Secretary under section 1321(c)(1) of the Affordable Care Act.

Full-time employee has the meaning given in section 4980H (c)(4) of the Code effective for plan years beginning on or after January 1, 2016, except for operations of a Federally-facilitated SHOP for which it is effective for plan years beginning on or after January 1, 2014 and in connection with open enrollment activities beginning October 1, 2013.

* * * * *

Large employer means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 101 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year. In the case of plan years beginning before January 1, 2016, a State may elect to define large employer by substituting “51 employees” for “101 employees.” The number of employees shall be determined using the method set forth in section 4980H(c)(2) of the Code, effective for plan years beginning on or after January 1, 2016, except for operations of a Federally-facilitated SHOP for which the method shall be used for plan years beginning on or after January 1, 2014 and in connection with open enrollment activities beginning October 1, 2013.

* * * * *

Small employer means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 1 but not more than 100 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year. In the case of plan years beginning before January 1, 2016, a State may elect to define small employer by substituting “50 employees” for “100 employees.” The number of employees shall be determined using the method set forth in section 4980H(c)(2) of the Code, effective for plan years beginning on or after January 1, 2016, except for operations of a Federally-facilitated SHOP for which the method shall be used for plan years beginning on or after January 1, 2014 and in connection with

open enrollment activities beginning October 1, 2013.

* * * * *

■ 30. Section 155.220 is amended by revising paragraph (b) to read as follows—

§ 155.220 Ability to States to permit agents and brokers to assist qualified individuals, qualified employers, or qualified employees enrolling in QHPs.

* * * * *

(b)(1) *Web site disclosure.* The Exchange or SHOP may elect to provide information regarding licensed agents and brokers on its Web site for the convenience of consumers seeking insurance through that Exchange and may elect to limit the information to information regarding licensed agents and brokers who have completed any required Exchange or SHOP registration and training process.

(2) A Federally-facilitated Exchange or SHOP will limit the information provided on its Web site regarding licensed agents and brokers to information regarding licensed agents and brokers who have completed registration and training.

* * * * *

■ 31. Section 155.305 is amended by revising paragraph (g)(3) to read as follows:

§ 155.305 Eligibility standards.

* * * * *

(g) * * *

(3) *Special rule for family policies.* To the extent that an enrollment in a QHP in the individual market offered through an Exchange under a single policy covers two or more individuals who, if they were to enroll in separate individual policies would be eligible for different cost sharing, the Exchange must deem the individuals under such policy to be collectively eligible only for the category of eligibility last listed below for which all the individuals covered by the policy would be eligible:

(i) Individuals not eligible for changes to cost sharing;

(ii) Individuals described in § 155.350(b) (the special cost-sharing rule for Indians regardless of income);

(iii) Individuals described in paragraph (g)(2)(iii) of this section;

(iv) Individuals described in paragraph (g)(2)(ii) of this section;

(v) Individuals described in paragraph (g)(2)(i) of this section; and

(vi) Individuals described in § 155.350(a) (the cost-sharing rule for Indians with household incomes under 300 percent of the FPL).

* * * * *

■ 32. Section 155.330 is amended by adding paragraph (g) to read as follows:

§ 155.330 Eligibility redetermination during a benefit year.

* * * * *

(g) *Recalculation of advance payments of the premium tax credit and cost-sharing reductions.* (1) When an eligibility redetermination in accordance with this section results in a change in the amount of advance payments of the premium tax credit for the benefit year, the Exchange must recalculate the amount of advance payments of the premium tax credit in such a manner as to—

(i) Account for any advance payments already made on behalf of the tax filer for the benefit year for which information is available to the Exchange, such that the recalculated advance payment amount is projected to result in total advance payments for the benefit year that correspond to the tax filer's total projected premium tax credit for the benefit year, calculated in accordance with 26 CFR 1.36B–3; and

(ii) Ensure that the advance payment provided on the tax filer's behalf is greater than or equal to zero and is calculated in accordance with 26 CFR 1.36B–3(d).

(2) When an eligibility redetermination in accordance with this section results in a change in cost-sharing reductions, the Exchange must determine an individual eligible for the category of cost-sharing reductions that corresponds to his or her expected annual household income for the benefit year (subject to the special rule for family policies set forth in § 155.305(g)(3)).

■ 33. Section 155.340 is amended by adding paragraphs (e), (f), and (g) to read as follows:

§ 155.340 Administration of advance payments of the premium tax credit and cost-sharing reductions.

* * * * *

(e) *Allocation of advance payments of the premium tax credit among policies.* If one or more advance payments of the premium tax credit are to be made on behalf of a tax filer (or two tax filers covered by the same plan(s)), and individuals in the tax filers' tax households are enrolled in more than one QHP or stand-alone dental plan, then the advance payment must be allocated as follows:

(1) That portion of the advance payment of the premium tax credit that is less than or equal to the aggregate adjusted monthly premiums, as defined in 26 CFR 1.36B–3(e), for the QHP policies properly allocated to EHB must be allocated among the QHP policies in a reasonable and consistent manner specified by the Exchange; and

(2) Any remaining advance payment of the premium tax credit must be allocated among the stand-alone dental policies in a reasonable and consistent manner specified by the Exchange.

(f) *Allocation of advance payments of the premium tax credit among policies offered through a Federally-facilitated Exchange.* If one or more advance payments of the premium tax credit are to be made on behalf of a tax filer (or two tax filers covered by the same plan(s)), and individuals in the tax filers' tax households are enrolled in more than one QHP or stand-alone dental plan offered through a Federally-facilitated Exchange, then that portion of the advance payment of the premium tax credit that is less than or equal to the aggregate adjusted monthly premiums, as defined in 26 CFR 1.36B–3(e), properly allocated to EHB for the QHP policies, will be allocated among the QHP policies, as described in § 155.340(f)(1); and any remaining advance payment of the premium tax credit will be allocated among the stand-alone dental policies based on the methodology described in § 155.340(f)(2).

(1) That portion of the advance payment(s) of the premium tax credit to be allocated among QHP policies will be allocated based on the number of enrollees covered under the QHP, weighted by the age of the enrollees, using the default uniform age rating curve established by the Secretary of HHS under 45 CFR 147.102(e), with the portion allocated to any single QHP policy not to exceed the portion of the QHP's adjusted monthly premium properly allocated to EHB. If the portion of the advance payment(s) of the premium tax credit allocated to a QHP under this subparagraph exceeds the portion of the same QHP's adjusted monthly premium properly allocated to EHB, the remainder will be allocated evenly among all other QHPs in which individuals in the tax filers' tax households are enrolled.

(2) That portion of the advance payment(s) of the premium tax credit to be allocated among stand-alone dental policies will be allocated based on the number of enrollees covered under the stand-alone dental policy, weighted by the age of the enrollees, using the default uniform age rating curve established by the Secretary of HHS under 45 CFR 147.102(e), with the portion allocated to any single stand-alone dental policy not to exceed the portion of the stand-alone dental policy premium properly allocated to EHB. If the portion of the advance payment(s) of the premium tax credit allocated to a stand-alone dental policy under this

subparagraph exceeds the portion of the same policy's premium properly allocated to EHB, the remainder will be allocated evenly among all other stand-alone dental policies in which individuals in the tax filers' tax households are enrolled.

(g) *Reduction of enrollee's portion of premium to account for advance payments of the premium tax credit.* If an Exchange is facilitating the collection and payment of premiums to QHP issuers and stand-alone dental plans on behalf of enrollees under § 155.240, and if a QHP issuer or stand-alone dental plan has been notified that it will receive an advance payment of the premium tax credit on behalf of an enrollee for whom the Exchange is facilitating such functions, the Exchange must—

(1) Reduce the portion of the premium for the policy collected from the individual for the applicable month(s) by the amount of the advance payment of the premium tax credit; and

(2) Include with each billing statement, as applicable, to or for the individual the amount of the advance payment of the premium tax credit for the applicable month(s) and the remaining premium owed for the policy.

■ 34. Section 155.705 is amended by revising paragraph (b)(3), (b)(10), and (b)(11) to read as follows:

§ 155.705 Functions of a SHOP.

* * * * *

(b) * * *

(3)(i) *SHOP options with respect to employer choice requirements.* With regard to QHPs offered through the SHOP, the SHOP may allow a qualified employer to make one or more QHPs available to qualified employees by a method other than the method described in paragraph (b)(2) of this section.

(ii) A Federally-facilitated SHOP will only permit a qualified employer to make available to qualified employees either:

(A) All QHPs at the level of coverage selected by the employer as described in paragraph (b)(2) of this section, or

(B) A single QHP.

* * * * *

(10) *Participation rules.* Subject to § 147.104 of this subchapter, the SHOP may authorize uniform group participation rules for the offering of health insurance coverage in the SHOP. If the SHOP authorizes a minimum participation rate, such rate must be based on the rate of employee participation in the SHOP, not on the rate of employee participation in any particular QHP or QHPs of any particular issuer.

(i) Subject to § 147.104 of this subchapter, a Federally-facilitated SHOP must use a minimum participation rate of 70 percent, calculated as the number of qualified employees accepting coverage under the employer's group health plan, divided by the number of qualified employees offered coverage, excluding from the calculation any employee who, at the time the employer submits the SHOP application, is enrolled in coverage through another employer's group health plan or through a governmental plan such as Medicare, Medicaid, or TRICARE.

(ii) Notwithstanding paragraph (b)(10)(i) of this section, a Federally-facilitated SHOP may utilize a different minimum participation rate in a State if there is evidence that a State law sets a minimum participation rate or that a higher or lower minimum participation rate is customarily used by the majority of QHP issuers in that State for products in the State's small group market outside the SHOP.

(11) *Premium calculator.* In the SHOP, the premium calculator described in § 155.205(b)(6) must facilitate the comparison of available QHPs after the application of any applicable employer contribution in lieu of any advance payment of the premium tax credit and any cost sharing reductions.

(i) To determine the employer and employee contributions, a SHOP may establish one or more standard methods that employers may use to define their contributions toward employee and dependent coverage.

(ii) A Federally-facilitated SHOP must use the following method for employer contributions:

(A) The employer will select a level of coverage as described in paragraph (b)(2) and (b)(3) of this section.

(B) The employer will select a QHP within that level of coverage to serve as a reference plan on which contributions will be based.

(C) The employer will define a percentage contribution toward premiums for employee-only coverage under the reference plan and, if dependent coverage is offered, a percentage contribution toward premiums for dependent coverage under the reference plan.

(D) Either State law or the employer may require that a Federally-facilitated SHOP base contributions on a calculated composite premium for the reference plan for employees, for adult dependents, and for dependents below age 21.

(E) The resulting contribution amounts for each employee's coverage

may then be applied toward the QHP selected by the employee.

■ 35. Section 155.1030 is added to read as follows:

§ 155.1030 QHP certification standards related to advance payments of the premium tax credit and cost-sharing reductions.

(a) *Review of plan variations for cost-sharing reductions.* (1) An Exchange must ensure that each issuer that offers, or intends to offer a health plan at any level of coverage in the individual market on the Exchange submits the required plan variations for the health plan as described in § 156.420 of this subchapter. The Exchange must certify that the plan variations meet the requirements of § 156.420.

(2) The Exchange must provide to HHS the actuarial values of each QHP and silver plan variation, calculated under § 156.135 of this subchapter, in the manner and timeframe established by HHS.

(b) *Information for administering advance payments of the premium tax credit and advance payments of cost-sharing reductions.* (1) The Exchange must collect and review annually the rate allocation, the expected allowed claims cost allocation, and the actuarial memorandum that an issuer submits to the Exchange under § 156.470 of this subchapter, to ensure that such allocations meet the standards set forth in § 156.470(c) and (d).

(2) The Exchange must submit, in the manner and timeframe established by HHS, to HHS the approved allocations and actuarial memorandum underlying the approved allocations for each health plan at any level of coverage or stand-alone dental plan offered, or intended to be offered in the individual market on the Exchange.

(3) The Exchange must collect annually any estimates and supporting documentation that a QHP issuer submits to receive advance payments of certain cost-sharing reductions, under § 156.430(a) of this subchapter, and submit, in the manner and timeframe established by HHS, the estimates and supporting documentation to HHS for review.

(4) HHS may use the information provided to HHS by the Exchange under this section for the approval of the estimates that an issuer submits for advance payments of cost-sharing reductions, as described in § 156.430 of this subchapter, and the oversight of the advance payments of cost-sharing reductions and premium tax credits programs.

(c) *Multi-State plans.* The U.S. Office of Personnel Management will ensure

compliance with the standards referenced in this section for multi-State plans, as defined in § 155.1000(a).

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 36. The authority citation for part 156 is revised to read as follows:

Authority: Title I of the Affordable Care Act, sections 1301–1304, 1311–1312, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, and 1412, Pub. L. 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

■ 37. Section 156.20 is amended by adding definitions for “Federally-facilitated SHOP” and “Issuer group” in alphabetical order to read as follows:

§ 156.20 Definitions.

* * * * *

Federally-facilitated SHOP has the meaning given to the term in § 155.20 of this subchapter.

* * * * *

Issuer group means all entities treated under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 as a member of the same controlled group of corporations as (or under common control with) a health insurance issuer, or issuers affiliated by the common use of a nationally licensed service mark.

* * * * *

■ 38. Section 156.50 is amended by revising paragraph (b) and by adding paragraph (c) to read as follows:

§ 156.50 Financial support.

* * * * *

(b) *Requirement for State-based Exchange user fees.* A participating issuer must remit user fee payments, or any other payments, charges, or fees, if assessed by a State-based Exchange under § 155.160 of this subchapter.

(c) *Requirement for Federally-facilitated Exchange user fee.* To support the functions of Federally-facilitated Exchanges, a participating issuer offering a plan through a Federally-facilitated Exchange must remit a user fee to HHS each month, in the timeframe and manner established by HHS, equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year and the monthly premium charged by the issuer for each policy under the plan where enrollment is through a Federally-facilitated Exchange.

■ 39. Section 156.200 is amended by adding paragraphs (f) and (g) to read as follows:

§ 156.200 QHP issuer participation standards.

* * * * *

(f) *Broker compensation in a Federally-facilitated Exchange.* A QHP issuer must pay the same broker compensation for QHPs offered through a Federally-facilitated Exchange that the QHP issuer pays for similar health plans offered in the State outside a Federally-facilitated Exchange.

(g) *Certification standard specific to a Federally-facilitated Exchange.* A Federally-facilitated Exchange may certify a QHP in the individual market of a Federally-facilitated Exchange only if the QHP issuer meets one of the conditions below:

(1) The QHP issuer also offers through a Federally-facilitated SHOP serving that State at least one small group market QHP at the silver level of coverage and one at the gold level of coverage as described in section 1302(d) of the Affordable Care Act;

(2) The QHP issuer does not offer small group market products in that State, but another issuer in the same issuer group offers through a Federally-facilitated SHOP serving that State at least one small group market QHP at the silver level of coverage and one at the gold level of coverage; or

(3) Neither the issuer nor any other issuer in the same issuer group has a share of the small group market, as determined by HHS, greater than 20 percent, based on the earned premiums submitted by all issuers in the State’s small group market, under § 158.110 of this subchapter, on the reporting date immediately preceding the due date of the application for QHP certification.

■ 40. Section 156.215 is added to read as follows:

§ 156.215 Advance payments of the premium tax credit and cost-sharing reduction standards.

(a) *Standards relative to advance payments of the premium tax credit and cost-sharing reductions.* In order for a health plan to be certified as a QHP initially and to maintain certification to be offered in the individual market on the Exchange, the issuer must meet the requirements related to the administration of cost-sharing reductions and advance payments of the premium tax credit set forth in subpart E of this part.

(b) [Reserved]

■ 41. Section 156.285 is amended by adding paragraph (c)(7) to read as follows:

§ 156.285 Additional standards specific to SHOP.

* * * * *

(c) * * *

(7) A QHP issuer must enroll a qualified employee only if the SHOP —

(i) Notifies the QHP issuer that the employee is a qualified employee; and
(ii) Transmits information to the QHP issuer as provided in § 155.400(a) of this subchapter.

* * * * *

■ 42. Subpart E is added to read as follows:

Subpart E—Health Insurance Issuer Responsibilities With Respect to Advance Payments of the Premium Tax Credit and Cost-Sharing Reductions

Sec.

156.400 Definitions.

156.410 Cost-sharing reductions for enrollees.

156.420 Plan variations.

156.425 Changes in eligibility for cost-sharing reductions.

156.430 Payment for cost-sharing reductions.

156.440 Plans eligible for advance payments of the premium tax credit and cost-sharing reductions.

156.460 Reduction of enrollee’s share of premium to account for advance payments of the premium tax credit.

156.470 Allocation of rates and claims costs for advance payments of cost-sharing reductions and the premium tax credit.

Subpart E—Health Insurance Issuer Responsibilities With Respect to Advance Payments of the Premium Tax Credit and Cost-Sharing Reductions

§ 156.400 Definitions.

The following definitions apply to this subpart:

Advance payments of the premium tax credit has the meaning given to the term in § 155.20 of this subchapter.

Affordable Care Act has the meaning given to the term in § 155.20 of this subchapter.

Annual limitation on cost sharing means the annual dollar limit on cost sharing required to be paid by an enrollee that is established by a particular qualified health plan.

De minimis variation means the allowable variation in the AV of a health plan that does not result in a material difference in the true dollar value of the health plan as established in § 156.140(c).

De minimis variation for a silver plan variation means a single percentage point.

Federal poverty level or *FPL* has the meaning given to the term in § 155.300(a) of this subchapter.

Indian has the meaning given to the term in § 155.300(a) of this subchapter.

Limited cost sharing plan variation means, with respect to a QHP at any level of coverage, the variation of such QHP described in § 156.420(b)(2).

Maximum annual limitation on cost sharing means the highest annual dollar amount that qualified health plans (other than QHPs with cost-sharing reductions) may require in cost sharing for a particular year, as established for that year under § 156.130.

Most generous or more generous means, between a QHP (including a standard silver plan) or plan variation, and one or more other plan variations of the same QHP, the QHP or plan variation designed for the category of individuals last listed in § 155.305(g)(3) of this subchapter.

Plan variation means a zero cost sharing plan variation, a limited cost sharing plan variation, or a silver plan variation.

Reduced maximum annual limitation on cost sharing means the dollar value of the maximum annual limitation on cost sharing for a silver plan variation that remains after applying the reduction, if any, in the maximum annual limitation on cost sharing required by section 1402 of the Affordable Care Act as announced in the annual HHS notice of benefit and payment parameters.

Silver plan variation means, with respect to a standard silver plan, any of the variations of that standard silver plan described in § 156.420(a).

Stand-alone dental plan means a plan offered through an Exchange under § 155.1065 of this subchapter.

Standard plan means a QHP offered at one of the four levels of coverage, defined at § 156.140, with an annual limitation on cost sharing that conforms to the requirements of § 156.130(a). A standard plan at the bronze, silver, gold, or platinum level of coverage is referred to as a standard bronze plan, a standard silver plan, a standard gold plan, and a standard platinum plan, respectively.

Zero cost sharing plan variation means, with respect to a QHP at any level of coverage, the variation of such QHP described in § 156.420(b)(1).

§ 156.410 Cost-sharing reductions for enrollees.

(a) *General requirement.* A QHP issuer must ensure that an individual eligible for cost-sharing reductions, as demonstrated by assignment to a particular plan variation, pays only the cost sharing required of an eligible individual for the applicable covered service under the plan variation. The cost-sharing reduction for which an individual is eligible must be applied when the cost sharing is collected.

(b) *Assignment to applicable plan variation.* If an individual is determined to be eligible to enroll in a QHP in the individual market offered through an Exchange and elects to do so, the QHP issuer must assign the individual under enrollment and eligibility information submitted by the Exchange as follows—

(1) If the individual is determined eligible by the Exchange for cost-sharing reductions under § 155.305(g)(2)(i), (ii), or (iii) of this subchapter (subject to the special rule for family policies set forth in § 155.305(g)(3) of this subchapter) and chooses to enroll in a silver health plan, the QHP issuer must assign the individual to the silver plan variation of the selected silver health plan described in § 156.420(a)(1), (2), or (3), respectively.

(2) If the individual is determined eligible by the Exchange for cost-sharing reductions for Indians with lower household income under § 155.350(a) of this subchapter (subject to the special rule for family policies set forth in § 155.305(g)(3) of this subchapter), and chooses to enroll in a QHP, the QHP issuer must assign the individual to the zero cost sharing plan variation of the selected QHP with all cost sharing eliminated described in § 156.420(b)(1).

(3) If the individual is determined by the Exchange to be eligible for cost-sharing reductions for Indians regardless of household income under § 155.350(b) of this subchapter (subject to the special rule for family policies set forth in § 155.305(g)(3) of this subchapter), and chooses to enroll in a QHP, the QHP issuer must assign the individual to the limited cost sharing plan variation of the selected QHP with the prohibition on cost sharing for benefits received from the Indian Health Service and certain other providers described in § 156.420(b)(2).

(4) If the individual is determined by the Exchange not to be eligible for cost-sharing reductions (including eligibility under the special rule for family policies set forth in § 155.305(g)(3) of this subchapter), and chooses to enroll in a QHP, the QHP issuer must assign the individual to the selected QHP with no cost-sharing reductions.

§ 156.420 Plan variations.

(a) *Submission of silver plan variations.* For each of its silver health plans that an issuer offers, or intends to offer in the individual market on an Exchange, the issuer must submit annually to the Exchange for certification prior to each benefit year the standard silver plan and three variations of the standard silver plan, as follows—

(1) For individuals eligible for cost-sharing reductions under § 155.305(g)(2)(i) of this subchapter, a variation of the standard silver plan with:

(i) An annual limitation on cost sharing no greater than the reduced maximum annual limitation on cost sharing specified in the annual HHS notice of benefit and payment parameters for such individuals, and

(ii) Other cost-sharing reductions such that the AV of the silver plan variation is 94 percent plus or minus the de minimis variation for a silver plan variation;

(2) For individuals eligible for cost-sharing reductions under § 155.305(g)(2)(ii) of this subchapter, a variation of the standard silver plan with:

(i) An annual limitation on cost sharing no greater than the reduced maximum annual limitation on cost sharing specified in the annual HHS notice of benefit and payment parameters for such individuals, and

(ii) Other cost-sharing reductions such that the AV of the silver plan variation is 87 percent plus or minus the de minimis variation for a silver plan variation; and

(3) For individuals eligible for cost-sharing reductions under § 155.305(g)(2)(iii) of this subchapter, a variation of the standard silver plan with:

(i) An annual limitation on cost sharing no greater than the reduced maximum annual limitation on cost sharing specified in the annual HHS notice of benefit and payment parameters for such individuals, and

(ii) Other cost-sharing reductions such that the AV of the silver plan variation is 73 percent plus or minus the de minimis variation for a silver plan variation (subject to § 156.420(h)).

(b) *Submission of zero and limited cost sharing plan variations.* For each of its health plans at any level of coverage that an issuer offers, or intends to offer in the individual market on an Exchange, the issuer must submit to the Exchange for certification the health plan and two variations of the health plan, as follows—

(1) For individuals eligible for cost-sharing reductions under § 155.350(a) of this subchapter, a variation of the health plan with all cost sharing eliminated; and

(2) For individuals eligible for cost-sharing reductions under § 155.350(b) of this subchapter, a variation of the health plan with no cost sharing on any item or service that is an EHB furnished directly by the Indian Health Service, an Indian Tribe, Tribal Organization, or

Urban Indian Organization (each as defined in 25 U.S.C. 1603), or through referral under contract health services.

(c) *Benefit and network equivalence in silver plan variations.* A standard silver plan and each silver plan variation thereof must cover the same benefits and providers, and require the same out-of-pocket spending for benefits other than essential health benefits. Each silver plan variation is subject to all requirements applicable to the standard silver plan (except for the requirement that the plan have an AV as set forth in § 156.140(b)(2)).

(d) *Benefit and network equivalence in zero and limited cost sharing plan variations.* A QHP and each zero cost sharing plan variation or limited cost sharing plan variation thereof must cover the same benefits and providers, and require the same out-of-pocket spending for benefits other than essential health benefits. A limited cost sharing plan variation must have the same cost sharing on items or services not described in paragraph (b)(2) of this section as the QHP with no cost-sharing reductions. Each zero cost sharing plan variation or limited cost sharing plan variation is subject to all requirements applicable to the QHP (except for the requirement that the plan have an AV as set forth in § 156.140(b)).

(e) *Decreasing cost sharing in higher AV silver plan variations.* The cost sharing required of enrollees under any silver plan variation of a standard silver plan for an essential health benefit from a provider (including a provider outside the plan's network) may not exceed the corresponding cost sharing required in the standard silver plan or any other silver plan variation thereof with a lower AV.

(f) *Minimum AV differential between 70 percent and 73 percent silver plan variations.* Notwithstanding any permitted de minimis variation in AV for a health plan or permitted de minimis variation for a silver plan variation, the AVs of a standard silver plan and the silver plan variation thereof described in paragraph (a)(3) of this section must differ by at least 2 percentage points.

(g) *Multi-state plans.* The U.S. Office of Personnel Management will determine the time and manner for multi-State plans, as defined in § 155.1000(a) of this subchapter, to submit silver plan variations, zero cost sharing plan variations, and limited cost sharing plan variations.

§ 156.425 Changes in eligibility for cost-sharing reductions.

(a) *Effective date of change in assignment.* If the Exchange notifies a

QHP issuer of a change in an enrollee's eligibility for cost-sharing reductions (including a change in the individual's eligibility under the special rule for family policies set forth in § 155.305(g)(3) of this subchapter due to a change in eligibility of another individual on the same policy), then the QHP issuer must change the individual's assignment such that the individual is assigned to the applicable standard plan or plan variation of the QHP as required under § 156.410(b) as of the effective date of eligibility required by the Exchange.

(b) *Continuity of deductible and out-of-pocket amounts.* In the case of a change in assignment to a different plan variation (or standard plan without cost-sharing reductions) of the same QHP in the course of a benefit year under this section, the QHP issuer must ensure that any cost sharing paid by the applicable individual under previous plan variations (or standard plan without cost-sharing reductions) for that benefit year is taken into account in the new plan variation (or standard plan without cost-sharing reductions) for purposes of calculating cost sharing based on aggregate spending by the individual, such as for deductibles or for the annual limitations on cost sharing.

§ 156.430 Payment for cost-sharing reductions.

(a) *Estimates of value of cost-sharing reductions for purposes of advance payments.* (1) For each health plan that an issuer offers, or intends to offer, in the individual market on an Exchange as a QHP, the issuer must provide to the Exchange annually prior to the benefit year, for approval by HHS, an estimate of the dollar value of the cost-sharing reductions to be provided over the benefit year. The estimate must:

(i) If the QHP is a silver health plan, identify separately the per member per month dollar value of the cost-sharing reductions to be provided under each silver plan variation identified in § 156.420(a)(1), (2), and (3);

(ii) Regardless of the level of coverage of the QHP, identify the per member per month dollar value of the cost-sharing reductions to be provided under the zero cost sharing plan variation;

(iii) Be accompanied by supporting documentation validating the estimate; and

(iv) Be developed using the methodology specified by HHS in the applicable annual HHS notice of benefit and payment parameters.

(2) If an issuer seeks advance payments for the cost-sharing reductions to be provided under the limited cost sharing plan variation of a

health plan it offers, or intends to offer, in the individual market on the Exchange as a QHP at any level of coverage, the issuer must provide to the Exchange annually prior to the benefit year, for approval by HHS, an estimate of the per member per month dollar value of the cost-sharing reductions to be provided over the benefit year under such limited cost sharing plan variation. The estimate must:

(i) Be accompanied by supporting documentation validating the estimate; and

(ii) Be developed using the methodology specified by HHS in the annual HHS notice of benefit and payment parameters.

(3) HHS's approval of the estimate will be based on whether the estimate is made consistent with the methodology specified by HHS in the annual HHS notice of benefit and payment parameters.

(4) Issuers of multi-State plans, as defined in § 155.1000(a) of this subchapter, must provide the estimates described in paragraphs (a)(1) and (2) of this section to the U.S. Office of Personnel Management, in the time and manner established by the U.S. Office of Personnel Management.

(b) *Advance payments for cost-sharing reductions.* (1) A QHP issuer will receive periodic advance payments based on the approved advance estimates provided under paragraph (a) of this section and the actual enrollment in the applicable plan variation.

(2) HHS may adjust the advance payment amount for a particular QHP during the benefit year if the QHP issuer provides evidence, certified by a member of the American Academy of Actuaries in accordance with generally accepted actuarial principles and methodologies, that the advance payments for a particular QHP are likely to be substantially different than the cost-sharing reduction amounts that the QHP provides that will be reimbursed by HHS.

(c) *Submission of actual amounts.* (1) *General.* For each plan variation that a QHP issuer offers on the Exchange, it must submit to HHS, in the manner and timeframe established by HHS, for each policy, the total allowed costs for essential health benefits charged for the policy for the benefit year, broken down by all of the following:

(i) The amount the issuer paid.

(ii) The amount the enrollee(s) paid.

(iii) The amount the enrollee(s) would have paid under the standard plan without cost-sharing reductions.

(2) *Standard methodology.* A QHP issuer must calculate the value of the amount the enrollee(s) would have paid

under the standard plan without cost-sharing reductions by applying the actual cost-sharing requirements for the standard plan to the allowed costs for essential health benefits under the enrollee's policy for the benefit year.

(3) [Reserved]

(4) [Reserved]

(5) *Reimbursement of providers.* In the case of a benefit for which the QHP issuer compensates an applicable provider in whole or in part on a fee-for-service basis, allowed costs associated with the benefit may be included in the calculation of the amount that an enrollee(s) would have paid under the standard plan without cost-sharing reductions only to the extent the amount was either payable by the enrollee(s) as cost sharing under the plan variation or was reimbursed to the provider by the QHP issuer.

(d) *Reconciliation of amounts.* HHS will perform periodic reconciliations of any advance payments of cost-sharing reductions provided to a QHP issuer under paragraph (b) of this section against—

(1) The actual amount of cost-sharing reductions provided to enrollees and reimbursed to providers by the QHP issuer for benefits for which the QHP issuer compensates the applicable providers in whole or in part on a fee-for-service basis; and

(2) The actual amount of cost-sharing reductions provided to enrollees for benefits for which the QHP issuer compensates the applicable providers in any other manner.

(e) *Payment of discrepancies.* If the actual amounts of cost-sharing reductions described in paragraphs (d)(1) and (2) of this section are—

(1) More than the amount of advance payments provided and the QHP issuer has timely provided the actual amounts of cost-sharing reductions as required under paragraph (c) of this section, HHS will reimburse the QHP issuer for the difference; and

(2) Less than the amount of advance payments provided, the QHP issuer must repay the difference to HHS in the manner and timeframe specified by HHS.

(f) *Cost-sharing reductions during special periods.* (1) Notwithstanding the cost-sharing reduction reconciliation process described in paragraphs (c) through (e) of this section, a QHP issuer will not be eligible for reimbursement of any cost-sharing reductions provided following a termination of coverage effective date with respect to a grace period as described in

§ 155.430(b)(2)(ii)(A) or (B) of this subchapter. However, the QHP issuer will be eligible for reimbursement of

cost-sharing reductions provided prior to the termination of coverage effective date. Advance payments of cost-sharing reductions will be paid to a QHP issuer prior to a determination of termination (including during any grace period, but the QHP issuer will be required to repay any advance payments made with respect to any month after any termination of coverage effective date during a grace period).

(2) Notwithstanding the cost-sharing reduction reconciliation process described in paragraphs (c) through (e) of this section, if the termination of coverage effective date is prior to the determination of termination other than in the circumstances described in paragraph (f)(1) of this section, and if the termination (or the late determination thereof) is the fault of the QHP issuer, as reasonably determined by the Exchange, the QHP issuer will not be eligible for advance payments and reimbursement for cost-sharing reductions provided during the period following the termination of coverage effective date and prior to the determination of the termination.

(3) Subject to the requirements of the cost-sharing reduction reconciliation process described in paragraphs (c) through (e) of this section, if the termination of coverage effective date is prior to the determination of termination other than in the circumstances described in paragraph (f)(1) of this section, and if the reason for the termination (or late determination thereof) is not the fault of the QHP issuer, as reasonably determined by the Exchange, the QHP issuer will be eligible for advance payments and reimbursement for cost-sharing reductions provided during such period.

(4) Subject to the requirements of the cost-sharing reduction reconciliation process described in paragraphs (c) through (e) of this section, a QHP issuer will be eligible for advance payments and reimbursement for cost-sharing reductions provided during any period of coverage pending resolution of inconsistencies in information required to determine eligibility for enrollment under § 155.315(f) of this subchapter.

(g) *Prohibition on reduction in payments to Indian health providers.* If an Indian is enrolled in a QHP in the individual market through an Exchange and is furnished an item or service directly by the Indian Health Service, an Indian Tribe, Tribal Organization, or Urban Indian Organization, or through referral under contract health services, the QHP issuer may not reduce the payment to any such entity for such item or service by the amount of any

cost sharing that would be due from the Indian but for the prohibitions on cost sharing set forth in § 156.410(b)(2) and (3).

§ 156.440 Plans eligible for advance payments of the premium tax credit and cost-sharing reductions.

Except as noted in paragraph (a) through (c) of this section, the provisions of this subpart apply to qualified health plans offered in the individual market on the Exchange.

(a) *Catastrophic plans.* The provisions of this subpart do not apply to catastrophic plans described in § 156.155.

(b) *Stand-alone dental plans.* The provisions of this subpart, to the extent relating to cost-sharing reductions, do not apply to stand-alone dental plans. The provisions of this subpart, to the extent relating to advance payments of the premium tax credit, apply to stand-alone dental plans.

(c) *Child-only plans.* The provisions of this subpart apply to child-only QHPs, described in § 156.200(c)(2).

§ 156.460 Reduction of enrollee's share of premium to account for advance payments of the premium tax credit.

(a) *Reduction of enrollee's share of premium to account for advance payments of the premium tax credit.* A QHP issuer that receives notice from the Exchange that an individual enrolled in the issuer's QHP is eligible for an advance payment of the premium tax credit must—

(1) Reduce the portion of the premium charged to or for the individual for the applicable month(s) by the amount of the advance payment of the premium tax credit;

(2) Notify the Exchange of the reduction in the portion of the premium charged to the individual in accordance with § 156.265(g); and

(3) Include with each billing statement, as applicable, to or for the individual the amount of the advance payment of the premium tax credit for the applicable month(s), and the remaining premium owed.

(b) *Delays in payment.* A QHP issuer may not refuse to commence coverage under a policy or terminate coverage on account of any delay in payment of an advance payment of the premium tax credit on behalf of an enrollee if the QHP issuer has been notified by the Exchange under § 155.340(a) of this subchapter that the QHP issuer will receive such advance payment.

§ 156.470 Allocation of rates and claims costs for advance payments of cost-sharing reductions and the premium tax credit.

(a) *Allocation to additional health benefits for QHPs.* An issuer must provide to the Exchange annually for approval, in the manner and timeframe established by HHS, for each health plan at any level of coverage offered, or intended to be offered, in the individual market on an Exchange, an allocation of the rate and the expected allowed claims costs for the plan, in each case, to:

(1) EHB, other than services described in § 156.280(d)(1), and

(2) Any other services or benefits offered by the health plan not described paragraph (a)(1) of this section.

(b) *Allocation to additional health benefits for stand-alone dental plans.* An issuer must provide to the Exchange annually for approval, in the manner and timeframe established by HHS, for each stand-alone dental plan offered, or intended to be offered, in the individual market on the Exchange, a dollar allocation of the expected premium for the plan, to:

(1) The pediatric dental essential health benefit, and

(2) Any benefits offered by the stand-alone dental plan that are not the pediatric dental essential health benefit.

(c) *Allocation standards for QHPs.* The issuer must ensure that the allocation described in paragraph (a) of this section—

(1) Is performed by a member of the American Academy of Actuaries in accordance with generally accepted actuarial principles and methodologies;

(2) Reasonably reflects the allocation of the expected allowed claims costs attributable to EHB (excluding those services described in § 156.280(d)(1));

(3) Is consistent with the allocation applicable to State-required benefits to be submitted by the issuer under § 155.170(c) of this subchapter, and the allocation requirements described in § 156.280(e)(4) for certain services; and

(4) Is calculated under the fair health insurance premium standards described at 45 CFR 147.102, the single risk pool standards described at 45 CFR 156.80, and the same premium rate standards described at 45 CFR 156.255.

(d) *Allocation standards for stand-alone dental plans.* The issuer must ensure that the dollar allocation described in paragraph (b) of this section is performed by a member of the American Academy of Actuaries in accordance with generally accepted actuarial principles and methodologies.

(e) *Disclosure of attribution and allocation methods.* An issuer of a health plan at any level of coverage or

a stand-alone dental plan offered, or intended to be offered, in the individual market on the Exchange must submit to the Exchange annually for approval, an actuarial memorandum, in the manner and timeframe specified by HHS, with a detailed description of the methods and specific bases used to perform the allocations set forth in paragraphs (a) and (b), and demonstrating that the allocations meet the standards set forth in paragraphs (c) and (d) of this section, respectively.

(f) *Multi-State plans.* Issuers of multi-State plans, as defined in § 155.1000(a) of this subchapter, must submit the allocations and actuarial memorandum described in this section to the U.S. Office of Personnel Management, in the time and manner established by the U.S. Office of Personnel Management.

PART 157—EMPLOYER INTERACTIONS WITH EXCHANGES AND SHOP PARTICIPATION

■ 43. The authority citation for part 157 continues to read as follows:

Authority: Title I of the Affordable Care Act, sections 1311, 1312, 1321, 1411, 1412, Pub. L. 111–148, 124 Stat. 199.

■ 44. Section 157.20 is amended by adding the definitions for “Federally-facilitated SHOP,” “Full-time employee,” and “Large employer” in alphabetical order to read as follows:

§ 157.20 Definitions.

* * * * *

Federally-facilitated SHOP has the meaning given to the term in § 155.20 of this subchapter.

Full-time employee has the meaning given to the term in § 155.20 of this subchapter.

Large employer has the meaning given to the term in § 155.20 of this subchapter.

* * * * *

PART 158—ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS

■ 45. The authority citation for part 158 continues to read as follows:

Authority: Section 2718 of the Public Health Service Act (42 U.S.C. 300gg–18), as amended.

■ 46. Section 158.110 is amended by revising paragraph (b) to read as follows:

§ 158.110 Reporting requirements related to premiums and expenditures.

* * * * *

(b) *Timing and form of report.* The report for each of the 2011, 2012, and 2013 MLR reporting years must be

submitted to the Secretary by June 1 of the year following the end of an MLR reporting year, on a form and in the manner prescribed by the Secretary. Beginning with the 2014 MLR reporting year, the report for each MLR reporting year must be submitted to the Secretary by July 31 of the year following the end of an MLR reporting year, on a form and in the manner prescribed by the Secretary.

* * * * *

■ 47. Section 158.130 is amended by adding paragraph (b)(5) to read as follows:

§ 158.130 Premium revenue.

* * * * *

(b) * * *

(5) Account for the net payments or receipts related to risk adjustment, risk corridors, and reinsurance programs under sections 1341, 1342, and 1343 of the Patient Protection and Affordable Care Act, 42 U.S.C. 18061, 18062, 18063.

■ 48. Section 158.140 is amended by adding paragraph (b)(4)(ii) and revising paragraph (b)(5)(i) to read as follows:

§ 158.140 Requirements for clinical services provided to enrollees.

* * * * *

(b) * * *

(4) * * *

(ii) Receipts related to the transitional reinsurance program and net payments or receipts related to risk adjustment and risk corridors programs under sections 1341, 1342, and 1343 of the Patient Protection and Affordable Care Act, 42 U.S.C. 18061, 18062, 18063.

(5) * * *

(i) Affiliated issuers that offer group coverage at a blended rate may choose whether to make an adjustment to each affiliate's incurred claims and activities to improve health care quality, to reflect the experience of the issuer with respect to the employer as a whole, according to an objective formula that must be defined by the issuer prior to January 1 of the MLR reporting year, so as to result in each affiliate having the same ratio of incurred claims to earned premium for that employer group for the MLR reporting year as the ratio of incurred claims to earned premium calculated for the employer group in the aggregate.

* * * * *

■ 49. Section 158.161 is amended by revising paragraph (a) to read as follows:

§ 158.161 Reporting of Federal and State licensing and regulatory fees.

(a) *Licensing and regulatory fees included.* The report required in § 158.110 must include statutory

assessments to defray operating expenses of any State or Federal department, transitional reinsurance contributions assessed under section 1341 of the Patient Protection and Affordable Care Act, 42 U.S.C. 18061, and examination fees in lieu of premium taxes as specified by State law.

* * * * *

■ 50. Section 158.162 is amended by revising paragraph (b)(1)(vii) and adding paragraph (b)(1)(viii) to read as follows:

§ 158.162 Reporting of Federal and State taxes.

* * * * *

(b) * * *

(1) * * *

(vii) Payments made by a Federal income tax exempt issuer for community benefit expenditures as defined in paragraph (c) of this section, limited to the highest of either:

(A) Three percent of earned premium; or

(B) The highest premium tax rate in the State for which the report is being submitted, multiplied by the issuer's earned premium in the applicable State market.

(viii) In lieu of reporting amounts described in paragraph (b)(1)(vi) of this section, an issuer that is not exempt from Federal income tax may choose to report payment for community benefit expenditures as described in paragraph (c) of this section, limited to the highest premium tax rate in the State for which the report is being submitted multiplied by the issuer's earned premium in the applicable State market.

* * * * *

■ 51. Section 158.221 is amended by revising paragraph (c) to read as follows:

§ 158.221 Formula for calculating an issuer's medical loss ratio.

* * * * *

(c) *Denominator.* The denominator of an issuer's MLR must equal the issuer's premium revenue, as defined in § 158.130, excluding the issuer's Federal and State taxes and licensing and regulatory fees, described in §§ 158.161(a) and 158.162(a)(1) and (b)(1), and after accounting for payments or receipts related to risk adjustment, risk corridors, and reinsurance, described in § 158.130(b)(5).

■ 52. Section 158.232 is amended by revising paragraph (c)(1)(i) and paragraph (d) introductory text to read as follows:

§ 158.232 Calculating the credibility adjustment.

* * * * *

(c) * * *

(1) * * *

(i) The per person deductible for a policy that covers a subscriber and the subscriber's dependents shall be the lesser of: the deductible applicable to each of the individual family members; or the overall family deductible for the subscriber and subscriber's family divided by two (regardless of the total number of individuals covered through the subscriber).

* * * * *

(d) *No credibility adjustment.*

Beginning with the 2013 MLR reporting year, the credibility adjustment for and MLR based on partially credible experience is zero if both of the following conditions are met:

* * * * *

■ 53. Section 158.240 is amended by revising paragraphs (c) and (d) to read as follows:

§ 158.240 Rebating premium if the applicable medical loss ratio standard is not met.

* * * * *

(c) *Amount of rebate to each enrollee.*

(1) For each MLR reporting year, an issuer must rebate to the enrollee the total amount of premium revenue, as defined in § 158.130, received by the issuer from the enrollee, after subtracting Federal and State taxes and licensing and regulatory fees as provided in §§ 158.161(a) and 158.162(a)(1) and (b)(1), and after accounting for payments or receipts for risk adjustment, risk corridors, and reinsurance as provided in § 158.130(b)(5), multiplied by the difference between the MLR required by § 158.210 or § 158.211, and the issuer's MLR as calculated under § 158.221.

(2) For example, an issuer must rebate a pro rata portion of premium revenue if it does not meet an 80 percent MLR for the individual market in a State that has not set a higher MLR. If an issuer has a 75 percent MLR for the coverage it offers in the individual market in a State that has not set a higher MLR, the issuer must rebate 5 percent of the premium paid by or on behalf of the enrollee for the MLR reporting year after subtracting a pro rata portion of taxes and fees and accounting for payments or receipts related to reinsurance, risk adjustment and risk corridors. If the issuer's total earned premium for the MLR reporting year in the individual market in the State is \$200,000, the issuer received transitional reinsurance payments of \$2,500, and made net payments related to risk adjustment and risk corridors of \$20,000, the issuer's gross earned premium in the individual market in the State would be \$200,000 plus \$2,500 minus \$20,000, for a total of

\$182,500. If the issuer's Federal and State taxes and licensing and regulatory fees, including reinsurance contributions, that may be excluded from premium revenue as described in §§ 158.161(a), 158.162(a)(1) and 158.162(b)(1), allocated to the individual market in the State are \$15,000, and the net payments related to risk adjustment and risk corridors, reduced by reinsurance receipts, that must be accounted for in premium revenue as described in §§ 158.130(b)(5), 158.221 and 158.240, are \$17,500 (\$20,000 reduced by \$2,500), then the issuer would subtract \$15,000 and add \$17,500 to gross premium revenue of \$182,500, for a base of \$185,000 in premium. The issuer would owe rebates of 5 percent of \$185,000, or \$9,250 in the individual market in the State. In this example, if an enrollee of the issuer in the individual market in the State paid \$2,000 in premiums for the MLR reporting year, or 1/100 of the issuer's total premium in that State market, then the enrollee would be entitled to 1/100 of the total rebates owed by the issuer, or \$92.50.

(d) *Timing of rebate.* For each of the 2011, 2012, and 2013 MLR reporting years, an issuer must provide any rebate owing to an enrollee no later than August 1 following the end of the MLR reporting year. Beginning with the 2014 MLR reporting year, an issuer must provide any rebate owing to an enrollee no later than September 30 following the end of the MLR reporting year.

* * * * *

■ 54. Section 158.241 is amended by revising paragraph (a)(2) to read as follows:

§ 158.241 Form of rebate.

(a) * * *

(2) For each of the 2011, 2012, and 2013 MLR reporting years, any rebate provided in the form of a premium credit must be provided by applying the full amount due to the first month's premium that is due on or after August 1 following the MLR reporting year. If the amount of the rebate exceeds the premium due for August, then any overage shall be applied to succeeding premium payments until the full amount of the rebate has been credited. Beginning with the 2014 MLR reporting year, any rebate provided in the form of a premium credit must be provided by applying the full amount due to the first month's premium that is due on or after September 30 following the MLR reporting year. If the amount of the rebate exceeds the premium due for October, then any overage shall be

applied to succeeding premium payments until the full amount of the rebate has been credited.

* * * * *

Dated: February 25, 2013.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: February 27, 2013.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2013-04902 Filed 3-1-13; 11:15 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 153 and 156

[CMS-9964-IFC]

RIN 0938-AR74

Patient Protection and Affordable Care Act; Amendments to the HHS Notice of Benefit and Payment Parameters for 2014

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Interim final rule with comment.

SUMMARY: This interim final rule with comment builds upon standards set forth in the HHS Notice of Benefit and Payment Parameters for 2014, published elsewhere in this issue of the **Federal Register**. This document will adjust risk corridors calculations that would align the calculations with the single risk pool provision, and set standards permitting issuers of qualified health plans the option of using an alternate methodology for calculating the value of cost-sharing reductions provided for the purpose of reconciliation of advance payments of cost-sharing reductions.

DATES: *Effective date:* These regulations are effective on April 30, 2013.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on April 30, 2013.

ADDRESSES: In commenting, please refer to file code CMS-9964-IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed)

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-9964-IFC, P.O. Box 8016, Baltimore, MD 21244-8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-9964-IFC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments only to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Sharon Arnold, (301) 492-4286; Laurie McWright, (301) 492-4311; or Jeff Wu, (301) 492-4305, for general information. Jaya Ghildiyal, (301) 492-5149 for matters relating to risk corridors. Johanna Lauer, (301) 492-4397 for matters relating to cost-sharing reductions.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments

received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will be also available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

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I. Executive Summary

A. Purpose

Beginning in 2014, individuals and small businesses will be able to purchase private health insurance—qualified health plans—through competitive marketplaces, called Affordable Insurance Exchanges, "Exchanges," or "Marketplaces." Section 1342 of the Affordable Care Act provides for a temporary risk corridors program. The program, which is Federally administered and in effect from 2014 through 2016, is intended to protect against uncertainty in rate setting for qualified health plans (QHPs) by limiting the extent of issuer losses and gains. In the rule entitled "Standards Related to Reinsurance, Risk Adjustment and Risk Corridors" (77 FR 17220) (Premium Stabilization Rule), we set forth a regulatory framework for this program. In the HHS Notice of Benefit and Payment Parameters for 2014 (2014 Payment Notice) published elsewhere in this issue of the **Federal Register**, we expanded upon these standards, and stated that we are publishing this

EXHIBIT 2



FEDERAL REGISTER

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Part II

Department of Health and Human Services

45 CFR Parts 144, 147, 153, et al.

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES**45 CFR Parts 144, 147, 153, 154, 155, 156 and 158****[CMS-9944-F]****RIN 0938-AS19****Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016****AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Final rule.

SUMMARY: This final rule sets forth payment parameters and provisions related to the risk adjustment, reinsurance, and risk corridors programs; cost sharing parameters and cost-sharing reductions; and user fees for Federally-facilitated Exchanges. It also finalizes additional standards for the individual market annual open enrollment period for the 2016 benefit year, essential health benefits, qualified health plans, network adequacy, quality improvement strategies, the Small Business Health Options Program, guaranteed availability, guaranteed renewability, minimum essential coverage, the rate review program, the medical loss ratio program, and other related topics.

DATES: These regulations are effective on April 28, 2015 except the amendments to §§ 156.235, 156.285(d)(1)(ii), and 158.162 are effective on January 1, 2016.

FOR FURTHER INFORMATION CONTACT:

For general information: Jeff Wu, (301) 492-4305.

For matters related to guaranteed availability, guaranteed renewability, rate review, or the applicability of Title I of the Affordable Care Act in the U.S. Territories: Jacob Ackerman, (301) 492-4179.

For matters related to risk adjustment or the methodology for determining the reinsurance contribution rate and payment parameters: Kelly Horney, (410) 786-0558.

For matters related to reinsurance generally, distributed data collection good faith compliance policy, or administrative appeals: Adrienne Glasgow, (410) 786-0686.

For matters related to the definition of common ownership for purposes of reinsurance contributions: Adam Shaw, (410) 786-1019.

For matters related to risk corridors: Jaya Ghildiyal, (301) 492-5149.

For matters related to essential health benefits, network adequacy, essential community providers, or other

standards for QHP issuers: Leigha Basini, (301) 492-4380.

For matters related to the qualified health plan good faith compliance policy: Cindy Yen, (301) 492-5142.

For matters related to the Small Business Health Options Program: Christelle Jang, (410) 786-8438.

For matters related to the Federally-facilitated Exchange user fee or minimum value: Krutika Amin, (301) 492-5153.

For matters related to cost-sharing reductions or the premium adjustment percentage: Pat Meisol, (410) 786-1917.

For matters related to re-enrollment, open enrollment periods, or exemptions from the individual shared responsibility payment: Christine Hammer, (301) 492-4431.

For matters related to special enrollment periods: Rachel Arguello, (301) 492-4263.

For matters related to minimum essential coverage: Cam Moultrie Clemmons, (206) 615-2338.

For matters related to quality improvement strategies: Marsha Smith, (410) 786-6614.

For matters related to the medical loss ratio program: Julie McCune, (301) 492-4196.

For matters related to meaningful access to QHP information, consumer assistance tools and programs of an Exchange, or cost-sharing reduction notices: Tricia Beckmann, (301) 492-4328.

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Acronyms

Affordable Care Act The collective term for the Patient Protection and Affordable Care Act (Pub. L. 111–148) and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), as amended

AHFS American hospital formulary system

AV Actuarial value

CFR Code of Federal Regulations

CMS Centers for Medicare & Medicaid Services

COBRA Consolidated Omnibus Budget Reconciliation Act of 1985 (Pub. L. 99–272) (29 U.S.C. 1161, *et seq.*)

ECP Essential community provider

EHB Essential health benefits

ERISA Employee Retirement Income Security Act of 1974 (Pub. L. 93–406)

FFE Federally-facilitated Exchange

FF–SHOP Federally-facilitated Small Business Health Options Program

FPL Federal Poverty Level

FQHC Federally qualified health center

HCC Hierarchical condition category

HHS United States Department of Health and Human Services

HIPAA Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191)

IRS Internal Revenue Service

LEP Limited English proficient/proficiency

MLR Medical loss ratio

MV Minimum value

NAIC National Association of Insurance Commissioners

OMB Office of Management and Budget

OPM United States Office of Personnel Management

PHS Act Public Health Service Act

PRA Paperwork Reduction Act of 1995

P&T committee Pharmacy and therapeutics committee

QHP Qualified health plan

QIS Quality improvement strategy

SADP Stand-alone Dental Plan

SEP Special enrollment period

SHOP Small Business Health Options Program

The Code Internal Revenue Code of 1986

TPA Third-party administrator

URL Uniform resource locator

USP United States Pharmacopeia

I. Executive Summary

Qualified individuals and qualified employers are now able to purchase private health insurance coverage through competitive marketplaces called Affordable Insurance Exchanges, or “Exchanges” (also called Health Insurance Marketplaces, or “Marketplaces”). Individuals who enroll in qualified health plans (QHPs) through individual market Exchanges may be eligible to receive a premium tax credit to make health insurance more affordable and for cost-sharing reductions to reduce out-of-pocket expenses for health care services. Additionally, in 2014, HHS began operationalizing the premium stabilization programs established by the Affordable Care Act. These programs—the risk adjustment, reinsurance, and risk corridors programs—are intended to mitigate the potential impact of adverse selection and stabilize the price of health insurance in the individual and small group markets. These programs, together with other reforms of the Affordable Care Act, are making high-quality health insurance affordable and accessible to millions of Americans.

We have previously outlined the major provisions and parameters related to the advance payments of the premium tax credit, cost-sharing reductions, and premium stabilization programs. This rule finalizes additional

provisions and modifications related to the implementation of the premium stabilization programs, as well as key payment parameters for the 2016 benefit year.

The HHS Notice of Benefit and Payment Parameters for 2014 (78 FR 15410) (2014 Payment Notice) finalized the risk adjustment methodology that HHS will use when it operates the risk adjustment program on behalf of a State. Risk adjustment factors reflect enrollee health risk and the costs of a given disease relative to average spending. This final rule recalibrates the HHS risk adjustment models for the 2016 benefit year by using 2011, 2012, and 2013 claims data from the Truven Health Analytics 2010 MarketScan® Commercial Claims and Encounters database (MarketScan) to develop updated risk factors.

Using the same methodology as set forth in the 2014 Payment Notice and the HHS Notice of Benefit and Payment Parameters for 2015 (79 FR 13744) (2015 Payment Notice), we finalize a 2016 uniform reinsurance contribution rate of \$27 annually per enrollee, and the 2016 uniform reinsurance payment parameters—a \$90,000 attachment point, a \$250,000 reinsurance cap, and a 50 percent coinsurance rate. We are decreasing the attachment point for the 2015 benefit year from \$70,000 to \$45,000, while retaining the \$250,000 reinsurance cap and a 50 percent coinsurance rate. In this rule, we also finalize the definition of “common ownership” for purposes of determining whether a contributing entity uses a third-party administrator for core administrative functions. In addition, this final rule discusses the reinsurance contribution payment schedule and accompanying notifications. We also extend the good faith safe harbor for non-compliance with the HHS-operated risk adjustment and reinsurance data requirements through the 2015 calendar year.

We are finalizing a clarification and a modification to the risk corridors program. We clarify that the risk corridors transitional adjustment policy established in the 2015 Payment Notice, which makes an adjustment to a QHP issuer's risk corridors calculation based on Statewide enrollment in transitional plans, does not include in that calculation enrollment in so-called “early renewal plans” (plans that renewed before January 1, 2014 and before the end of their 12-month terms) unless and until the plans renew in 2014 and become transitional plans. Additionally, for the 2016 benefit year, we are finalizing an approach for the treatment of risk corridors collections

under the policy set forth in our April 11, 2014, FAQ on Risk Corridors and Budget Neutrality,¹ in the event that risk corridors collections available in 2016 exceed risk corridors payment requests from QHP issuers.

We also finalize several provisions related to cost sharing. First, we establish the premium adjustment percentage for 2016, which is used to set the rate of increase for several parameters detailed in the Affordable Care Act, including the maximum annual limitation on cost sharing for 2016. We establish the maximum annual limitations on cost sharing for the 2016 benefit year for cost-sharing reduction plan variations. For reconciliation of 2014 cost-sharing reductions, we are finalizing and expanding our proposal to permit issuers whose plan variations meet certain criteria to estimate the portion of claims attributable to non-essential health benefits to calculate cost-sharing reductions provided.

For 2016, we finalize a Federally-facilitated Exchange (FFE) user fee rate of 3.5 percent of premium, the same rate as for 2015. This rule also finalizes provisions to enhance the transparency and effectiveness of the rate review program and standards related to minimum essential coverage, the individual market annual open enrollment period for the 2016 benefit year, and amendments to a number of Small Business Health Options Program (SHOP) provisions, including minimum participation rates. This final rule amends the medical loss ratio (MLR) provisions relating to the treatment of cost-sharing reductions and certain taxes in MLR and rebate calculations, as well as the distribution of rebates by group health plans not subject to the Employee Retirement Income Security Act of 1974 (Pub. L. 93–406) (ERISA). This final rule provides more specificity about the meaningful access requirements applicable to Exchanges, to QHP issuers, and to agents and brokers subject to § 155.220(c)(3)(i), related to access for individuals with limited English proficiency (LEP). This final rule requires issuers to provide a summary of benefits and coverage (SBC) for each plan variation of the standard QHP and to provide adequate notice to enrollees of changes in cost-sharing reduction eligibility. This final rule also includes additional quality improvement strategy reporting provisions for QHP issuers, specifies the circumstances that may lead an

Exchange to suppress a QHP from being offered to new enrollees through an Exchange, and extends the good faith compliance policy for QHP issuers in the FFEs through the 2015 calendar year.

In this final rule, we are finalizing a number of standards relating to essential health benefits (EHBs), including a definition of rehabilitative services, coverage of pediatric services, and coverage of prescription drugs. This final rule also provides examples of discriminatory plan designs and amends requirements for essential community providers (ECPs).

II. Background

A. Legislative and Regulatory Overview

The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010. In this final rule, we refer to the two statutes collectively as the “Affordable Care Act.”

Subtitles A and C of title I of the Affordable Care Act reorganized, amended, and added to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets.

Section 2701 of the PHS Act, as added by the Affordable Care Act, restricts the variation in premium rates that may be charged by a health insurance issuer for non-grandfathered health insurance coverage in the individual or small group market to certain specified factors. The factors are: Family size, rating area, age, and tobacco use (within specified limits).

Section 2701 of the PHS Act operates in coordination with section 1312(c) of the Affordable Care Act. Section 1312(c) of the Affordable Care Act generally requires a health insurance issuer to consider all enrollees in all health plans (except for grandfathered health plans) offered by such issuer to be members of a single risk pool for each of its individual and small group markets. States have the option to merge the individual market and small group market risk pools under section 1312(c)(3) of the Affordable Care Act.

Section 2702 of the PHS Act, as added by the Affordable Care Act, requires health insurance issuers that offer health insurance coverage in the group or individual market in a State to offer coverage to and accept every employer

¹ Available at: <http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/faq-risk-corridors-04-11-2014.pdf>.

and individual in the State that applies for such coverage unless an exception applies.

Section 2703 of the PHS Act, as added by the Affordable Care Act, requires health insurance issuers that offer health insurance coverage in the group or individual market to renew or continue in force such coverage at the option of the plan sponsor or individual unless an exception applies.

Section 2718 of the PHS Act, as added by the Affordable Care Act, generally requires health insurance issuers to submit an annual MLR report to HHS and provide rebates to enrollees if they do not achieve specified MLR thresholds.

Section 2794 of the PHS Act, as added by the Affordable Care Act, directs the Secretary of HHS (the Secretary), in conjunction with the States, to establish a process for the annual review of “unreasonable increases in premiums for health insurance coverage.”² The law also requires health insurance issuers to submit justifications to the Secretary and the applicable State entities for unreasonable premium increases prior to the implementation of the increases. Section 2794(b)(2) of the PHS Act further specifies that, beginning in 2014, the Secretary, in conjunction with the States, will monitor premium increases of health insurance coverage offered through an Exchange and outside of an Exchange.

Section 1302 of the Affordable Care Act provides for the establishment of an essential health benefits (EHB) package that includes coverage of EHB (as defined by the Secretary) and cost-sharing limits, and meets statutorily defined actuarial value (AV) requirements. The law directs that EHBs be equal in scope to the benefits covered by a typical employer plan and that they cover at least the following 10 general categories: Ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care.

Sections 1302(b)(4)(A) through (D) establish that the Secretary must define

EHB in a manner that: (1) Reflects appropriate balance among the 10 categories; (2) is not designed in such a way as to discriminate based on age, disability, or expected length of life; (3) takes into account the health care needs of diverse segments of the population; and (4) does not allow denials of EHBs based on age, life expectancy, disability, degree of medical dependency, or quality of life.

Section 1302(d) of the Affordable Care Act describes the various levels of coverage based on AV. Consistent with section 1302(d)(2)(A) of the Affordable Care Act, AV is calculated based on the provision of EHB to a standard population. Section 1302(d)(3) of the Affordable Care Act directs the Secretary to develop guidelines that allow for *de minimis* variation in AV calculations.

Section 1311(b)(1)(B) of the Affordable Care Act directs the SHOP to assist qualified small employers in facilitating the enrollment of their employees in QHPs offered in the small group market. Sections 1312(f)(1) and (2) of the Affordable Care Act define qualified individuals and qualified employers. Under section 1312(f)(2)(B) of the Affordable Care Act, beginning in 2017, States will have the option to allow issuers to offer QHPs in the large group market through the SHOP.³

Section 1311(c)(1)(B) of the Affordable Care Act requires the Secretary to establish minimum criteria for provider network adequacy that a health plan must meet to be certified as a QHP. Section 1311(c)(1)(E) of the Affordable Care Act specifies that, to be certified as a QHP participating in Exchanges, each health plan must implement a quality improvement strategy (QIS), which is described in section 1311(g)(1) of the Affordable Care Act.

Section 1311(c)(5) of the Affordable Care Act requires the Secretary to continue to operate, maintain, and update the Internet portal developed under section 1103 of the Affordable Care Act to provide information to consumers and small businesses on affordable health insurance coverage options.

Section 1311(c)(6)(B) of the Affordable Care Act states that the Secretary is to set annual open enrollment periods for Exchanges for

calendar years after the initial enrollment period.

Section 1301(a)(1)(B) of the Affordable Care Act directs all issuers of QHPs to cover the EHB package described in section 1302(a) of the Affordable Care Act, including the services described in section 1302(b) of the Affordable Care Act, to adhere to the cost-sharing limits described in section 1302(c) of the Affordable Care Act, and to meet the AV levels established in section 1302(d) of the Affordable Care Act. Section 2707(a) of the PHS Act, which is effective for plan or policy years beginning on or after January 1, 2014, extends the coverage of the EHB package to non-grandfathered individual and small group coverage, irrespective of whether such coverage is offered through an Exchange. In addition, section 2707(b) of the PHS Act directs non-grandfathered group health plans to ensure that cost sharing under the plan does not exceed the limitations described in sections 1302(c)(1) and (2) of the Affordable Care Act.

Sections 1313 and 1321 of the Affordable Care Act provide the Secretary with the authority to oversee the financial integrity of State Exchanges, their compliance with HHS standards, and the efficient and non-discriminatory administration of State Exchange activities. Section 1321 of the Affordable Care Act provides for State flexibility in the operation and enforcement of Exchanges and related requirements.

Section 1321(a) of the Affordable Care Act provides the Secretary with broad authority to establish standards and regulations to implement statutory requirements related to Exchanges, QHPs, and other components of title I of the Affordable Care Act. Under the authority established in section 1321(a)(1) of the Affordable Care Act, the Secretary promulgated the regulations at § 155.205(d) and (e). Section 155.205 authorizes Exchanges to perform certain consumer service functions. Section 155.205(d) provides that each Exchange must conduct consumer assistance activities, including the Navigator program described in § 155.210, and § 155.205(e) provides that each Exchange must conduct outreach and education activities to inform consumers about the Exchange and insurance affordability programs to encourage participation. Sections 155.205(d) and (e) also allow for the establishment of a non-Navigator consumer assistance program. Section 155.215 establishes standards for Navigators and non-Navigator assistance personnel in FFEs and for non-Navigator assistance personnel that are

² The implementing regulations in part 154 limit the scope of the requirements under section 2794 of the PHS Act to health insurance issuers offering health insurance coverage in the individual market or small group market. See Rate Increase Disclosure and Review; Final Rule, 76 FR 29964, 29966 (May 23, 2011).

³ If a State elects to offer QHPs in the large group market through the SHOP, the rating rules in section 2701 of the PHS Act and its implementing regulations will apply to all coverage offered in such State's large group market (except for self-insured group health plans) under section 2701(a)(5) of the PHS Act.

funded with Exchange establishment grant funds under section 1311(a) of the Affordable Care Act.

When operating an FFE under section 1321(c)(1) of the Affordable Care Act, HHS has the authority under sections 1321(c)(1) and 1311(d)(5)(A) of the Affordable Care Act to collect and spend user fees. In addition, 31 U.S.C. 9701 permits a Federal agency to establish a charge for a service provided by the agency. Office of Management and Budget (OMB) Circular No. A-25 Revised establishes Federal policy regarding user fees and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public.

Section 1321(c)(2) of the Affordable Care Act authorizes the Secretary to enforce the Exchange standards using civil money penalties (CMPs) on the same basis as detailed in section 2723(b) of the PHS Act. Section 2723(b) of the PHS Act authorizes the Secretary to impose CMPs as a means of enforcing the individual and group market reforms contained in Part A of title XXVII of the PHS Act when a State fails to substantially enforce these provisions.

Section 1321(d) of the Affordable Care Act provides that nothing in title I of the Affordable Care Act should be construed to preempt any State law that does not prevent the application of title I of the Affordable Care Act. Section 1311(k) of the Affordable Care Act specifies that Exchanges may not establish rules that conflict with or prevent the application of regulations issued by the Secretary.

Section 1341 of the Affordable Care Act provides for the establishment of a transitional reinsurance program in each State to help pay the cost of treating high-cost enrollees in the individual market in the 2014 through 2016 benefit years. Section 1342 of the Affordable Care Act directs the Secretary to establish a temporary risk corridors program that protects against inaccurate rate setting in the 2014 through 2016 benefit years. Section 1343 of the Affordable Care Act establishes a permanent risk adjustment program that is intended to provide increased payments to health insurance issuers that attract higher-risk populations, such as those with chronic conditions, funded by payments from those that attract lower-risk populations, thereby reducing incentives for issuers to avoid higher-risk enrollees.

Sections 1402 and 1412 of the Affordable Care Act provide for reductions in cost sharing for EHBs for

qualified low- and moderate-income enrollees in silver level health plans offered through the individual market Exchanges. These sections also provide for reductions in cost sharing for Indians enrolled in Exchange plans at any metal level.

Section 5000A of the Internal Revenue Code (the Code), as added by section 1501(b) of the Affordable Care Act, requires an individual to have minimum essential coverage for each month, qualify for an exemption, or make a shared responsibility payment with his or her Federal income tax return. Section 5000A(f) of the Code defines minimum essential coverage as any of the following: (1) Coverage under a specified government sponsored program; (2) coverage under an eligible employer-sponsored plan; (3) coverage under a health plan offered in the individual market within a State; or (4) coverage under a grandfathered health plan. Section 5000A(f)(1)(E) of the Code authorizes the Secretary, in coordination with the Secretary of the Treasury, to designate other health benefits coverage as minimum essential coverage.

1. Premium Stabilization Programs

In the July 15, 2011 **Federal Register** (76 FR 41930), we published a proposed rule outlining the framework for the premium stabilization programs. We implemented the premium stabilization programs in a final rule, published in the March 23, 2012 **Federal Register** (77 FR 17220) (Premium Stabilization Rule). In the December 7, 2012 **Federal Register** (77 FR 73118), we published a proposed rule outlining the benefit and payment parameters for the 2014 benefit year to expand the provisions related to the premium stabilization programs, and establish payment parameters for those programs (proposed 2014 Payment Notice). We published the 2014 Payment Notice final rule in the March 11, 2013 **Federal Register** (78 FR 15410).

In the December 2, 2013 **Federal Register** (78 FR 72322), we published a proposed rule outlining the benefit and payment parameters for the 2015 benefit year to expand upon the provisions related to the premium stabilization programs, setting forth certain oversight provisions, and establishing the 2015 payment parameters for those programs (proposed 2015 Payment Notice). We published the 2015 Payment Notice final rule in the March 11, 2014 **Federal Register** (79 FR 13744).

2. Program Integrity

In the June 19, 2013 **Federal Register** (78 FR 37032), we published a proposed

rule that proposed certain program integrity standards related to Exchanges and the premium stabilization programs (proposed Program Integrity Rule). The provisions of that proposed rule were finalized in two rules, the “first Program Integrity Rule” published in the August 30, 2013 **Federal Register** (78 FR 54070) and the “second Program Integrity Rule” published in the October 30, 2013 **Federal Register** (78 FR 65046).

3. Exchanges

We published a request for comment relating to Exchanges in the August 3, 2010 **Federal Register** (75 FR 45584). We issued initial guidance to States on Exchanges on November 18, 2010. We proposed a rule in the July 15, 2011 **Federal Register** (76 FR 41866) to implement components of the Exchange, and a rule in the August 17, 2011 **Federal Register** (76 FR 51202) regarding Exchange functions in the individual market, eligibility determinations, and Exchange standards for employers. A final rule implementing components of the Exchanges and setting forth standards for eligibility for Exchanges was published in the March 27, 2012 **Federal Register** (77 FR 18310) (Exchange Establishment Rule).

We established standards for the administration and payment of cost-sharing reductions and the SHOP in the 2014 Payment Notice and in the Amendments to the HHS Notice of Benefit and Payment Parameters for 2014 interim final rule, published in the March 11, 2013 **Federal Register** (78 FR 15541). The provisions established in the interim final rule were finalized in the second Program Integrity Rule. We also set forth standards related to Exchange user fees in the 2014 Payment Notice. We also established an adjustment to the FFE user fee in the Coverage of Certain Preventive Services Under the Affordable Care Act final rule, published in the July 2, 2013 **Federal Register** (78 FR 39870) (Preventive Services Rule).

In a final rule published in the July 17, 2013 **Federal Register** (78 FR 42859), we established standards for Navigators and non-Navigator assistance personnel in FFEs and for non-Navigator assistance personnel funded through an Exchange establishment grant.

4. Essential Health Benefits and Actuarial Value

We initially established requirements relating to EHBs and AVs in the Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation Final Rule, which was

published in the February 25, 2013 **Federal Register** (78 FR 12834) (EHB Rule). We established standards for updating the AV Calculator for future plan years in the 2015 Payment Notice and established an expedited prescription drug exception process based on exigent circumstances for plans providing EHB in the Exchange and Insurance Market Standards for 2015 and Beyond Final Rule (2015 Market Standards Rule) that was published in the May 27, 2014 **Federal Register** (79 FR 30240).

5. Market Rules

A proposed rule relating to the Health Insurance Market Rules was published in the November 26, 2012 **Federal Register** (77 FR 70584). A final rule implementing the Health Insurance Market Rules was published in the February 27, 2013 **Federal Register** (78 FR 13406) (2014 Market Rules).

A proposed rule relating to Exchanges and Insurance Market Standards for 2015 and Beyond was published in the March 21, 2014 **Federal Register** (79 FR 15808) (2015 Market Standards Proposed Rule). The 2015 Market Standards Rule was published in the May 27, 2014 **Federal Register** (79 FR 30240).

6. Rate Review

We published a proposed rule to establish the rate review program in the December 23, 2010 **Federal Register** (75 FR 81004). We implemented the rate review program in a final rule published in the May 23, 2011 **Federal Register** (76 FR 26694). We subsequently amended the rate review provisions in a final rule published in the September 6, 2011 **Federal Register** (76 FR 54969) and in the 2014 Market Rules.

7. Medical Loss Ratio (MLR)

We published a request for comment on section 2718 of the PHS Act in the April 14, 2010 **Federal Register** (75 FR 19297), and published an interim final rule with a 60-day comment period relating to the MLR program on December 1, 2010 (75 FR 74864). A final rule with a 30-day comment period was published in the December 7, 2011 **Federal Register** (76 FR 76574). An interim final rule with a 60-day comment period was published in the December 7, 2011 **Federal Register** (76 FR 76596). A final rule was published in the **Federal Register** on May 16, 2012 (77 FR 28790).

B. Stakeholder Consultation and Input

HHS has consulted with stakeholders on policies related to the operation of Exchanges, including the SHOP and the

premium stabilization programs. HHS has held a number of listening sessions with consumers, providers, employers, health plans, the actuarial community, and State representatives to gather public input. HHS consulted with stakeholders through regular meetings with the National Association of Insurance Commissioners (NAIC), regular contact with States through the Exchange Establishment grant and Exchange Blueprint approval processes, and meetings with Tribal leaders and representatives, health insurance issuers, trade groups, consumer advocates, employers, and other interested parties. We considered all of the public input as we developed the policies in this final rule.

III. Provisions of the Final Regulations and Analysis and Responses to Public Comments

In the November 26, 2014 **Federal Register** (79 FR 70674), we published the “Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016” proposed rule. We received 313 comments from various stakeholders, including States, health insurance issuers, consumer groups, labor entities, industry groups, provider groups, patient safety groups, national interest groups, and other stakeholders. The comments ranged from general support of or opposition to the proposed provisions to very specific questions or comments regarding proposed changes. We received a number of comments and suggestions that were outside the scope of the proposed rule and therefore will not be addressed in this final rule.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the provisions we are finalizing.

Comment: We received a number of comments requesting that the comment period be extended to 60 days. Several commenters asked that HHS develop a standard timeline for issuance of the proposed and final Payment Notices, one commenter asked that the final Payment Notice be published by mid-January each year, and another asked that it be published by February 1st each year.

Response: The timeline for publication of this final rule accommodates issuer filing deadlines for the 2016 benefit year. We appreciate the deadlines that States, Exchanges, issuers, and other entities face in implementing these rules.

Comment: We received one comment disapproving of the wide array of topics covered in the rule.

Response: Many of the programs covered by this final rule are closely linked. To simplify the regulatory process, facilitate public comment, and provide the information needed to meet statutory deadlines, we elected to propose and finalize these regulatory provisions in one rule.

Comment: One commenter asked that HHS allow States to continue their oversight of their insurance markets and defer to the NAIC for the development of important industry-wide, State-based standards.

Response: Title XXVII of the PHS Act contemplates that States will exercise primary enforcement authority over health insurance issuers in the group and individual markets to ensure compliance with the Federal market reforms. HHS has the responsibility to enforce these provisions in the event that a State notifies HHS that it does not have the statutory authority to enforce or that it is not otherwise enforcing, or if HHS determines that a State is not substantially enforcing, these requirements. This enforcement framework, in place since 1996, ensures that all consumers in all States have the protections of the Affordable Care Act and other parts of the PHS Act. We aim to establish Federal oversight standards that complement State standards while meeting Federal obligations, and intend to continue to coordinate with State authorities to address compliance issues and to reduce the burden on stakeholders.

Comment: One commenter urged HHS to ensure that all regulatory information related to the premium stabilization programs be presented in a transparent and timely fashion.

Response: We strive to publicize and present all information related to the premium stabilization programs in a transparent and timely fashion.

A. Part 144—Requirements Relating to Health Insurance Coverage

1. Definitions (§ 144.103)

Section 144.103 sets forth definitions of terms that are used throughout parts 146 through 150. In the proposed rule, we proposed to amend the definitions of “plan” and “State.”

a. Plan

We proposed to make the definition of “plan” more specific by clarifying that the term means the pairing of the health insurance coverage benefits under a “product” with a particular cost-sharing structure, provider network, and service

area.⁴ The same definition would be used for purposes of part 154, rate review, and part 156, health insurance issuer standards.

We noted that issuers can modify the health insurance coverage for a product upon coverage renewal and sought comment on standards for determining when a plan that has been modified should be considered to be the “same plan” for purposes of rate review, plan identification in the Health Insurance Oversight System (HIOS), and other programs. In particular, we sought comment on whether these standards should be similar to those applicable at the product level under the uniform modification provision at § 147.106(e).

We are finalizing the amendments to the definition of “plan” as proposed. We are also specifying standards for determining when a plan that has been modified will be considered to be the “same plan.”

Comment: Many commenters were supportive of the proposed definition of “plan” stating it more closely aligns with issuer operations and consumer expectations. However, some commenters believed that parts of the definition were too vague, such as the references to “cost-sharing structure” and “provider network.” For example, one commenter stated that the reference to a “particular” cost-sharing structure could mean that each cost-sharing reduction plan variation of the standard QHP would constitute a separate “plan.” One commenter recommended adding the prescription drug formulary as a distinct plan characteristic. Other commenters cautioned HHS to be mindful of the operational impacts of changing the definition of “plan.”

Response: We believe the proposed definition accurately reflects the key features of a plan: a package of benefits paired with a cost-sharing structure and provider network that operates within a service area. By “provider network,” we mean the defined set of providers under contract with the issuer for the delivery of medical care (including items and services paid for as medical care), if applicable. We recognize that the prescription drug formulary is an important element of plan coverage, but do not specifically include it in the definition, because each aspect of the formulary—the covered drugs and the

tiering design—are represented by the plan’s benefits and cost-sharing structure. Further, we clarify that each plan variation of a standard QHP would not constitute a “particular cost-sharing structure” for purposes of the definition and thus would not constitute a separate plan.

The final rule adopts the definition of “plan” as proposed. We believe many issuers already distinguish their plans according to these characteristics, and we do not anticipate significant downstream issues as a result of these clarifications. Nevertheless, we will work with States and issuers to make any necessary adjustments to plan identifiers in Federal systems.

Comment: We received some comments addressing when a plan should be considered to be the “same plan” following modifications at the plan level. Several commenters agreed with the option we presented in the preamble to the proposed rule of using standards similar to those for uniform modification of a product for identifying modifications to a plan that would result in the plan remaining the “same plan.” Commenters stated that we should permit changes to cost sharing designed to maintain the same metal level and modifications attributable to Federal or State legal requirements to constitute the same plan. Two commenters recommended standards regarding provider network and service area.

Response: In this final rule, we specify when a plan that has been modified will be considered to be the “same plan.” Based on the comments received, the final rule generally adopts the standards for uniform modification at the product level for changes made at the plan level. These standards reflect characteristics relevant to the definition of “plan,” including provider network, an additional characteristic not reflected in the uniform modification provision. We specifically omit those standards at § 147.106(e)(3) related to issuer, product network type, and covered benefits, which are relevant only at the product level. We note that modifications to these characteristics in a manner that exceeds the standards for uniform modification would result in a new product and, consequently, new plans within the product.

The final rule provides that a plan that has been modified at the time of coverage renewal in accordance with § 147.106 will be considered to be the same plan if it meets the following conditions:

- Has the same cost-sharing structure as before the modification, or any variation in cost sharing is solely related

to changes in cost or utilization of medical care (that is, medical inflation or demand for services based on inflationary increases in the cost of medical care), or is to maintain the same metal tier level described in sections 1302(d) and (e) of the Affordable Care Act (that is, bronze, silver, gold, platinum, or catastrophic).

- Continues to cover a majority of the same service area.

- Continues to cover a majority of the same provider network (as applicable).

We recognize that a plan’s provider network may change throughout the plan year. Therefore, for purposes of determining whether a plan maintains a majority of the same provider network, the plan’s provider network on the first day of the plan year is compared with the plan’s provider network on the first day of the preceding plan year. If at least 50 percent of the contracted providers at the beginning of the plan year are still contracted providers at the beginning of the next plan year, the plan will be considered to have maintained a majority of the same provider network.

Furthermore, similar to the standard for uniform modification of a product, a plan also will not fail to be treated as the same plan to the extent the changes are made uniformly and solely pursuant to applicable Federal or State requirements, provided that the changes are made within a reasonable time period after the imposition or modification of the Federal or State requirement and are directly related to the imposition or modification of the Federal or State requirement.

The cost-sharing provision under this final rule is identical to the cost-sharing provision under the uniform modification standard. In the 2015 Market Standards Rule (79 FR 30251), which established criteria for uniform modification, we stated that the cost-sharing provision is intended to establish basic parameters around cost-sharing modifications to protect consumers from extreme changes in deductibles, copayments, and coinsurance, while preserving issuer flexibility to make reasonable and customary adjustments from year to year.

Finally, as with the uniform modification provision, States have flexibility to broaden the definition of “same plan.” States may, at their option, permit greater changes to cost-sharing structure, or designate a lower threshold than the “majority” standard in this final rule for changes in provider network and service area, to constitute the same plan. We intend to monitor issues around compliance with the

⁴ Under § 144.103, the term “product” means a discrete package of health insurance coverage benefits that a health insurance issuer offers using a particular product network type within a service area. Examples of product network types include health maintenance organization (HMO), preferred provider organization (PPO), exclusive provider organization (EPO), point of service (POS), and indemnity.

categorization of “plans” and may provide future guidance as necessary.

b. State

We proposed to amend the definition of “State” to exclude application of the Affordable Care Act market reforms under part 147 to issuers in the U.S. Territories of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands. The change codifies HHS’s interpretation, outlined in letters to the Territories on July 16, 2014, that the new provisions of the PHS Act enacted in title I of the Affordable Care Act are appropriately governed by the definition of “State” set forth in that title, and therefore do not apply to group or individual health insurance issuers in the Territories.⁵

As explained in the July 16, 2014 letters and reiterated in the preamble to the proposed rule (79 FR 70681), this interpretation applies only to health insurance that is governed by the PHS Act. It does not affect the PHS Act requirements that were enacted in the Affordable Care Act and incorporated into ERISA and the Code and apply to group health plans (whether insured or self-insured), because such applicability does not rely upon the term “State” as it is defined in either the PHS Act or Affordable Care Act. It also does not affect the PHS Act requirements that were enacted in the Affordable Care Act and apply to non-Federal governmental plans. As a practical matter, therefore, PHS Act, ERISA, and Code requirements applicable to group health plans continue to apply to such coverage, and issuers selling policies to both private sector and public sector employers in the Territories should ensure their products comply with the relevant Affordable Care Act amendments to the PHS Act applicable to group health plans since their customers—the group health plans—are subject to those provisions. These include the prohibition on lifetime and annual limits (section 2711 of the PHS Act), the prohibition on rescissions (section 2712 of the PHS Act), coverage of preventive health services (section 2713 of the PHS Act), and the revised internal and external appeals process (section 2719 of the PHS Act).

We are finalizing these amendments as proposed.

Comment: Several commenters supported the proposed amendments to the term “State” to avoid undermining the stability of the Territories’ health

insurance markets. One commenter encouraged HHS to work with the Territories to improve access to coverage for their residents.

Response: We are committed to partnering with the Territories to ensure their markets are robust and competitive, so that consumers have access to quality, affordable health insurance.

B. Part 147—Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets

1. Guaranteed Availability of Coverage (§ 147.104)

We proposed several modifications to the guaranteed availability requirements under § 147.104. First, we proposed to remove regulation text in § 147.104(b)(2) establishing a special enrollment period (also referred to as a “limited open enrollment period”) for individuals enrolled in non-calendar year individual market plans, because the requirement is incorporated through cross-reference in the same paragraph to the Exchange rules at § 155.420(d)(1)(ii).

Second, we proposed to add new paragraph § 147.104(f), which would move and recodify, with minor modifications for clarity, the requirement under existing § 147.104(b)(2) for non-grandfathered individual and merged market plans to be offered on a calendar year basis.

Third, we proposed to amend § 147.104(b)(4) by adding a cross-reference to the advance availability of special enrollment periods under § 155.420(c)(2). This would align with the Exchange regulations and allow individuals to make a plan selection 60 days before and after certain triggering events when enrolling inside or outside the individual market Exchanges.

Finally, we proposed amending § 147.104(b)(1)(i)(C) to update the citation to the SHOP regulations to conform with changes made in this rulemaking. The cross-reference is changed from § 155.725(a)(2) to § 155.725.

We are finalizing these amendments as proposed.

Comment: Most commenters supported extending the 60-day advance availability provisions to ensure market-wide consistency in special enrollment periods. One commenter recommended a 30-day special enrollment period. Other commenters recommended maintaining the 60-day special enrollment period.

Response: We agree with commenters who urged consistency in access to special enrollment periods inside and outside the individual market

Exchanges. We believe these provisions will help consumers avoid gaps in coverage when they experience certain significant life changes without resulting in adverse selection.

2. Guaranteed Renewability of Coverage (§ 147.106)

Consistent with previous guidance, we proposed that an issuer will not satisfy the requirements for product discontinuation under the guaranteed renewability regulations at § 146.152(c)(2), § 147.106(c)(2), or § 148.122(d)(2) if the issuer automatically enrolls a plan sponsor or individual (as applicable) into a product of another licensed health insurance issuer.⁶ However, this would not prevent an issuer that decides to withdraw from the market in a State from mapping enrollees to a product of another licensed issuer, to the extent permitted by applicable State law, and provided the issuer otherwise satisfies the requirements for market withdrawal.

We stated that allowing an issuer to transfer blocks of business to another issuer could create opportunities for risk segmentation, but also recognized that regulating these matters could have implications for certain corporate reorganization practices. We sought comment on how to interpret the guaranteed renewability provisions in the context of various corporate transactions involving a change of ownership, such as acquisitions, mergers, or other corporate transactions; how common such transactions are and how they are typically structured; whether auto-enrollment should be allowed into a product of the post-transaction issuer; how the market reforms such as the single risk pool provision should be applied; and what protections should be provided to consumers when their product is transferred.

Because ownership transfers have implications for the operational processes of HHS-administered programs, such as advance payments of the premium tax credit, cost-sharing reduction payments, FFE user fees, and the premium stabilization programs, we proposed a notification requirement on

⁶ See Insurance Standards Bulletin, Form and Manner of Notices When Discontinuing or Renewing a Product in the Group or Individual Market, section IV (September 2, 2014). Available at: <http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Renewal-Notices-9-3-14-FINAL.PDF>. See also Patient Protection and Affordable Care Act; Annual Eligibility Redeterminations for Exchange Participation and Insurance Affordability Programs; Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges, 79 FR at 53000 (September 5, 2014).

⁵ See for example, Letter to Virgin Islands on the Definition of State (July 16, 2014). Available at: <http://www.cms.gov/CCIIO/Resources/Letters/Downloads/letter-to-Francis.pdf>.

issuers of a QHP, a plan otherwise subject to risk corridors, or a reinsurance-eligible plan or a risk adjustment covered plan, in cases of changes of ownership. We proposed that the post-transaction issuer notify HHS of the transaction by the date the transaction is entered into or the 30th day prior to the effective date of the transaction, whichever is later. We sought comments on all aspects of the notification, including what further notification requirements should apply to ownership transfers, and whether the notification requirement should apply to all plans subject to the guaranteed renewability requirements, including grandfathered health plans.

We are finalizing the notification requirement in cases of changes of ownership as recognized by the State in which the issuer offers coverage. In light of the comments discussed below, we are not codifying the provision prohibiting an issuer from automatically enrolling plan sponsors or individuals (as applicable) into a product of another licensed health insurance issuer. We intend to consult with the NAIC and other stakeholders before releasing further guidance on this issue.

Comment: Many commenters encouraged HHS to defer to State determinations on matters regarding change of ownership, including when it is appropriate for an issuer to renew coverage through another licensed issuer. One commenter requested that HHS expressly recognize an offer of coverage by an affiliated issuer as an exception to the prohibition on auto-enrollment. Several commenters emphasized the need for continuity of care and recommended that, in cases of mid-year changes of ownership, the acquiring issuer retain some or all of the characteristics of the original plan, such as the same benefits, cost sharing, formulary, and network. Conversely, another commenter noted that the same coverage features rarely remain in place after an ownership transfer. Some commenters recommended HHS work with States and issuers before releasing guidance on how corporate transactions should be handled.

Response: After careful review of the comments submitted on this issue and the relevant statutory language, we are not codifying the prohibition on auto-enrollment into a product of another licensed issuer at this time. We intend to consult with the NAIC and other stakeholders to develop guidance on how to handle corporate transactions involving a change of ownership. We will generally look to the applicable State authority on matters regarding changes of ownership until further

guidance is issued. In the interim, we will continue to apply our interpretation of the guaranteed renewability requirements, set forth in previous guidance,⁷ to prohibit auto-enrollment into a product of another issuer in cases where the auto-enrollment does not occur in connection with a change of ownership.

Comment: Some commenters recommended that HHS provide flexibility to issuers to determine liability of each party in a transaction for advance payments of the premium tax credit, cost-sharing reductions payments, and the premium stabilization programs.

Response: We intend to take these comments into consideration as we consider whether guidance on liability is necessary as it relates to the HHS-administered programs described above.

Comment: In response to the proposed notification requirement for issuers experiencing a change of ownership, some commenters recommended that HHS defer to State definitions of change of ownership. One commenter suggested notice is unnecessary, as QHP issuers in the FFEs must already provide HHS with notice of change of ownership under § 156.330. One commenter recommended issuers be required to provide notice only after a transaction is completed, and sought clarification that HHS will collect only the minimum information necessary to facilitate operational processes and has no intention of collecting the information for purposes other than for continuity of operations.

Response: We are finalizing the proposal to require notification when an issuer experiences a change of ownership, as recognized by the State in which the issuer offers coverage. The definition of change of ownership for the purpose of notification is intended simply to capture situations in which such a change may have operational implications for the above mentioned programs. We recognize that States have existing regulatory processes for reviewing changes of ownership.

We also recognize that FFE issuers are subject to a notification requirement under § 156.330; however, changes of ownership may have operational implications for HHS-administered programs beyond the FFEs. The HHS-administered programs described above affect QHP issuers in both the FFEs and State-based Exchanges, as well as issuers offering plans outside of Exchanges. To work closely with issuers to anticipate and resolve potential issues arising from such transactions,

we are finalizing the notice requirement for an issuer of a QHP, a plan otherwise subject to risk corridors, a risk adjustment covered plan, or a reinsurance-eligible plan, as proposed. We intend to limit the information collected to those elements necessary for HHS and issuers to determine how the change of ownership affects operations of HHS-administered programs. These elements include the legal name, HIOS plan identifier, tax identification number of the original and post-transaction issuers, the effective date of the change of ownership, and the summary description of transaction. Depending on the nature of the transaction, additional information may be necessary to ensure smooth operations of affected programs. We anticipate addressing the need for additional information on a case-by-case basis, through discussion with affected issuers, with the participation of affected issuers.

Finally, we are sensitive to the fluid nature of change of ownership transactions, but believe that our proposed dates for notification accommodate most transactional timelines. In addition, the information we intend to require from issuers is limited in scope and should not substantially burden either issuers or HHS, even if the transaction is not ultimately consummated. To ensure continuity of operations, particularly for administration of monthly payments and charges for advance payments of the premium tax credit and cost-sharing reductions, it is in the interest of both issuers and HHS to coordinate prior to the effective date of the transaction.

C. Part 153—Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment Under the Affordable Care Act

1. Provisions for the State Notice of Benefit and Payment Parameters (§ 153.100)

In § 153.100(c), we established a deadline of March 1 of the calendar year prior to the applicable benefit year for a State to publish a State notice of benefit and payment parameters if the State is required to do so under § 153.100(a) or (b)—that is, if the State is operating a risk adjustment program, or if the State is establishing a reinsurance program and wishes to modify the data requirements for issuers to receive reinsurance payments from those specified in the HHS notice of benefit and payment parameters for the benefit year, wishes to collect additional reinsurance contributions or use

⁷ *Id.*

additional funds for reinsurance payments, or elects to use more than one applicable reinsurance entity. As of the date of publication of this final rule, Connecticut is the only State that has elected to establish a transitional reinsurance program and Massachusetts is the only State that has elected to operate a risk adjustment program. We proposed to modify § 153.100(c) so that the publication deadline for the State notice of benefit and payment parameters would be the later of March 1 of the calendar year prior to the applicable benefit year, or the 30th day following publication of the final HHS notice of benefit and payment parameters for that benefit year.

We are finalizing this modification as proposed.

Comment: One commenter disagreed with our proposal, stating that delaying the publication of the State notices would not give issuers enough time to develop product and rate filings.

Response: Although HHS intends to issue the final HHS notice of benefit and payment parameters in a timely fashion, it is difficult for States to publish such a notice by the required deadline if the final HHS notice of benefit and payment parameters for the applicable benefit year has not yet been published.

2. Provisions and Parameters for the Permanent Risk Adjustment Program

The risk adjustment program is a permanent program created by section 1343 of the Affordable Care Act that transfers funds from lower risk, non-grandfathered plans to higher risk, non-grandfathered plans in the individual and small group markets, inside and outside the Exchanges, to balance risk and maintain market stability. In subparts D and G of the Premium Stabilization Rule, we established standards for the administration of the risk adjustment program. A State that is approved or conditionally approved by the Secretary to operate an Exchange may establish a risk adjustment program, or have HHS do so on its behalf.

a. Risk Adjustment User Fee

If a State is not approved to operate or chooses to forgo operating its own risk adjustment program, HHS will operate risk adjustment on the State's behalf. As described in the 2014 Payment Notice, HHS's operation of risk adjustment on behalf of States is funded through a risk adjustment user fee. Section 153.610(f)(2) provides that an issuer of a risk adjustment covered plan must remit a user fee to HHS equal to the product of its monthly enrollment in the plan and the per-enrollee-per-month

risk adjustment user fee specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year.

OMB Circular No. A-25R establishes Federal policy regarding user fees, and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public. The risk adjustment program will provide special benefits as defined in section 6(a)(1)(b) of Circular No. A-25R to issuers of risk adjustment covered plans because it will mitigate the financial instability associated with potential adverse risk selection. The risk adjustment program also will contribute to consumer confidence in the health insurance industry by helping to stabilize premiums across the individual and small group health insurance markets.

In the 2015 Payment Notice, we estimated Federal administrative expenses of operating the risk adjustment program to be \$0.96 per-enrollee-per-year, based on our estimated contract costs for risk adjustment operations. For the 2016 benefit year, we proposed to use the same methodology to estimate our administrative expenses to operate the program. These contracts cover development of the risk adjustment model and methodology, collections, payments, account management, data collection, data validation, program integrity and audit functions, operational and fraud analytics, stakeholder training, and operational support. To calculate the user fee, we divided HHS's projected total costs for administering the risk adjustment programs on behalf of States by the expected number of enrollees in risk adjustment covered plans in HHS-operated risk adjustment programs for the benefit year (other than plans not subject to market reforms and student health plans, which are not subject to payments and charges under the risk adjustment methodology HHS uses when it operates risk adjustment on behalf of a State).

We estimated that the total cost for HHS to operate the risk adjustment program on behalf of States for 2016 will be approximately \$50 million, and that the risk adjustment user fee would be \$1.75 per enrollee per year. The increased risk adjustment user fee for 2016 is the result of the increased contract costs to support the risk adjustment data validation process when HHS operates risk adjustment, which HHS will administer for the first time in 2016. We are finalizing the proposed methodology for benefit year

2016 and are finalizing a per capita risk adjustment user fee of \$1.75 per enrollee per year, which we will apply as a per-enrollee-per-month risk adjustment user fee of \$0.15.

Comment: One commenter did not support the higher risk adjustment user fee for 2016, noting that issuers are already bearing significant costs for risk adjustment data validation audits, and requested that CMS identify efficiencies that could be leveraged in risk adjustment data validation operations that will keep costs down. Another commenter supported the higher risk adjustment user fee for 2016 to support risk adjustment data validation audits, reiterating the importance of these audits to ensure that the risk adjustment program is as accurate and effective as possible over time. One commenter requested clarification that the risk adjustment user fee is assessed on issuers, not States.

Response: As we stated in the 2014 Payment Notice, we believe that a reliable funding source is necessary to ensure a robust Federal risk adjustment program. We also agree with the commenter that risk adjustment data validation audits are critical to ensure that risk adjustment is as accurate, fair, and effective as possible over time. The risk adjustment user fee was established for the sole purpose of funding HHS's costs for operating the Federal risk adjustment program, and we intend to keep the user fee amount as low as possible. The risk adjustment user fee must be remitted by issuers of risk adjustment covered plans, rather than States.

b. Overview of the HHS Risk Adjustment Model

The HHS risk adjustment model predicts plan liability for an enrollee based on that person's age, sex, and diagnoses (risk factors), producing a risk score. The HHS risk adjustment methodology utilizes separate models for adults, children, and infants to account for cost differences in each of these age groups. In each of the adult and child models, the relative costs assigned to an individual's age, sex, and diagnoses are added together to produce a risk score. Infant risk scores are determined by inclusion in one of 25 mutually exclusive groups based on the infant's maturity and the severity of his or her diagnoses. If applicable, the risk score is multiplied by a cost-sharing reduction adjustment.

The enrollment-weighted average risk score of all enrollees in a particular risk adjustment-covered plan, or the plan liability risk score, within a geographic rating area is one input into the

payment transfer formula, which determines an issuer's transfer (payment or charge) for that plan. Thus, the HHS risk adjustment model predicts individual-level risk scores, but is designed to predict average group costs to account for risk across plans, which, as we stated in the 2014 Payment Notice, accords with the Actuarial Standards Board's Actuarial Standards of Practice for risk classification. We received several general comments about the HHS risk adjustment model.

Comment: Several commenters requested additional guidance about the ICD-10 transition and how the risk adjustment model will implement these changes.

Response: We will publish updated ICD-9 instructions and software and then a combined set of ICD-9 and ICD-10 instructions and software on our Web site, as we did for the original ICD-9 software and instructions, which we have updated annually.⁸ Because ICD-10 codes will be accepted for risk adjustment beginning October 1, 2015, we intend to publish these documents shortly.

Comment: One commenter requested an additional 60 days for review of the risk adjustment recalibration, stating that the 30-day comment period was insufficient to review the model and provide sufficient comments. Another commenter stressed that issuers need 60 to 90 days prior to filing dates to account for final risk adjustment model changes.

Response: We are sympathetic to these concerns; however, we received numerous detailed, substantive comments on the proposed risk adjustment recalibration. Additionally, the timeline for publication of this final rule accommodates many commenters' requests that the final rule be published prior to filing deadlines for the 2016 benefit year.

Comment: One commenter requested that the § 153.420(b) data submission deadline of April 30 of the year following the benefit year be moved to July 31 for the initial year of risk adjustment.

Response: We have been working with issuers to ensure that issuers' data submissions for 2014 benefit year risk adjustment and reinsurance will be complete and accurate by April 30, 2015. We do not intend to delay the final data submission deadline for 2014 risk adjustment (and reinsurance).

c. Proposed Updates to Risk Adjustment Models

We proposed to continue to use the same risk adjustment methodology finalized in the 2014 Payment Notice, with changes to reflect more current data, as described below. As we stated above, in the adult and child models, enrollee health risks are estimated using the HHS risk adjustment methodology, which assigns a set of additive factors that reflect the relative costs of demographics and diagnoses. Risk adjustment factors are developed using claims data and reflect the costs of a given disease relative to average spending. The longer the lag in data used to develop the risk factors, the greater the potential that the costs of treating one disease versus another have changed in a manner not fully reflected in the risk factors.

To provide risk adjustment factors that best reflect more recent treatment patterns and costs, we proposed to recalibrate the HHS risk adjustment models for 2016 by using more recent claims data to develop updated risk factors. The risk factors published in the 2014 Payment Notice for use in 2014 and 2015 were developed using the Truven Health Analytics 2010 MarketScan® Commercial Claims and Encounters database (MarketScan); we proposed to update the risk factors in the HHS risk adjustment models using 2010, 2011, and 2012 MarketScan data. We also proposed that if 2013 MarketScan data becomes available after the publication of the proposed rule, we would update the risk factors in the HHS risk adjustment model using the 3 most recent years of data available—MarketScan 2011, 2012, and 2013 data. These updated risk factors would be published and finalized in this final rule.

We proposed to implement the recalibrated risk adjustment factors in 2016 to provide sufficient time for issuers to account for risk adjustment model changes. However, we also sought comment on making the recalibrated HHS risk adjustment models effective beginning for the 2015 benefit year instead of the 2016 benefit year. We sought comment on this approach, including whether we should update risk factors based on 2013 MarketScan data when it becomes available after publication of the proposed rule, and whether the updated risk factors should be implemented for 2015 or 2016. We are finalizing the HHS risk adjustment recalibration using 2011, 2012, and 2013 MarketScan data to develop final risk adjustment factors to be implemented in the 2016 benefit

year. We are making no changes for the 2015 benefit year.

Comment: Commenters supported recalibrating the risk adjustment model based on the most recent data available, noting that the underlying data is dated and that updating the factors will boost issuers' confidence in the model's predictive power, which could reduce risk selection behaviors and help stabilize premiums. One commenter suggested that we provide simulated results between the proposed 3-year recalibration approach and the 2014 risk adjustment factors for the 2015 benefit year. Another commenter requested that CMS provide a report that includes a detailed analysis of the impact that recalibration may have, including details sufficient for issuers to make adjustments to premium rates as appropriate. Most commenters supported recalibrating for the 2016 benefit year, since 2015 rates have already been set, with some commenters supporting implementation of recalibration in the 2015 benefit year. Commenters supported using 2013 data as long as the data would be available prior to publication of the final 2016 Payment Notice and would be available prior to 2016 rate filings. Other commenters did not support using 2013 MarketScan data, instead suggesting that 2010, 2011, and 2012 data are sufficient.

Response: We agree on the importance of using recent data to calibrate our models. However, we also agree that timely notice of risk adjustment model changes is necessary for orderly rate development. Therefore, we will implement the recalibrated risk adjustment models in the 2016 benefit year. Additionally, because we received and were able to prepare the 2013 MarketScan dataset prior to the publication of this final rule, we have developed the 2016 risk adjustment factors using 2011, 2012, and 2013 MarketScan data. We believe this incorporation allows for the use of the most recent data available to HHS, while giving issuers the notice required for rate setting for the 2016 benefit year. We will continue to assess how we may ameliorate the data lag in future recalibrations. We believe that the transfer equation provided in the 2014 Payment Notice and the updated risk adjustment factors provided in this final Payment Notice are sufficient for issuers to evaluate the impact of risk adjustment on their rate development for 2016.

We believe that using multiple years of data will promote market stability and minimize volatility in coefficients for certain rare diagnoses. In using multiple years of data to recalibrate the

⁸ The HHS-Developed Risk Adjustment Model Algorithm Software and Instructions are available at: <http://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/index.html> under "Regulations & Guidance" (posted under "Guidance" on June 2, 2014).

risk adjustment model, we considered either pooling data from 3 sample years or averaging coefficients from three separately estimated calibrations, based on the 2010, 2011, and 2012 data, and sought comment on the two approaches. We examined the effects of pooling data and averaging separate calibrations, and did not find a quantitatively important difference between the resulting coefficients. However, we believe that averaging coefficients offers the advantage of transparency and ease in future recalibrations. Averaging coefficients using the 3 most recent years of separately estimated calibrations allows for most recent data to be incorporated into the model, while ensuring that coefficients remain relatively stable, and are therefore finalizing our approach to average the coefficients from 3 separately estimated sample years. Below we publish the R-squared statistics of the 3 separately estimated sample years' estimates, and the blended coefficient for each risk adjustment factor.

Comment: Commenters supported the transparency and ease of averaging coefficients from three separately estimated calibrations, with one commenter recommending that we consider statistical best practices in the decision as to whether to average coefficients or pool data. Another commenter requested that we average coefficients, validate the results using pooled data, and publish a report detailing the results of the two methods.

Response: We carefully considered the two approaches, noting the benefits of each approach—transparency with averaging, and a single R-squared statistic and larger sample sizes for each model with pooling. However, when we compared the coefficients from both approaches, we did not find quantitatively important differences across the coefficients. We will continue to evaluate the coefficient averaging approach and consider any refinements in future recalibrations.

We made minor refinements to the underlying MarketScan recalibration samples from which the risk adjustment factors are derived. In particular, we changed our treatment of Age 0 infants without birth hierarchical condition categories (HCCs). There may be cases in which there is no separate infant birth claim from which to gather diagnoses. For example, mother and infant claims may be bundled such that infant diagnoses appear on the mother's record. Where newborn diagnoses appear on the mother's claims, HHS has issued operational guidance on how

best to associate those codes with the appropriate infant.⁹

However, we proposed a change in how we categorize age 0 infants who do not have birth codes. We previously stated in the operational guidance referenced above that infants without birth codes would be assigned an "Age 0, Term" factor in risk adjustment operations. We did so under the assumption that issuers paid the birth costs, yet the birth HCCs were missing (perhaps because claims were bundled with the mother's, whose claims were excluded). Upon further analysis of age 0 and age 1 claims, we found that age 0 infants without birth HCCs had costs more similar to age 1 infants by severity level. We believe that these infants should be assigned to age 1 in situations where the issuer did not pay the birth costs during the plan year. For many age 0 infants without birth HCCs, the birth could have occurred in the prior year or was paid for by a different issuer. We proposed that age 0 infants without birth HCCs be assigned to "Age 1" by severity level. We have made this change in the recalibration samples that we are using to calculate risk factors for proposed implementation in the 2016 benefit year. We also proposed to make this change in the operation of the risk adjustment methodology for the year in which we would implement the recalibrated risk adjustment factors. We are finalizing our approach as proposed, for implementation in the 2016 benefit year with the recalibrated risk adjustment models.

Comment: Some commenters supported our reassignment of age 0 infants without birth codes from "Age 0, Term" to "Age 1, severity level," noting the reduction in the factor that occurs from these infants' reassignment. Other commenters disagreed with our reassignment of age 0 infants without birth codes to "Age 1, severity level." Commenters suggested that bundling claims is standard industry practice and infants on bundled claims without birth codes should be assigned to "Age 0, Term," while another commenter suggested that this reassignment would result in incorrect payments for infant claims with discharge dates that overlap benefit years.

Response: In previous guidance, we have stated that issuers should unbundle claims to receive credit for all diagnoses. We believe that many age 0 infants without birth codes more closely resemble the risk profiles of age 1

infants. In many cases, the birth codes have been appropriately excluded due to a birth in the previous year or a change in insurance status. We will continue to treat infants with discharge dates that overlap benefit years as age 0, unless they do not have birth codes, in which case we would assign them to "age 1, severity level," as with age 0 infants without birth codes whose discharge dates do not overlap benefit years.

d. List of Factors To Be Employed in the Model

The HHS risk adjustment models predict annualized plan liability expenditures using age and sex categories and the HHS HCCs included in the HHS risk adjustment model. Dollar coefficients were estimated for these factors using weighted least squares regression, where the weight was the fraction of the year enrolled.

We are including the same HCCs that were included in the original risk adjustment calibration in the 2014 Payment Notice. For each model, the factors are the statistical regression dollar values for each HCC in the model divided by a weighted average plan liability for the full modeling sample. The factors represent the predicted relative incremental expenditures for each HCC. The proposed factors resulting from the averaged factors from the 2011, 2012, and 2013 separately solved models are shown in the tables below. For a given enrollee, the sums of the factors for the enrollee's HCCs are the total relative predicted expenditures for that enrollee. Table 1 contains the factors for each adult model, including the interactions. Table 3 contains the factors for each child model. Table 4 contains the factors for each infant model.

Comment: One commenter requested that HHS provide the rationale for the modification of the child model transplant factors.

Response: We constrained the six transplant status HCC coefficients (other than kidney) in the child model. The sample sizes of transplants are smaller in the child than the adult model. The levels and changes in the child transplant relative coefficients appeared to be dominated by random instability and therefore, we believe the accuracy of the model will be improved by constraining these coefficients. We intend to monitor the child transplant relative coefficients, and adjust them if needed in future recalibrations.

Comment: Several commenters suggested that the model is not equipped to accurately account for the introduction of new treatments, and

⁹ HHS-Developed Risk Adjustment Model Algorithm Software Instructions. June 2, 2014. <http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/DIY-instructions-5-20-14.pdf>

recommended that HHS add drug utilization or selected classes of prescription medicines to the list of risk adjustment model factors. Commenters suggested that plans placing medications to treat serious chronic diseases on formulary tiers with the highest cost sharing is evidence that current plan designs discourage enrollment by higher-risk enrollees, which suggests that the current risk adjustment model is not effectively reducing plans' incentives to design benefits that discourage enrollment by higher risk and higher cost patients. One commenter recommended that HHS evaluate additional medical conditions

or characteristics for new enrollees which may indicate future expenditures. Another commenter suggested that HHS analyze the difference between Truven and Medicaid claim variables for age 0–1 and that HHS assess the impact of habilitative and Medicaid-like benefits on costs which are generally not present in commercial claims. Lastly, a commenter suggested that the risk adjustment factors may be more appropriately calculated and applied regionally.

Response: As stated above, we wish to use the same risk adjustment models finalized in the 2014 Payment Notice,

with changes to reflect more current data. We did not intend to change the models' structure, for example by including pharmacy utilization. However, we will continue to consider including prescription drug data in future model recalibrations. Similarly, we intend to evaluate additional medical conditions and characteristics for new enrollees which may indicate future expenditures, including through Medicaid claims comparisons. The risk adjustment methodology takes into account Statewide average premium and geographic rating area in the transfer formula.

TABLE 1—ADULT RISK ADJUSTMENT MODEL FACTORS

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors					
Age 21–24, Male	0.250	0.202	0.139	0.076	0.070
Age 25–29, Male	0.260	0.208	0.141	0.074	0.067
Age 30–34, Male	0.311	0.248	0.168	0.083	0.075
Age 35–39, Male	0.375	0.302	0.209	0.109	0.099
Age 40–44, Male	0.459	0.374	0.269	0.149	0.138
Age 45–49, Male	0.548	0.451	0.334	0.198	0.184
Age 50–54, Male	0.701	0.584	0.445	0.273	0.255
Age 55–59, Male	0.814	0.681	0.529	0.339	0.319
Age 60–64, Male	0.982	0.824	0.650	0.428	0.404
Age 21–24, Female	0.408	0.326	0.208	0.089	0.078
Age 25–29, Female	0.505	0.406	0.271	0.130	0.116
Age 30–34, Female	0.634	0.520	0.376	0.222	0.207
Age 35–39, Female	0.735	0.612	0.466	0.308	0.292
Age 40–44, Female	0.824	0.689	0.532	0.358	0.340
Age 45–49, Female	0.849	0.709	0.548	0.361	0.343
Age 50–54, Female	0.962	0.809	0.636	0.420	0.397
Age 55–59, Female	0.989	0.830	0.652	0.427	0.403
Age 60–64, Female	1.088	0.911	0.720	0.473	0.447
Diagnosis Factors					
HIV/AIDS	6.157	5.598	5.302	5.310	5.315
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	12.643	12.435	12.334	12.417	12.429
Central Nervous System Infections, Except Viral Meningitis	7.550	7.419	7.353	7.389	7.394
Viral or Unspecified Meningitis	5.290	5.002	4.868	4.805	4.803
Opportunistic Infections	10.151	10.027	9.969	9.964	9.963
Metastatic Cancer	26.334	25.786	25.486	25.597	25.610
Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	12.032	11.615	11.394	11.418	11.421
Non-Hodgkin's Lymphomas and Other Cancers and Tumors	6.543	6.254	6.097	6.045	6.039
Colorectal, Breast (Age <50), Kidney, and Other Cancers	5.929	5.641	5.482	5.426	5.420
Breast (Age 50+) and Prostate Cancer, Benign/Uncertain	3.447	3.235	3.117	3.051	3.043
Brain Tumors, and Other Cancers and Tumors	1.651	1.476	1.368	1.239	1.224
Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors	1.651	1.476	1.368	1.239	1.224
Pancreas Transplant Status/Complications	6.947	6.726	6.616	6.645	6.650
Diabetes with Acute Complications	1.344	1.193	1.100	0.959	0.942
Diabetes with Chronic Complications	1.344	1.193	1.100	0.959	0.942
Diabetes without Complication	1.344	1.193	1.100	0.959	0.942
Protein-Calorie Malnutrition	15.443	15.449	15.444	15.532	15.541
Mucopolysaccharidosis	2.379	2.239	2.160	2.088	2.080
Lipidoses and Glycogenosis	2.379	2.239	2.160	2.088	2.080
Amyloidosis, Porphyria, and Other Metabolic Disorders	2.379	2.239	2.160	2.088	2.080
Adrenal, Pituitary, and Other Significant Endocrine Disorders	2.379	2.239	2.160	2.088	2.080
Liver Transplant Status/Complications	16.879	16.651	16.547	16.575	16.581
End-Stage Liver Disease	6.272	5.972	5.825	5.852	5.857
Cirrhosis of Liver	2.548	2.348	2.252	2.213	2.210

TABLE 1—ADULT RISK ADJUSTMENT MODEL FACTORS—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Chronic Hepatitis	2.339	2.170	2.077	1.994	1.987
Acute Liver Failure/Disease, Including Neonatal Hepatitis	4.521	4.324	4.225	4.215	4.216
Intestine Transplant Status/Complications	41.078	41.016	40.976	41.009	41.010
Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	13.554	13.224	13.049	13.108	13.115
Intestinal Obstruction	7.453	7.114	6.952	6.996	7.004
Chronic Pancreatitis	6.273	5.985	5.849	5.891	5.898
Acute Pancreatitis/Other Pancreatic Disorders and Intestinal Malabsorption	3.183	2.950	2.834	2.778	2.772
Inflammatory Bowel Disease	3.283	2.988	2.831	2.693	2.677
Necrotizing Fasciitis	7.506	7.254	7.120	7.153	7.157
Bone/Joint/Muscle Infections/Necrosis	7.506	7.254	7.120	7.153	7.157
Rheumatoid Arthritis and Specified Autoimmune Disorders	3.834	3.534	3.373	3.349	3.348
Systemic Lupus Erythematosus and Other Autoimmune Disorders	1.306	1.154	1.066	0.949	0.936
Osteogenesis Imperfecta and Other Osteodystrophies	3.633	3.399	3.262	3.188	3.179
Congenital/Developmental Skeletal and Connective Tissue Disorders	3.633	3.399	3.262	3.188	3.179
Cleft Lip/Cleft Palate	1.639	1.453	1.348	1.246	1.236
Hemophilia	46.716	46.362	46.145	46.164	46.167
Myelodysplastic Syndromes and Myelofibrosis	13.937	13.773	13.686	13.711	13.714
Aplastic Anemia	13.937	13.773	13.686	13.711	13.714
Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	10.383	10.181	10.065	10.058	10.057
Sickle Cell Anemia (Hb-SS)	10.383	10.181	10.065	10.058	10.057
Thalassemia Major	10.383	10.181	10.065	10.058	10.057
Combined and Other Severe Immunodeficiencies	5.543	5.353	5.257	5.270	5.272
Disorders of the Immune Mechanism	5.543	5.353	5.257	5.270	5.272
Coagulation Defects and Other Specified Hematological Disorders	3.203	3.085	3.015	2.982	2.978
Drug Psychosis	3.915	3.627	3.471	3.346	3.332
Drug Dependence	3.915	3.627	3.471	3.346	3.332
Schizophrenia	3.294	3.004	2.852	2.750	2.741
Major Depressive and Bipolar Disorders	1.889	1.703	1.590	1.449	1.433
Reactive and Unspecified Psychosis, Delusional Disorders	1.889	1.703	1.590	1.449	1.433
Personality Disorders	1.234	1.097	0.994	0.840	0.822
Anorexia/Bulimia Nervosa	2.860	2.670	2.560	2.473	2.462
Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	2.958	2.806	2.723	2.663	2.655
Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes	1.262	1.152	1.073	0.972	0.960
Autistic Disorder	1.234	1.097	0.994	0.840	0.822
Pervasive Developmental Disorders, Except Autistic Disorder	1.234	1.097	0.994	0.840	0.822
Traumatic Complete Lesion Cervical Spinal Cord	14.620	14.420	14.307	14.313	14.313
Quadriplegia	14.620	14.420	14.307	14.313	14.313
Traumatic Complete Lesion Dorsal Spinal Cord	10.397	10.195	10.085	10.079	10.078
Paraplegia	10.397	10.195	10.085	10.079	10.078
Spinal Cord Disorders/Injuries	6.455	6.200	6.068	6.041	6.039
Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	3.907	3.620	3.478	3.430	3.427
Quadriplegic Cerebral Palsy	1.158	0.914	0.795	0.709	0.701
Cerebral Palsy, Except Quadriplegic	0.126	0.080	0.050	0.020	0.017
Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies	0.090	0.021	0.000	0.000	0.000
Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	5.561	5.383	5.290	5.262	5.259
Muscular Dystrophy	2.284	2.088	1.993	1.902	1.893
Multiple Sclerosis	9.513	9.024	8.764	8.834	8.842
Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders	2.284	2.088	1.993	1.902	1.893
Seizure Disorders and Convulsions	1.588	1.408	1.305	1.202	1.192
Hydrocephalus	8.049	7.897	7.806	7.777	7.773
Non-Traumatic Coma, and Brain Compression/Anoxic Damage	10.501	10.329	10.227	10.228	10.227
Respirator Dependence/Tracheostomy Status	40.044	40.031	40.014	40.103	40.113
Respiratory Arrest	12.390	12.191	12.082	12.179	12.191
Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes	12.390	12.191	12.082	12.179	12.191
Heart Assistive Device/Artificial Heart	37.771	37.451	37.284	37.380	37.392
Heart Transplant	37.771	37.451	37.284	37.380	37.392
Congestive Heart Failure	3.598	3.462	3.391	3.390	3.391

TABLE 1—ADULT RISK ADJUSTMENT MODEL FACTORS—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Acute Myocardial Infarction	11.768	11.329	11.100	11.278	11.300
Unstable Angina and Other Acute Ischemic Heart Disease	6.075	5.719	5.555	5.592	5.600
Heart Infection/Inflammation, Except Rheumatic	7.146	6.980	6.891	6.869	6.867
Specified Heart Arrhythmias	3.350	3.170	3.073	3.007	3.000
Intracranial Hemorrhage	11.056	10.700	10.519	10.548	10.554
Ischemic or Unspecified Stroke	4.012	3.770	3.665	3.685	3.690
Cerebral Aneurysm and Arteriovenous Malformation	4.709	4.455	4.331	4.287	4.284
Hemiplegia/Hemiparesis	6.343	6.218	6.155	6.223	6.231
Monoplegia, Other Paralytic Syndromes	3.968	3.805	3.724	3.700	3.699
Atherosclerosis of the Extremities with Ulceration or Gangrene	12.395	12.261	12.194	12.299	12.311
Vascular Disease with Complications	8.583	8.349	8.230	8.246	8.249
Pulmonary Embolism and Deep Vein Thrombosis	4.542	4.335	4.229	4.206	4.204
Lung Transplant Status/Complications	37.791	37.528	37.388	37.504	37.517
Cystic Fibrosis	12.367	11.975	11.747	11.763	11.764
Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	1.090	0.958	0.871	0.762	0.750
Asthma	1.090	0.958	0.871	0.762	0.750
Fibrosis of Lung and Other Lung Disorders	2.365	2.217	2.143	2.098	2.093
Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	8.585	8.482	8.429	8.454	8.457
Kidney Transplant Status	11.146	10.803	10.642	10.645	10.649
End Stage Renal Disease	42.543	42.217	42.036	42.222	42.243
Chronic Kidney Disease, Stage 5	2.440	2.308	2.248	2.244	2.245
Chronic Kidney Disease, Severe (Stage 4)	2.440	2.308	2.248	2.244	2.245
Ectopic and Molar Pregnancy, Except with Renal Failure, Shock, or Embolism	1.455	1.260	1.139	0.891	0.856
Miscarriage with Complications	1.455	1.260	1.139	0.891	0.856
Miscarriage with No or Minor Complications	1.455	1.260	1.139	0.891	0.856
Completed Pregnancy With Major Complications	4.050	3.489	3.288	3.066	3.065
Completed Pregnancy With Complications	4.050	3.489	3.288	3.066	3.065
Completed Pregnancy with No or Minor Complications	4.050	3.489	3.288	3.066	3.065
Chronic Ulcer of Skin, Except Pressure	2.575	2.425	2.354	2.337	2.337
Hip Fractures and Pathological Vertebral or Humerus Fractures	10.290	10.016	9.873	9.943	9.951
Pathological Fractures, Except of Vertebrae, Hip, or Humerus	2.010	1.868	1.782	1.681	1.669
Stem Cell, Including Bone Marrow, Transplant Status/Complications	34.090	34.078	34.067	34.095	34.098
Artificial Openings for Feeding or Elimination	11.500	11.373	11.306	11.372	11.379
Amputation Status, Lower Limb/Amputation Complications	5.978	5.779	5.679	5.721	5.728
Severe illness x Opportunistic Infections	12.043	12.306	12.433	12.560	12.572
Severe illness x Metastatic Cancer	12.043	12.306	12.433	12.560	12.572
Severe illness x Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	12.043	12.306	12.433	12.560	12.572
Severe illness x Non-Hodgkin's Lymphomas and Other Cancers and Tumors	12.043	12.306	12.433	12.560	12.572
Severe illness x Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	12.043	12.306	12.433	12.560	12.572
Severe illness x Heart Infection/Inflammation, Except Rheumatic	12.043	12.306	12.433	12.560	12.572
Severe illness x Intracranial Hemorrhage	12.043	12.306	12.433	12.560	12.572
Severe illness x HCC group G06 (G06 is HCC Group 6 which includes the following HCCs in the blood disease category: 67, 68)	12.043	12.306	12.433	12.560	12.572
Severe illness x HCC group G08 (G08 is HCC Group 8 which includes the following HCCs in the blood disease category: 73, 74)	12.043	12.306	12.433	12.560	12.572
Severe illness x End-Stage Liver Disease	2.634	2.785	2.855	2.974	2.984
Severe illness x Acute Liver Failure/Disease, Including Neonatal Hepatitis	2.634	2.785	2.855	2.974	2.984
Severe illness x Atherosclerosis of the Extremities with Ulceration or Gangrene	2.634	2.785	2.855	2.974	2.984
Severe illness x Vascular Disease with Complications	2.634	2.785	2.855	2.974	2.984
Severe illness x Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	2.634	2.785	2.855	2.974	2.984
Severe illness x Artificial Openings for Feeding or Elimination	2.634	2.785	2.855	2.974	2.984

TABLE 1—ADULT RISK ADJUSTMENT MODEL FACTORS—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Severe illness x HCC group G03 (G03 is HCC Group 3 which includes the following HCCs in the musculo-skeletal disease category: 54, 55)	2.634	2.785	2.855	2.974	2.984

TABLE 2—HHS HCCs IN THE SEVERITY ILLNESS INDICATOR VARIABLE

Description
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock. Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis. Seizure Disorders and Convulsions. Non-Traumatic Coma, Brain Compression/Anoxic Damage. Respirator Dependence/Tracheostomy Status. Respiratory Arrest. Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes. Pulmonary Embolism and Deep Vein Thrombosis.

TABLE 3—CHILD RISK ADJUSTMENT MODEL FACTORS

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors					
Age 2–4, Male	0.262	0.191	0.097	0.016	0.009
Age 5–9, Male	0.179	0.128	0.058	0.000	0.000
Age 10–14, Male	0.229	0.176	0.099	0.034	0.028
Age 15–20, Male	0.302	0.241	0.161	0.084	0.077
Age 2–4, Female	0.212	0.150	0.066	0.004	0.002
Age 5–9, Female	0.141	0.095	0.036	0.000	0.000
Age 10–14, Female	0.213	0.162	0.093	0.037	0.033
Age 15–20, Female	0.358	0.283	0.180	0.079	0.070
Diagnosis Factors					
HIV/AIDS	3.905	3.443	3.195	3.035	3.022
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	19.194	19.011	18.921	18.952	18.957
Central Nervous System Infections, Except Viral Meningitis	12.691	12.467	12.344	12.356	12.357
Viral or Unspecified Meningitis	3.766	3.517	3.386	3.226	3.210
Opportunistic Infections	25.545	25.461	25.417	25.403	25.402
Metastatic Cancer	40.241	39.934	39.739	39.739	39.738
Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	13.408	13.064	12.852	12.768	12.758
Non-Hodgkin's Lymphomas and Other Cancers and Tumors	10.279	9.971	9.778	9.654	9.639
Colorectal, Breast (Age < 50), Kidney, and Other Cancers Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors	4.078	3.830	3.661	3.498	3.479
Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors	3.274	3.044	2.901	2.749	2.731
Pancreas Transplant Status/Complications	1.832	1.650	1.520	1.360	1.342
Diabetes with Acute Complications	35.005	34.817	34.724	34.753	34.755
Diabetes with Chronic Complications	2.695	2.350	2.169	1.832	1.794
Diabetes without Complication	2.695	2.350	2.169	1.832	1.794
Protein-Calorie Malnutrition	2.695	2.350	2.169	1.832	1.794
Mucopolysaccharidosis	15.577	15.458	15.387	15.437	15.442
Lipidoses and Glycogenosis	6.759	6.440	6.245	6.182	6.176
Congenital Metabolic Disorders, Not Elsewhere Classified Amyloidosis, Porphyria, and Other Metabolic Disorders	6.759	6.440	6.245	6.182	6.176
Adrenal, Pituitary, and Other Significant Endocrine Disorders	6.759	6.440	6.245	6.182	6.176
Liver Transplant Status/Complications	6.759	6.440	6.245	6.182	6.176
End-Stage Liver Disease	35.005	34.817	34.724	34.753	34.755
Cirrhosis of Liver	15.326	15.150	15.059	15.061	15.063
Chronic Hepatitis	10.171	9.978	9.868	9.837	9.836
Acute Liver Failure/Disease, Including Neonatal Hepatitis	1.316	1.149	1.025	0.917	0.908
Intestine Transplant Status/Complications	10.916	10.745	10.640	10.615	10.614
Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	35.005	34.817	34.724	34.753	34.755
.....	17.618	17.189	16.947	16.982	16.986

TABLE 3—CHILD RISK ADJUSTMENT MODEL FACTORS—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Intestinal Obstruction	6.347	6.064	5.897	5.782	5.768
Chronic Pancreatitis	11.190	10.860	10.691	10.687	10.687
Acute Pancreatitis/Other Pancreatic Disorders and Intestinal Malabsorption	3.182	3.026	2.921	2.791	2.774
Inflammatory Bowel Disease	6.004	5.576	5.331	5.179	5.161
Necrotizing Fasciitis	5.256	4.965	4.789	4.706	4.699
Bone/Joint/Muscle Infections/Necrosis	5.256	4.965	4.789	4.706	4.699
Rheumatoid Arthritis and Specified Autoimmune Disorders	3.436	3.177	3.005	2.858	2.843
Systemic Lupus Erythematosus and Other Autoimmune Disorders	1.257	1.086	0.962	0.795	0.775
Osteogenesis Imperfecta and Other Osteodystrophies	1.796	1.655	1.544	1.435	1.421
Congenital/Developmental Skeletal and Connective Tissue Disorders	1.796	1.655	1.544	1.435	1.421
Cleft Lip/Cleft Palate	1.859	1.618	1.468	1.300	1.281
Hemophilia	59.085	58.511	58.167	58.146	58.143
Myelodysplastic Syndromes and Myelofibrosis	21.395	21.190	21.067	21.051	21.050
Aplastic Anemia	21.395	21.190	21.067	21.051	21.050
Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	8.368	8.039	7.846	7.752	7.742
Sickle Cell Anemia (Hb-SS)	8.368	8.039	7.846	7.752	7.742
Thalassemia Major	8.368	8.039	7.846	7.752	7.742
Combined and Other Severe Immunodeficiencies	7.081	6.862	6.737	6.659	6.649
Disorders of the Immune Mechanism	7.081	6.862	6.737	6.659	6.649
Coagulation Defects and Other Specified Hematological Disorders	5.332	5.169	5.053	4.945	4.932
Drug Psychosis	5.134	4.831	4.672	4.584	4.576
Drug Dependence	5.134	4.831	4.672	4.584	4.576
Schizophrenia	5.630	5.184	4.940	4.795	4.784
Major Depressive and Bipolar Disorders	2.003	1.776	1.618	1.392	1.366
Reactive and Unspecified Psychosis, Delusional Disorders	1.974	1.745	1.588	1.360	1.334
Personality Disorders	0.857	0.726	0.603	0.390	0.363
Anorexia/Bulimia Nervosa	2.863	2.630	2.484	2.385	2.374
Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	3.910	3.649	3.524	3.486	3.481
Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes	1.795	1.582	1.460	1.334	1.320
Autistic Disorder	1.899	1.691	1.543	1.329	1.304
Pervasive Developmental Disorders, Except Autistic Disorder	0.958	0.819	0.685	0.447	0.417
Traumatic Complete Lesion Cervical Spinal Cord	14.568	14.494	14.454	14.554	14.565
Quadriplegia	14.568	14.494	14.454	14.554	14.565
Traumatic Complete Lesion Dorsal Spinal Cord	12.632	12.373	12.237	12.245	12.248
Paraplegia	12.632	12.373	12.237	12.245	12.248
Spinal Cord Disorders/Injuries	5.814	5.533	5.376	5.274	5.263
Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	10.349	10.046	9.870	9.821	9.813
Quadriplegic Cerebral Palsy	4.321	3.997	3.842	3.871	3.876
Cerebral Palsy, Except Quadriplegic	1.066	0.840	0.715	0.595	0.582
Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies	1.352	1.182	1.075	0.973	0.961
Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	10.325	10.110	9.984	9.926	9.919
Muscular Dystrophy	3.561	3.323	3.187	3.077	3.064
Multiple Sclerosis	6.515	6.125	5.899	5.854	5.850
Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders	3.561	3.323	3.187	3.077	3.064
Seizure Disorders and Convulsions	2.308	2.110	1.968	1.774	1.751
Hydrocephalus	6.416	6.260	6.175	6.167	6.166
Non-Traumatic Coma, and Brain Compression/Anoxic Damage	9.357	9.165	9.058	9.011	9.005
Respirator Dependence/Tracheostomy Status	43.573	43.432	43.370	43.553	43.572
Respiratory Arrest	14.726	14.485	14.364	14.374	14.375
Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes	14.726	14.485	14.364	14.374	14.375
Heart Assistive Device/Artificial Heart	35.005	34.817	34.724	34.753	34.755
Heart Transplant	35.005	34.817	34.724	34.753	34.755
Congestive Heart Failure	7.529	7.399	7.313	7.259	7.252
Acute Myocardial Infarction	8.526	8.355	8.262	8.268	8.270
Unstable Angina and Other Acute Ischemic Heart Disease	4.832	4.731	4.675	4.688	4.692
Heart Infection/Inflammation, Except Rheumatic	18.137	17.976	17.883	17.866	17.865
Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders	7.760	7.525	7.350	7.178	7.156

TABLE 3—CHILD RISK ADJUSTMENT MODEL FACTORS—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Major Congenital Heart/Circulatory Disorders	2.184	2.053	1.918	1.752	1.734
Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders	1.355	1.243	1.121	0.985	0.970
Specified Heart Arrhythmias	5.208	4.988	4.842	4.750	4.739
Intracranial Hemorrhage	19.273	18.970	18.808	18.815	18.816
Ischemic or Unspecified Stroke	8.661	8.495	8.414	8.461	8.466
Cerebral Aneurysm and Arteriovenous Malformation	4.442	4.184	4.044	3.962	3.950
Hemiplegia/Hemiparesis	6.306	6.169	6.101	6.077	6.074
Monoplegia, Other Paralytic Syndromes	4.394	4.195	4.095	4.052	4.049
Atherosclerosis of the Extremities with Ulceration or Gangrene	15.443	15.201	15.064	14.935	14.918
Vascular Disease with Complications	17.744	17.530	17.416	17.432	17.433
Pulmonary Embolism and Deep Vein Thrombosis	16.259	16.035	15.925	15.959	15.964
Lung Transplant Status/Complications	35.005	34.817	34.724	34.753	34.755
Cystic Fibrosis	14.929	14.393	14.082	14.107	14.110
Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	0.519	0.439	0.332	0.187	0.170
Asthma	0.519	0.439	0.332	0.187	0.170
Fibrosis of Lung and Other Lung Disorders	4.441	4.279	4.165	4.066	4.055
Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	9.634	9.540	9.477	9.494	9.494
Kidney Transplant Status	16.696	16.265	16.038	16.049	16.054
End Stage Renal Disease	38.999	38.735	38.594	38.720	38.733
Chronic Kidney Disease, Stage 5	8.885	8.683	8.557	8.433	8.417
Chronic Kidney Disease, Severe (Stage 4)	8.885	8.683	8.557	8.433	8.417
Ectopic and Molar Pregnancy, Except with Renal Failure, Shock, or Embolism	1.245	1.056	0.919	0.640	0.606
Miscarriage with Complications	1.245	1.056	0.919	0.640	0.606
Miscarriage with No or Minor Complications	1.245	1.056	0.919	0.640	0.606
Completed Pregnancy With Major Complications	3.528	3.009	2.801	2.513	2.500
Completed Pregnancy With Complications	3.528	3.009	2.801	2.513	2.500
Completed Pregnancy with No or Minor Complications	3.528	3.009	2.801	2.513	2.500
Chronic Ulcer of Skin, Except Pressure	1.703	1.596	1.500	1.407	1.397
Hip Fractures and Pathological Vertebral or Humerus Fractures	6.420	6.099	5.893	5.758	5.744
Pathological Fractures, Except of Vertebrae, Hip, or Humerus	1.784	1.641	1.509	1.327	1.308
Stem Cell, Including Bone Marrow, Transplant Status/Complications	35.005	34.817	34.724	34.753	34.755
Artificial Openings for Feeding or Elimination	16.599	16.457	16.401	16.574	16.594
Amputation Status, Lower Limb/Amputation Complications	9.440	9.135	8.972	8.856	8.841

TABLE 4—INFANT RISK ADJUSTMENT MODELS FACTORS

Group	Platinum	Gold	Silver	Bronze	Catastrophic
Extremely Immature *, Severity Level 5 (Highest)	434.244	432.604	431.540	431.548	431.554
Extremely Immature *, Severity Level 4	218.568	216.965	215.930	215.892	215.892
Extremely Immature *, Severity Level 3	63.306	62.118	61.302	60.931	60.895
Extremely Immature *, Severity Level 2	63.306	62.118	61.302	60.931	60.895
Extremely Immature *, Severity Level 1 (Lowest)	63.306	62.118	61.302	60.931	60.895
Immature *, Severity Level 5 (Highest)	218.648	217.060	216.033	216.039	216.046
Immature *, Severity Level 4	97.820	96.171	95.105	95.087	95.091
Immature *, Severity Level 3	56.283	54.855	53.924	53.770	53.758
Immature *, Severity Level 2	33.845	32.464	31.571	31.302	31.279
Immature *, Severity Level 1 (Lowest)	33.845	32.464	31.571	31.302	31.279
Premature/Multiples *, Severity Level 5 (Highest)	177.856	176.320	175.329	175.253	175.251
Premature/Multiples *, Severity Level 4	36.022	34.500	33.543	33.349	33.338
Premature/Multiples *, Severity Level 3	19.582	18.378	17.607	17.163	17.121
Premature/Multiples *, Severity Level 2	10.730	9.739	9.072	8.420	8.342
Premature/Multiples *, Severity Level 1 (Lowest)	7.152	6.431	5.831	5.073	4.987
Term *, Severity Level 5 (Highest)	155.054	153.597	152.653	152.503	152.492
Term *, Severity Level 4	19.318	18.169	17.434	16.891	16.841
Term *, Severity Level 3	7.022	6.305	5.738	4.947	4.851
Term *, Severity Level 2	4.219	3.676	3.163	2.300	2.193
Term *, Severity Level 1 (Lowest)	1.785	1.511	1.033	0.268	0.196
Age 1 *, Severity Level 5 (Highest)	42.616	41.994	41.549	41.337	41.318
Age 1 *, Severity Level 4	7.142	6.731	6.402	6.146	6.123
Age 1 *, Severity Level 3	2.678	2.410	2.191	1.927	1.899
Age 1 *, Severity Level 2	1.625	1.426	1.231	0.958	0.931

TABLE 4—INFANT RISK ADJUSTMENT MODELS FACTORS—Continued

Group	Platinum	Gold	Silver	Bronze	Catastrophic
Age 1 *, Severity Level 1 (Lowest)	0.636	0.527	0.321	0.138	0.124
Age 0 Male	0.728	0.673	0.659	0.607	0.594
Age 1 Male	0.158	0.137	0.128	0.094	0.090

TABLE 5—HHS HCCS INCLUDED IN INFANT MODEL MATURITY CATEGORIES

Maturity category	HCC/Description
Extremely Immature	Extremely Immature Newborns, Birthweight <500 Grams.
Extremely Immature	Extremely Immature Newborns, Including Birthweight 500–749 Grams.
Extremely Immature	Extremely Immature Newborns, Including Birthweight 750–999 Grams.
Immature	Premature Newborns, Including Birthweight 1000–1499 Grams.
Immature	Premature Newborns, Including Birthweight 1500–1999 Grams.
Premature/Multiples	Premature Newborns, Including Birthweight 2000–2499 Grams.
Premature/Multiples	Other Premature, Low Birthweight, Malnourished, or Multiple Birth Newborns.
Term	Term or Post-Term Singleton Newborn, Normal or High Birthweight.
Age 1	All age 1 infants.

TABLE 6—HHS HCCS INCLUDED IN INFANT MODEL SEVERITY CATEGORIES

Severity category	HCC
Severity Level 5 (Highest)	Metastatic Cancer.
Severity Level 5	Pancreas Transplant Status/Complications.
Severity Level 5	Liver Transplant Status/Complications.
Severity Level 5	End-Stage Liver Disease.
Severity Level 5	Intestine Transplant Status/Complications.
Severity Level 5	Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis.
Severity Level 5	Respirator Dependence/Tracheostomy Status.
Severity Level 5	Heart Assistive Device/Artificial Heart.
Severity Level 5	Heart Transplant.
Severity Level 5	Congestive Heart Failure.
Severity Level 5	Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders.
Severity Level 5	Lung Transplant Status/Complications.
Severity Level 5	Kidney Transplant Status.
Severity Level 5	End Stage Renal Disease.
Severity Level 5	Stem Cell, Including Bone Marrow, Transplant Status/Complications.
Severity Level 4	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock.
Severity Level 4	Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia.
Severity Level 4	Mucopolysaccharidosis.
Severity Level 4	Major Congenital Anomalies of Diaphragm, Abdominal Wall, and Esophagus, Age <2.
Severity Level 4	Myelodysplastic Syndromes and Myelofibrosis.
Severity Level 4	Aplastic Anemia.
Severity Level 4	Combined and Other Severe Immunodeficiencies.
Severity Level 4	Traumatic Complete Lesion Cervical Spinal Cord.
Severity Level 4	Quadriplegia.
Severity Level 4	Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease.
Severity Level 4	Quadriplegic Cerebral Palsy.
Severity Level 4	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy.
Severity Level 4	Non-Traumatic Coma, Brain Compression/Anoxic Damage.
Severity Level 4	Respiratory Arrest.
Severity Level 4	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes.
Severity Level 4	Acute Myocardial Infarction.
Severity Level 4	Heart Infection/Inflammation, Except Rheumatic.
Severity Level 4	Major Congenital Heart/Circulatory Disorders.
Severity Level 4	Intracranial Hemorrhage.
Severity Level 4	Ischemic or Unspecified Stroke.
Severity Level 4	Vascular Disease with Complications.
Severity Level 4	Pulmonary Embolism and Deep Vein Thrombosis.
Severity Level 4	Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections.
Severity Level 4	Chronic Kidney Disease, Stage 5.
Severity Level 4	Hip Fractures and Pathological Vertebral or Humerus Fractures.
Severity Level 4	Artificial Openings for Feeding or Elimination.
Severity Level 3	HIV/AIDS.
Severity Level 3	Central Nervous System Infections, Except Viral Meningitis.
Severity Level 3	Opportunistic Infections.
Severity Level 3	Non-Hodgkin's Lymphomas and Other Cancers and Tumors.
Severity Level 3	Colorectal, Breast (Age <50), Kidney and Other Cancers.
Severity Level 3	Breast (Age 50+), Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors.
Severity Level 3	Lipidoses and Glycogenosis.

TABLE 6—HHS HCCs INCLUDED IN INFANT MODEL SEVERITY CATEGORIES—Continued

Severity category	HCC
Severity Level 3	Adrenal, Pituitary, and Other Significant Endocrine Disorders.
Severity Level 3	Acute Liver Failure/Disease, Including Neonatal Hepatitis.
Severity Level 3	Intestinal Obstruction.
Severity Level 3	Necrotizing Fasciitis.
Severity Level 3	Bone/Joint/Muscle Infections/Necrosis.
Severity Level 3	Osteogenesis Imperfecta and Other Osteodystrophies.
Severity Level 3	Cleft Lip/Cleft Palate.
Severity Level 3	Hemophilia.
Severity Level 3	Disorders of the Immune Mechanism.
Severity Level 3	Coagulation Defects and Other Specified Hematological Disorders.
Severity Level 3	Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes.
Severity Level 3	Traumatic Complete Lesion Dorsal Spinal Cord.
Severity Level 3	Paraplegia.
Severity Level 3	Spinal Cord Disorders/Injuries.
Severity Level 3	Cerebral Palsy, Except Quadriplegic.
Severity Level 3	Muscular Dystrophy.
Severity Level 3	Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders.
Severity Level 3	Hydrocephalus.
Severity Level 3	Unstable Angina and Other Acute Ischemic Heart Disease.
Severity Level 3	Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders.
Severity Level 3	Specified Heart Arrhythmias.
Severity Level 3	Cerebral Aneurysm and Arteriovenous Malformation.
Severity Level 3	Hemiplegia/Hemiparesis.
Severity Level 3	Cystic Fibrosis.
Severity Level 3	Fibrosis of Lung and Other Lung Disorders.
Severity Level 3	Pathological Fractures, Except of Vertebrae, Hip, or Humerus.
Severity Level 2	Viral or Unspecified Meningitis.
Severity Level 2	Thyroid, Melanoma, Neurofibromatosis, and Other Cancers and Tumors.
Severity Level 2	Diabetes with Acute Complications.
Severity Level 2	Diabetes with Chronic Complications.
Severity Level 2	Diabetes without Complication.
Severity Level 2	Protein-Calorie Malnutrition.
Severity Level 2	Congenital Metabolic Disorders, Not Elsewhere Classified.
Severity Level 2	Amyloidosis, Porphyria, and Other Metabolic Disorders.
Severity Level 2	Cirrhosis of Liver.
Severity Level 2	Chronic Pancreatitis.
Severity Level 2	Inflammatory Bowel Disease.
Severity Level 2	Rheumatoid Arthritis and Specified Autoimmune Disorders.
Severity Level 2	Systemic Lupus Erythematosus and Other Autoimmune Disorders.
Severity Level 2	Congenital/Developmental Skeletal and Connective Tissue Disorders.
Severity Level 2	Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn.
Severity Level 2	Sickle Cell Anemia (Hb-SS).
Severity Level 2	Drug Psychosis.
Severity Level 2	Drug Dependence.
Severity Level 2	Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes.
Severity Level 2	Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies.
Severity Level 2	Seizure Disorders and Convulsions.
Severity Level 2	Monoplegia, Other Paralytic Syndromes.
Severity Level 2	Atherosclerosis of the Extremities with Ulceration or Gangrene.
Severity Level 2	Chronic Obstructive Pulmonary Disease, Including Bronchiectasis.
Severity Level 2	Chronic Ulcer of Skin, Except Pressure.
Severity Level 1 (Lowest)	Chronic Hepatitis.
Severity Level 1	Acute Pancreatitis/Other Pancreatic Disorders and Intestinal Malabsorption.
Severity Level 1	Thalassemia Major.
Severity Level 1	Autistic Disorder.
Severity Level 1	Pervasive Developmental Disorders, Except Autistic Disorder.
Severity Level 1	Multiple Sclerosis.
Severity Level 1	Asthma.
Severity Level 1	Chronic Kidney Disease, Severe (Stage 4).
Severity Level 1	Amputation Status, Lower Limb/Amputation Complications.
Severity Level 1	No Severity HCCs.

e. Cost-Sharing Reductions Adjustments

We proposed to continue to include an adjustment for the receipt of cost-sharing reductions in the model, and proposed to continue not to adjust for receipt of reinsurance payments in the

model. We have updated the adjustments to the HHS risk adjustment models for individuals who receive cost-sharing reductions to be consistent with the cost-sharing reductions advance payment formula finalized in

the 2015 Payment Notice, for implementation in 2015 benefit year risk adjustment. The silver plan variation and zero cost sharing factors are unchanged from those finalized in the 2014 Payment Notice. The

adjustment factors are set forth in Table 7. These adjustments are multiplied against the sum of the demographic,

diagnosis, and interaction factors. We will continue to evaluate this adjustment as more data becomes

available. We received no comments on this approach, and are finalizing it as proposed.

TABLE 7—COST-SHARING REDUCTION ADJUSTMENT

Household income	Plan AV	Induced utilization factor
Silver Plan Variation Recipients		
100–150% of FPL	Plan Variation 94%	1.12
150–200% of FPL	Plan Variation 87%	1.12
200–250% of FPL	Plan Variation 73%	1.00
>250% of FPL	Standard Plan 70%	1.00
Zero Cost Sharing Recipients		
<300% of FPL	Platinum (90%)	1.00
<300% of FPL	Gold (80%)	1.07
<300% of FPL	Silver (70%)	1.12
<300% of FPL	Bronze (60%)	1.15
Limited Cost Sharing Recipients		
>300% of FPL	Platinum (90%)	1.00
>300% of FPL	Gold (80%)	1.07
>300% of FPL	Silver (70%)	1.12
>300% of FPL	Bronze (60%)	1.15

f. Model Performance Statistics

To evaluate model performance, we examined R-squared statistics and predictive ratios. The R-squared statistic, which calculates the percentage of individual variation explained by a model, measures the predictive accuracy of the model overall. The predictive ratios measure the predictive accuracy of a model for different validation groups or

subpopulations. The predictive ratio for each of the HHS risk adjustment models is the ratio of the weighted mean predicted plan liability for the model sample population to the weighted mean actual plan liability for the model sample population. The predictive ratio represents how well the model does on average at predicting plan liability for that subpopulation. A subpopulation that is predicted perfectly would have a predictive ratio of 1.0. For each of the

HHS risk adjustment models, the R-squared statistic and the predictive ratio are in the range of published estimates for concurrent risk adjustment models.¹⁰ Because we are averaging the coefficients from separately solved models based on MarketScan 2011, 2012 and 2013 data, we are publishing the R-squared statistic for each model and year separately to verify their statistical validity. The R-squared statistic for each model is shown in Table 8.

TABLE 8—R-SQUARED STATISTIC FOR HHS RISK ADJUSTMENT MODELS

Risk adjustment model	R-squared statistic		
	2011	2012	2013
Platinum Adult	0.368	0.394	0.382
Platinum Child	0.283	0.286	0.277
Platinum Infant	0.337	0.284	0.322
Gold Adult	0.363	0.389	0.377
Gold Child	0.278	0.280	0.272
Gold Infant	0.335	0.282	0.319
Silver Adult	0.360	0.387	0.374
Silver Child	0.275	0.277	0.268
Silver Infant	0.334	0.281	0.318
Bronze Adult	0.358	0.384	0.372
Bronze Child	0.272	0.273	0.265
Bronze Infant	0.334	0.281	0.318
Catastrophic Adult	0.358	0.384	0.371
Catastrophic Child	0.271	0.273	0.265
Catastrophic Infant	0.334	0.281	0.318

¹⁰ Winkleman, Ross and Syed Mehmud. “A Comparative Analysis of Claims-Based Tools for

Health Risk Assessment.” Society of Actuaries. April 2007.

g. Overview of the Payment Transfer Formula

We do not propose to alter our payment transfer methodology. Plan average risk scores would be calculated as the member month-weighted average of individual enrollee risk scores. We defined the calculation of plan average actuarial risk and the calculation of payments and charges in the Premium Stabilization Rule. In the 2014 Payment Notice, we combined those concepts into a risk adjustment payment transfer formula. Risk adjustment transfers (payments and charges) will be calculated following the completion of issuer risk adjustment data reporting.

The payment transfer formula includes a set of cost adjustment terms that require transfers to be calculated at the geographic rating area level for each plan (that is, HHS will calculate two separate transfer amounts for a plan that operates in two rating areas).

The payment transfer formula is designed to provide a per member per month (PMPM) transfer amount. The PMPM transfer amount derived from the payment transfer formula will be multiplied by each plan's total member months for the benefit year to determine the total payment due or charge owed by the issuer for that plan in a rating area.

(1) Overview of the Payment Transfer Formula

Though we did not propose to change the payment transfer formula from what was finalized in the 2014 Payment Notice (78 FR 15430–15434), we believe it useful to republish the formula in its entirety, since we are finalizing recalibrated HHS risk adjustment models. Transfers (payments and charges) will be calculated as the difference between the plan premium estimate reflecting risk selection and the plan premium estimate not reflecting risk selection. As finalized in the 2014 Payment Notice, the HHS risk adjustment payment transfer formula is:

$$T_i = \left[\frac{PLRS_i \cdot IDF_i \cdot GCF_i}{\sum_i (s_i \cdot PLRS_i \cdot IDF_i \cdot GCF_i)} - \frac{AV_i \cdot ARF_i \cdot IDF_i \cdot GCF_i}{\sum_i (s_i \cdot AV_i \cdot ARF_i \cdot IDF_i \cdot GCF_i)} \right] \bar{P}_s$$

Where:

$\bar{P}_s$ = State average premium;

$PLRS_i$ = plan i 's plan liability risk score;

AV_i = plan i 's metal level AV;

ARF_i = allowable rating factor;

IDF_i = plan i 's induced demand factor;

GCF_i = plan i 's geographic cost factor;

s_i = plan i 's share of State enrollment;

and the denominator is summed across all plans in the risk pool in the market in the State.

The difference between the two premium estimates in the payment transfer formula determines whether a plan pays a risk transfer charge or receives a risk transfer payment. Note that the value of the plan average risk score by itself does not determine whether a plan would be assessed a charge or receive a payment—even if the risk score is greater than 1.0, it is possible that the plan would be assessed a charge if the premium compensation that the plan may receive through its rating practices (as measured through the allowable rating factor) exceeds the plan's predicted liability associated with risk selection. Risk adjustment transfers are calculated at the risk pool level and catastrophic plans are treated as a separate risk pool for purposes of risk adjustment.

h. HHS Risk Adjustment Methodology Considerations

In the 2014 Payment Notice, we finalized the methodology that HHS will use when operating a risk adjustment program on behalf of a State. In the second Program Integrity Rule (78 FR 65046), we clarified the modification to the transfer formula to accommodate community rated States that utilize family tiering rating factors. We further clarified this formula in the proposed

rule to ensure that the allowable rating factor (ARF) is appropriately applied in the transfer formula in community rated States for 2014 risk adjustment. In the second Program Integrity Rule, we stated that the ARF formula should be modified so that the numerator is a summation over all subscribers of the product of the family tiering factor and the subscriber member months, and the denominator the sum of billable member months. However, we do not believe the revised formula accurately reflects that description, as it does not distinguish between subscriber months (months attributed to the sole subscriber) and billable member months (months attributed to all allowable members of the family factored into the community rating). The calculation of ARF for family tiering States that was published in the second Program Integrity Rule that would be calculated at the level of the subscriber, was as follows:

$$ARF_i = \frac{\sum_s (ARF_s \cdot M_s)}{\sum_s (M_s)}$$

Where:

ARF_s is the rating factor for the subscriber(s) (based on family size/composition), and M_s is the number of billed person-months that are counted in determining the premium(s) for the subscriber(s).

While the preamble description in the second Program Integrity Rule is correct, as we noted, the formula itself is incorrect in that it does not distinguish between billable member months and subscriber months by using the same variable for both. Therefore, we proposed a technical change to the ARF calculation for family tiering States, as follows:

$$ARF_i = \frac{\sum_s (ARF_s \cdot MS_s)}{\sum_s (MB_s)}$$

Where:

ARF_i is the allowable rating factor for plan i , ARF_s is the allowable rating factor—also known as the family rating tier—for subscriber (family) s in plan i ,

MS_s is the number of subscriber months for subscriber s , and

MB_s is the number of billable member months for subscriber (family) s .

The numerator is summed over the product of the allowable rating factor and the number of subscriber months (that is, months of family subscription), and the denominator is the sum over all billable members. Each family unit covered under a single contract is considered a single “subscriber.” Therefore, a family of four that purchases coverage for a period from January through December will accumulate 12 subscriber months (MS_s), although coverage is being provided for 48 member months (both billable and non-billable). Billable members are individuals who are counted for purposes of placing the subscriber in a family tier. For example, in a community rated State that rates based on two adults and one or more children with one full year of enrollment, the family of four would have 36 billable member months (MB_s), (12 billable member months for the subscriber, 12 billable member months for the second adult, and 12 billable months for the first child). We received no comments on this correction and are finalizing it as proposed.

i. State-Submitted Alternate Risk Adjustment Methodology

For 2016, we are recertifying the alternate risk adjustment methodology submitted by Massachusetts and certified in the 2014 Payment Notice (78 FR 15439–15452).

3. Provisions and Parameters for the Transitional Reinsurance Program

The Affordable Care Act directs that a transitional reinsurance program be established in each State to help stabilize premiums for coverage in the individual market from 2014 through 2016. In the 2014 Payment Notice, we expanded on the standards set forth in subparts C and E of the Premium Stabilization Rule and established the reinsurance payment parameters and uniform reinsurance contribution rate for the 2014 benefit year. In the 2015 Payment Notice, we established the reinsurance payment parameters and uniform reinsurance contribution rate for the 2015 benefit year and certain oversight provisions related to the operation of the reinsurance program.

a. Common Ownership Clarification

The definition of a “contributing entity” at § 153.20 provides that for the 2015 and 2016 benefit years, a contributing entity is (i) a health insurance issuer or (ii) a self-insured group health plan, including a group health plan that is partially self-insured and partially insured, where the health insurance coverage does not constitute major medical coverage, that uses a TPA in connection with claims processing or adjudication, including the management of internal appeals, or plan enrollment for services other than for pharmacy benefits or excepted benefits within the meaning of section 2791(c) of the PHS Act. Solely for purposes of the reinsurance program, a self-insured group health plan will not be deemed to use a TPA if it uses an unrelated third party: (a) To obtain a provider network and related claims repricing services; or (b) for up to 5 percent of claims processing or adjudication or plan enrollment, based on either the number of transactions processed by the third party, or the value of the claims processing and adjudication and plan enrollment services provided by the third party.

The definition of a “contributing entity” does not include qualifying self-administered, self-insured group health plans for the purpose of the requirement to make reinsurance contributions for the 2015 and 2016 benefit years. In the preamble to the 2015 Payment Notice, we indicated that we consider a TPA to

be, with respect to a self-insured group health plan, an entity that is not under common ownership or control with the self-insured group health plan or its plan sponsor that provides the specified core administrative services (79 FR 13773).

We received a number of inquiries seeking clarification on how to determine common ownership or control for purposes of the definition of a “contributing entity” in § 153.20. In response, in the proposed rule, we proposed to clarify that principles similar to the controlled group rules of section 414(b) and (c) of the Code be used to determine whether the TPA is under common ownership or control with the self-insured group health plan or the plan sponsor, because these rules are familiar to many stakeholders. We also noted that similar ownership or control rules apply for other purposes under the Affordable Care Act, such as the shared responsibility payment for applicable large employers that do not offer full-time employees and dependents the opportunity to enroll in minimum essential coverage, and the annual fee on health insurance issuers under section 9010 of the Affordable Care Act.

We sought comment on this proposal and on alternative definitions that would be familiar to stakeholders for determining whether a TPA is under common ownership or control with the self-insured group health plan or its sponsor for purposes of the definition of “contributing entity” at § 153.20.

We finalize this proposal with one clarification—we are limiting the incorporation of the section 414 rules to sections 414(b) and (c).

Comment: One commenter stated that the common ownership or control test should mirror, “not use similar principles to,” the section 414 controlled group rules, so that one consistent test of determining common ownership applies for all employer compliance purposes under the Affordable Care Act.

Response: The section 414 controlled group rules address a variety of structures for related corporations and businesses, some of which are not relevant to defining a “contributing entity,” such as sections 414(m), (n), and (o). The intent of the proposed language was to limit the incorporation of the section 414 rules to sections 414(b) and (c), the provisions most applicable to defining a contributing entity. Therefore, we are finalizing the proposal with that clarification.

b. Reinsurance Contributing Entities and Minimum Value

Section 1341(b)(3)(B) of the Affordable Care Act and the implementing regulations at § 153.400(a)(1) require contributing entities to make reinsurance contributions for major medical coverage that is considered to be part of a commercial book of business. We define major medical coverage at § 153.20 as coverage meeting minimum value (MV) or that is subject to the actuarial value (AV) requirements. In light of this definition, stakeholders have asked whether plans that do not offer inpatient hospital coverage, but that are considered to offer MV for purposes of the employer shared responsibility payment because they were in place before HHS and IRS guidance¹¹ on MV was issued November 4, 2014, must make reinsurance contributions for the 2015 benefit year. As detailed in the November 4, 2014 guidance, we clarify that plans that entered into a binding agreement or began enrolling employees prior to November 4, 2014, with plan years beginning by March 1, 2015, are considered to meet MV requirements until the end of the current plan year for purposes of the employer shared responsibility penalties. We clarify that these plans will therefore also be deemed to satisfy the definition of “major medical coverage” in § 153.20 for purposes of reinsurance contributions, since these plans meet the previous definition of MV until plan renewal.

c. Self-Insured Expatriate Plans (§ 153.400(a)(1)(iii))

Section 1341(b)(3)(B) of the Affordable Care Act and the implementing regulations at § 153.400(a)(1) require contributing entities to make reinsurance contributions for major medical coverage that is considered to be part of a commercial book of business. In the 2014 Payment Notice (78 FR 15457), we stated that we interpret this language to exclude expatriate health coverage, as defined by the Secretary, and we codified this approach in regulatory text at § 153.400(a)(1)(iii). In the March 8, 2013, FAQs about the Affordable Care Act Implementation Part XIII,¹² an expatriate health plan is defined as an *insured* group health plan for which

¹¹ Group Health Plans that Fail to Cover In-Patient Hospitalization Services, Notice 2014–69, available at: <http://www.irs.gov/pub/irs-drop/n-14-69.pdf>.

¹² Available at: http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs13.html.

enrollment is limited to primary insured who reside outside of their home country for at least 6 months of the plan year and any covered dependents, and its associated group health insurance coverage. Therefore, under our current regulation, *self-insured* expatriate plans that would otherwise meet the conditions outlined in the March 8, 2013 FAQ are required to make reinsurance contributions if these plans provide major medical coverage, unless another exemption in § 153.400(a) applies, because the definition in the FAQ applies only to *insured* expatriate plans.

We proposed to amend § 153.400(a)(1)(iii), which currently exempts expatriate health coverage, as defined by the Secretary, from reinsurance contributions, so that it also exempts, for the 2015 and 2016 benefit years only, any self-insured group health plan for which enrollment is limited to participants, and any covered dependents, who reside outside of their home country for at least 6 months of the plan year. This definition would be applicable solely to the transitional reinsurance program.

We received one comment in support of this proposal, which also stated that the expatriate plan requirements should be revised to reflect the effect of the recently enacted Expatriate Health Coverage Clarification Act of 2014, as part of the Consolidated and Further Continuing Appropriations Act, 2015, H.R. 83 (2014 Expatriate Health Coverage Act). Since the expatriate plan requirements (and accompanying definitions) enacted in the 2014 Expatriate Health Coverage Act only apply to expatriate plans issued or renewed on or after July 1, 2015, we are finalizing the amendment as proposed, and we intend to undertake future rulemaking in conjunction with the Departments of the Treasury and Labor governing the application of the Affordable Care Act to expatriate plans to harmonize our regulations (as may be necessary) with the 2014 Expatriate Health Coverage Act. We do not anticipate that this future rulemaking will affect the availability of the exemption for the expatriate plans described in this final rule.

d. Determination of Debt (§ 153.400(c))

Consistent with the determination of debt provision set forth in § 156.1215(c), we proposed to clarify in § 153.400(c) that any amount owed to the Federal government by a self-insured group health plan (including a group health plan that is partially self-insured and partially insured, where the health insurance coverage does not constitute

major medical coverage), including reinsurance contributions that are not remitted in full in a timely manner, would be a determination of a debt.

We received no comments on this proposal and are finalizing this provision as proposed.

e. Reinsurance Contribution Submission Process

On May 22, 2014, we released an FAQ about the reinsurance contribution submission process.¹³ As detailed in this FAQ, we implemented a streamlined process for the collection of reinsurance contributions. A contributing entity, or a TPA or administrative services-only (ASO) contractor on behalf of the contributing entity, must complete all required steps for the reinsurance contribution submission process on www.pay.gov (Pay.gov). The “ACA Transitional Reinsurance Program Annual Enrollment and Contributions Submission Form” available on Pay.gov must be completed and submitted by a contributing entity or a TPA or ASO contractor on its behalf no later than November 15 of the benefit year under § 153.405(b).

We proposed to amend § 153.405(b), which requires a contributing entity to submit its annual enrollment count of the number of covered lives of reinsurance contribution enrollees for the applicable benefit year to HHS no later than November 15 of benefit year 2014, 2015, or 2016. When November 15 does not fall on a business day, we proposed that a contributing entity submit its annual enrollment count of the number of covered lives of reinsurance contribution enrollees for the applicable benefit year to HHS no later than November 15, 2014, 2015, or 2016, or, if such date is not a business day, the next business day. Similarly, because November 15, 2015 and January 15, 2017 do not fall on a business day, we proposed to amend § 153.405(c)(2) so that a contributing entity must remit reinsurance contributions to HHS no later than January 15, 2015, 2016, or 2017, as applicable, or, if such date is not a business day, the next applicable business day, if making a combined contribution or the first payment of the bifurcated contribution; and no later than November 15, 2015, 2016, or 2017, as applicable, or, if such date is not a business day, the next applicable business day, if making the second

payment of the bifurcated contribution.¹⁴

Although we stated in the 2015 Payment Notice (79 FR 13776) that, for operational reasons, HHS would not permit contributing entities to elect to make the entire benefit year’s reinsurance contribution by January 15, 2015, 2016, or 2017, as applicable, we have resolved those operational barriers, and now offer contributing entities the option to pay: (1) The entire 2014, 2015 or 2016 benefit year contribution in one payment no later than January 15, 2015, 2016, or 2017, as applicable (or, if such date is not a business day, the next applicable business day), reflecting the entire uniform contribution rate applicable to each benefit year (that is, \$63 per covered life for 2014, \$44 per covered life for 2015, and \$27 per covered life for 2016); or (2) in two separate payments for the 2014, 2015, or 2016 benefit years, with the first remittance due by January 15, 2015, 2016, and 2017, as applicable (or, if such date is not a business day, the next applicable business day) reflecting the first payment of the bifurcated contribution (that is, \$52.50 per covered life for 2014, \$33.00 per covered life for 2015, and \$21.60 per covered life for 2016); and the second remittance due by November 15, 2015, 2016, or 2017, as applicable (or, if such date is not a business day, the next applicable business day) reflecting the second payment of the bifurcated contribution (that is, \$10.50 reinsurance fee per covered life for 2014, \$11.00 per covered life for 2015, and \$5.40 per covered life for 2016).

Under § 153.405(c)(1), HHS must notify the contributing entity of the reinsurance contribution amount allocated to reinsurance payments and administrative expenses to be paid for the applicable benefit year following submission of the annual enrollment count. We clarified that this notification will occur when the contributing entity enters the gross annual enrollment count into the Pay.gov form and the form auto-calculates the contribution amount owed. No separate notification or invoice will be sent to a contributing entity, unless a discrepancy in data or payment has been identified by the entity or HHS after the form is submitted. In addition, we proposed to delete § 153.405(c)(2), to be consistent with HHS permitting flexibility for a contributing entity (or the TPA or ASO contractor on its behalf) to remit the

¹³ Available at: <http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/Reinsurance-contributions-process-FAQ-5-22-14.pdf>.

¹⁴ To be comprehensive, we included all reinsurance contribution submission dates throughout the entirety of the program, understanding that some dates noted here have passed.

entire contribution in one payment, rather than requiring a bifurcated payment. Notification of the reinsurance contribution amount related to the allocation for reinsurance payments, administrative expenses, and payments to the U.S. Treasury for the applicable benefit year will also be made through the automatic calculation of this amount when a contributing entity (or the TPA or ASO contractor on its behalf) completes the reinsurance contribution submission process and submits the form through Pay.gov.

We also proposed to amend and redesignate § 153.405(c)(3) to (c)(2) to clarify that a contributing entity must schedule its contribution payment for the applicable benefit year to occur no later than January 15, 2015, 2016, or 2017, as applicable (or, if such date is not a business day, the next applicable business day) if making a combined payment or the first payment of the bifurcated payment, and no later than November 15, 2015, 2016, or 2017, as applicable (or, if such date is not a business day, the next applicable business day) if making the second payment of the bifurcated payment. However, we noted that the form must be completed and the reinsurance contribution payment(s) must be *scheduled* no later than November 15, 2014, 2015, or 2016, as applicable, to successfully comply with the deadline set forth in § 153.405(b) and complete the reinsurance contribution submission process through Pay.gov.¹⁵ The reinsurance contribution payments must be scheduled by this deadline regardless of whether the contributing entity (or the TPA or ASO contractor on its behalf) is remitting a combined payment or two payments under the bifurcated schedule.

We noted that if a contributing entity elects to follow the bifurcated schedule, then the contributing entity is required to submit two separate forms through Pay.gov. However, the annual enrollment count reported on both forms must be the same. This is consistent with § 153.405(b) and previous guidance, which provide that no later than November 15 of benefit year 2014, 2015, or 2016, as applicable, a contributing entity must submit an annual enrollment count of the number of covered lives of reinsurance contribution enrollees one time for the applicable benefit year to HHS.

Finally, we proposed to amend § 153.405(g)(4)(1)(i) and (ii), which require a plan sponsor who maintains multiple group health plans to report to

HHS the average number of covered lives calculated, the counting method used, and the names of the multiple plans being treated as a single group health plan as determined by the plan sponsor. A plan sponsor would continue to be required to determine this information, but would only need to report to HHS the average number of covered lives calculated and the other data elements required through the Pay.gov reinsurance contribution submission process. Under § 153.405(h), plan sponsors should retain this additional information (that is, the counting method used and the names of the multiple plans being treated as a single group health plan), as this information may be requested to assess the plan sponsor's compliance with the reinsurance contribution requirements.

We are finalizing these provisions as proposed.

Comment: Several commenters asked that HHS publicize the amount of reinsurance contributions collected by December 31st of the benefit year for issuers to assess the possible proration of reinsurance payments.

Response: We intend to issue a report of the estimated total contributions collected in the spring of the year following the applicable benefit year. This estimate would include the amount of contributions already paid and scheduled to be paid for the entire benefit year.

f. Consistency in Counting Methods for Health Insurance Issuers (§ 153.405(d))

As noted in the 2014 Payment Notice (78 FR 15462), the counting methods for the transitional reinsurance program are designed to align with the methods permitted for purposes of the fee to fund the Patient-Centered Outcomes Research Trust Fund (PCORTF). The PCORTF Final Rule (77 FR 72729) requires consistency in the use of counting methods for calculating covered lives for the duration of the year. We proposed for the 2015 and 2016 benefit years¹⁶ to amend § 153.405(d) to similarly require a contributing entity that is a health insurance issuer to use the same counting method to calculate its annual enrollment count of covered lives of reinsurance contribution enrollees in a State (including both the individual and group markets) for a benefit year even if the fully insured major medical plans for which reinsurance contributions are required enroll different covered lives. If a health

insurance issuer has multiple major medical plans covering different lives in different States, the issuer may use different counting methods for all major medical plans in each State (including both the individual and group markets). We noted that this amendment would not prevent an issuer from using different counting methods for different benefit years. We did not propose a similar requirement for self-insured group health plans and sought comments on whether a similar uniformity requirement should extend to self-insured group health plans that are contributing entities.

We are finalizing this provision as proposed.

Comment: One commenter stated that it is difficult for self-insured plans to use consistent counting methods for multiple plans.

Response: In many instances, a plan sponsor's multiple group health plans may be administered by different entities, making implementation of a uniformity of counting method requirement potentially more difficult. Therefore, we are finalizing this policy.

g. Snapshot Count and Snapshot Factor Counting Methods (§§ 153.405(d)(2) and (e)(2))

Under § 153.400(a)(1), reinsurance contributions are generally required for major medical coverage that is considered to be part of a commercial book of business, but contributions are not required to be paid more than once for the same covered life. Reinsurance contributions are generally calculated based on the number of covered lives covered by a plan or coverage that provides major medical coverage. The reinsurance contribution required from a contributing entity is calculated by multiplying the number of covered lives (determined under a permitted counting method set forth in § 153.405(d) through § 153.405(g)) during the applicable calendar year for all applicable plans and coverage of the contributing entity by the applicable contribution rate for the respective benefit year.

We proposed to clarify how the counting methods set forth in §§ 153.405(d)(2) and (e)(2) are to be used in those situations when a plan terminates or is established in the middle of a quarter to effectuate the principle that contributions are required to be paid once for the same covered life. Under the snapshot count method, described at § 153.405(d)(2), to determine the number of covered lives for the purposes of reinsurance contributions, the issuer or self-insured group health plan must add the total number of lives covered on any date (or

¹⁵ We note that for the 2014 benefit year, we extended the filing deadline to December 5, 2014.

¹⁶ As noted in an FAQ issued on October 21, 2014, we also encouraged this approach for the 2014 benefit year. Available at: <https://www.regtap.info/>, FAQ# 6037.

more dates, if an equal number of dates are used for each quarter) during the same corresponding month in each of the first 3 quarters of the benefit year, and divide that total by the number of dates on which a count was made. Under the snapshot factor method, described at § 153.405(e)(2), to determine the number of covered lives for the purposes of reinsurance contributions, the self-insured group health plan must add the total number of lives covered on any date (or more dates, if an equal number of dates are used for each quarter) during the same corresponding month in each of the first 3 quarters of the benefit year, and divide that total by the number of dates on which a count was made, except that the number of lives covered on a date is calculated by adding the number of participants with self-only coverage on the date to the product of the number of participants with coverage other than self-only coverage on the date and a factor of 2.35. For each of these counting methods, the same months must be used for each quarter (for example, January, April, July), and the date used for the second and third quarter must fall within the same week of the quarter as the corresponding date used for the first quarter.

We understand that a health insurance plan or coverage may be established, terminated, or change funding mechanisms (that is, from fully insured to self-insured or self-insured to fully insured), in the middle of a quarter. In these circumstances, it is possible that the new plan or coverage would not have covered lives enrolled in the plan or coverage for the entire quarter. If this occurs, a contributing entity could, due to its selection of dates, be required to pay an amount significantly greater or lesser than the amount that would be due based on its average count of covered lives over the course of the 9-month counting period. To avoid this result, we proposed to clarify that, if the plan or coverage in

question had enrollees on any day during a quarter and if the contributing entity elects to (and is permitted to) use either the snapshot count or snapshot factor method, it must choose a set of counting dates for the 9-month counting period such that the plan or coverage has enrollees on each of the dates, if possible. However, the enrollment count for a date during a quarter in which the plan or coverage was in existence for only part of the quarter could be reduced by a factor reflecting the amount of time during the quarter for which the plan or coverage was not in existence. This approach is intended to accurately capture the amount of time during the quarter for which major medical coverage that is part of a commercial book of business and subject to reinsurance contributions was provided to enrollees, while not requiring contributions to be paid more than once for the same covered life. For example, a contributing entity that has a plan that terminates on August 31st (that is, 62 days into the third quarter) would not be permitted to use September 1st as the date for the third quarter under the snapshot count or snapshot factor methods because this would not properly reflect the number of covered lives of reinsurance contribution enrollees under the plan in the third quarter of the benefit year. However, it would be entitled to reduce its count of covered lives during that quarter by 30/92, the proportion of the quarter during which the plan had no enrollment. This reduction factor would only be applicable for the snapshot count and snapshot factor methods set forth in §§ 153.405(d)(2) and (e)(2), respectively, as all of the other permitted counting methods automatically account for partial year enrollment.

Comment: One commenter asked that the 2.35 factor in the snapshot factor counting method set forth in § 153.405(e)(2) be optional, rather than required, since some plans may only

cover one employee and a spouse or only one employee and one dependent.

Response: We decline to make this change, but note that a number of different counting methods are available and contributing entities have flexibility to choose the one that best meets their needs and circumstances.

h. Uniform Reinsurance Contribution Rate for 2016

Section 153.220(c) provides that HHS is to publish in the annual HHS notice of benefit and payment parameters the uniform reinsurance contribution rate for the upcoming benefit year. Section 1341(b)(3)(B)(iii) of the Affordable Care Act specifies that \$10 billion for reinsurance contributions are to be collected from contributing entities for the 2014 benefit year (the reinsurance payment pool), \$6 billion for the 2015 benefit year, and \$4 billion for the 2016 benefit year. Additionally, sections 1341(b)(3)(B)(iv) and 1341(b)(4) of the Affordable Care Act direct that \$2 billion in funds are to be collected for contribution to the U.S. Treasury for the 2014 benefit year, \$2 billion for the 2015 benefit year, and \$1 billion for the 2016 benefit year. Finally, section 1341(b)(3)(B)(ii) of the Affordable Care Act authorizes the collection of additional amounts for administrative expenses. Taken together, these three components make up the total dollar amount to be collected from contributing entities for each of the 2014, 2015, and 2016 benefit years under the uniform reinsurance contribution rate.

As discussed in the 2014 and 2015 Payment Notices, each year, the uniform reinsurance contribution rate will be calculated by dividing the sum of the three amounts (the reinsurance payment pool, the U.S. Treasury contribution, and administrative costs) by the estimated number of enrollees in plans that must make reinsurance contributions:

Uniform Reinsurance Contribution Rate

$$= \frac{\text{Reinsurance payment pool} + \text{Treasury contribution} + \text{Administrative costs}}{\text{Estimate of enrollees in plans required to make reinsurance contributions}}$$

As discussed in greater detail below, we proposed collecting \$32 million for administrative expenses for the 2016 benefit year. Therefore, the total amount to be collected for the 2016 benefit year would be approximately \$5.032 billion. Our estimate of the number of enrollees

in plans that must make reinsurance contributions yields an annual per capita contribution rate of \$27 for the 2016 benefit year.

(1) Allocation of Uniform Reinsurance Contribution Rate

Section 153.220(c) provides that HHS is to establish in the annual HHS notice of benefit and payment parameters for the applicable benefit year the proportion of contributions collected

under the uniform reinsurance contribution rate to be allocated to reinsurance payments, payments to the U.S. Treasury, and administrative expenses. In the 2014 and 2015 Payment Notices, we stated that reinsurance contributions collected for the 2014 and 2015 benefit years would be allocated pro rata to the reinsurance payment pool, administrative expenses, and the U.S. Treasury, up to \$12.02 billion for 2014 and up to \$8.025 billion for 2015. However, we amended this approach in the 2015 Market Standards Rule,¹⁷ such that, if reinsurance collections fall short of our estimates for a particular benefit year, we will allocate reinsurance contributions collected first to the reinsurance payment pool, with any remaining amounts being then allocated to the U.S. Treasury and administrative expenses, on a pro rata basis. We proposed following a similar approach for the 2016 benefit year, such that if reinsurance contributions fall short of our estimates, contributions collected will first be allocated to the reinsurance payment pool, with any remaining amounts being then allocated to the U.S. Treasury and administrative expenses, on a pro rata basis. In the proposed rule, we also proposed to use any excess contributions for reinsurance payments for the current benefit year by increasing the coinsurance rate for the 2016 benefit year up to 100 percent before rolling over any remaining funds to the next year and sought comment on whether to expend all of the contributions in 2016

or roll over any excess funds to the 2017 benefit year.

(2) Administrative Expenses

In the 2015 Payment Notice, we estimated that the Federal administrative expenses of operating the reinsurance program would be \$25.4 million, based on our estimated contract and operational costs. We used the same methodology to estimate the administrative expenses for the 2016 benefit year. These estimated costs would cover the costs related to contracts for developing the uniform reinsurance payment parameters and the uniform reinsurance contribution rate, collecting reinsurance contributions, making reinsurance payments, and conducting account management, data collection, program integrity and audit functions, operational and fraud analytics, training for entities involved in the reinsurance program, and general operational support. To calculate our reinsurance administrative expenses for 2016, we divided HHS's projected total costs for administering the reinsurance programs on behalf of States by the expected number of covered lives for which reinsurance contributions are to be made for 2016.

We estimated this amount to be approximately \$32 million for the 2016 benefit year. This estimate increased for the 2016 benefit year due to increased audit and data validation contract costs. We believe that this amount reflects the

Federal government's significant economies of scale, which helps to decrease the costs associated with operating the reinsurance program. Based on our estimate of covered lives for which reinsurance contributions are to be made for 2016, we proposed a uniform reinsurance contribution rate of \$0.17 annually per capita for HHS administrative expenses. We provide details below on the methodology we used to develop the 2016 enrollment estimates.

Similar to the allocation for 2015, for the 2016 benefit year, administrative expenses are allocated equally between contribution and payment-related activities. Because we anticipate that our additional activities in the 2016 benefit year, including our program integrity and audit activities, will also be divided approximately equally between contribution and payment-related activities, we again proposed to allocate the total administrative expenses equally between these two functions. Therefore, as shown in Table 9, we will apportion the annual per capita amount of \$0.17 of administrative expenses as follows: (a) \$0.085 of the total amount collected per capita for administrative expenses for the collection of contributions from contributing entities; and (b) \$0.085 of the total amount collected per capita for administrative expenses for reinsurance payment activities, supporting the administration of payments to issuers of reinsurance-eligible plans.

TABLE 9—BREAKDOWN OF ADMINISTRATIVE EXPENSES
[Annual, per capita]

Activities	Estimated expenses
Collecting reinsurance contributions from health insurance issuers and certain self-insured group health plans	\$0.085
Calculation and disbursement of reinsurance payments	0.085
Total annual per capita administrative expenses for HHS to perform all reinsurance functions	0.17

If HHS operates the reinsurance program on behalf of a State, HHS would retain the annual per capita fee to fund HHS's performance of all reinsurance functions, which would be \$0.17. If a State establishes its own reinsurance program, HHS would transfer \$0.085 of the per capita administrative fee to the State for purposes of administrative expenses incurred in making reinsurance payments, and retain the remaining \$0.085 to offset HHS's costs of collecting contributions. We note that the administrative expenses for reinsurance

payments will be distributed to those States that operate their own reinsurance program in proportion to the State-by-State total requests for reinsurance payments made under the uniform reinsurance payment parameters.

We are finalizing the 2016 contribution rate as proposed and finalizing our policy to increase the 2016 coinsurance rate to 100 percent prior to rolling over any excess funds to 2017.

Comment: Several commenters supported our proposal to increase the

2016 coinsurance rate to 100 percent if collections exceed the requests for reinsurance payments. Some commenters further supported rolling over any excess collections to 2017 if excess funds remain after increasing the coinsurance rate to 100 percent, while other commenters disagreed with our proposal to roll over the excess funds to 2017 asking that HHS instead increase the reinsurance cap in 2016 to expend all contributions collected in 2016.

Response: We will continue with our policy to increase the coinsurance rate to 100 percent for the 2016 benefit year

¹⁷ 79 FR 30259.

in the event collections exceed the requests for reinsurance payments. If additional funds remain after the increase in the coinsurance rate to 100 percent, we will roll over the excess funds to 2017 to extend the premium stabilization effects of the program.

i. Uniform Reinsurance Payment Parameters for 2016

Section 1341(b)(2)(B) of the Affordable Care Act directs the Secretary, in establishing standards for the transitional reinsurance program, to include a formula for determining the amount of reinsurance payments to be made to issuers for high-risk individuals that provides for the equitable allocation of funds. In the Premium Stabilization Rule, we provided that reinsurance payments to eligible issuers will be made for a portion of an enrollee's claims costs paid by the issuer (the coinsurance rate, meant to reimburse a proportion of claims while giving issuers an incentive to contain costs) that exceeds an attachment point (when reinsurance would begin), subject to a reinsurance cap (when the reinsurance program stops paying claims for a high-cost individual). The coinsurance rate, attachment point, and reinsurance cap together constitute the uniform reinsurance payment parameters.

Given the smaller pool of reinsurance contributions to be collected for the 2016 benefit year, we proposed that the uniform reinsurance payment parameters for the 2016 benefit year be established at an attachment point of \$90,000, a reinsurance cap of \$250,000, and a coinsurance rate of 50 percent. We estimated that these uniform reinsurance payment parameters will result in total requests for reinsurance payments of approximately \$4 billion for the 2016 benefit year. We believe setting the coinsurance rate at 50 percent and increasing the attachment point allows for the reinsurance program to help pay for nearly the same group of high-cost enrollees as was the case for the 2014 and 2015 benefit years, while still encouraging issuers to contain costs.

As discussed in the 2014 and 2015 Payment Notices, to assist with the development of the uniform reinsurance payment parameters and the premium adjustment percentage index, HHS developed the Affordable Care Act Health Insurance Model (ACAHiM). The ACAHiM generates a range of national and State-level outputs for 2016, using updated assumptions reflecting more recent data, but using the same

methodology described in the 2014 and 2015 Payment Notices.¹⁸

Specifically, the ACAHiM uses the Health Intelligence Company, LLC (HIC) database from calendar year 2010, with the claims data trended to 2016 to estimate total medical expenditures per enrollee by age, gender, and area of residence. The expenditure distributions are further adjusted to take into account plan benefit design, or "metal" level (that is, "level of coverage," as defined in § 156.20) and other characteristics of individual insurance coverage in an Exchange. To describe a State's coverage market, the ACAHiM computes the pattern of enrollment using the model's predicted number and composition of participants in a coverage market. These estimated expenditure distributions were the basis for the uniform reinsurance payment parameters.

We are finalizing the 2016 payment parameters as proposed.

Comment: Several commenters supported the proposed 2016 uniform reinsurance payment parameters. One commenter asked that HHS consider when setting the parameters that some issuers are unable to obtain commercial reinsurance and therefore are left unprotected from large losses.

Response: We are finalizing the 2016 uniform reinsurance payment parameters as proposed, and as we explained above and in the 2014 and 2015 Payment Notices, these parameters are set in an effort not to interfere with commercial reinsurance, although we understand not all issuers can obtain commercial reinsurance. Additionally, we believe that maintaining the reinsurance cap for the 2016 benefit year while ensuring that the coinsurance rate sufficiently compensates issuers for high-risk individuals will make it easier for issuers to estimate the effects of reinsurance.

Comment: Several commenters asked that HHS not change the uniform reinsurance payment parameters for 2016 finalized in this rule in subsequent rulemaking.

Response: We are finalizing the 2016 uniform payment parameters as proposed, and do not intend to make any future adjustments to these parameters.

j. Uniform Reinsurance Payment Parameters for 2015

In the proposed rule, we proposed lowering the 2015 attachment point

from \$70,000 to \$45,000 as this would allow the reinsurance program to make more payments for high-cost enrollees in individual market reinsurance-eligible plans without increasing the contribution rate. We did not propose to adjust the 2015 coinsurance rate of 50 percent or reinsurance cap of \$250,000.

We are finalizing the reduction of the 2015 attachment point to \$45,000 as proposed.

Comment: Some commenters supported our proposal to lower the 2015 attachment point to \$45,000. Other commenters disagreed with our proposal to lower the 2015 attachment point, noting that this change would affect premium rates already submitted. One commenter noted that lowering the attachment point would result in lower MLRs, requiring issuers to rebate excess funds. Additionally, some noted that changing the 2015 payment parameters at this point could interfere with any State supplemental reinsurance program that depends on the national reinsurance payment parameters.

Response: In the 2015 Market Standards Rule,¹⁹ we signaled our intention to propose to lower the 2015 attachment point from \$70,000 to \$45,000 for the 2015 benefit year in an effort to notify issuers of this change in advance of rate settings for 2015 coverage. Additionally, we believe that lowering the attachment point to \$45,000 will further the premium stabilization effects of the program in 2015 as more individuals enroll in non-grandfathered, individual market plans that are compliant with §§ 147.102, 147.104 (subject to § 147.145), 147.106 (subject to § 147.145), 156.80, and subpart B of part 156 than in 2014.

k. Deducting Cost-Sharing Reduction Amounts From Reinsurance Payments

We proposed to modify the methodology finalized in the 2015 Payment Notice (79 FR 13780) regarding the deduction of cost-sharing reduction amounts from reinsurance payments. Under § 156.410, if an individual is determined eligible to enroll in an individual market Exchange QHP and elects to do so, the QHP issuer must assign the individual to a standard plan or cost-sharing plan variation based on the enrollment and eligibility information submitted by the Exchange. Issuers of individual market Exchange QHPs will receive cost-sharing reduction payments for enrollees who have effectuated coverage in cost-sharing plan variations. To avoid double payment by the Federal government, we indicated in the 2014 Payment Notice

¹⁸ See the proposed 2014 Payment Notice (77 FR 73160) and the proposed 2015 Payment Notice (78 FR 72344) for more information on the ACAHiM methodology.

¹⁹ 79 FR 30259.

(78 FR 15499) that the enrollee-level claims data submitted by an issuer of a reinsurance-eligible plan should be net of cost-sharing reductions provided through a cost-sharing plan variation (which are reimbursed by the Federal government).

In the 2015 Payment Notice (79 FR 13780), we explained the methodology HHS will use to deduct the amount of cost-sharing reductions paid on behalf of an enrollee enrolled in a QHP in an individual market through an Exchange. For each enrollee enrolled in a QHP plan variation,²⁰ we will subtract from the QHP issuer's total plan paid amounts for the enrollee in a reinsurance-eligible plan the difference between the annual limitation on cost sharing for the standard plan and the annual limitation on cost sharing for the plan variation. For policies with multiple enrollees, such as family policies, we stated we would allocate the difference in annual limitation in cost sharing across all enrollees covered by the family policy in proportion to the enrollees' QHP issuer total plan paid amounts.

We also stated that for an enrollee who is assigned to different plan variations during the benefit year, we would calculate the adjustment for cost-sharing reductions based on the annual limitation on cost sharing applicable to the plan variation in which the enrollee was last enrolled during the benefit year, because cost sharing accumulates over the benefit year across plan variations of the same standard plan. We proposed a modification to this particular policy.

Specifically, if an enrollee is assigned to different plan variations during the benefit year, we proposed to calculate the adjustment for cost-sharing reductions based on the difference between the annual limitation on cost sharing for the standard plan and the average annual limitation on cost sharing in the plan variations (including any standard plan), weighted by the number of months the enrollee is enrolled in each plan variation during the benefit year.²¹

We are finalizing this proposal as proposed.

Comment: Several commenters stated that our proposed modification was too complex, and would increase the burden on issuers to make additional

calculations and data system enhancements.

Response: We believe that our modified approach will permit HHS to more accurately allocate the difference in annual limitations in a family policy to individual family members when a member exits or enters the policy mid-year, or if there are other changes in circumstances that impact the cost-sharing reductions provided to enrollees covered by the family policy. We will continue to work with issuers and provide technical support to help with the updates to the calculations and data system enhancements that may be necessary.

4. Provisions for the Temporary Risk Corridors Program

a. Application of the Transitional Policy Adjustment in Early Renewal States

On November 14, 2013, the Federal government announced a transitional policy under which it will not consider certain health insurance coverage in the individual or small group markets that is renewed for a policy year starting after January 1, 2014, under certain conditions to be out of compliance with specified 2014 market rules, and requested that States adopt a similar non-enforcement policy.^{22 23} In the 2015 Payment Notice, HHS implemented an adjustment to the administrative cost ceiling and profit floor of the risk corridors formula for the 2014 benefit year to help further offset losses that might occur under the transitional policy as a result of increased claims costs not accounted for when setting 2014 premiums. Because we believe that the Statewide effect on the risk pool in States that adopted the Federal transitional policy would increase with an increase in the percentage enrollment in transitional plans in the State, we stated that we would vary the State-specific percentage adjustment to the risk corridors formula with the percentage of member-months enrollment in these transitional plans in the State.²⁴

In response to stakeholder questions, we proposed to clarify in the 2016

Payment Notice that the transitional adjustment applies only for plans under the transitional policy—that is, plans that renew after January 1, 2014 for which HHS and the applicable State are not enforcing market rules. We proposed to further clarify that member-months of enrollees in early renewal plans would not be counted towards the risk corridors transitional policy adjustment (that is, unless and until the plan becomes a transitional plan in a transitional State upon renewal in 2014).²⁵ We are finalizing this clarification as proposed, and are maintaining the policy previously finalized in the 2015 Payment Notice under § 153.500 and § 153.530 without modification.

Comment: Several commenters recommended that HHS modify our policy to include the experience of early renewal plans. One commenter suggested that HHS include early renewals in the adjustment because our announcement did not occur until November 11, 2013, which was too late to be reflected in the rates that were finalized in July 2013. Another commenter requested that HHS modify its policy to accommodate issuers in States that decided to allow early renewals after the announcement of the transitional policy.

Response: We believe that issuers were aware of State policy for early renewals when they set their 2014 rates; moreover, the transitional policy adjustment was intended to address the Federal transitional policy, not State early renewal policies. Under our current policy, HHS counts months occurring after an early renewal plan becomes a transitional plan when we calculate the transitional adjustment for each State. We believe that this approach for counting member months towards the risk corridors transitional adjustment is consistent with the intent of the transitional policy adjustment set forth in the 2015 Payment Notice.

Comment: One commenter suggested that the transitional adjustment be applied to the risk corridors calculation for the entire market for 2014, not just in markets where the transitional policy is in effect. Another commenter requested that HHS implement the transitional adjustment in a manner that does not disadvantage States that did not adopt the Federal transitional policy for 2014.

²⁵ § 153.530 sets forth the data requirements for this information collection. HHS published 60-day and 30-day notices in the **Federal Register**, providing the public with an opportunity to submit written comments on the information collection. The data collection is approved under OMB Control Number 0938-1267.

²⁰ Except for limited cost-sharing plan variations, for which we stated we would not reduce the QHP issuer's plan paid amounts.

²¹ We did not propose any changes to the approach finalized in the 2015 Payment Notice with respect to the QHP issuer's plan paid amounts for purposes of calculating reinsurance payments for an Indian in a limited cost-sharing plan variation.

²² Letter to Insurance Commissioners, Center for Consumer Information and Insurance Oversight, November 14, 2013. Available at: <http://www.cms.gov/CCIIO/Resources/Letters/Downloads/commissioner-letter-11-14-2013.PDF>.

²³ HHS extended the transitional policy on March 5, 2014, permitting issuers to renew transitional policies through policy years beginning on or before October 1, 2016.

²⁴ As stated in the 2015 Payment Notice, HHS will calculate the amount of the adjustment that applies to each State based on the State's member-month enrollment count for transitional plans and non-transitional plans in the individual and small group markets.

Response: We are maintaining the policy finalized in the 2015 Payment Notice under § 153.500 and § 153.530, which provides, for 2014, that the effect of the transitional adjustment will vary according to the member-month enrollment in a State, such that the 3 percent profit floor and 20 percent allowable administrative cost ceiling will apply in States that did not adopt the Federal transitional policy (QHP issuers in these States will receive a risk corridors transitional adjustment equal to zero). We believe that issuers in States that did not adopt the Federal transitional policy will not require the transitional adjustment to help mitigate mispricing that may have occurred due to unexpected changes in the risk pool resulting from the Federal transitional policy. We note that the adjustment will account for the effect of the Federal transitional policy in the entire market within a State that adopted the transitional policy, such that a QHP issuer in a transitional State will be eligible to receive an adjustment to its risk corridors calculation even if the issuer has not issued transitional policies.

b. Risk Corridors Payments for 2016

On April 11, 2014, we issued a bulletin titled “Risk Corridors and Budget Neutrality,” which described how we intend to administer risk corridors over the 3-year life of the program.²⁶ Specifically, we stated that if any risk corridors funds remain after prior and current year payment obligations have been met, they will be held to offset potential insufficiencies in risk corridors collections in the next year. We also stated that we would establish in future guidance how we would calculate risk corridors payments in the event that cumulative risk corridors collections do not equal cumulative risk corridors payment requests.

In the proposed 2016 Payment Notice, we proposed that if, for the 2016 benefit year, cumulative risk corridors collections exceed cumulative risk corridors payment requests, we would make an adjustment to our administrative expense definitions (that is, the profit margin floor and the ceiling for allowable administrative costs) to account for the excess funds. That is, if, when the risk corridors program concludes, cumulative risk corridors collections exceed both 2016 payment

requests under the risk corridors formula and any unpaid risk corridors amounts from previous years, we would increase the administrative cost ceiling and the profit floor in the risk corridors formula by a percentage calculated to pay out all collections to QHP issuers. The administrative cost ceiling and the profit floor would be adjusted by the same percentage.

We proposed to determine the percentage adjustment to the administrative cost ceiling and profit margin floor by evaluating the amount of excess risk corridors collections (if any) available after risk corridors payments for benefit year 2016 have been calculated. As stated in our bulletin on risk corridors and budget neutrality, after receiving charges from issuers for the 2016 benefit year, we would first prioritize payments to any unpaid risk corridors payments remaining from the 2015 benefit year. We would then calculate benefit year 2016 risk corridors payments for eligible issuers based on the 3 percent profit floor and 20 percent allowable administrative cost ceiling, as required by regulation. If, after making 2015 payments and calculating (but not paying) risk corridors payments for benefit year 2016, we determine that the aggregate amount of collections (including any amounts collected for 2016 and any amounts remaining from benefit years 2014 and 2015) exceed what is needed to make 2016 risk corridors payments, we would implement an adjustment to the profit floor and administrative cost ceiling to increase risk corridors payments for eligible issuers for benefit year 2016. We would examine data that issuers have submitted for calculation of their 2016 risk corridors ratios (that is, allowable costs and target amount) and determine, based on the amount of collections available, what percentage increase to the administrative cost ceiling and profit floor could be implemented for eligible issuers while maintaining budget neutrality for the program overall. Although all eligible issuers would receive the same percentage adjustment, we proposed that the amount of additional payment made to each issuer would vary based on the issuer’s allowable costs and target amount. We proposed that, once HHS calculated the adjustment and applied it to eligible issuers’ risk corridors formulas, it would make a single risk corridors payment for benefit year 2016 that would include any additional, adjusted payment amount.

Because risk corridors collections are a user fee to be used to fund premium stabilization under risk corridors and no

other programs, we proposed to limit this adjustment to excess amounts collected. We also proposed to apply this adjustment to allowable administrative costs and profits for the 2016 benefit year only to plans whose allowable costs (as defined at § 153.500) are at least 80 percent of their after-tax premiums, because issuers under this threshold would generally be required to pay out MLR rebates to consumers.²⁷ For plans whose ratio of allowable costs to after-tax premium is below 80 percent, we proposed that the 3 percent risk corridors profit margin and 20 percent allowable administrative cost ceiling would continue to apply. Furthermore, we proposed that, to the extent that applying the proposed adjustment to a plan could increase its risk corridors payment and affect its MLR calculation, the MLR calculation would ignore these adjustments.

As previously stated, we anticipate that risk corridors collections will be sufficient to pay for all risk corridors payments. HHS recognizes that the Affordable Care Act requires the Secretary to make full payments to issuers. In the unlikely event that risk corridors collections, including any potential carryover from the prior years, are insufficient to make risk corridors payments for the 2016 program year, HHS will use other sources of funding for the risk corridors payments, subject to the availability of appropriations.

We are finalizing this policy as proposed.

Comment: We received one comment on the proposed approach for allocating excess risk corridors collections at the end of the program. The commenter supported our approach. Another commenter supported language in the proposed Payment Notice that reaffirmed HHS’s commitment to make full risk corridors payments if collections are insufficient to fund payments.

Response: We are finalizing the policy regarding allocation of excess risk corridors collections for 2016 as proposed.

²⁶ The Centers for Medicare and Medicaid Services, Center for Consumer Information and Insurance Oversight, “Risk Corridors and Budget Neutrality,” April 11, 2014. Available at: <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/faq-risk-corridors-04-11-2014.pdf>.

²⁷ Because of some differences in the MLR numerator and the definition of allowable costs that applies with respect to the risk corridors formula, in a small number of cases, an issuer with allowable costs that are at least 80 percent of after-tax premium, may be required to pay MLR rebates to consumers.

5. Distributed Data Collection for the HHS-Operated Risk Adjustment and Reinsurance Programs

a. Good Faith Safe Harbor (§ 153.740(a))

In the second Program Integrity Rule,²⁸ HHS finalized a good faith safe harbor policy which provided that civil money penalties (CMPs) will not be imposed for non-compliance with the HHS-operated risk adjustment and reinsurance data requirements during 2014, if the issuer has made good faith efforts to comply with these requirements.²⁹ That safe harbor parallels a similar safe harbor for QHP issuers in FFEs under § 156.800.

We proposed to amend § 153.740(a) to extend the safe harbor for non-compliance with the HHS-operated risk adjustment and reinsurance data requirements during the 2015 calendar year if the issuer has made good faith efforts to comply with these requirements. This proposal acknowledged that the distributed data collection requirements have been the subject of modifications through the 2014 calendar year, including the introduction of cloud-based virtual options for the distributed data environment. We note that good faith efforts could include notifying, communicating with, and cooperating with HHS for issues that arise with the establishment and provisioning of the issuers' dedicated distributed data environment.

The extension of this good faith safe harbor would not affect HHS's ability to assess issuers of risk adjustment covered plans a default risk adjustment charge under § 153.740(b).³⁰ Additionally, we noted that the good faith safe harbor would not apply to non-compliance with dedicated distributed data environment standards applicable during 2016, even if the non-compliance in the 2016 calendar year relates to data for the 2015 benefit year. For example, the data loading schedule applicable to the 2015 benefit year for risk adjustment

and reinsurance data extends into the 2016 calendar year (the final loading deadline is April 30, 2016). Therefore, the good faith safe harbor would not apply to non-compliance with the dedicated distributed data environment standards applicable during 2016.

Comment: Several commenters supported our proposal to extend the good faith safe harbor to the 2015 benefit year. The commenters asked that we clarify that the safe harbor extension would apply to conduct that occurred in a covered year (2014 or 2015) regardless of when an enforcement action is initiated. These commenters also asked that the good faith safe harbor apply for any risk adjustment or reinsurance data requirements that apply to the 2015 benefit year, even if the data is reported in 2016.

Response: As we clarified in the 2015 Payment Notice (79 FR 13791), HHS will not impose CMPs for noncompliance for dedicated distributed data environment standards for the 2014 benefit year, if the issuer attempted in good faith to comply, simply by waiting until 2015 to initiate the enforcement action. We will follow the same approach with respect to the extension of the good faith safe harbor through the 2015 calendar year. However, the good faith safe harbor will not apply to non-compliance with dedicated distributed data environment standards applicable during the 2016 calendar year, even if the non-compliance in 2016 relates to data for the 2015 benefit year.

Comment: One commenter asked that we extend the good faith safe harbor to 2016.

Response: We are not extending the good faith compliance safe harbor to 2016.

b. Default Risk Adjustment Charge (§ 153.740(b))

In the second Program Integrity Rule and the 2015 Payment Notice, HHS indicated that a default risk adjustment

charge will be assessed if an issuer does not establish a dedicated distributed data environment or submits inadequate risk adjustment data. However, we did not establish how the money collected from the default charge will be allocated among risk adjustment covered plans.

We proposed to allocate collected per member per month default charge funds proportional to each plan's relative revenue requirement, the product of $PLRS_i \cdot IDF_i \cdot GCF_i$ (Plan Liability Risk Score * Induced Demand Factor * Geographic Cost Factor) relative to the market average of these products, across all risk adjustment covered plans in the market in the State. This approach would allocate funds proportionally to a plan's enrollment, adjusted for factors such as health risk, actuarial value, and geographic cost differences. This approach would also allocate the default charge funds in accordance with plans' expected revenue requirements as calculated in the transfer formula. By contrast, an approach that allocates risk adjustment default charge funds in accordance with enrollment or premiums, for example, would favor plans with lower metal levels, low risk selection, or lower geographic costs.

This allocation would occur only in risk adjustment markets with at least one noncompliant plan, and these steps would be used to calculate each compliant plan's allocation of the default charges collected from the noncompliant plan(s). We would calculate risk transfers among the compliant plans only and exclude all data from noncompliant plans. Using the same inputs of the compliant plans as used in the transfer formula, we would calculate the distribution of default charges paid by noncompliant plans among the compliant plans using the following formula:

$$DC_i = \text{total default charges collected} \times s_i \left[\frac{PLRS_i \cdot IDF_i \cdot GCF_i}{\sum (s_i \cdot PLRS_i \cdot IDF_i \cdot GCF_i)} \right]$$

Where:

DC_i is the total amount of default charges allocated to plan i ;

"Total default charges collected" is the sum, in dollars, collected from all noncompliant plans (aggregate dollars,

that is, *not* on a per member per month basis);

Other terms are as defined in the usual risk transfer calculations, and restricted to

²⁸ 78 FR 65046.

²⁹ We note that HHS also clarified in a March 28, 2014 FAQ that CMPs would not be imposed on an issuer for non-compliance during the 2014 calendar year, if the issuer made good efforts to comply with these requirements. See, FAQ 1212, published

March 28, 2014. Available at: https://www.regtop.info/faq_viewu.php?id=1212.

³⁰ According to § 153.740(b), if an issuer of a risk adjustment covered plan fails to establish a dedicated distributed data environment or fails to provide HHS with access to the required data in such environment in accordance with § 153.610(a),

§ 153.700, § 153.710, or § 153.730 such that HHS cannot apply the applicable Federally certified risk adjustment methodology to calculate the risk adjustment payment transfer amount for the risk adjustment covered plan in a timely fashion, HHS will assess a default risk adjustment charge.

compliant plans only (s_i = plan i 's share of State enrollment; $PLRS_i$ = plan i 's plan liability risk score, IDF_i = plan i 's induced demand factor, GCF_i = plan i 's geographic cost factor); and i indexes compliant plans, and the summation in the denominator is over compliant plans only.

Comment: One commenter agreed with the proposed allocation of default risk adjustment charges to risk adjustment compliant plans, noting that it provides an equitable distribution of default risk adjustment charges.

Response: We are finalizing the allocation of default risk adjustment charges as proposed.

c. Information Sharing (§ 153.740(c))

In § 153.740, we established the enforcement remedies available to HHS for an issuer of a risk adjustment covered plan or a reinsurance-eligible plan's failure to comply with HHS-operated risk adjustment and reinsurance data requirements. Consistent with the policy set forth at § 156.800(d), as finalized in the 2015 Market Standards Rule,³¹ we proposed adding paragraph (c) to clarify that HHS may consult with and share information about issuers of a risk adjustment covered plan or a reinsurance-eligible plan with other Federal and State regulatory and enforcement entities to the extent that the consultation or information is necessary for HHS to determine whether an enforcement remedy against the issuer of the risk adjustment covered plan or reinsurance-eligible plan under § 153.740 is appropriate. For example, HHS may consult other Federal and State regulatory and enforcement entities to identify issuers within a State that have failed to establish a dedicated distributed data environment. No personally identifiable information would be transferred as part of such a consultation.

We received no comments on this proposal. We are finalizing this provision as proposed.

D. Part 154—Health Insurance Issuer Rate Increases: Disclosure and Review Requirements

1. General Provisions

In the proposed rule, we proposed several modifications to enhance the transparency and effectiveness of the rate review program under part 154. These provisions were proposed to apply generally beginning with rates filed in 2015 for coverage effective on or after January 1, 2016. We requested comment on whether the proposal

provides States and issuers sufficient time to transition to the new rate review requirements.

Comment: While some commenters believed the proposed timeframe was adequate, others suggested that issuers would not have sufficient time to implement the requirements to meet deadlines for the 2015 filing year. Some commenters noted it would take time for HHS to modify the Unified Rate Review Template (URRT) to accommodate the new plan-level trigger under proposed § 154.200(c). Commenters recommended the plan-level requirements not apply until the 2016 filings for plan years beginning in 2017.

Response: In response to comments, to provide adequate time to make necessary adjustments to the URRT, the revised definition of “rate increase” and plan-level trigger under §§ 154.102 and 154.200(c) of this final rule will apply beginning with rates filed in 2016 for coverage effective on or after January 1, 2017. The uniform rate review and disclosure timelines under §§ 154.220 and 154.301 of this final rule will apply beginning with rates filed in 2015 for coverage effective on or after January 1, 2016. As discussed below, the individual market annual open enrollment period for the 2016 benefit year will not begin until November 1, 2015, which provides additional time to meet the filing deadlines for 2016 rates.

a. Definitions (§ 154.102)

Under § 154.102, we set forth definitions of terms that are used throughout part 154. We proposed adding a new definition of “plan” and revising the definitions of “individual market,” “small group market,” and “State.” For the most part, these terms would have the meaning given such terms in § 144.103. For a discussion of the terms “plan” and “State,” please see the preamble for § 144.103 in this final rule.

We also proposed to modify the definition of “rate increase.” The revisions would conform with our proposal in § 154.200 to consider rate increases at the plan-level when determining whether a rate increase is subject to review.

We did not receive comments on the definitions of “individual market,” “small group market,” and “rate increase.” We are finalizing these revisions as proposed, except that the revised definition of “rate increase” has been modified to clarify that the changes made to conform with the proposal in § 154.200 will apply for rates filed for coverage effective on or after January 1, 2017. The other

definitions will apply for rates filed for coverage effective on or after January 1, 2016.

Comment: Several commenters did not agree with our proposal to apply the definition of “plan” in the context of the rate review program. The commenters expressed concern that this would add complexity and create delays to the product filing and review process.

Response: Because this final rule establishes a trigger for review of rate increases at the plan level, we are adopting the definition of “plan” at § 144.103 of this final rule for purposes of the rate review requirements under part 154. While changing to a plan-level trigger may increase the number of rate filings subject to review, we believe doing so will more accurately reflect consumer expectations for the rate review program. We note that nothing in this final rule changes the scope of issuer rate filings, which will continue to be submitted at the product level.

2. Disclosure and Review Provisions

a. Rate Increases Subject to Review (§ 154.200)

In § 154.200, we proposed modifications to the standards for rate increases that are subject to review. In paragraphs (a)(1) and (2), we proposed technical corrections to clarify that rate increases are applicable to a 12-month period that begins on January 1 rather than September 1 of each year.

In paragraph (c), we proposed that rate increases would be calculated at the plan level (as opposed to the product level) when determining whether an increase is subject to review. Under this approach, if any plan within a product in the individual or small group market experiences an increase in the plan-adjusted index rate (as described in § 156.80) that meets or exceeds the applicable threshold (either 10 percent or a State-specific threshold), the entire product would be subject to review to determine whether the rate increase is unreasonable. This proposal was intended to ensure that a plan that experiences a significant rate increase could not avoid review simply because the average increase for the product did not meet or exceed the applicable threshold.

We sought comment on all aspects of these proposals, including the benefits and costs to States of carrying out the plan-level trigger for review.

Comment: We received comments that suggested some confusion as to whether rate increases would be reviewed at the product level or the plan level when determining whether an increase is an unreasonable rate increase.

³¹ 79 FR 30240.

Response: We clarify that the plan-level threshold under this final rule is simply a trigger for review. The review will continue to occur, as it does today, at the product level, taking into account the combined experience of the plans within the product.

Comment: Many commenters supported the proposal to apply the trigger for review at the plan level, suggesting it better reflected the intent of Congress to protect consumers against unreasonable rate increases. Other commenters opposed the proposal and urged HHS to retain the current product-level trigger for review. Many of these commenters were concerned that the proposed rule would significantly increase the number of rate filings subject to review, placing greater burden on State regulators and increasing administrative cost to issuers. Several commenters additionally stated the plan-level trigger is inappropriate because plan-level rates vary naturally due to common market factors, such as provider contracting and deductible leveraging. Multiple other commenters urged us to lower the threshold for review—for example, tying it to growth in national health expenditures. One commenter suggested maintaining a 10 percent threshold at the product level and applying a 20 percent threshold at the plan level.

Response: Because consumers are affected by rate increases at the plan level, we believe that increases for the plan, not the product, should be the trigger for determining whether an increase is subject to review. We acknowledge the concerns about burden, but believe the consumer protection benefits of this policy outweigh the costs and further the intent of section 2794 of the PHS Act to protect consumers against unreasonable rate increases. Therefore, we are finalizing the trigger for determining whether an increase is subject to review based on rate increases at the plan level. However, as noted above, we are modifying the final rule to apply this change effective for rates filed for coverage beginning on or after January 1, 2017. We have updated the regulation text at § 154.200(a) to maintain the current trigger for determining whether the increase is subject to review for rates filed for coverage effective before January 1, 2017. HHS will continue to collect and review available data on trends in rate and medical increases in assessing whether to modify the 10 percent threshold for review.

Comment: One commenter recommended considering not only increases in the plan-adjusted index rate, but also changes in premium rating

factors including those for geography and tobacco use.

Response: We interpret section 2794 of the PHS Act as requiring the Secretary to establish a process for the annual review of unreasonable increases in the underlying rates that are used to develop the premiums, as opposed to the actual premiums themselves (75 FR 81009). Therefore, the final rule considers only increases in the plan-adjusted index rate described in § 156.80 rather than the premium rating factors described in § 147.102. We note that nothing in this regulation prevents a State from reviewing other aspects of an insurance rate filing, including premium rating factors.

b. Submission of Rate Filing Justification (§ 154.215)

In § 154.215(a), we proposed a technical correction to clarify that issuers must submit a rate filing justification for all products in the issuer's single risk pool when "any plan within a product" in the individual or small group market is subject to a rate increase. This is true regardless of whether the rate increase meets or exceeds the subject to review threshold. We proposed this clarification take effect with the effective date of the final rule. We are finalizing this clarification as proposed.

Comment: Some commenters encouraged HHS to clarify throughout § 154.215 that issuers must justify rate increases at the plan level, in addition to justifying them at the product level.

Response: The final rule does not adopt this suggestion. Because rate increases that are subject to review are reviewed at the product level, issuers will likewise submit the rate filing justification at the product level rather than the plan level.

c. Timing of Providing the Rate Filing Justification (§ 154.220)

To provide consistency and transparency in the rate submission process, ensure a more meaningful opportunity for public review and comment, and reduce the opportunity for anti-competitive behavior, we proposed to modify § 154.220 to establish a uniform timeline by which health insurance issuers must submit to CMS or the applicable State a completed rate filing justification for proposed rate increases—for both QHPs and non-QHPs—in the individual and small group markets. Under the proposed rule, the issuer would be required to submit the justification by the earlier of the following: (1) The date by which the State requires a proposed rate increase to be filed with the State; or (2) the date

specified by the Secretary in guidance. We suggested that we were considering specifying a deadline to coincide with the end of the QHP application window for the FFE. States would have flexibility to impose earlier rate filing deadlines to meet their specific State needs. We sought comment on this proposal.

We are finalizing these provisions as proposed. We intend to specify the submission deadline for the 2015 filing year in forthcoming guidance.

Comment: We received many comments regarding the proposal to establish a uniform rate filing timeline. Commenters who supported the proposal generally agreed it would increase transparency and encourage public participation in the rate review process. Commenters also viewed the common submission deadline for both QHP and non-QHP rate filings as a positive step to protect against shadow pricing among competing issuers and create a level playing field inside and outside the Exchange.

Commenters who opposed the proposal were concerned that the HHS deadline would not provide issuers sufficient time to collect claims data and appropriately develop rates for the upcoming benefit year. Commenters also expressed concern that requiring rates for QHPs and non-QHPs to be submitted at the same time would impose an increased workload on State regulators, making it difficult to conduct thorough reviews and potentially creating delays in the review and approval process. Many commenters objected to a nationally uniform rate review timeline and urged State flexibility to set their own filing deadlines, particularly in States with effective rate review programs and States that operate their own Exchanges. Some commenters believed it would be sufficient for HHS to simply establish a deadline for States to complete their reviews.

Several commenters remarked on the specific deadline for rate filing submissions. One commenter recommended HHS establish a rate filing deadline of no sooner than May 15, while another commenter recommended a mid-summer deadline. Another commenter recommended that issuers have 90 days after the end of the FFE QHP application window to prepare the rate filing justification. Some commenters asserted that the filing deadline must accommodate a sufficient public comment period.

One commenter suggested that grandfathered and transitional plans should not be subject to the same filing deadlines as single risk pool compliant

plans. Finally, some commenters recommended the NAIC convene a workgroup to make recommendations to HHS regarding the rate review timeline.

Response: We believe the rate review process should be both predictable and transparent. To achieve this objective, we believe it is necessary to establish a uniform submission deadline for issuers to submit proposed rate increases for single risk pool coverage in the individual and small group markets. Therefore, we are finalizing proposed § 154.220 authorizing the Secretary to establish in guidance the deadline for issuers to submit the rate filing justification for proposed rate increases for both QHPs and non-QHPs in the individual and small group markets. We will carefully consider commenters' suggestions and consult with the NAIC and other interested parties when developing such guidance which we expect to issue soon. We anticipate the deadline will provide issuers adequate time to develop rates and afford States and the public the necessary time for review.

We note that States retain significant flexibility to stage the timing of their reviews consistent with this final rule. This could include establishing filing deadlines prior to the HHS deadline, staggering the submission of forms and rates, or establishing varying deadlines for the individual and small group markets.

Finally, we clarify that, while transitional plans are generally subject to the rate review requirements, the uniform submission timeline applies only to non-grandfathered individual and small group market coverage that is subject to the single risk pool requirement. Grandfathered health plans are not subject to the Federal rate review program.

d. CMS's Determinations of Effective Rate Review Programs (§ 154.301)

We proposed to amend § 154.301(b) to specify the timeframe for a State with an effective rate review program to provide public access to information about proposed and final rate increases.

Under the proposed rule, for proposed rate increases subject to review, the State would be required to provide public access from its Web site to the information contained in Parts I, II, and III of the rate filing justification that CMS makes available on its Web site (or provide CMS's web address for such information). The proposed rule would require that the State take this action no later than the date specified by the Secretary in guidance. We suggested the 10th business day following receipt of all rate filings in the relevant State

market as the potential timeframe we may specify for this purpose. The proposed rule would also continue to require that the State have a mechanism for receiving public comments on those proposed rate increases.

For all final rate increases (including those not subject to review), the proposed rule would similarly require that the State provide public access from its Web site to the information contained in Parts I, II, and III of the rate filing justification that CMS makes available on its Web site (or provide CMS's web address for such information). The State would be required to take this action no later than the first day of the individual market annual open enrollment period.

Nothing in this proposal would prevent States from making additional information available to the public, or prevent States from establishing earlier timeframes for public disclosure. States that elect to establish earlier posting timeframes would be required under the proposed rule to notify CMS in writing at least 30 days prior to the date the information will be made public. States would also be required to ensure that rate information released to the public is made available at a uniform time for all proposed and final rate increases (as applicable) in the relevant market segment and without regard to whether coverage is offered through an Exchange or outside of an Exchange.

We sought comment on these proposals, including how the timeframes may interact with current State practice and workload. We also sought comment on whether States with effective rate review programs should be required to post rate information on the State's Web site, rather than being permitted to provide a link to CMS's Web site for such information.

We are finalizing these provisions as proposed. We are also maintaining the option for States to continue to provide public access from their Web site via link to rate information made available on the CMS Web site.

Comment: Some commenters suggested that CMS should not require the release of rate information before rates are finalized. Another commenter requested that all proposed rates be made available to the public, not only those subject to review.

Response: Section 2794 of the PHS Act requires the Secretary to ensure the public disclosure of information, including the justification for an unreasonable rate increase. We believe that Congress intended the rate review process to be transparent, and that this objective is served by giving consumers timely access to basic information

regarding the proposed increase that is under review by CMS or States and prior to the implementation of the increase. The proposed rule and this final rule do not change the existing requirements regarding the scope of the information that must be disclosed under the current regulations.

Comment: Several commenters expressed opposition to our proposal to specify the timeframe for posting information about proposed rate increases that are subject to review. Commenters generally asserted that States have existing processes for rate disclosure and requested State flexibility to manage publication timeframes in the way most appropriate to their market and regulatory structure. One commenter suggested CMS establish a timeframe of 5 business days for States to post information about proposed rate increases subject to review. Another commenter requested clarification about the information CMS intends to post on its Web site and how the suggested timeframe of 10 business days from the filing deadline would provide sufficient time to redact issuers' confidential and proprietary information protected by the Freedom of Information Act.

Response: We are finalizing the proposal for the Secretary to specify the timeframe for States with effective rate review programs to provide public access to information about proposed rate increases that are subject to review. This timeframe will be specified in guidance. We anticipate specifying a deadline of the 10th business day after receipt of all rate filings in the relevant State market. We note this provision applies only to products with proposed rate increases that are subject to review and only includes the information in Parts I, II, and III of the rate filing justification that CMS makes available on its Web site. Under § 154.215(h), CMS makes available on its Web site only the information that is not considered a trade secret or confidential commercial or financial information as defined in Freedom of Information Act regulations, 45 CFR 5.65. We note that States may choose to make additional information available as permitted by applicable State law and regulations.

Comment: Many commenters emphasized the need for sufficient opportunity for public review and comment before rates are finalized, with suggested timeframes ranging from 30 to 90 days of public comment.

Response: Under current regulations, a State with an effective rate review program must have a mechanism for receiving public comments on proposed rate increases that are subject to review.

We believe this standard is sufficient to encourage public participation in the rate review process, while affording States flexibility to manage the public comment process in the way most appropriate for the State.

Comment: Some commenters stated that information about final rate increases should be released prior to the start of the annual open enrollment period to allow consumers, assisters, and other interested stakeholders greater opportunity to familiarize themselves with issuer rates. These commenters offered various suggestions, most commonly recommending that final rates be posted 15 days in advance of the annual open enrollment period. Other commenters were concerned about the workload and burden on States of completing reviews for both Exchange and non-Exchange plans at the same time.

Response: The final rule retains the proposal that information about final rate increases must be posted by the first day of the annual open enrollment period. We believe this timeframe strikes the appropriate balance between providing State and Federal regulators sufficient time to complete their reviews, while providing consumers the information needed to make informed purchasing decisions. We note that States may establish earlier posting timeframes with appropriate notice to CMS.

Comment: One commenter recommended clarifying in § 154.301(b)(1)(ii) that the term “annual open enrollment period” refers to the open enrollment period in the individual market.

Response: The final rule adopts the suggestion to reference the “individual market” annual open enrollment period under § 154.301(b)(1)(ii).

Comment: One commenter stated that CMS should also establish posting deadlines for States in which CMS is conducting the reviews.

Response: While the rate review timeline under this final rule establishes minimum standards for submission and posting of rate information in States with effective rate review programs, we will also apply these timelines in States without effective rate review programs where CMS conducts the reviews.

Comment: Some commenters recommended that States be required to post rate information directly on their Web sites instead of relying on the CMS Web site. Other commenters stated it would be costly and unnecessary to impose this requirement on States, since CMS already provides consumers with information about rate increases on its Web site. These commenters

recommended that States continue to be permitted to link to the CMS Web site.

Response: We agree that specifying that States must separately post rate information is not necessary at this time. Through CMS’s Web site (www.ratereview.healthcare.gov), consumers and other stakeholders can easily review rate increases requested by issuers in every State.³² We therefore retain the option for States to continue to provide public access from their Web site via link to rate information made available on the CMS Web site.

Comment: Some commenters believed that States should be required to provide public access to the entire rate filing justification, rather than only the information contained in Parts I, II and III that CMS makes available on its Web site. Other commenters indicated that States have policies and procedures governing rate increase disclosure and contended that States should have discretion to determine what information to release.

Response: The proposed rule and this final rule do not change the scope of information disclosure under the current regulations. The existing rules establish the minimum level of information that States with effective rate review programs must make available to the public, either directly on their Web sites or via link to the CMS Web site. We note that States have discretion to make additional information available to the public, as permitted by applicable State law and regulation.

Comment: Some commenters opposed the requirement that States must notify CMS in writing 30 days prior to making rate information public. The commenters were concerned the 30-day notice requirement was impractical and unnecessary, and may interfere with State and issuer rate negotiations and timelines. One commenter recommended that States simply make a good-faith effort to provide advance notice to CMS.

Response: We maintain in the final rule the requirement that States must provide at least 30-day notice of their intent to release proposed or final rate information when the State publication timeline is earlier than that specified by CMS. As we stated in the preamble to the proposed rule (79 FR 70703), this information will enable CMS to better coordinate the availability of rate information, increasing transparency nationally into the rate-setting process.

³² Rate filing information can also be accessed at <http://www.cms.gov/CCHIO/Resources/Data-Resources/ratereview.html>.

E. Part 155—Exchange Establishment Standards and Other Related Standards Under the Affordable Care Act

1. General Provisions

a. Definitions (§ 155.20)

In § 155.20, we proposed to amend the definitions of “applicant,” “enrollee,” and “qualified employee.” First, we proposed to specify that a qualified employer could elect to offer coverage through a SHOP to its former employees that may include retirees, as well as former employees to whom an employer might be obligated to provide continuation coverage under applicable State or Federal law. Second, we proposed to specify that a qualified employer could also elect to offer coverage through the SHOP to dependents of employees or former employees. Third, we proposed to specify that business owners may enroll in SHOP coverage provided that at least one employee enrolls. We proposed to amend these definitions to make it clear that SHOPS may allow small group enrollment practices that were in place before the Affordable Care Act to continue, to preserve continuity for issuers and employers, and to reduce the administrative complexity involved with transitioning to SHOP coverage for qualified employers.

We are finalizing the amendments to the definitions of applicant and qualified employee as proposed, and are modifying the amendments to the definition of enrollee in light of comments we received.

The preamble to the proposed rule also sought comment on whether other provisions of the Exchange rules in parts 155 and 156 would need to be amended to implement the changes proposed to these definitions. HHS interprets § 155.220(i) to give SHOPS the flexibility to permit web-brokers to enroll not just “qualified employees,” but all enrollees, consistent with the expansion of the definition of “enrollee” that is being finalized in this rule. Therefore, we are also modifying § 155.220(i) to refer to facilitating enrollment in coverage through the SHOP for enrollees instead of qualified employees.

Comment: One commenter commented that the proposed definition of an “applicant” does not capture all situations in which a person could become eligible for continuation coverage, such as divorce or loss of dependent child status.

Response: Not every person eligible to enroll in coverage purchased through the SHOP is considered a SHOP applicant. In the case of individuals

eligible to enroll in coverage through the SHOP due to a continuation coverage qualifying event, such as a divorce or a loss of dependent status, such an individual qualifies for such coverage by virtue of his or her coverage through the SHOP that existed on the day prior to the qualifying event. Such an individual need not file an application with the SHOP to continue to receive coverage after a qualifying event. Instead, consistent with current business practices, the qualified beneficiary should notify the employer or plan administrator of his or her desire to participate in continuation coverage. The employer or plan administrator must then notify the SHOP.³³ Where appropriate, such notification will allow the SHOP to individually bill the continuation coverage enrollee.

Comment: One commenter asked for clarification on whether at least one employee has to be eligible for or enrolled in SHOP coverage, and requested that HHS clarify whether a business owner may enroll in a QHP through the SHOP if at least one employee is *eligible* for coverage through SHOP but has not enrolled.

Response: We clarify that where a business's only enrollee(s) in coverage through the SHOP would be the owner(s) of the business, the owner is not eligible to enroll in coverage sold through the SHOP.³⁴

Comment: Some commenters requested clarification on whether an employee may enroll dependents without enrolling him or herself in the plan. Another commenter opposed the exclusion of child-only plans in the SHOP and stated that all children should have access to coverage even if they do not qualify as a "qualified employee."

Response: We note that under common market practice, dependents of an employee offered employer-sponsored coverage generally may enroll in such coverage only as a

dependent, if the employee enrolls in the coverage.³⁵ Except for continuation coverage, coverage offered through the SHOP does not depart from this general practice. Except as may be provided under otherwise applicable law, dependents of a qualified employee may enroll in a QHP through the SHOP through the qualified employee only if the qualified employee also enrolls in the same QHP through the SHOP. We note that this does not relieve issuers from the obligation to offer child-only coverage under the group health plan where the child is the primary subscriber, such as where the employee is 18 years old. Consistent with our policy for individual market QHPs at section 1302(f) of the Affordable Care Act, QHP issuers could satisfy this standard by offering employee-only coverage under the group health plan to qualified applicants seeking child-only coverage, as long as the QHP includes rating for child-only coverage in accordance with applicable premium rating rules.³⁶

In light of this comment, we note that the proposed amendments to the definition of "enrollee" did not account for a situation in which a person is enrolled in coverage because she is eligible for continuation coverage, but is no longer a dependent of the qualified employee or other primary subscriber. To account for this situation, we are modifying the proposed definition of "enrollee" to include any other person who is enrolled in a QHP through the SHOP consistent with applicable law and the terms of the group health plan.

Comment: Some commenters stated that the inclusion of "former employees" in the definition of qualified employee is not appropriate except in the case of continuation coverage.

Response: The inclusion of "former employee" in the Exchange rules' definitions of "applicant" and "qualified employee" does not provide eligibility for individuals to enroll in coverage if they are not otherwise eligible to enroll in small group coverage under HIPAA, COBRA, and other applicable Federal or State law. If individuals qualify for coverage under the terms of the plan and under existing statute and regulations governing eligibility to enroll in group health coverage, they may enroll in group

health coverage through the SHOP.³⁷ The SHOP regulations do not impose any additional obligation upon employers to offer former employees coverage sold through the SHOP, and employers may do so where permitted under the terms of the plan. In light of this comment, and to clarify that the persons listed in the definition of "enrollee" are generally meant to include all those who have enrolled in coverage through the SHOP consistent with applicable law and the terms of the group health plan, we are modifying the definition of "enrollee" to include, in addition to the listed individuals, any other person who is enrolled in a QHP through the SHOP consistent with applicable law and the terms of the group health plan.

Comment: One commenter asked how expanding the definition of "enrollee" to include a business owner will impact eligibility thresholds for the Small Business Health Care Tax Credit.

Response: The inclusion of owners in the definition of "enrollee" does not modify qualification requirements for the Small Business Health Care Tax Credit, as determinations for the credit do not rely on the SHOP's definition of "enrollee."

2. General Functions of an Exchange

a. Consumer Assistance Tools and Programs of an Exchange (§ 155.205)

In the proposed rule, we proposed to amend § 155.205(c) to specify the oral interpretation services that are required for certain entities subject to § 155.205(c). Specifically, for each Exchange, QHP issuer, and agent or broker subject to § 155.220(c)(3)(i) (referred to in this section as a "web-broker"), we proposed that the requirement to provide oral interpretation services under § 155.205(c)(2)(i) would include making available telephonic interpreters in at least 150 languages. We also proposed amendments to § 156.250 that are discussed below, and that would require QHP issuers to provide all information that is critical for obtaining health insurance coverage or access to health care services through the QHP, including applications, forms, and notices, to qualified individuals, applicants, qualified employers, qualified employees, and enrollees in

³³ 26 CFR 54.4980B-6 A-1(b) defines an election to enroll in continuation coverage as the date the notification is sent to the plan administrator, and § 157.205(f) requires qualified employers participating in the SHOP to provide the SHOP with information regarding changes in dependent or employee eligibility status for coverage.

³⁴ Persons may enroll in coverage available through the SHOP only if the plan constitutes a group health plan maintained by a small employer. A group health plan is an "employee welfare benefit plan" as defined by the Employee Retirement Income Security Act of 1974 (ERISA), and is a form of employee benefit plan, see ERISA § 3(3), 29 U.S.C. 1002(3). An "employee benefit plan" does not exist if there are no "employees" participating in the plan, 29 CFR 2510.3-3(b), and for the purpose of identifying an employee benefit plan an "employee" does not include the sole owner of a business or a spouse of the business owner, *Id.* §§ 2510.3-3(c), 2590.732(d).

³⁵ See, for example, 29 U.S.C. 1002(7) & (8), defining a beneficiary of an employee welfare benefit plan in relationship to a participant in such a plan.

³⁶ Exchange Establishment Rule, 77 FR 18310 at 18415.

³⁷ See, for example, § 146.145(a)(1) defining a "group health plan" as, among other things, a plan that provides medical care to current and former employees, and § 146.150(b) defining an individual eligible to enroll in coverage sold in the small group market as an individual eligible to enroll in group health insurance coverage offered to a group health plan in accordance with the terms of the group health plan.

accordance with the standards described in § 155.205(c), including the provision of telephonic interpreter services in at least 150 languages.

We proposed to limit the applicability of the proposed 150 languages standard for telephonic interpreter services to Exchanges, web-brokers, and QHP issuers. We did not propose to apply this standard to Navigators and non-Navigator assistance personnel because, as we stated in the proposed rule, the smaller non-profit organizations that frequently make up the bulk of these consumer assistance entities have limited resources.

In the proposed rule, we also solicited comment on whether we should consider more or different language accessibility standards in § 155.205(c). We provided certain examples in the preamble. With respect to written translations, we gave an example of requiring written translations in the languages spoken by the top 10 limited English proficiency (LEP) groups in the State or spoken by 10,000 persons or greater, whichever yields the greater number of languages. With respect to taglines (short statements informing individuals of the availability of language access services), we gave an example of requiring taglines in the top 30 non-English languages spoken nationwide on documents required by State or Federal law or containing information that is critical to obtaining health insurance coverage or access to health care services through a QHP. We also provided an example that would establish a uniform, national standard that written translations, taglines on notices and Web site content, and oral interpretation services be provided in the top 15 languages spoken by LEP individuals in the United States. Finally, we provided an example specific to Web site content that would have required the content to be translated in each non-English language spoken by an LEP population that reaches 10 percent of the State population.

Based on comments received, as discussed below, we are finalizing the proposal with the following modifications:

To give new web-brokers more time for implementation, we are revising § 155.205(c)(2)(i) to specify that for an agent or broker subject to § 155.220(c)(3)(i), the standard to provide telephonic interpreter services in at least 150 languages applies no later than November 1, 2015, the first day of the individual market open enrollment period for the 2016 benefit year, or 1 year after such entity has been

registered with the Exchange, whichever is later.

We are revising § 155.205(c)(2)(iii) to specify that, beginning at the start of the individual market open enrollment period for the 2017 benefit year, for Exchanges, QHP issuers, and agents or brokers subject to § 155.220(c)(3)(i), the general standard to provide taglines in non-English languages indicating the availability of language services includes taglines on Web site content and documents that are critical for obtaining health insurance coverage or access to health care services through a QHP for qualified individuals, applicants, qualified employers, qualified employees, or enrollees indicating the availability of language services in at least the top 15 languages spoken by the LEP population of the relevant State, as determined in HHS guidance. Documents are considered to be “critical” if the entity is required by State or Federal law or regulation to provide them to a qualified individual, applicant, qualified employer, qualified employee, or enrollee. We added that for an agent or broker subject to § 155.220(c)(3)(i), this standard will apply beginning no later than at the start of the individual market open enrollment period for the 2017 benefit year, or when the entity has been registered with the Exchange for at least 1 year, whichever date is later. HHS plans to provide sample taglines in all languages triggered by this threshold. For purposes of § 155.205(c)(2), the meaning of the terms “qualified individual,” “applicant,” “qualified employer,” “qualified employee,” and “enrollee” is intended to be consistent with the definitions for these terms under § 155.20.

We also modified the language following § 155.205(c)(2)(i) and § 155.205(c)(2)(iii) to make clear that the general standards with respect to oral interpretation and taglines continue to apply to all entities subject to § 155.205(c).

We added § 155.205(c)(2)(iv) to create a new standard related to translations of Web site content for Exchanges, QHP issuers, and agents or brokers subject to § 155.220(c)(3)(i). The new standard specifies that beginning at the start of the individual market open enrollment period for the 2017 benefit year, the content of a Web site maintained by an Exchange or QHP issuer must be translated into any non-English language that is spoken by an LEP population that reaches 10 percent or more of the population of the relevant State, as determined in HHS guidance. For an agent or broker subject to § 155.220(c)(3)(i), this standard will

apply beginning at the start of the individual market open enrollment period for the 2017 benefit year or when the entity has been registered with the Exchange for at least 1 year, whichever date is later. We clarify that for Exchanges and web-brokers, this requirement applies to all content that is intended for qualified individuals, applicants, qualified employers, qualified employees, or enrollees that is maintained by the entity on the Web site and is not limited to information that is critical for obtaining health insurance coverage or access to health care services through a QHP. We note that QHP issuers are not required to translate all Web site content that is intended for qualified individuals, applicants, qualified employers, qualified employees, or enrollees; rather, the type of Web site content that must be translated aligns with the definition of “critical” information to which QHP issuers must provide meaningful access under § 156.250 as finalized in this rule. In addition, an entity that is required to translate Web site content consistent with this provision must also still include taglines, in accordance with § 155.205(c)(2)(iii), on its English version Web pages. This entity would not, however, be required to include taglines on its non-English version Web pages, but it could do so voluntarily.

Comment: The majority of comments received regarding the proposed standard for telephonic interpreter services in 150 languages were supportive. A few commenters stated that telephonic interpretation is a cost-effective means of providing language access relative to written translations, which, according to the commenters, are demanded with much less frequency than oral interpretation. Many commenters stated that the proposal would help ensure that LEP individuals obtain language access, helping them enroll in health insurance coverage. These commenters suggested requiring bilingual customer service representatives in addition to language lines. Several commenters stated that specifying telephonic interpreter services in 150 languages was arbitrary, overly prescriptive, and potentially burdensome for smaller entities. Some commenters suggested that telephonic interpreter services be available in any language requested, as they are under certain State laws, like California’s, or in as many languages as are necessary to serve the oral interpretation needs of applicants and enrollees within the applicable service area.

Response: We appreciate the comments regarding this proposal. We believe that providing telephonic

interpreter services in 150 languages is a useful and cost-effective tool to ensure that most LEP consumers in the service area are able to receive oral interpretation services that are required by existing Federal regulations at § 155.205(c)(2)(i). HHS expects to monitor the extent that the industry standard for telephonic interpreter services might diverge substantially from the 150-language threshold. We also clarify that this standard should not be construed to mean that other ways of providing oral interpretation, such as in-person interpreters or bilingual customer service representatives, are prohibited or should be displaced by telephonic interpreter services. We recognize that these alternative services can provide a superior experience for the consumer which, in turn, can ultimately benefit the entity.

Comment: Commenters generally supported our proposal that web-brokers provide telephonic interpreter services. In particular, one supporter reasoned that because web-brokers are “standing in” for an issuer or Exchange, they should be subject to the same requirement as issuers and Exchanges. Another commenter, while supporting the goal of increasing language accessibility and extending health coverage to diverse populations, opposed the requirement and suggested that we give new participant web-brokers to the Exchange more time to comply.

Response: We believe that, in regard to language access, a web-broker should be expected to provide the same minimum level of service to a consumer as would be expected from an Exchange or QHP issuer. In response to the concerns that newer web-brokers may be smaller companies less able to incur the costs of this requirement, we are providing web-brokers until November 1, 2015, the first day of the open enrollment period for the 2016 benefit year, or 1 year from the date the web-broker registers with the Exchange, whichever date is later, to comply. As a reminder, we note that a web-broker, like every other entity subject to § 155.205(c), is required to provide accessible information to individuals who are LEP according to the more general standards under § 155.205(c)(2), even before the web-broker would be subject to the more specific standards finalized in this rule. Moreover, under § 155.205(c)(3), a web-broker is required to inform individuals who are LEP of the availability of the full range of language access services described in § 155.205(c)(2), and how to access such services. If a web-broker is not yet providing telephonic interpreter

services in at least 150 languages directly, it must provide oral interpretation services and inform individuals of the availability of this service from other sources, such as the Exchange’s Call Center.

Comment: With respect to our proposal to not require Navigators and non-Navigator assistance personnel to provide telephonic interpreter services in at least 150 languages, comments were mixed. Some commenters believed that our approach of exempting Navigators ran counter to a Navigator’s statutory duty to provide information in a manner that is culturally and linguistically appropriate to the needs of the population being served by the Exchange or Exchanges.³⁸ Others who opposed the proposal stated that while these entities should strive to hire bi- or multi-lingual staff for the most prevalent non-English languages spoken by LEP individuals in their community, for less frequently encountered languages, or for smaller entities for whom hiring staff with special language skills is not possible, requiring access to telephonic interpreter services is a cost-effective strategy for providing language access services. Among those who agreed with our proposal, commenters stated that specifically requiring each entity to provide telephonic interpreter services in 150 languages could be cost prohibitive and potentially force organizations to opt out of serving as assisters. At the same time, these commenters also stated that Navigators and non-Navigator assistance personnel should be responsive to and accommodate, to the extent possible, any LEP consumer’s language access needs. These commenters suggested a number of options, such as requiring referrals to the Exchange’s Call Center if an entity cannot meet a specific need; partnering with other organizations to provide telephonic interpreter services; hiring bi- and multi-lingual staff to meet the “most significant” language needs of the community; or having HHS contract with a language line that these entities could use so that the entity would not bear additional costs.

Response: We are not extending the requirement to provide telephonic interpreter services in 150 languages to Navigators and non-Navigator assistance personnel at this time. We recognize that ensuring that the language needs of a consumer are met is an important component of providing high-quality application and enrollment assistance. We will continue to consider options for making language access services more

robust for Navigators and non-Navigator assistance personnel.

There are a number of existing language access standards under current regulations applicable to Navigators that are consistent with the requirement under section 1311(i)(3)(E) of the Affordable Care Act that Navigators provide information in a manner that is culturally and linguistically appropriate to the needs of the population being served by the Exchange or Exchanges. For example, under § 155.210(e)(5), Navigators in all Exchanges must provide information in a manner that is culturally and linguistically appropriate to the needs of the population being served by the Exchange, including individuals with LEP. Further, the general requirements at § 155.205(c) to provide oral interpretation, written translations, and taglines in non-English languages indicating the availability of language services, continue to apply to all entities carrying out activities under § 155.205(d) and (e), including Navigators and non-Navigator assistance personnel, even though the more specific standards finalized here do not apply to those entities. As noted above, included in this general requirement is the requirement under § 155.205(c)(3) to inform individuals who are LEP about the availability of the full range of language access services described in § 155.205(c)(2) and how to access such services. As such, if they lack the immediate capacity to help an LEP individual, all Navigators and non-Navigator assistance personnel in every Exchange should inform that individual about the availability of language access services through other sources, such as the Exchange Call Center. In addition, Navigators and non-Navigator assistance personnel in FFEs and State Partnership Exchanges, and non-Navigator assistance personnel funded through an Exchange Establishment grant, must comply with the standards set forth in § 155.215(c)(3), which require them to provide consumers with information and assistance in the consumer’s preferred language, at no cost to the consumer, including the provision of oral interpretation of non-English languages and the translation of written documents in non-English languages when necessary or when requested by the consumer to ensure effective communication. Exempting Navigators and non-Navigator assistance personnel from the specific requirements finalized here does not exempt them from complying with other applicable laws and regulations that govern the language accessibility of their work.

Comment: We received comments regarding whether we should consider

³⁸ Section 1311(i)(3)(E) of Affordable Care Act.

additional, specific standards pertaining to written translations, taglines, and Web site content, as well as suggestions for standards other than those that we had specifically mentioned in the preamble of the proposed rule, as described above. Some commenters agreed in principle that improved language access services will help consumers. While some commenters broadly agreed that language access services should account for the demographics in a particular service area, comments were mixed with respect to the specific thresholds that should trigger written translations. Some commenters opposed requiring more specific standards beyond the proposed telephonic interpreter services standard. Still other commenters added that written translations should be required only upon request, rather than automatically, reasoning that limiting the standard to requests would help reduce the burden on entities as well as on State insurance departments, which often require issuers to file translated versions of previously filed forms for State review. One commenter asserted that additional standards for stand-alone dental plan issuers were not warranted.

Response: We are not finalizing any specific standards with respect to written translations at this time. We will continue to consider solutions that balance the language access needs of consumers who apply for and enroll in coverage through Exchanges with the burdens on entities in providing quality written translations in a timely fashion. It is important to note that even though we are not finalizing specific written translations standards, the general standard under § 155.205(c)(2)(ii) continues to apply to all entities subject to § 155.205(c), as do the general standards with respect to oral interpretation and taglines in non-English languages indicating the availability of language services. We have modified the language following § 155.205(c)(2)(i) and § 155.205(c)(2)(iii) to make clear that the general standards with respect to oral interpretation and taglines continue to apply to all entities subject to § 155.205(c).

Comment: Some commenters who commented on our proposal on language accessibility standards for taglines suggested that notices and Web site content provided by HHS should be available in the top 30 languages spoken nationwide by LEP populations. Some commenters suggested that for all other entities besides the FFEs, a State-specific approach should be adopted, specifically recommending that notices and Web site content provided by a State Exchange, QHP issuer, or web-

broker include taglines in the top 15 languages spoken in the relevant State(s) by LEP populations. One commenter did not suggest a specific numeric threshold, but stressed that a uniform standard should be adopted across entities.

Response: We agree with many commenters' views that the demographics of a State's LEP population, rather than nationwide demographics, should be taken into account when taglines are used. This approach identifies languages tailored to the needs of each State and thus is more attuned to the anticipated language access needs of individuals serviced by entities. We also believe we should avoid creating a situation in which 30 taglines take up significant space on written content, potentially adding to printing costs.

In light of these considerations, we are finalizing a standard whereby an Exchange, QHP issuer, or web-broker would be required to include taglines on Web site content and any document that is critical for obtaining health insurance coverage or access to health care services through a QHP for qualified individuals, applicants, qualified employers, qualified employees, or enrollees in at least the top 15 languages spoken by the LEP population in the relevant State. If an entity's service area covers multiple States, the top 15 languages spoken by LEP individuals may be determined by aggregating the top 15 languages spoken by all LEP individuals among the total population of the relevant States. A document is deemed to be critical for obtaining health insurance coverage or access to health care services through a QHP if it is required to be provided by State or Federal law or regulation to a qualified individual, applicant, qualified employer, qualified employee, or enrollee. Taglines must be included if a document is considered "critical" information to which QHP issuers must provide meaningful access under § 156.250 as finalized in this rule, so that most LEP consumers might receive notice of language access services regardless of whether such "critical" information is being provided to them by an Exchange, a QHP issuer, or a web-broker. This requirement with respect to taglines adds to the standard set forth in § 156.250 because it applies to all Web site content that is provided to qualified individuals, applicants, qualified employers, qualified employees, and enrollees by an Exchange, QHP issuer, or web-broker, regardless of whether such content must be translated in accordance with § 155.205(c)(2)(iv) as finalized in this rule. We included this

requirement because all consumers, regardless of their English proficiency, are encouraged to apply for and enroll in coverage through an Exchange online, and we believe that consumers with LEP should be able to immediately identify taglines informing them of their ability to obtain language access services on the Web sites of entities subject to this standard.

It is also important that LEP consumers, whether they are being served by an Exchange, QHP issuer, or web-broker, are able to obtain the same minimum number of taglines on such documents, and therefore are applying this standard equally across these entities. However, in recognition of the fact that newer web-brokers are often smaller entities that may not as easily meet this standard as an Exchange or QHP issuer, we are providing them additional lead time to comply, specifically, until the first day of the individual market open enrollment period for the 2017 benefit year or when such entity has been registered with the Exchange for at least 1 year, whichever is later. To facilitate compliance with this standard, beginning in early 2016, we plan to issue guidance which identifies the applicable non-English languages in each State.³⁹ We also expect to provide sample taglines in all languages triggered by this threshold beginning in early 2016.

Comment: We received comments supporting a possible additional standard discussed in the preamble to the proposed rule, under which Web site content should be translated into each non-English language spoken by an LEP population that reaches 10 percent of the State population, though one commenter suggested that we consider requiring translation into the top three languages spoken by the LEP population in a given State. A few commenters expressed concerns about costs. Another commenter opposed applying the standard to web-brokers, and suggested that we give new participant web-brokers to the Exchange more time to comply.

Response: We recognize that Web site content is an important source of information for qualified individuals, applicants, qualified employers, qualified employees, and enrollees, particularly in light of the fact that applying for and enrolling into a QHP or insurance affordability programs online is a generally more efficient process than other means. In addition,

³⁹ We anticipate releasing this guidance on an annual basis beginning in early 2016, soon after the most recently published American Community Survey data is expected to become available.

the Web site content of an Exchange or web-broker often contains consumer tools and education materials that, while not always “critical” for obtaining health care coverage or access to health care services through a QHP within the meaning of § 156.250, nonetheless can help consumers understand their eligibility for coverage, how much financial assistance they might qualify for, and other important information that help consumers make an informed decision. We believe it is appropriate to require Exchanges, QHP issuers, and web-brokers to translate Web site content into each non-English language spoken by an LEP population that reaches 10 percent or more of a State’s population beginning at the start of the individual market open enrollment period for the 2017 benefit year. We note that the FFE is already meeting this standard. We clarify that for Exchanges and web-brokers, this requirement applies to all information intended for qualified individuals, applicants, qualified employers, qualified employees, or enrollees that is maintained by the entity on the Web site and is not limited to information that is critical for obtaining health insurance coverage or access to health care services through a QHP. We note that for QHP issuers, the type of Web site content for which translation is required aligns with the definition set forth in § 156.250, as finalized in this rule, of “critical” information to which QHP issuers must provide meaningful access. If certain Web site content that is maintained by an Exchange, QHP issuer, or web-broker contains information that specifically applies to non-QHPs only and does not contain information that is either (for Exchanges and web-brokers) intended for a qualified individual, applicant, qualified employer, qualified employee, or enrollee or (for QHP issuers) “critical” within the meaning of § 156.250, then the entity is not required to translate it into an applicable non-English language.

Given the substantial effort and resources involved in translating Web site content, we believe that the suggestion to translate Web site content in the top three languages spoken by the LEP population in the State is too burdensome. In addition, partly because of concerns raised about burden as well as our guiding principle of focusing on the demographics and anticipated language needs of the community being served using stable and reliable data, we are also not finalizing the standard discussed in the preamble to the proposed rule that would have required a uniform standard for written

translations, taglines, and Web site content translations in the top 15 languages spoken nationwide among the LEP population.

We also believe it is important that LEP consumers in a given State are able to obtain the same minimum level of language access services from the Exchange, QHP issuers operating in the Exchange, and web-brokers operating in the State and therefore are applying a Web site content translation standard across these entities. However, we are providing web-brokers additional time to comply. Specifically, web-brokers will have until the first day of the individual market open enrollment period for the 2017 benefit year, or when such entity has been registered with the Exchange for at least 1 year, whichever is later.

As noted above, regardless of whether an entity is required to translate Web site content into an applicable non-English language under this provision, the entity’s English Web site content will always be required to display taglines in at least the top 15 non-English languages spoken among the LEP population of the relevant State, consistent with § 155.205(c)(2)(iii) of this rule, so that a wider range of LEP individuals whose language does not meet the 10 percent threshold in § 155.205(c)(2)(iv) may still obtain language access services through oral interpretation or written translations, as applicable. For example, if an entity is required to translate Web site content into Spanish because the Spanish-speaking LEP population in the applicable State reaches 10 percent of the State’s population, the entity’s English version Web site must still display taglines in the top 15 non-English languages spoken by the LEP population of the relevant State. To facilitate compliance with this standard, beginning in early 2016, we plan to issue guidance that identifies the applicable languages and States meeting this threshold.

We note that for an entity whose service area covers multiple States, if at least one language in one of the States it serves meets the 10 percent threshold in § 155.205(c)(2)(iv), then the applicable information on the entity’s Web site must be translated into that language.

Comment: In regards to our solicitation for comment regarding the proposed implementation date for the 150-language standard and other possible specific language access standards, a few commenters indicated that they were already meeting or exceeding the 150-language standard for their language line. Many commenters

stated that to the extent additional requirements beyond telephonic interpreter services are required, additional time would be necessary.

Response: With respect to the requirement to provide telephonic interpreter services in at least 150 languages, Exchanges and QHP issuers will be required to comply with this requirement when this rule takes effect. Web-brokers will have until the later of November 1, 2015, the first day of the individual market open enrollment period for the 2016 benefit year, or 1 year from the date the web-broker registers with the Exchange to comply with the requirement to provide telephonic interpreter services in at least 150 languages. For the requirements finalized for taglines and translation of Web site content, as stated in the regulation text, such standards will apply for Exchanges and QHP issuers no later than the first day of the open enrollment period in the individual market for the 2017 benefit year. To give web-brokers participating on an Exchange additional time, the specific requirements to provide taglines and translated Web site content will apply on the first day of the individual market open enrollment period for the 2017 benefit year, or when the web-broker has been registered with the Exchange for at least 1 year, whichever date is later.

Comment: Several commenters requested that we emphasize that the provisions set forth in § 155.205(c) do not limit or abrogate requirements under Title VI of the Civil Rights Act of 1964 and section 1557 of the Affordable Care Act.

Response: As we stated in the preamble of the proposed rule, we remind relevant covered entities of the obligations they may have under other Federal laws to meet existing effective communication requirements for individuals with disabilities and limited English proficiency. Such obligations are independent of the responsibilities these entities may have under §§ 155.205(c), 155.230(b), 156.200(e), and 156.250.

b. Standards Applicable to Navigators and Non-Navigator Assistance Personnel Carrying Out Consumer Assistance Functions Under §§ 155.205(d) and (e) and 155.210 in a Federally-Facilitated Exchange and to Non-Navigator Assistance Personnel Funded Through an Exchange Establishment Grant (§ 155.215)

To clarify that only a non-Navigator entity must maintain a physical presence in the Exchange service area, rather than each individual non-

Navigator associated with a non-Navigator entity, we proposed to amend § 155.215(h) to limit the physical presence requirement specified under that section to non-Navigator entities. In the proposed rule, we explained that we believe that the amendment would strike an appropriate balance in allowing individuals providing non-Navigator assistance subject to § 155.215 to provide assistance via the telephone, Internet, or through other remote means, particularly in circumstances in which remote assistance would be more effective or practical than face-to-face assistance, while also ensuring that the organization with which they are affiliated is in a position to understand and meet the specific needs of the communities they serve and to facilitate consumer protection efforts, as applicable, in their State. We added that if an individual non-Navigator is not affiliated with a larger entity, we would consider the individual to be the entity specified in the amended language under proposed § 155.215(h). We also proposed to add the title “Physical presence” to paragraph (h) for improved clarity.

We are finalizing this clarification as proposed.

Comment: The vast majority of commenters expressed support for this proposal, indicating that the proposed change would benefit consumers seeking remote assistance from individual non-Navigators who may not be physically present in the area served by the Exchange but who can nonetheless provide effective assistance to an individual through the use of technology tools. One commenter suggested that we require non-Navigator entities to ensure that at least half of their personnel serving a particular State conduct in-person assistance in the State. Another opposed the proposal on the grounds that it was too prescriptive because it would bar an otherwise well-suited organization from serving consumers in the State if the organization maintained no physical presence.

Response: We agree with commenters that remote assistance is valuable, especially when a consumer is unable to meet in person with an individual non-Navigator. We believe that the requirement on the organization to maintain a physical presence in the State is a reasonable measure to facilitate a State’s consumer protection efforts and enhance the organization’s ability to provide culturally competent assistance⁴⁰ which, at the same time,

does not preclude an organization’s ability to provide remote assistance to consumers.⁴¹ We also note that an organization that is well-suited to performing application and enrollment assistance but does not maintain a physical presence in the Exchange service area may be able to participate in the certified application counselor program because the Federal requirements governing this program do not include the requirement to maintain a physical presence.

c. Ability of States To Permit Agents and Brokers To Assist Qualified Individuals, Qualified Employers, or Qualified Employees Enrolling in QHPs (§ 155.220)

In § 155.20, we are amending the definition of enrollee in the SHOP to include individuals other than qualified employees. To conform to this amendment, we are finalizing a modification to § 155.220(i). For a discussion of this amendment, please see the preamble for § 155.20.

d. Standards for HHS-Approved Vendors of Federally-Facilitated Exchange Training and Information Verification for Agents and Brokers (§ 155.222)

In § 155.222, we proposed a process for HHS to approve vendors to offer training and information verification services as an additional avenue to the available HHS training, by which State licensed agents and brokers could complete the training requirements necessary to assist consumers seeking coverage through the FFEs. In § 155.222(a), we proposed an application and approval process for vendors seeking recognition as HHS-approved vendors of FFE training and information verification for agents and brokers. As part of an approved training and information verification program, we proposed that the vendor must require agents and brokers to successfully complete identity proofing, provide identifying information, and successfully complete the required curriculum. Further, we proposed that no training program would be recognized unless it included an information verification component under which the vendor confirms the identity and applicable State licensure of the person who is credited with successful completion of the training

appropriate standards which apply in an Exchange operated by HHS during the exercise of its authority under § 155.105(f) and to non-Navigator assistance personnel funded through an Exchange Establishment Grant under section 1311(a) of the Affordable Care Act.

⁴¹ 79 FR 30287 (May 27, 2014).

program. We proposed that only HHS-approved vendors that meet the designated standards would have their programs recognized by HHS. We proposed that vendors be approved for one-year terms, and that vendors seeking to continue their recognition as HHS-approved vendors for FFE agent and broker training and information verification the following year be re-approved through a process to be determined by HHS.

In paragraph (b), we proposed the standards that a vendor must meet to be approved by HHS to offer FFE training and information verification to agents and brokers. In paragraph (b)(1), we proposed that the vendor submit a complete and accurate application by the deadline established by HHS, which demonstrates prior experience with successfully conducting online training and identity proofing, as well as providing technical support to a large customer base. We proposed in paragraph (b)(2) that the vendor be required to adhere to HHS specifications for content, format, and delivery of training and information verification. HHS would require vendors to have their training approved for continuing education units accepted by State regulatory entities. In paragraph (b)(3) we proposed that vendors be required to collect, store, and share with HHS all data from agent and broker users of the vendor’s training and information verification in a manner specified by HHS, and protect the data in accordance with applicable privacy and security laws and regulations. In paragraph (b)(4), we proposed that the vendor be required to execute an agreement with HHS, in a form and manner to be determined by HHS, which requires the vendor to comply with HHS guidelines for interfacing with HHS data systems, the implementation of the training and information verification processes, and the use of all data collected. We also proposed to require vendors to adopt a fee structure that is consistent with the fee structure for comparable trainings offered by the vendor to comparable audiences. In paragraph (b)(5), we proposed that the vendor be required to permit any individual who holds a valid State license or equivalent State authority to sell health insurance products to access the vendor’s training and information verification process.

In paragraph (c), we proposed that once HHS has completed the approval process for vendors for a given year, HHS would publish a list of approved entities on an HHS Web site. In paragraph (d), we proposed that HHS may monitor and audit approved vendors and their records related to the

⁴⁰ See § 155.215(c) for a list of standards regarding the provision of culturally and linguistically

FFE training and information verification functions to ensure the approved vendors' ongoing compliance with the standards outlined in paragraph (b). We proposed that if HHS determines that the approved vendor is no longer in compliance with standards under paragraph (b), HHS may remove the vendor from the list described in paragraph (c), and may direct the vendor to cease performing the training and information verification functions described in this section.

In paragraph (e), we proposed that such a vendor may appeal HHS's decision by notifying HHS in writing within 15 days of receipt of the notification by HHS of not being approved or having its approval revoked, and submitting additional documentation demonstrating how the vendor meets the standards in paragraph (b) and (if applicable) the terms of their agreement with HHS. HHS will review the submitted documentation and make a final determination within 30 days from receipt of the submission of the additional documentation.

We are finalizing these provisions as proposed, with the modifications detailed below.

Comment: Most commenters generally supported the proposal to permit approved vendors to provide training and information verification to agents and brokers assisting consumers in the FFEs, so that agents and brokers would have more choice and greater opportunity to complete the required FFE training. Several commenters expressed concern that external vendors would not be able to provide training that is comprehensive, accurate, and without bias. These commenters urged HHS to provide standards for quality control and oversight.

Response: We agree that expanding the available avenues for agents and brokers to fulfill the FFE training requirements will allow the FFEs to leverage the experience, contacts, and networks of approved vendors. To ensure that the training and information verification programs adhere to uniform standards for content, format, and delivery, under § 155.222(b)(2), HHS-approved vendors will be required to adhere to HHS specifications for content, format, and delivery of training and information verification. Vendors may choose to charge agents and brokers for their training; HHS will consider current training costs for State-licensed agents and brokers for comparable trainings to comparable audiences when reviewing vendor applications with proposed fee structures.

After HHS launches 2016 plan year training, planned for the summer of the 2015 calendar year, HHS intends to monitor vendor training programs and work with vendors to make sure that the FFE training content and delivery continues to meet HHS standards. HHS may audit approved vendors throughout the plan year in accordance with § 155.222(d). HHS intends to issue future guidance regarding § 155.222(b)(2) that will outline the training specifications for content and coverage. If a vendor's training program fails to meet HHS standards after public release, HHS may revoke the vendor's approval to offer FFE training, and would work with affected agents and brokers to ensure they have the required training.

Comment: Several commenters had recommendations and requests for further clarification of requirements relating to the application and the agreement between HHS and vendors. One commenter requested clarification on what constitutes an enforcement action for purposes of the application and the agreement. One commenter asked about demonstrating experience with identity proofing, since most vendors offering training and continuing education programs do not conduct identity proofing in the same manner as HHS.

Response: HHS intends to release the application form to become an HHS approved vendor of FFE training and information verification for the 2016 plan year in the first quarter of 2015. HHS further intends to release guidance related to the application process in the first quarter of 2015 to help interested vendors better understand the application process. The vendor must submit the application by the deadline specified by HHS. We intend to issue guidance that will provide details on the timeline for the application process. We expect that vendors will be approved for one-year terms.

In the preamble to paragraph (b)(1) (79 FR 70706), we explained that HHS would only approve vendors if no current or past regulatory, enforcement, or legal action has been taken by a State or Federal regulator against the entity in the 3 years prior to the application or renewal application deadline under this section. After careful consideration of the various events at the State and Federal level that may constitute an "enforcement" action, we note that HHS will take into consideration justifications, corrective actions taken, or other mitigating or aggravating circumstances (for example, the financial impact of the violation, or the number of individuals affected by the

violation) in evaluating whether a past or current violation would exclude a potential vendor from participation. Vendors whose applications are denied will have the opportunity to appeal HHS's decision under § 155.222(e), and may submit additional documentation for HHS to consider about potential mitigating circumstances.

To more accurately describe the information verification functionality that vendors must provide to agents and brokers, we are adding "proof of valid State licensure" in paragraph (a)(2). Because HHS expects vendors to demonstrate prior experience with verifying State licensure on the application, we are adding "verification of valid State license" in paragraph (b)(1)(i). In response to a comment that explained that organizations that currently conduct agent and broker training may not have experience with identity proofing, we are amending the requirement in paragraph (b)(1)(ii) so that vendors must demonstrate the ability to conduct identity proofing, but do not have to provide proof of prior experience. The goal of the information verification process is to confirm the State licensure and identity of agents and brokers who successfully complete FFE training before they are permitted by HHS to assist consumers with FFE eligibility determinations and QHP selections as an agent or broker. Therefore, vendors must demonstrate a current capability of verifying both the identity of the person completing the training, as well as his or her State licenses or equivalent State authorizations to sell health insurance products.

Comment: Several commenters made suggestions for training content, and the format and frequency for exchanging training and information verification data with HHS.

Response: All of the recommended training topics are currently part of the existing HHS FFE training for agents and brokers (for example, advance payments of the premium tax credit and cost-sharing reductions, and Medicaid and CHIP eligibility). Vendors approved to offer training in the future will be required to include those topics in the curriculum for their respective FFE training programs for agents and brokers. Based on the comments we received, we are adding language at paragraph (b)(3) to indicate that vendors must be able to share training and information verification data with HHS in a manner, format, and frequency specified by HHS. Specifically, we are adding "format, and frequency" to paragraph (b)(3) with respect to the collection, storage, and sharing of data

to further protect the personally identifiable information of agents and brokers, and aid HHS in the monitoring of vendors' training and information verification programs. We anticipate issuing future technical guidance that will detail the manner, format, and frequency for the exchange of data under § 155.222(b)(3).

Comment: In response to the solicitation of comments on what additional components a training program should include in order to qualify for HHS approval, some commenters requested that the training be applicable across States and that vendors be required to offer continuing education units (CEUs) in multiple States. Other commenters suggested that States should incorporate Federal materials in existing training and licensing programs to promote cost-effectiveness and efficiency, and that HHS should eliminate the requirement that agents and brokers receive approval by an Exchange. One commenter suggested that States be able to become vendors.

Response: HHS will require vendors to offer training that is applicable in all FFE States, consistent with the current HHS training. As noted in the preamble to the proposed rule (79 FR 70706), the establishment of standards for HHS-approved vendors of alternative training and information verification processes, we seek to make the FFE training and registration process easier for agents and brokers while also attracting greater agent and broker participation in the FFEs through the development of partnerships with vendors. After careful consideration of these comments, we have amended paragraph (b)(2) to require vendors to offer CEU credit for their training programs in at least five States in which an FFE is operating, effective for plan year 2016 training. Many businesses, trade associations, and States currently offer training that qualifies for CEUs, so we do not believe this requirement will be a significant burden for vendors. We believe five is a reasonable number of States in this initial year of the vendor-hosted FFE training and information verification alternative avenue, and we intend to monitor and evaluate whether this number should be modified in future years. States may apply to be recognized as HHS-approved vendors to offer FFE training and information verification to agents and brokers, and must comply with the same standards as other vendor applicants. HHS will continue to require the Exchanges, including FFEs, to enter into agreements with and register agents and brokers, as described in § 155.220(d) and § 155.260(b).

We are finalizing these provisions as proposed, with the following modifications. We are dividing proposed paragraph (a) into three paragraphs. To add description to the information verification functionality that vendors must provide to agents and brokers, we are adding "proof of valid licensure" in paragraph (a)(2), and also adding "verification of valid State license" to the new paragraph (b)(1)(i). We are adding paragraph (b)(1)(ii) to clarify that vendors must have the ability to host identity proofing, but do not need to demonstrate prior experience. In paragraph (b)(2), we are adding "offering continuing education units (CEUs) for at least five States in which an FFE is operating." We are adding "format, and frequency" to paragraph (b)(3) with respect to the collection, storage, and sharing of data to further protect the personally identifiable information of agents and brokers, and aid HHS in the monitoring of vendors' training and information verification programs.

3. Exchange Functions in the Individual Market: Eligibility Determinations for Exchange Participation and Insurance Affordability Programs

a. Annual Eligibility Redetermination (§ 155.335)

In § 155.335, we proposed permitting Exchanges to implement alternative re-enrollment hierarchies in future benefit years. We sought comment on a default re-enrollment hierarchy that consumers could opt into that would be triggered if the enrollee's current plan's premium increased from the prior year, or increased relative to the premium of other similar plans (such as plans of the same metal tier), by more than a threshold amount, such as 5 percent or 10 percent. We also sought comment on whether SBMs should have the flexibility to implement alternative re-enrollment hierarchies beginning with the 2016 open enrollment and whether to adopt any such alternatives in the FFE for 2017 open enrollment.

In light of the comments discussed below, we are not finalizing our proposal to explore alternative re-enrollment hierarchies for the FFE at this time. However our current rules permit Exchanges to implement alternative re-enrollment hierarchies under § 155.335(a)(2)(iii) based on a showing by the Exchange that the alternative procedures would facilitate continued enrollment in coverage for which the enrollee remains eligible, provide clear information about the process to the qualified individual or enrollee (including regarding any action

by the qualified individual or enrollee necessary to obtain the most accurate redetermination of eligibility), and provide adequate program integrity protections, and we welcome efforts by SBEs to develop alternative hierarchies consistent with these standards that meet the needs of their consumers.

Comment: We received many comments regarding the proposed alternative re-enrollment hierarchies. Commenters who opposed permitting alternative enrollment hierarchies, particularly those that prioritize low-premium plans, noted that, in most cases, the plan a consumer chooses during open enrollment is one that the consumer has shopped for and has determined best meets his or her needs. Additionally, commenters highlighted that low-cost premiums do not necessarily lead to lower overall cost of coverage because deductibles, copayments, coinsurance, and out-of-pocket limits may be higher.

In contrast, some commenters supported the proposal's emphasis on low-cost premiums. One commenter believed that multiple re-enrollment hierarchies should be available to consumers, but cautioned that these options should be limited to two, and be easy to understand.

Commenters had concerns that consumers may not realize that opting into a default enrollment hierarchy based on low-cost premiums may result in other significant changes to their coverage, as noted above. Commenters also requested that, if alternative hierarchies are implemented, consumers be made aware of the consequences of selecting this default re-enrollment option both at the time of initial enrollment when a person could opt into this and also prior to re-enrollment.

Some commenters noted that the proposal may not keep consumers actively engaged in the process of re-enrollment and making coverage choices. Commenters emphasized that, if alternative hierarchies are implemented, Exchanges must educate consumers at the time of enrollment about their choice and what it may mean for their future health coverage and costs. Commenters stressed that consumer notices should emphasize the benefit of returning to the Exchange during the open enrollment period to examine plan options and encouraged focus testing to determine messaging that best communicates the implications of opting into a re-enrollment hierarchy.

We received a few alternative ideas for re-enrollment hierarchies, including basing re-enrollment on factors consumers identify as most important to them. One commenter recommended

permitting consumers to choose between a default re-enrollment hierarchy that prioritizes the consumer's choice of plan, as the current policy does, versus prioritizing the consumer's original choice of premium. The commenter believed that presenting these two hierarchy choices to consumers would greatly increase consumer understanding of the significance and consequences of selecting one hierarchy over the other. Another commenter suggested limiting the low-cost premium hierarchy option to only those consumers who are currently enrolled in the lowest-cost or second-lowest cost silver plan to target consumers who are most likely to notice a change in premium and make it administratively easier to implement.

Finally, several commenters emphasized the need to continue to focus on the development of the current redetermination and re-enrollment process. Commenters noted improvements should be made to the technical ability to support automatic eligibility redeterminations, particularly those including determinations for advance payments of the premium tax credit and cost-sharing reductions. We received several comments recommending that HHS wait to implement any alternative hierarchies until the current enrollment hierarchies have operated for a few years and more information and lessons can be gleaned from the experience. In contrast, a few commenters, who supported the proposal, encouraged early adoption of the policy, and one commenter suggested that consumers would not want to wait to take advantage of this low-cost option.

Response: We appreciate the many comments received regarding alternative re-enrollment hierarchies and are sensitive to the concerns raised by commenters. Consumers consider many factors when selecting health coverage in addition to the premium, including the provider network, cost-sharing, deductibles, and other factors which affect overall costs, continuity of care, and the consumer experience. At the same time, we continue to believe that default re-enrollment of consumers in the same plan (or a similar plan) may not best serve consumers' interests in cases where the premium for their plan relative to available alternatives has changes substantially. Due to concerns expressed by commenters, we are not finalizing changes to the re-enrollment hierarchies. Instead, the existing re-enrollment hierarchies will remain in place. In accordance with commenters' suggestions, we may revisit alternative hierarchies as we learn more about

consumer preferences and gain implementation experience. We will also work to continue to improve the current annual redetermination and renewal processes, including the concerns expressed by commenters for the need for greater consumer education and engagement efforts. As noted below, we encourage SBEs to consider alternative re-enrollment hierarchies.

Comment: Most commenters, including those representing SBEs, supported the proposed flexibility for SBEs to implement alternative re-enrollment hierarchies. Commenters saw this flexibility as a way to further test alternative hierarchies before they are implemented more widely, and also as a way to meet the unique characteristics of each Exchange. Additionally, one commenter expressed opposition to providing State flexibility by the 2016 benefit year out of concern that consumers would not have enough time to be properly educated about re-enrollment by operation of the alternative hierarchy and because no precedent exists for reassigning a consumer to an entirely new set of coverage benefits. Finally, one commenter, who supported permitting State flexibility in this regard, did not believe HHS should permit States to prioritize issuer continuity.

Response: SBEs play an important role in implementing policies and providing important feedback regarding their success and difficulties, particularly because each SBE has a unique consumer base and market. As noted above, under our current regulations, SBEs may gain approval from HHS to implement alternative default re-enrollment hierarchies. We encourage SBEs to consider alternative hierarchies and we will closely examine the results of any SBE actions in this area.

Comment: We received a few comments requesting more information regarding how this proposal would impact stand-alone dental plans (SADPs). Several commenters noted that the process for re-enrolling in a SADP should be separate and independent from re-enrollment in a QHP.

Response: Because we will not implement the proposed alternative re-enrollment hierarchies at this time, we are not addressing how this policy would affect SADPs. However, we appreciate the comments raising this issue and, if the proposal is revisited in the future, we will address concerns regarding SADPs then.

4. Exchange Functions in the Individual Market: Enrollment in Qualified Health Plans

a. Enrollment of Qualified Individuals Into QHPs (\$ 155.400)

We proposed to amend § 155.400(e) to explicitly provide for an Exchange to establish a standard policy for setting deadlines for payment of the first month's premium.

For the FFEs, we proposed several possible payment deadlines tied to the coverage effective date for regular effective dates (meaning coverage effective the first day of the following month for plan selections made between the first and fifteenth of the month, and coverage effective the first day of the second month following a plan selection made between the 16th and the end of the month). Some options we considered included providing consumers until the coverage effective date, or the day before the coverage effective date, to make their first month premium payment. Alternatively, we considered providing consumers additional time after the coverage effective date to make their premium payment (5 days, 10 days, or 30 days after the coverage effective date). We sought comment on the period of time following the coverage effective date an issuer could be required or permitted to accept a first month's premium payment for that coverage.

With respect to effective dates other than regular effective dates, meaning retroactive or accelerated coverage effective dates resulting from enrollment under certain special enrollment periods (including birth and marriage), resulting from the resolution of appeals, or resulting from amounts newly due for prior coverage based on issuer corrections of under-billing, we considered a premium payment deadline of 10–15 business days from when the issuer receives the enrollment transaction.

We sought comment on which proposed premium payment deadlines give issuers an acceptable amount of time to send an invoice and allow for timely payment by the consumer, and give consumers sufficient time to make the payment. We also sought comment on how such a policy would likely affect issuer operations and consumers' ability to obtain coverage.

We noted that because this rulemaking will likely not be finalized until after open enrollment for 2015, any such deadlines would not be applicable for that open enrollment period.

We are finalizing the provisions proposed in § 155.400 of the proposed

rule, with the inclusion of premium payment deadline policies for the FFEs, selected from among the options described in the proposed rule. Specifically, we revised paragraph § 155.400(e) to establish a standard policy for premium payment deadlines in the FFEs, while leaving other Exchanges the option of establishing such policies. We added § 155.400(e)(1) to establish a premium payment deadline policy for the first month's premium payment for a first-time enrollment on an FFE or for an active or passive reenrollment in a plan within a new product or with a new issuer.

In new § 155.400(e)(1)(i), we establish a policy for the FFEs that premium payment deadlines for the first month's premium for a new enrollment must be no earlier than the coverage effective date, but no later than 30 calendar days from the coverage effective date in cases where coverage becomes effective with regular coverage effective dates, as provided for in § 155.410(f) and § 155.420(b)(1).

We also added § 155.400(e)(1)(ii) whereby the premium payment deadlines for the first month's premium must be 30 calendar days from the date the issuer receives the enrollment transaction, in cases where coverage becomes effective under special effective dates, as provided for in § 155.420(b)(2).

Comment: We received several comments recommending that HHS give issuers flexibility surrounding payment deadlines, with the rationale that flexibility in the first year helped maximize enrollment by accommodating those who require additional time to make payment. Several commenters suggested giving consumers 30 days to make their first month's premium payment, while a large number of commenters supported establishing a standard policy requiring consumers to make their first month's premium payment prior to the effective date. Most concerns raised by commenters opposed allowing premium payments after the coverage effective date due to the uncertainty of payment for services provided after the coverage effective date if a premium is not paid and the enrollee is subsequently cancelled.

Response: We recognize that decisions regarding payment of the first month's premium have traditionally been business decisions made by issuers, subject to State rules. We believe that having some minimum standards could benefit issuers and consumers by ensuring a consistent operational procedure while still giving issuers flexibility. Within this context,

we also sought to provide flexibility for SBEs to establish their own policies for premium payment deadlines. Accordingly, we are finalizing § 155.400(e) to indicate that an Exchange may establish a standard policy for setting premium payment deadlines, and are establishing a policy for the FFEs, as described above.

This policy gives issuers flexibility while allowing additional time for individuals who may have circumstances that would not otherwise provide standard timeframes for payment.

Comment: Several commenters were confused about the additional language to allow first month's premium payments after the coverage effective date, thinking that a person's coverage could be effectuated prior to the person making their payment. Many providers and some issuers were opposed to allowing more individuals to appear to have effective coverage and then have the coverage not be effectuated due to non-payment of premium by the payment deadline, resulting in having to reverse claims for payment for services rendered during the time between the intended coverage effective date and the payment deadline.

Response: Payment for first month's premium is still required prior to coverage being effectuated. For the FFE, in cases where a person, consistent with an issuer's payment policy, makes their premium payment after the coverage effective date, but before the premium payment deadline set by the issuer, the consumer would receive a retroactive effective date. Issuers may pend claims while waiting for the first month's premium payment and either deny or reverse those claims based on whether the individual makes their first month's payment by the premium payment deadline. We believe that it is better to allow payments, if the issuer chooses, after the coverage effective date.

Comment: Several commenters supported a uniform payment deadline, but wanted clarification that SBEs can establish their own policy for premium payments.

Response: While we believe that having uniform minimum standards for all issuers for payment of a first month's premium to effectuate enrollments could benefit issuers and consumers by ensuring a consistent operational procedure while still giving issuers flexibility, our intent in the proposed rule was to let each Exchange decide whether to develop its own payment deadline policy for the first month's premium. We are finalizing a revised § 155.400(e) indicating an Exchange may establish a standard policy for

setting premium payment deadlines, and establishing the FFEs premium payment deadline policy for the first month's premium payment.

Comment: Some commenters suggested that if HHS implements a uniform policy for the first month's premium payment deadlines, HHS should take into account consumers who have unusual circumstances (for example, when consumers are eligible for retroactive effective dates, an issuer fails to issue a bill in a timely manner, a consumer's payment is misdirected by mail, etc.).

We also received several comments suggesting that for irregular effective dates, the premium payment date should be 10–15 business days from when the consumer receives the invoice from the issuer, not when the issuer receives the enrollment transaction. Commenters suggested that this would create a level playing field for consumers since some issuers may take longer to process their enrollment transactions.

Response: In this final rule, we are adding § 155.400(e)(1)(ii), which accommodates consumers who are given an accelerated or retroactive effective date based, for example, on a change in circumstance. We want to give consumers with irregular effective dates sufficient time to pay the first month's premium and we believe, based on comments received that suggested giving consumers with irregular effective dates more time to make their first month's premium payment, 30 calendar days is sufficient and reduces the complexity of accounting for weekends and holidays. We also recognize that issuers do not all have a mandated standard for timeliness of billing consumers, but we believe issuers want to collect the first month's premium payment and have no intention to delay billing on their end. Furthermore, depending on the issuers and how the consumer elects to make payment, not all enrollees will be sent an invoice (for instance, in cases where a consumer is redirected by the FFE to the issuer's Web site and pays the premium online), whereas the FFE will always send an enrollment transaction to the issuer when a consumer selects a plan. Therefore, we are finalizing this rule with a standard under which these individuals are given 30 calendar days from the date the issuer receives the enrollment transaction to make their first month's premium payment.

b. Annual Open Enrollment Period (§ 155.410)

In § 155.410, we proposed to amend paragraph (e), which provides the dates

for the annual open enrollment period in which qualified individuals and enrollees may apply for or change coverage in a QHP. We proposed to restructure paragraph (e) by placing the current provision regarding the 2015 benefit year in paragraph (e)(1) and the proposed requirement for all benefit years beginning on or after 2016 in paragraph (e)(2). Specifically, in paragraph (e)(2), we proposed that for benefit years beginning on or after January 1, 2016, the annual open enrollment period would begin on October 1 and extend through December 15 of the calendar year preceding the benefit year. We also proposed to redesignate the annual open enrollment coverage effective date provisions in paragraphs (f) and (f)(1) through (3) as (f)(1) and (f)(1)(i) through (iii), and to add a new (f)(2), which would specify that, for enrollments made under any annual open enrollment periods for benefit years beginning on or after January 1, 2016, coverage would be effective on January 1 of the year following the open enrollment period.

We are finalizing the provisions only with regard to the 2016 benefit year, with a modification. In response to comments, at § 155.410(e)(2), we are providing that for the benefit year beginning on January 1, 2016, the annual open enrollment period begins on November 1, 2015 and extends through January 31, 2016 (2 weeks earlier but the same length as the open enrollment period for the 2015 benefit year). Additionally, we have revised the proposed language at § 155.410(f)(2) and added three paragraphs to require that for the 2016 benefit year, the Exchange must ensure that coverage is effective January 1, 2016, for QHP selections received by the Exchange on or before December 15, 2015, February 1, 2016, for QHP selections received by the Exchange from December 16, 2015, through January 15, 2016, or March 1, 2016, for QHP selections received by the Exchange from January 16, 2016, through January 31, 2016.

Comment: We received a variety of comments regarding our proposal to set the annual open enrollment period for benefit year 2016 and beyond. A large portion of comments focused on the specific dates proposed for the annual open enrollment period. Several commenters noted their support for establishing a standard annual open enrollment period to promote consistency from year to year. Commenters also supported annual open enrollment dates that overlap with Medicare's annual open enrollment period as well as the annual open enrollment period for much employer-

sponsored coverage, which commenters believed would ensure a smoother transition for consumers moving between the group and individual markets. One commenter supported the proposed timeframe and noted that starting the Exchange annual open enrollment period 2 weeks before Medicare's annual open enrollment period may reduce stress on resources, particularly customer service call centers, agents, brokers, and other consumer resources that are frequently relied on during open enrollment periods.

A few commenters supported establishing the annual open enrollment period during the last quarter of the calendar year, but recommended slight variations on the proposed timeframe. For example, one commenter recommended the annual open enrollment period run November 1 through December 15, suggesting that a longer enrollment period does not lead to better consumer decisions and that issuers may benefit from a later start to the annual open enrollment period. Another commenter indicated that ending the enrollment period on December 15 was too late to accommodate the operational steps necessary to ensure a universal January 1 coverage effective date, particularly given the complexity associated with managing active selections, automatic renewals, and other changes. The commenter suggested ending the enrollment period on November 30 to give more time to issuers and Exchanges to handle renewals. A few commenters recommended aligning with Medicare's annual open enrollment period, October 15 through December 7. In contrast, a few commenters requested that HHS extend the proposed annual open enrollment period to the end of January to capture additional consumers. Of particular concern for these commenters were consumers who are auto-renewed into a new plan and will not have an opportunity to use the plan before the end of the annual open enrollment period, following which they could be unable to shop for coverage, absent a special enrollment period (SEP).

Finally, a few commenters representing State-based Exchanges (SBEs) and health insurance issuers shared concerns that shifting the annual open enrollment period to October would significantly strain timelines for product development, rate setting, product filing, and review. These groups questioned whether notices, regulations, and templates would be completed by HHS in time for issuers and States to fulfill their obligations prior to annual open enrollment. Commenters noted

that starting the annual open enrollment period earlier would increase administrative burden and constrain resources and requested giving States and issuers additional time to prepare.

Response: We agree that establishing a consistent timeframe for annual open enrollment will help reduce consumer confusion, and administrative complexity. However, we understand that beginning annual open enrollment more than a month earlier for 2016 than for 2015 requires significant advanced planning and preparation by Exchanges, State regulatory authorities, issuers, and assisters. We were persuaded by the concerns expressed by many commenters about the additional burden caused by shifting the annual open enrollment period, and therefore we are finalizing an annual open enrollment period for the 2016 benefit year that begins 1 month later than the one we had proposed, and that will run from November 1, 2015 through January 31, 2016. We anticipate that this timeframe will ease the burden on State regulatory authorities, Exchanges, and issuers while giving HHS the time to conduct a thorough certification process. Additionally, the finalized timeframe will permit additional time for consumers following the winter holidays to complete plan selection or to select a different plan if they do not like the plan into which they were auto-enrolled. Finally, the finalized timeframe will continue to partially overlap with Medicare annual open enrollment and most employer offerings, which will benefit consumers by creating smooth transitions between coverage and create process efficiencies for issuers handling enrollments and re-enrollments during the same period.

Comment: Many commenters focused on the length of the proposed annual open enrollment period. Several commenters supported establishing a shorter annual open enrollment period. However, a few commenters considered the proposed annual open enrollment period too short to provide consumers sufficient time to research coverage options and seek help from assisters. These commenters noted that consumers are still becoming familiar with Exchange-based coverage and that the length of the proposed open enrollment period will be a barrier to obtaining insurance. Similarly, many commenters requested that consumers have the opportunity to preview and compare plans starting on September 15 of each year, even if they are unable to enroll, to provide additional time for consumers to review and compare plans to make informed decisions. One commenter recommended that plans be

made available as soon as they are certified so that consumers, assisters, non-profit organizations, and researchers can review the plan options available.

Response: Recognizing that consumers, issuers, State regulatory authorities, and Exchanges may still be acclimating to the annual open enrollment process, we are finalizing the provisions with modification to set the annual open enrollment period for the 2016 benefit year to run from November 1, 2015 through January 31, 2016. We will take these recommendations under advisement as we consider options for the 2017 annual open enrollment period and beyond.

Comment: Several commenters recommended establishing the annual open enrollment period so that it either overlaps or aligns with tax filing season. In support of this idea, commenters noted that consumer financial liquidity is lowest during the months of November and December whereas many consumers receive tax refunds beginning in late January through April, which could encourage consumers to enroll in coverage. Commenters also noted that incurring a fee at tax filing for not being enrolled in coverage could create an opportune moment to encourage enrollment. One commenter maintained that aligning annual open enrollment with tax filing would alleviate private-sector administrative burdens because open enrollment periods for Medicare, employer plans, and the Exchange will then not all overlap, increasing the workload on issuers and agents and brokers. Finally, commenters noted that tax filing provides the best possible income information for consumers to increase accuracy of eligibility determinations, minimize repayments, and strengthen program integrity.

Response: We appreciate the concerns that commenters raised. As noted above, for the 2016 benefit year, we are finalizing the provisions with modification to set the annual open enrollment period for the 2016 benefit year to run from November 1, 2015 through January 31, 2016. We note that there are several SEPs that provide an opportunity to enroll in coverage mid-year if a qualifying event occurs. In addition, there are several exemptions available to consumers, including hardship-based exemptions, which will help prevent a consumer from being assessed a fee, and may be claimed on a consumer's Federal income tax return. Although commenters saw overlapping annual open enrollment with Medicare and employer offerings as burdensome, we maintain that this overlap

maximizes process efficiencies for issuers and streamlines transitions between different forms of coverage for consumers.

Aligning more closely with the calendar year permits consumers to plan financially on a calendar year basis. We also note that consumers who qualify for financial assistance can immediately receive it with their premium upon enrollment, and consumers also may be given additional time in which to pay their initial premium, pursuant to the amendment to § 155.400(e) described in section III.E.4.a of this final rule, both of which should help alleviate low consumer financial liquidity.

Comment: A few commenters representing SBEs requested that SBEs be permitted to set their own annual open enrollment period and maintain their own QHP filing timing.

Response: Section 1311(c)(6)(B) of the Affordable Care Act specifically directs the Secretary to provide for annual open enrollment periods, as determined by the Secretary for calendar years after the initial open enrollment period. We have determined that permitting multiple annual open enrollment periods that differ by State will be confusing for consumers and create additional burdens on issuers to meet variable deadlines for QHP certification, re-certification, and rate-setting. Therefore, we are finalizing this rule with a uniform annual open enrollment period across all Exchanges for the 2016 benefit year.

Comment: One commenter requested that when the end of annual open enrollment falls on a weekend (Saturday or Sunday) or a Federal holiday, it should extend to the next business day.

Response: While we understand the concern raised by this comment, we believe the value of establishing set dates for the annual open enrollment period outweigh it. We anticipate that it will be easiest for all stakeholders, particularly consumers, to remember and implement annual open enrollment processes based on a standard set of dates from year to year.

Comment: One commenter requested that HHS commit to publishing more enrollment data and analyze it to maximize enrollment.

Response: HHS has published weekly enrollment reports for the 37 States using HealthCare.gov during the 2015 annual open enrollment period. We intend to continue to gather and analyze information to improve our processes over the course of future annual open enrollment periods.

c. Special Enrollment Periods (§ 155.420)

In § 155.420, we proposed certain provisions relating to special enrollment periods. We proposed to revise paragraphs (b)(2)(i), (b)(2)(ii), (b)(2)(iv), and add paragraphs (b)(2)(v), (b)(2)(vi), and (b)(2)(vii), which pertain to effective dates for special enrollment periods; to amend paragraphs (c)(2)(i) and (c)(2)(ii), which pertain to availability and length of special enrollment periods, and to revise paragraphs (d)(1)(ii), (d)(1)(v), (d)(2), (d)(4), and remove paragraph (d)(10), which pertain to specific types of special enrollment periods. We also proposed to delete the option for consumers to choose a coverage effective date of the first of the month following the birth, adoption, placement for adoption or placement in foster care and to permit the Exchange to allow a qualified individual or enrollee to elect a regular coverage effective date in accordance with paragraph (b)(1) of this section.

We proposed to amend paragraph (b)(2)(iv) to allow persons who make a permanent move as described in paragraph (d)(7) to have a coverage effective date of the first day of the month following the move if plan selection is made before or on the day of the loss of coverage and, effective January 1, 2016, allow consumers advanced access to the special enrollment period where a qualified individual or enrollee, or his or her dependent, gains access to new QHPs due to a permanent move under paragraph (d)(7).

In addition, we proposed to add new paragraphs (b)(2)(v) and (b)(2)(vi), which pertain to effective dates for coverage that must be obtained under court orders, including child support orders, and the death of an enrollee or his or her dependent. In paragraph (b)(2)(v), we proposed to require an Exchange to make coverage effective the first day the court order is effective to minimize any gap in coverage the individual may experience and allow Exchanges to provide consumers with a choice for regular effective dates under paragraph (b)(1). In paragraph (b)(2)(vi), we proposed to require that an Exchange ensure coverage is effective the first day of the month following a death of the enrollee or his or her dependent, and at the option of the Exchange and the consumer, allow for regular effective dates under paragraph (b)(1) of this section.

We proposed to combine paragraphs (c)(2)(i) and (c)(2)(ii) to a new paragraph (c)(2) to simplify the regulatory text. In addition, we proposed to allow

consumers to report a permanent move 60 days in advance of the move for the purposes of receiving special enrollment period to reduce the likelihood of a gap in coverage. We proposed that this change would take effect on January 1, 2016.

We proposed to amend paragraph (d)(1)(ii) so that this special enrollment period is available for a qualified individual or his or her dependent who, in any year, has coverage under a group health plan or an individual plan with a plan or policy year that is not offered on a calendar year basis. We proposed to add paragraph (d)(2)(i) to include situations where a court order requires a qualified individual to cover a dependent or other person. We also proposed to add paragraph (d)(2)(ii) to allow enrollees who experience a loss of a dependent or lose dependent status through legal separation, divorce, or death to be determined eligible for a special enrollment period. We proposed to amend paragraph (d)(4), to include situations where a non-Exchange entity is providing enrollment assistance. Concurrently, we proposed to strike paragraph (d)(10) which provides a separate special enrollment period for non-Exchange entity misconduct.

We proposed to add paragraph (d)(6)(iv) to create a special enrollment period for a qualified individual in a non-Medicaid expansion State who was previously ineligible for advance payments of the premium tax credit solely because the qualified individual had a household income below 100 percent of the FPL, who was ineligible for Medicaid during that same timeframe, and experienced a change in household income that made the individual newly eligible for advance payments of the premium tax credit.

We also sought comments on other situations that may warrant a special enrollment period, particularly situations specific to the initial years in which consumers have an opportunity to purchase coverage through an Exchange.

We are finalizing paragraph (b)(2)(i) with a minor modification. Specifically, we are retaining the option of the Exchange to allow consumers to elect a coverage effective date of the first of the month following a birth, adoption, placement for adoption, or placement in foster care or on the date of the birth, adoption, placement for adoption, or placement in foster care. These options are in addition to the option for regular effective dates in paragraph (b)(1) of this section as proposed. We are amending paragraph (b)(2)(iv) to allow these persons to have a coverage effective date of the first day of the month following

the move if plan selection is made before or on the day of the move. We are adding paragraph (b)(2)(v) to make coverage effective the first day of the court order and to allow Exchanges to provide consumers with a choice for a regular effective date, in accordance with paragraph (b)(1). We are adding paragraph (b)(2)(vi) to require Exchanges to ensure coverage is effective the first day of the month following the date of plan selection due to a death of the enrollee or his or her dependent and to allow Exchanges to provide consumer with a choice for a regular effective date, as specified in paragraph (b)(1). The proposed paragraph (b)(2)(vi) incorrectly referenced paragraph (d)(2)(iv), which was changed to correctly reference paragraph (d)(2)(ii) for loss of a dependent or dependent status. Additionally, we corrected paragraph (b)(2)(vi) to state that coverage will be effective following the date of plan selection, instead of following the date of death.

We are combining paragraphs (c)(2)(i) and (c)(2)(ii) to a new paragraph (c)(2), and, in paragraph (c)(2), we are also adding a reference in this paragraph to individuals who receive a special enrollment period under paragraph (d)(7) to allow these consumers to report a permanent move 60 days in advance of the move for the purposes of receiving a special enrollment period to reduce the likelihood of a gap in coverage. After consideration of comments received, persons who are eligible for a special enrollment period under paragraph (d)(7) will be able to exercise this flexibility effective January 1, 2017, or earlier at the option of the Exchange. In paragraph (c)(3), we are removing reference to paragraph (d)(10), which is now included in paragraph (d)(4).

As proposed, in paragraph (d)(1)(ii), we are deleting the expiration date of 2014 for non-calendar year health insurance policies. We are adding paragraph (d)(2)(i), which includes when a qualified individual gains a dependent or becomes a dependent through marriage, birth, adoption, placement for adoption, placement in foster care, or through a child support or other court order. At the option of the Exchange, we are adding paragraph (d)(2)(ii) for where an enrollee loses a dependent or is no longer considered a dependent through divorce or legal separation, as defined by State law. Paragraph (d)(4) is amended to include situations where a non-Exchange entity is providing enrollment assistance. Concurrently, we proposed to strike paragraph (d)(10) which provides a

separate special enrollment period for non-Exchange entity misconduct. We are adding paragraph (d)(6)(iv) to include qualified individuals in non-Medicaid expansion States who were previously ineligible for advance payments of premium tax credits solely because the individual had household income under 100 percent of the FPL, who was ineligible for Medicaid during that same timeframe, and experiences a change in household income to become eligible for advance payments of the premium tax credit.

Comment: Commenters were divided in their responses to the proposed changes to coverage effective dates for special enrollment periods resulting from birth, adoption, placement for adoption, and placement in foster care, as proposed in paragraph (b)(2)(i) of this section. Some commenters expressed concern about the potential gap in coverage if a parent were to elect a prospective coverage effective date for the child, while others expressed concern regarding our proposal to remove the option for coverage to be effective the first day of the month following the triggering event. We also received comments in support of our proposal to increase flexibility for electing a coverage effective date that best fits the family's needs.

Response: Current regulations require Exchanges to ensure coverage is effective retroactive to the date of birth, adoption, placement for adoption, or placement in foster care and allow Exchanges the option to provide prospective coverage effective dates to the first of the month following the triggering event. We agree with commenters emphasizing the importance of coverage effective dates that best fit the needs of a family. Accordingly, we are finalizing the addition of a new option for coverage to be effective following regular effective dates, as proposed, and are not removing the option for coverage to be effective the first of the month following a birth, adoption, placement for adoption, or placement in foster care. If the Exchange allows for prospective coverage effective dates, it would be at the option of the consumer to elect this date or to elect the retroactive coverage effective date back to the date of birth, adoption, placement for adoption, or placement in foster care.

Comment: Several commenters urged HHS to clarify the proposed changes to the special enrollment period for a permanent move, including specifying that consumers must submit proof of a change of address and providing clarification that changes to the special enrollment period for a permanent move

includes individuals who are being released from incarceration. There was also a request to amend the proposed implementation effective date for this special enrollment period, which was set for January 1, 2016.

Response: Exchanges must verify residency information as outlined in § 155.315(d) to make an eligibility determination, which includes a determination of eligibility for enrollment periods, per § 155.305(b). As noted in the preamble to Exchange Establishment Rule, 77 FR 18310 (March 27, 2012), qualified individuals newly released from incarceration are eligible for the special enrollment period afforded to individuals who gain access to a new qualified health plan as a result of a permanent move. Therefore, under the rule being finalized, incarcerated individuals would be able to report a permanent move up to 60 days in advance of their release from incarceration, once a formal release date has been set. Recognizing that Exchanges may need more time than previously afforded in the proposed rule to implement this special enrollment period, it will be effective January 1, 2017. Exchanges are encouraged to implement as soon as possible.

Comment: Several commenters requested HHS provide authority for additional triggering events for special enrollment periods. Some commenters requested that pregnancy trigger a special enrollment period, so that women who are either not enrolled or are enrolled in a catastrophic plan can select and enroll in or change qualified health plan coverage prior to the birth of a newborn. Other commenters requested that, when an individual reports that he or she is a victim of domestic abuse, it triggers a special enrollment period, so that he or she may select and enroll in a qualified health plan on a separate application from his or her abuser, along with any dependents.

Response: We are not finalizing additional triggering events based on life changes at this time. Specifically, flexibility afforded under § 155.420(d)(9) allows the Secretary to provide for additional special enrollment periods in the case of exceptional circumstances, as determined appropriate, and HHS will continue to exercise that authority through sub regulatory guidance. Furthermore, a State may establish additional special enrollment periods to supplement those described in this section as long as they are more consumer protective than those contained in this section and otherwise

comply with applicable laws and regulations.

Comment: We received comments both in support of, and opposed to, changes to coverage effective dates for the newly proposed special enrollment period for court orders, including a child support order at § 155.420(b)(2)(v). Some commenters supported increased flexibility for consumers to elect a retroactive coverage effective date back to the day of the court order, while other commenters requested that changes always be made effective the first of the month following the court order.

Response: Based on comments received, we believe that it is most consistent to treat consumers who gain a dependent, regardless of the means, in an equitable manner. In addition, a court order may be effective in the middle of a month and requiring the individual to wait until the first of the following month to enroll in coverage may violate State law. Accordingly, we are finalizing the rule as proposed whereby the effective date for the special enrollment period for a court order will be effective in accordance with paragraph (b)(2)(i) of this section.

Comment: We received comments that requested changes to coverage effective dates for the newly proposed special enrollment period for losing a dependent as a result of death at § 155.420(b)(2)(vi). Some commenters requested coverage be effective retroactive to the date of death, others supported the proposed regulatory text to provide coverage effective the first day of the month following the death, while other commenters requested that HHS limit the number of situations which will allow for retroactivity. Some commenters also requested that all family members, regardless of whether they are part of the enrollment group or are enrolled in a qualified health plan through the Exchange, receive a special enrollment period. Another commenter requested that no special enrollment period be given for death as other special enrollment periods likely apply.

Response: In response to comments, we believe it makes sense to limit the number of situations that will allow for retroactivity, we have modified the proposed regulatory text to finalize the coverage effective date as the first day of the month following the date of plan selection, rather than the date of death. Providing a coverage effective date of the first of the month following the date of death would give the consumer retroactivity if they are reporting the death late in the special enrollment period window. We believe this balances the need to provide dependents of the deceased a special

enrollment period, while addressing requests from commenters to limit the middle of the month and retroactive coverage effective dates. In addition, we encourage issuers to maintain qualified health plan coverage for remaining members of the enrollment group through the end of the month. The special enrollment period as a result of a death is intended for remaining enrollees on an application whose health insurance coverage is impacted due to the death; therefore, only the affected members will be provided a special enrollment period. As noted by commenters, non-enrollees may be determined eligible for other special enrollment periods including that for loss of coverage.

Comment: Commenters supported the proposed language which provided for a special enrollment period for individuals enrolled in non-calendar year group health plans or individual health insurance coverage. One commenter requested clarification that this would also apply to group health plans outside of the Exchange.

Response: We are finalizing this policy as proposed. We note that, as specified in the proposed rule, this policy provides a special enrollment period inside the Exchange for individuals whose coverage in group health plans and individual market plans offered outside of the Exchange is expiring, including grandfathered and transitional plans. Under § 147.104, this special enrollment period also applies to individuals who seek to enroll in individual market coverage off the Exchange.

Comment: Commenters requested that HHS provide additional clarification and flexibility for the special enrollment period for loss of a dependent or dependent status due to legal separation, divorce, or death. Comments included requests to extend this special enrollment period to individuals not currently enrolled in a qualified health plan, to include same sex couples who enter into a legally recognized relationship other than marriage, such as domestic partnerships and civil unions, and to provide Exchanges increased flexibility for implementation.

Response: We believe the text provides flexibility for consumers to be determined eligible for the special enrollment period if the separation or termination of a civil union or domestic partnership is in accordance with State law. In addition, we note that consumers not currently enrolled in a qualified health plan who experience one of the life events described in this provision may be determined eligible for a special enrollment period in

accordance with existing special enrollment period provisions, specifically loss of coverage. Recognizing that Exchanges may need more time to implement the necessary functional IT changes, we are making paragraph (d)(2)(ii) effective January 1, 2017. Exchanges are encouraged to implement the policy as soon as possible.

Comment: Several commenters requested that the special enrollment period provided in paragraph (d)(8) of this section be extended to include the dependents of Indians to allow them to change enrollment in a qualified health plan once per month.

Response: An Indian as provided under section 4(d) of the Indian Self-Determination and Education Assistance Act (ISDEAA) and section 4 of the Indian Health Care Improvement Act (IHCIA) is defined as an individual who is a member of an Indian tribe. Both ISDEAA and IHCIA have nearly identical language that refers to a number of Indian entities that are included in this definition on the basis that they are recognized as eligible for the special programs and services provide by the United States to Indians because of their status as Indians. As such, the statute specifically provides the special enrollment period defined in paragraph (d)(8) of this section as applying to the individual who is eligible for special programs and services because of their status as an Indian, and not their dependents.

Comment: We received many comments in response to our proposal to extend a special enrollment period to individuals below 100 percent of the FPL in non-Medicaid expansion States that later become eligible for advance payments of the premium tax credit at § 155.420(d)(6)(iv). A few commenters asked for HHS to clarify that an individual would be eligible for the special enrollment period if he or she experienced a change in household composition or size, in addition to a change in household income, and one commenter requested that change in household income required a change in percentage of the FPL.

Response: We are finalizing this policy as proposed. We note that for purposes of determining eligibility for this special enrollment period, an individual's percentage of the FPL is a function of household income, composition and size; therefore, individuals who gain eligibility because of a change in income or a change in household composition will be eligible for this special enrollment period.

Comment: Several commenters requested that HHS include additional

special enrollment periods pertaining to provider networks, specifically when a consumer enrolls in a qualified health plan with an inaccurate provider directory, enrolls in a plan which changes their health plan's provider or pharmacy networks mid-year, or enrolls in a plan with no in-network providers within a 25 mile radius of the consumer.

Response: We acknowledge the need for consumers to have access to correct information about their QHPs and participating providers and pharmacies, and have promulgated provisions pertaining to the maintenance and dissemination of provider and pharmacy directories in this rule. However, provider and pharmacy network participation changes frequently. Therefore, determining who would be eligible for the type of special enrollment period suggested by commenters would require that issuers report to the Exchange whenever provider and pharmacy network participation changes and that the Exchange notify consumers potentially impacted by such changes. As such, we are not making changes in response to these comments, and note that consumers may be determined eligible for the special enrollment period provided in paragraph (d)(5) of this section if an issuer substantially violates their contract with the enrollee.

Comment: We received comments that requested the length of the special enrollment period for loss of coverage provided in paragraph (d)(1) of this section be shortened from 120 days to 30 or 60 days, to reduce the administrative burden on the Exchange and issuer to enroll the consumer in retroactive coverage.

Response: We note that the special enrollment period for loss of coverage, as provided in paragraph (c)(2) of this section, is 60 days. We clarify that, while an individual has 60 days before and after the loss of coverage to select a qualified health plan through the Marketplace, the coverage generally may not be effective until the first day of the month following the loss of coverage in accordance with paragraph (b)(2)(iv) of this section. Both the advanced availability of this special enrollment period and its duration are intended to minimize the likelihood that an individual will experience a significant gap in coverage.

Comment: We received comments requesting that Exchanges provide health insurance companies with the specific reason for a special enrollment period so that the health insurance company may determine during the benefit year if a change to a policy is a

result of a special enrollment period or a modification to an existing policy.

Response: HHS has issued technical guidance, including the Standard Companion Guide Version 1.5 (issued March 22, 2013), which provides Exchanges with the information necessary to build the ability to send the reason for Special Enrollment Periods on the enrollment transaction. The FFEs also use a casework system to provide insurance companies with the type of special enrollment period being provided to a consumer.

Comment: A commenter requested that HHS reduce the number of special enrollment periods other than qualifying life events.

Response: We believe that the current special enrollment periods requirements appropriately account for changes in circumstances that necessitate when individuals would need to select a new or different qualified health plan and balance these needs with the administrative burdens of enrollment changes for issuers.

Comment: A commenter requested that all special enrollment periods be available both through the Exchange, and individual and small group market plans.

Response: We note that in accordance with § 147.104(b)(2) health insurance issuers in the individual market must provide a limited open enrollment period for the special enrollment periods provided in paragraph (d) of this section, with the exclusion of paragraphs (3), (8), and (9).

Comment: We received general support for the proposed changes to include non-Exchange entities in the special enrollment period where enrollment or non-enrollment in a qualified health plan through the Marketplace is a result of the error of the Exchange. Commenters noted concern regarding the subjectivity of defining an error of the Exchange and requested CMS outline the specific scenarios which would warrant such a special enrollment period.

Response: We believe the flexibility for Exchanges to determine when a special enrollment period is warranted due to an error of the Exchange protects consumers. HHS has issued guidance and will continue to issue guidance, as needed, related to how Exchanges define errors of the Exchange in accordance with paragraph (d)(4) of this section.

Comment: We received a comment that HHS provide clarification that the existing special enrollment period available for loss of minimum essential coverage (MEC) at paragraph (d)(1)(i) should not be triggered when a

consumer's policy ends at the end of the benefit year because guaranteed renewability prevents the consumer from losing their coverage.

Response: We do not think the recommended clarification is necessary. The existing language in the final rule specifies that the date of the loss of coverage is the last day the consumer would have coverage under his or her previous plan is sufficient. We also note the availability of the special enrollment period in § 155.420(d)(1)(ii) for consumers in individual market plans with non-calendar year plan years.

d. Termination of Exchange Enrollment or Coverage (§ 155.430)

Under our current rules, § 155.430(b)(1) requires an Exchange to permit an enrollee to terminate his or her coverage in a qualified health plan (QHP) following appropriate notice to the Exchange or the QHP. We proposed to amend this paragraph by adding a sentence to clarify that, to the extent the enrollee has the right to cancel the coverage under applicable State laws, including "free look" cancellation laws—that is, laws permitting cancellation within a certain period of time, even following effectuation of the enrollment, the enrollee may do so, in accordance with the requirements of such laws. Furthermore, we proposed to amend § 155.430(d)(2) to add a new paragraph (d)(2)(v) allowing a retroactive termination effective date when an enrollee initiates the termination, if specified by applicable State laws, such as "free look" provisions.

Additionally, we proposed to amend § 155.430(b)(1) by removing the language requiring the appropriate notice to the Exchange or QHP since the notice requirement is addressed in § 155.430(d) and this would give greater flexibility for other enrollee initiated terminations where appropriate notice is not defined.

We also proposed to explicitly state that the requirement for Exchanges to ensure appropriate actions are taken in connection with retroactive terminations, currently set forth in paragraph (d)(6) regarding special enrollment periods, applies to all retroactive terminations, including valid cancellations of coverage under a "free look" law. To do so, we proposed to move the applicable language to a new paragraph (d)(8). We also proposed to add reconciliation of Exchange user fees to the list of items Exchanges would need to address. Under that requirement, the Exchange will ensure that appropriate actions are taken to make necessary adjustments to advance

payments of the premium tax credit, cost-sharing reductions, Exchange user fees, premiums, and claims, while adhering to any State law. We noted that, under our proposal, the enrollee would not become eligible to receive a special enrollment period as a direct result of the "free look" cancellation.

We also proposed to add a new paragraph (b)(1)(iii) which would require Exchanges to establish processes for a third party to report the death of a consumer.

We noted that we interpret market-wide guaranteed availability and renewability requirements to mean that a QHP offered through the Exchange must generally be available and renewable outside the Exchange. We proposed to make changes to Exchange regulations that could be construed to limit coverage in a QHP to coverage through the Exchange. For example, we proposed to amend Exchange regulations referencing "termination of coverage" so that they appropriately refer to termination of enrollment through the Exchange and not necessarily termination of the coverage altogether.

We are finalizing the provisions proposed in § 155.430 of the proposed rule, with a minor modification. We are revising § 155.430(b)(1)(i) to specify that an enrollee has a right to terminate, and not just cancel coverage according to any applicable State law. Cancellation is a specific type of termination and, as further explained below, we want to accommodate State laws that provide for termination, not just cancellation. We also corrected a typographical error in § 155.430(b)(1)(iii). We also make conforming revisions to §§ 155.430, 155.735, 156.270, 156.285 and 156.290 of the Exchange and SHOP regulations to align them with our interpretation of the guaranteed availability and guaranteed renewability requirements, changing references to "coverage" to now also refer to "enrollment through the Exchange," "enrollment through the SHOP," or "enrollment," as applicable.

Comment: Commenters, mainly issuers, opposed allowing termination of coverage after the coverage effective date, citing an increase in administrative costs and a potential to create a less healthy risk pool; many consumer advocates and the NAIC supported the free-look proposal. Other commenters stated that HHS should not establish specific requirements related to free look periods, but should explicitly state that issuers should continue to adhere to existing State laws for Exchange enrollees.

Response: Our intent in the proposed rule was to accommodate State laws that

provided consumer protections such as "free look" provisions, to give consumers in States with such laws the right to terminate coverage in accordance with those laws. Therefore, the intent of the regulation is to ensure that issuers adhere to existing State laws for Exchange enrollees, not to create new Federal laws. Thus, this change should not increase the burden on issuers. To make sure that we do not unintentionally limit the applicability of these types of laws, we are finalizing § 155.430(b)(1)(i) to use the word "terminate" in place of "cancel," specifying that the enrollee has the right to terminate their coverage under any applicable State laws.

Comment: Some commenters were concerned with the cost and burden of correcting financial information for retroactive terminations, and the uncertainty of payment for services as a result of retroactive terminations.

Response: We acknowledge that retroactive terminations may cause some administrative burden for correcting financial information. However, there are scenarios that currently exist in the Exchange that result in retroactive terminations. Furthermore, it remains necessary that the enrollment group pay the correct amounts for a given policy as already codified in § 155.430(d)(6). We note issuers and providers should continue to follow existing policies when dealing with retroactive terminations. Therefore, we are finalizing § 155.430(d)(8) to ensure that appropriate actions are taken to make necessary adjustments to advance payments of the premium tax credit, cost-sharing reductions, Exchange user fees, premiums, and claims, while to adhering to State law.

Comment: We received several comments urging that an SEP be given to consumers who exercise their free-look provision outside of open enrollment. These commenters suggested that the unavailability of an SEP significantly undercuts the value of the free-look provision.

Response: Granting an SEP for an individual exercising a retroactive termination under State law could result in multiple successive enrollments and terminations pursuant to a free look law, which we believe would create unwarranted burden on issuers and providers.

Comment: Several commenters asked us to clarify that the protection outlined in § 155.430 applies in States with "free look laws." One commenter recommended that the protection apply more widely, including for States that have policies related to termination of coverage, like "free look provisions,"

that may not be law but that are otherwise enforceable by the State. Another commenter expressed concern on deferring to State laws because of the resulting variance in applicable standards. The commenter recommended establishing Federal standards and allowing States the option to establish more protective standards.

Response: Our intent was to clarify that consumers in States with such laws have the right to terminate coverage in accordance with those laws. We do not intend to create Federal standards that give consumers additional reasons to terminate coverage. For States that have policies related to termination of coverage, like “free look provisions,” that may not be law but that are otherwise enforceable by the State, issuers must adhere to such policy as enforced by the State. Accordingly, we are finalizing § 155.430(b)(1)(i) to specify that the enrollee has the right to terminate their coverage under applicable State laws.

Comment: We received a comment recommending that HHS reflect retroactive termination dates on 834s and include termination reason codes.

Response: The 834s currently include the effective date of the termination as well as a high-level maintenance reason (INS04) and an additional maintenance reason indicating that the transaction is a termination or cancellation. We are working on future functionality to indicate more specific additional maintenance reasons for terminations and cancellations.

Comment: Commenters generally supported the proposed provisions that require Exchanges to establish a process for a third party to report the death of a qualified health plan enrollee. One commenter requested clarification regarding whether the report of death may be made to the issuer or the Exchange.

Response: We are finalizing this provision as proposed, and clarify that Exchanges have flexibility to establish a process for reporting the death of an enrollee. For instance, in the Federally-facilitated Exchange, the reporting of a death of an enrollee is initiated with the Exchange.

Comment: One commenter requested that an individual’s agent or broker be able to report their client’s death to the Exchange to initiate a termination of their coverage.

Response: An individual’s agent or broker may report their client’s death to the Exchange in accordance with the process established by the Exchange. Depending on the Exchange-specific procedures, the agent or broker may be

required to submit documentation proving the death of the individual.

Comment: We received several comments on our proposal to conform the Exchange regulations with our interpretation of the guaranteed availability and renewability requirements. Many commenters supported the proposal. One commenter was concerned about Exchanges’ ability to distinguish circumstances warranting termination of Exchange enrollment from circumstances warranting full termination of coverage. Another commenter was concerned about issuers’ ability to seamlessly continue coverage of terminated Exchange enrollees outside the Exchange and recommended that HHS delay finalizing the proposal until its operational feasibility could be assessed.

Response: Loss of eligibility for enrollment in a QHP through the Exchange is not necessarily a basis for non-renewal or termination of an individual’s or employer’s coverage in the market outside the Exchange. Therefore, we make conforming amendments in this final rule to the following sections of the Exchange and SHOP rules: §§ 155.430, 155.735, 156.270, 156.285 and 156.290. These amendments are intended to more clearly distinguish termination of enrollment through the Exchange from termination of coverage with the issuer. Termination of coverage is governed by the guaranteed renewability provisions in section 2703 of the PHS Act and § 147.106. Therefore, § 156.270(a) is further amended to include to a cross-reference to § 147.106 to clarify when and how an issuer may terminate coverage under applicable law. We also made a conforming amendment in § 155.430(b)(2)(vi) clarifying that any of the exceptions to guaranteed renewability that would permit an issuer to terminate an enrollee’s coverage also could be a basis for terminating enrollment through the Exchange.

We acknowledge the operational concerns of commenters, but note that these revisions are simply technical clarifications to eliminate potential conflict with the requirements that currently apply to issuers under sections 2702 and 2703 of the PHS Act. Furthermore, it is anticipated that, in most situations involving termination by the Exchange, such as decertification of the QHP or non-payment of premium, the issuer will know the reason for the termination. When the issuer knows the reason for Exchange termination and it is not a basis for non-renewal or termination of the enrollee’s coverage, the issuer generally must continue the

coverage outside the Exchange, at the option of the enrollee, in order to satisfy the issuer’s responsibilities under the guaranteed renewability requirements, unless an exception applies. When the issuer does not know the reason for termination of an enrollee’s Exchange enrollment, the issuer should continue the enrollee’s coverage outside the Exchange if approached by the enrollee to do so, unless following investigation, the reason for the termination will permit the issuer to terminate the coverage.

5. Exchange Functions in the Individual Market: Eligibility Determinations for Exemptions

a. Eligibility Standards for Exemptions (§ 155.605)

In § 155.605, we proposed amendments to two hardship exemptions and a correction to a cross-reference. First, we proposed to amend § 155.605(g)(3) to permit an individual with gross income below the filing threshold and who is not a dependent of another taxpayer to qualify for a hardship exemption through the tax filing process and without having to obtain an exemption certificate number (ECN) from the Exchange. Second, we proposed amending § 155.605(g)(6)(i) to correct the citation to 42 CFR 447.50 by changing it to 42 CFR 447.51, which cross-references the Medicaid definition for Indian. Third, we proposed new paragraph § 155.605(g)(6)(iii) to align the exemption process for those individuals who are eligible for services through the Indian Health Service (IHS), a Tribal health facility, or an Urban Indian organization (collectively, ITU) with the process available to members of Federally-recognized Tribes. Specifically, the proposed amendment will provide individuals who are eligible for services through an ITU to claim an exemption on their Federal income tax return without obtaining an ECN.

We are finalizing the provisions as proposed.

Comment: Comments on this provision supported the proposed changes. We received a few comments noting that, despite this additional avenue to receive an exemption, some American Indians/Alaskan Natives (AI/ANs) who qualify for a recurring ECN may continue to prefer the Exchange exemption process rather than claiming an exemption annually through the Federal tax-filing process. For this reason, these commenters encouraged CMS to retain and improve the Exchange exemption application process.

Response: We remain committed to improving the Exchange exemptions process. We note that the Exchange exemptions process remains available to AI/ANs under § 155.605(f) and (g)(6)(i).

b. Required Contribution Percentage (§ 155.605)

Under section 5000A of the Code, an individual must have minimum essential coverage for each month, qualify for an exemption, or make a shared responsibility payment with his or her Federal income tax return. Section 5000A of the Code and section 1311(d)(4)(H) of the Affordable Care Act authorizes the Secretary to determine individuals' eligibility for exemptions, including the hardship exemption. Under section 5000A(e)(1) of the Code, an individual is exempt if the amount that he or she would be required to pay for minimum essential coverage (required contribution) exceeds a particular percentage (the required contribution percentage) of his or her actual household income for a taxable year. In addition, under § 155.605(g)(2) an individual is exempt if his or her required contribution exceeds the required contribution percentage of his or her projected household income for a year. Finally, under § 155.605(g)(5), certain employed individuals are exempt if, on an individual basis, the cost of self-only coverage is less than the required contribution percentage but the aggregate cost of self-only coverage through employers exceeds the required contribution percentage and no family coverage is available through an employer at a cost less than the required contribution percentage.

The required contribution percentage for 2014 is 8 percent under section 5000A(e)(1)(A) of the Code. Section 5000A(e)(1)(D) of the Code and 26 CFR 1.5000A-3(e)(2)(ii) provide that for plan years after 2014, the required contribution percentage is the percentage determined by the Secretary that reflects the excess of the rate of premium growth between the preceding calendar year and 2013, over the rate of income growth for that period. In the 2015 Market Standards Rule, we established a method for determining the excess of the rate of premium growth over the rate of income growth each year, and published the 2015 rate. We stated that future adjustments would be published annually in the HHS notice of benefit and payment parameters.

Under the method previously established, the rate of premium growth over the rate of income growth for 2016 is the quotient of (x), which is equal to one plus the rate of premium growth

between the preceding year (in this case, 2015), and 2013, carried out to ten significant digits, divided by (y), which is equal to one plus the rate of income growth between the preceding year (2015), and 2013, carried out to ten significant digits.⁴² The result of this calculation is carried out to ten significant digits and multiplied by the required contribution percentage specified in section 5000A(e)(1)(A) of the Code (8.00 percent). The result is then rounded to the nearest hundredth of a percent, to yield the required contribution percentage for 2016.

Under the methodology described above, the total rate of premium growth for the 2-year period from 2013–2015 is 1.0831604752, or 8.3 percent. We describe the methodology for obtaining this number below in § 156.130(e). In the 2015 Market Standards rule, we also established a methodology for calculating the rate of income growth for the purpose of calculating the annual adjustment to the required contribution percentage.

The measure of income growth is based on projections of per capita Gross Domestic Product (GDP) used for the National Health Expenditure Accounts (NHEA), which is calculated by the CMS Office of the Actuary. Accordingly, using the NHEA data, the rate of income growth for 2016 is the percentage (if any) by which the most recent projection of per capita GDP for the preceding calendar year (\$56,660 for 2015) exceeds the per capita GDP for 2013, (\$53,186), carried out to ten significant digits. The total rate of income growth for the 2-year period from 2013–2015 is estimated to be 1.0653179408 or 6.5 percent. We note that the 2013 per capita GDP used for this calculation has been updated to reflect the latest NHEA data.

Thus, the excess of the rate of premium growth over the rate of income growth for 2013–2015 is 1.0831604752/1.0653179408, or 1.0167485534, or 1.7 percent. This results in a required contribution percentage for 2016 of 8.00*1.0167485534, or 8.13 percent, when rounded to the nearest one-hundredth of one percent.

We received no comments on the calculation of the required contribution percentage and are therefore finalizing the percentage as proposed.

⁴² We defined premium growth for this measure as the same annually adjusted measure of premium growth used below in this rule to establish the annual maximum and reduced maximum limitations on cost sharing for plan benefit designs. That is, the premium adjustment percentage.

6. Exchange Functions: Small Business Health Options Program (SHOP)

a. Standards for the Establishment of a SHOP (§ 155.700)

We proposed to amend § 155.700(b) such that the previous definition of “group participation rule” would conform with the terminology we proposed to use in § 155.705(b)(10). Specifically, we proposed to modify the term to refer to a “group participation rate,” which is a minimum percentage of all eligible individuals or employees of an employer that must be enrolled.

We received no comments on this proposal and we are finalizing this amendment as proposed.

b. Functions of a SHOP (§ 155.705)

In § 155.705, we proposed to redesignate paragraph (b)(4)(ii)(B) as new paragraph (b)(4)(ii)(C), redesignate paragraph (b)(4)(ii)(A) as new paragraph (b)(4)(ii)(B), add new paragraph (b)(4)(ii)(A), and amend paragraphs (b)(4)(i)(B), (b)(7), and (b)(10).

In the proposed amendment to paragraph (b)(4)(i)(B) and proposed new paragraph (b)(4)(ii)(A), we proposed to permit the SHOP to assist a qualified employer in the administration of continuation coverage in which former employees seek to enroll through the SHOP. We proposed that where a qualified employer is offering Federal or State continuation coverage,⁴³ and where a SHOP has entered into an agreement with a qualified employer to provide this service, the SHOP may assist the employer in administration of such coverage by billing for and collecting premiums for the continuation coverage directly from the covered employee or qualified beneficiary, rather than the employer, if the qualified employer elects to have the SHOP carry out this function. We sought comment on the interaction of the FF–SHOP's payment grace periods and termination policies at § 155.735 with the COBRA rules the IRS has codified at 26 CFR part 54. We are finalizing the proposed changes to § 155.705(b) with a modification to clarify that individuals other than former employees might be enrolled in continuation coverage through a SHOP, and we are also amending § 155.735 to better align the SHOP rules with the IRS's COBRA rules in light of the comments discussed below.

We considered whether the FF–SHOP should accept premium payment using a credit card. Currently, qualified employers participating in the FF–

⁴³ 29 U.S.C. 1161, *et seq.* (“COBRA”) or applicable State law.

SHOP may only pay premiums to the FF-SHOP using a check or bank draft. We sought comment on the extent to which employers would use this option. Some commenters stated that it may be more convenient for a small employer to pay by credit card than by check or bank draft. However, in light of the comments discussed below, HHS does not intend to take action on this policy at this time.

We also proposed to revise paragraph (b)(7) to align the SHOP regulations with the Protecting Access to Medicare Act of 2014 (Pub. L. 113-93), which repealed requirements related to deductible maximums for employer-sponsored coverage at section 1302(c)(2) of the Affordable Care Act. This proposal would remove the only reference in the SHOP regulations to the requirements of Affordable Care Act section 1302(c)(2). We did not receive any comments on the proposed revisions to paragraph (b)(7) of this section and are finalizing this proposal as proposed.

In paragraph (b)(10), we proposed to modify the calculation of minimum participation rates in the SHOP. We proposed that a SHOP (either a State-based or an FF-SHOP) that elects to establish a minimum participation rate would be required to establish a single, uniform rate that applies to all groups and issuers in the SHOP, rather than establishing general rules about minimum participation rates or a threshold over which the minimum percentage may not be raised. We also proposed that if a SHOP authorizes a minimum participation rate, such a rate would have to be based on the rate of employee participation in the SHOP and in coverage through another group health plan, governmental coverage (such as Medicare, Medicaid or TRICARE), coverage sold through the individual market, or in other minimum essential coverage, and not on the rate of employee participation in any particular QHP or QHPs of any particular issuer. We proposed that State-based SHOPS would be expected to conform to the proposal by its effective date.

In paragraph (b)(10)(i), we proposed to amend existing language about employees accepting coverage under the employer's group health plan to instead refer to employees accepting coverage offered by a qualified employer to better account for employee choice.

We also proposed to amend paragraph (b)(10)(i) regarding how the minimum participation rate would be calculated in the FF-SHOP. We proposed to calculate the minimum participation rate in the FF-SHOP as the number of full-time employees accepting coverage

offered by the qualified employer through the SHOP plus the number of full-time employees who are enrolled in coverage through another group health plan, in governmental coverage (such as Medicare, Medicaid or TRICARE), in coverage sold through the individual market, or in other minimum essential coverage, divided by the number of full-time employees offered coverage through the SHOP.

We sought comment on whether this definition of which employees would be included in the calculation should be extended beyond the SHOP to the entire small group market to create uniformity among issuer practices and prevent further gaming by issuers through their use of non-standard definitions for other acceptable coverage.

We are finalizing the proposed amendments to paragraph (b)(10) with modifications. We are modifying the proposed amendments to the language following (b)(10); adding the amendments we proposed at paragraph (b)(10)(i) at a new paragraph (b)(10)(ii); amending current paragraph (b)(10)(i) to reflect that it will remain in effect for plan years beginning prior to January 1, 2016; and redesignating paragraph (b)(10)(ii) as (b)(10)(iii) and making a minor conforming amendment to that paragraph to reflect the addition of new paragraph (b)(10)(ii). The modifications clarify that the amendments to the minimum participation rate calculation methodology requiring counting of employees accepting coverage offered by the qualified employer through the SHOP, and counting of employees enrolled in coverage through another group health plan, in governmental coverage (such as Medicare, Medicaid, or TRICARE), in coverage sold through the individual market, or in other minimum essential coverage, will apply only to the FF-SHOP, effective for plan years beginning on or after January 1, 2016. For plan years beginning prior to January 1, 2016, the FF-SHOP will apply the methodology at current (b)(10)(i). We are also modifying paragraph (b)(10)(i) to explain that former employees would be excluded from the calculation of minimum participation rates in the FF-SHOP under the methodology that will remain in effect for plan years beginning prior to January 1, 2016, to ensure that the same methodology currently being used will continue to be used after the modification to the definition of qualified employee in this rule takes effect. State-based SHOPS and small group markets outside of the Exchanges are not expected to conform to the amended calculation methodology.

Comment: Several commenters supported the proposal that would permit a SHOP to bill for and collect premiums for COBRA. One commenter disagreed with the policy. One commenter requested that HHS preserve the flexibility proposed for SHOPS to determine whether they wish to offer this service.

Many commenters requested that HHS align SHOP rules with applicable COBRA standards and work with the applicable agencies to ensure clarity. These commenters expressed concern that a lack of harmony between the SHOP rules, COBRA standards, and requirements from other Federal agencies would lead to confusion. One commenter requested HHS specify which IRS rules are applicable.

Response: As we indicated in the preamble to the proposed rule, the IRS has promulgated rules regarding the administration of COBRA continuation coverage at 26 CFR 54.4980B, *et seq.* Our SHOP regulations do not affect or narrow an individual's existing substantive and procedural rights under COBRA or other Federal agencies' rules interpreting COBRA. To harmonize existing SHOP rules regarding terminations of coverage with the IRS's COBRA rules at § 54.4980B-8, we are adding paragraphs (c)(2)(iv) and (c)(3) to § 155.735 in this final rule. Paragraph (c)(2)(iv) is necessary because, in cases other than COBRA continuation coverage, the FF-SHOP does not provide an additional grace period for payments less than the total premium amount due for a group's cost of coverage. Paragraph (c)(3) is necessary to specify that the section does not modify existing obligations under 26 CFR 54.4980B.

To further align with existing COBRA requirements, including COBRA eligibility for dependents and former dependents, we are modifying the language of paragraph (b)(4)(ii)(A) of § 155.705 to permit the collection of such premiums from any person enrolled in continuation coverage through the SHOP consistent with applicable law and the terms of the group health plan. For improved clarity, we are also replacing the reference in proposed § 155.705(b)(4)(ii)(A) to "Federally mandated continuation coverage" with a reference to continuation coverage required under 29 U.S.C. 1161, *et seq.*

Comment: One commenter stated that SHOPS should also administer required notices that relate to continuation of coverage.

Response: HHS continues to examine the feasibility of expanding SHOP's flexibility to support additional COBRA

administration functions, including COBRA notification requirements. Significant modifications may be necessary to existing SHOP rules to ensure conformity with existing IRS rules if a SHOP were to fully administer COBRA on behalf of an employer. Therefore, HHS does not intend to take action on this policy at this time.

Comment: Some commenters stated that both a State-based SHOP's and a FF-SHOP's implementation of continuation coverage administration should extend to State-mandated continuation coverage. Some commenters expressed concern that limiting FF-SHOP continuation coverage support to COBRA may cause confusion among small employers regarding responsibility for continuation coverage requirements. Another commenter requested relief from existing SHOP payment rules requiring the flow of funds through the SHOP where a SHOP fails to provide payment support for continuation coverage.

Response: The finalized language does not require SHOPs to limit this service to the collection of premiums related to Federal continuation coverage. Both State-based SHOPs and the FF-SHOP may elect to collect payments related to State-required continuation coverage sold through the SHOP on behalf of small employers.

We continue to examine applicable State law to determine the feasibility of the FF-SHOP providing this service for both State and Federal continuation coverage. Variation in State continuation coverage laws would add substantial complexity to the FF-SHOP's implementation of premium collection for State continuation coverage. Therefore, the FF-SHOP may more quickly provide relief to small employers by first supporting COBRA continuation coverage administration while HHS determines how it may best support State-mandated continuation coverage.

HHS continues to believe that the flow of funds through the SHOP best supports the administration of employee choice and therefore is not modifying existing requirements related to the flow of funds through the SHOP.

Comment: One commenter sought clarification on how continuation coverage would be operationalized, including whether 820 and 834 transactions will identify members covered under continuation coverage.

Response: HHS recognizes that QHP issuers will need substantially more detailed information to effectively integrate with a SHOP facilitating continuation coverage. If the FF-SHOP implements administration of premiums

for continuation coverage, HHS intends to issue further guidance.

Comment: We received several comments about whether the FF-SHOP should accept premium payments made with a credit card. Several commenters were in favor of this idea. However, these commenters also noted that HHS should consider the benefits of this option against the costs that will be incurred with this additional functionality. Some commenters opposed accepting premium payments through a credit card and were particularly concerned about the fees associated with the use of a credit card. Some commenters recommended that the credit card fee should be included as part of the user fee that HHS is already collecting, while other commenters stated that the credit card fee should be borne by the FF-SHOP and not issuers. One commenter noted that the cost of the credit card fee will add to the cost of coverage for consumers and may impact the calculation of the Medical Loss Ratio if it is considered an administrative cost payable by an issuer. One commenter believed that the use of credit cards to make premium payments should not be limited to the initial payment, and instead should be used for recurring payments.

Response: HHS will continue to consider whether there is a cost-effective way to permit employers to pay premiums through the SHOP with a credit card. HHS does not intend to take action on this policy at this time.

Comment: We received one comment on our proposed amendments to the SHOP rules about the minimum participation rate in § 155.705(b)(10), asking whether issuers may maintain varying participation requirements based on group size if this policy is finalized to extend to the small group market outside the SHOP. We also received comments on the proposed calculation methodology for calculating the minimum participation rate. Some commenters supported our proposal and some believed that our proposed methodology will weaken the ability of the FF-SHOP to protect against adverse selection and is not considered common market practice. One commenter recommended not including individuals with coverage in the individual market Exchanges because it undercuts employer-based coverage. One commenter stated that minimum participation rates are a barrier to coverage for businesses.

While we received some comments supporting the extension of our proposed policy to the entire small group market, several commenters

opposed such an extension, including State-based SHOPs. One commenter opposed our proposal because SHOP issuers are protected by programs that issuers not participating in the SHOP are not protected by, such as the risk corridors program. Several of these commenters stated that the off-Exchange market should use a methodology that works best for their market and State, and that it should be up to the State to establish how to calculate the minimum participation rate inside and outside of the Exchanges.

In addition to these comments, we received queries on how HHS would verify the coverage of individuals included in the calculation of the minimum participation rate. Several commenters also asked for details on the one-month exception period for minimum participation rates.

Response: We are finalizing a policy under which a SHOP (either a State-based SHOP or an FF-SHOP) that elects to establish a minimum participation rate would be required to establish a single, uniform rate that applies to all groups and issuers in the SHOP, rather than establishing general rules about minimum participation rates or a threshold over which the minimum percentage may not be raised. Under the methodology we have finalized for calculating a minimum participation rate, a SHOP cannot vary its minimum participation rate based on the employer group size. In the final rule, we are modifying the proposal to give State-based SHOPs the flexibility to establish a different minimum participation rate calculation methodology than the one being finalized for the FF-SHOP, but State-based SHOPs must continue to base the rate on employee participation in the SHOP or in the SHOP and other coverage (as in the FF-SHOP), and may not base the rate on employee participation in a particular QHP or QHPs of any particular issuer. We believe that providing State-based SHOPs with this flexibility will allow States to set a calculation methodology that aligns with their current market practice. We are also finalizing our proposal on the calculation of the minimum participation rate in the FF-SHOP and who is included in the methodology, but are modifying the proposal to specify that the new FF-SHOP calculation methodology will take effect only for plan years beginning on or after January 1, 2016. For plan years beginning before January 1, 2016, the calculation methodology currently in place for the FF-SHOP will remain in effect.

We note that consistent with current § 155.705(b)(10)(ii) (which is

redesignated at § 155.705(b)(10)(iii) in this rule), the FF-SHOP may establish a different minimum participation rate in a State if there is evidence that a State law sets a different minimum participation rate or that a higher or lower minimum participation rate is customarily used by the majority of QHP issuers in the State for products in the State's small group market outside the SHOP. HHS considered various minimum participation rate calculation methodologies, and believes that the calculation methodology we are finalizing for the FF-SHOP aligns with current practice in many States' small group markets. The difficulty of verifying other coverage exists today in the market and is not exacerbated by this rule. Additionally, HHS believes that using this approach to calculating minimum participation rates reduces unnecessary barriers for employer groups seeking to cover their employees because the calculation includes individuals with other forms of coverage, thus making it easier for employer groups to reach the required minimum participation rate. By including in the calculation individuals with individual market coverage, we believe this methodology does not undercut employer-based coverage, but rather treats employers fairly. Under the approach taken in the final rule to accommodate for State-specific policies, State-based SHOPs may use a calculation methodology that aligns with current market practice in their State, and that works best for their market and State, and are therefore not required to follow the same calculation methodology as will apply in the FF-SHOPs.

The final rule does not modify or eliminate the one-month period between November 15 and December 15 of each year, during which employer groups may enroll in coverage notwithstanding any employer contribution or group participation rules under § 147.104(b)(1)(i)(B). Thus, SHOPs may not apply the minimum participation rate to prevent initial enrollments and renewals that occur during this one-month period.

We do not believe the proposed modification to calculation of the FF-SHOP minimum participation rate will result in significant adverse selection. In some States in which the FF-SHOP currently operates, its minimum participation rate is more restrictive on enrollment than the rate currently generally applied by issuers in the market. The proposed modifications to the FF-SHOP's minimum participation rate will align the calculation of the rate with current practices in these States by

including other sources of coverage in the calculation. We acknowledge that this change will make the FF-SHOP's minimum participation rate more inclusive than minimum participation rates in the market in some other States. However, under current law, no group may be excluded from the small group market altogether because it fails to meet a minimum participation rate. Any group may enroll during the annual month-long period under § 147.104(b)(1)(B) during which no minimum participation rate can be applied to deny coverage. Further, the new methodology for the participation rate calculation is only more permissive in that it lets in groups with additional sources of other coverage. There is no basis to suggest that such a group represents worse than average risk.

c. Eligibility Standards for SHOP (§ 155.710)

In § 155.710, we proposed to amend paragraph (e) to specify that where an employer has offered dependent coverage, a qualified employee would be eligible to enroll his or her dependents in coverage through the SHOP.

We received a comment supporting our proposal. We are finalizing our amendment as proposed.

d. Enrollment of Employees Into QHPs Under SHOP (§ 155.720 and § 156.285)

In § 155.720, we proposed to remove paragraph (b)(7), which requires all SHOPs to establish effective dates for employee coverage in the SHOP, and to make minor conforming changes to the list structure in paragraph (b). Current § 155.720(b)(7) is redundant in light of the proposed requirements to establish effective dates under § 155.725, which we are finalizing as proposed.

We received no comments on these proposed amendments. We are finalizing the amendments as proposed.

We proposed to amend paragraph (e), which provides that issuers must notify SHOP consumers regarding coverage effective dates so that the provision would refer to enrollees and not qualified employees, and proposed to remove a reference in this section to § 156.260(b), in keeping with the proposed amendments to § 155.725 regarding coverage effective dates. Under the proposal, issuers would be required to provide this notice to anyone who enrolled in coverage through the SHOP under the proposed amendments to the definitions of qualified employee and enrollee, including dependents (including a new dependent of the employee, when the dependent separately joins the plan),

former employees of a qualified employer, and certain business owners. We noted that the notices required under this proposal could be incorporated into existing notifications that QHPs provide to their new customers, for example in a welcome document. We also proposed a conforming amendment to § 156.285(c) to ensure that QHP issuers participating in the SHOP would provide notice to a new enrollee of the enrollee's effective date of coverage.

We are finalizing the provisions with the modifications noted below.

Comment: We received several comments on our proposed amendments to effective date notices pursuant to § 155.720(e). Some commenters supported continuing to require issuers to send the required notices, while others stated that the notice requirement should be shifted to the SHOP. We also received comments on expanding the notice requirement to the amended definition of an enrollee, which includes dependents. Some commenters stated that notices regarding the coverage effective date should only be provided to qualified employees and adult dependents. Some commenters stated that these notices should be provided separately to dependents of qualified employees if the last known address for the dependent is different from the subscriber. We also received one comment requesting additional time and flexibility for issuers to implement the notice requirement for dependents under the new definition of an enrollee.

Response: We agree that generally, when a dependent lives with the qualified employee, separate notification to the dependent is duplicative. As such, we are modifying the proposal to specify that when a primary subscriber and his or her dependents live at the same address, a separate notice need not be sent to each dependent at that address, so long as the notice sent to each primary subscriber at that address contains all the required information about the coverage effective date for the primary subscriber and each of his or her dependents at that address. We note that when dependents live at a different address from the primary subscriber a separate notice must be sent to those dependents.

Amending the definition of an enrollee and amending § 155.720(e) to require notice to enrollees will create additional notice obligations for issuers. To permit issuers to update their systems and fulfill this requirement, we will provide issuers until plan years beginning on or after January 1, 2017 to fulfill the requirement of sending

effective date notices to enrollees other than qualified employees. Because issuers have already been providing these notices to qualified employees under the current rule, we do not believe the inclusion of former employees that is being finalized in this rulemaking presents similar system challenges. Thus, issuers will be required to send the notices to everyone who meets the new definition of qualified employee as soon as this rule takes effect. We are providing an additional year only for issuers to begin providing notice to enrollees other than qualified employees.

We are also making minor changes to the wording of the proposed requirement at 156.285(c)(3), so that the final rule refers to a requirement to “notify” new enrollees, rather than to “provide” them “with notice.”

e. Enrollment Periods Under SHOP (§ 155.725 and § 156.285)

We proposed to amend paragraphs (a), (g), (h), and (j)(5) of § 155.725 and § 156.285(b)(1) and (b)(4) to provide clarity regarding the effective dates for coverage that all SHOP Exchanges must establish. First, we proposed to remove the reference at current § 155.725(a)(1) to the start of the initial open enrollment period for 2014 coverage, and the reference in current § 155.725(a)(2) to § 156.260. We proposed to remove the reference to effective dates under § 156.260 because we are proposing to specify effective dates in § 155.725 or to more directly cross-reference the appropriate effective date. Second, we proposed to amend § 155.725(h) so that SHOPs would need only establish effective dates for employees enrolling in coverage during the initial group enrollment and the employee annual open enrollment period, rather than for special enrollment periods. At proposed paragraph (h)(2), we also codified the effective dates for coverage in the FF-SHOP for enrollments during initial and annual open enrollment periods. Specifically, we proposed to include language in the SHOP regulations specifying the same effective dates that were previously adopted for the FF-SHOP under our interpretation of the cross reference in § 156.285(b)(4) to § 156.260, which in turn cross-references § 155.410(c). We noted that the dates set forth in § 155.725(h)(2) would apply only to the FF-SHOP and State-based SHOPs would be free to establish their own effective dates for initial and annual open enrollment.

Third, we proposed several amendments to paragraph § 155.725(g) regarding enrollment for newly

qualified employees. A newly qualified employee is an employee who becomes eligible to participate in the employer’s group health plan outside of a qualified employer’s initial or annual enrollment period; for example, because he or she was hired outside of those periods. We proposed to move paragraph (g) to paragraph (g)(1), and proposed amendments to the existing language to make explicit our interpretation of current paragraph (g), which is that a newly qualified employee becomes eligible for an enrollment period that begins on the first day of becoming a newly qualified employee regardless of whether the employee is subject to a waiting period. Additionally, we proposed that the duration of a newly qualified employee’s enrollment period be at least 30 days. Where the employee is subject to a waiting period in excess of 45 days, we proposed that the duration of the employee’s enrollment period extend until 15 days before what would be the conclusion of the waiting period if the employee selected a plan on the first day of becoming eligible. We noted that if an employee waits to choose a plan until the end of such an extended enrollment period, this could have the effect of further delaying the effective date of coverage, consistent with § 147.116(a). We also proposed to add a new paragraph (g)(2) in § 155.725 to provide that the effective date for a newly hired employee would be determined using the same rule for initial and open enrollments that would be established by the SHOP under proposed § 155.725(h). Thus, in the FF-SHOP, coverage effective dates for newly qualified employees would be established according to § 155.725(h)(2): Plan selections made between the first and the fifteenth day of any month would be effective the first day of the following month, and plan selections made between the 16th and the last day of any month would be effective the first day of the second following month. A newly qualified employee may also be subject to a waiting period under § 147.116, however, and in such cases, the effective date may be on the first day of a month that is later than the month in which coverage would take effect under the usual rules established by the SHOP under § 155.725(h). However, in no case could the effective date fail to comply with the limitations on waiting period durations at § 147.116 of this subchapter.

Fourth, we proposed to amend paragraph § 155.725(j)(5) to make it clearer that the effective dates for special enrollment periods in the SHOP

should be determined according to § 155.420(b).

Fifth, we proposed to harmonize § 156.285(b)(1) and (4) with the proposed amendments to effective dates described above, to specify that QHP issuers must abide by the effective dates established under § 155.725, and must enroll qualified employees in accordance with the qualified employer’s initial and annual enrollment periods in § 155.725.

We also proposed to amend § 155.725(b) to harmonize rolling enrollment in the SHOP with the regulations applicable to guaranteed availability in States with merged individual and small group markets. Section 147.104(f), as moved from § 147.104(b)(2) by this rule, requires that all individual and small group health insurance coverage sold in a State with merged individual and small group risk pools be offered on a calendar year basis, meaning that it must end on December 31 of the year in which the policy was issued. Section 155.725(b), in contrast, requires that SHOPs permit qualified employers to purchase coverage for a small group at any point throughout the calendar year, and that SHOPs ensure that a participating group’s plan year lasts for 12 months beginning with the first effective date of coverage. Section 155.725(b) was intended to ensure that qualified employers can offer health insurance through the SHOP at any point during the year while receiving a guaranteed rate 12 months following the purchase of coverage, consistent with the current practice in the small group market. We proposed to harmonize these two provisions in States with merged markets, by proposing that SHOP plan years in a State with merged risk pools would terminate on December 31st of the year in which they began, even if certain qualified employers’ plan years would thus be shorter than 12 months. This proposal would not affect a small employer’s ability to enroll in coverage at any point in the year. Instead, it would standardize the renewal date of such a plan in a State with merged risk pools at the beginning of each calendar year.

We also proposed to modify paragraph (i) to permit a SHOP to elect to renew a qualified employer’s offer of coverage where the employer has taken no action during its annual election period to modify or withdraw the prior year’s offer of coverage. The qualified employer’s offer would not be automatically renewed under this proposal if the employer is no longer eligible to participate in the SHOP. Renewal of the coverage offer would

also not be automatic if the employer is offering a single QHP and that QHP will no longer be available through the SHOP. We proposed this modification at the request of State-based SHOPs that desire to conform to existing small group market practice regarding automatic annual renewal of coverage for an employer group. A SHOP would not be required to implement this rule.

Finally, we proposed to add paragraph (k) to make clear that SHOP coverage may not be effectuated if the policy may not be issued to the employer because the group fails to meet an applicable minimum participation rate calculated at the time of initial group enrollment or renewal, subject to § 147.104(b)(1)(i)(B).

We did not receive comments on the proposed amendments to § 156.285(b)(1) and (4), and are finalizing them as proposed. We are also finalizing the provisions under § 155.725 as proposed.

Comment: We received one comment on establishing effective dates for employees enrolling in coverage during the initial group enrollment and the annual open enrollment period. The commenter supported our proposed provision because it establishes flexibility for State-based SHOPs to establish their own effective dates during the initial and annual open enrollment periods, including mid-month effective dates. Commenters supported the proposed provision to keep effective dates for special enrollment periods standardized. Some commenters supported the proposed provision to ensure effective dates for special enrollment periods are consistent with § 155.420(b). One commenter opposed the effective dates for special enrollment periods under § 155.725(j) and recommended allowing States flexibility to prescribe their own effective dates for initial, annual, and special enrollment periods, because there may be other implications to the effectuation of coverage for employees and dependents with a special enrollment period.

Response: We are finalizing the provisions as proposed. We believe that the proposed amendments allow flexibility for State-based SHOPs to set and maintain effective dates for initial and annual open enrollment periods to accommodate coverage effective dates for a group as soon as possible under local market conditions. Coverage effective dates for initial and annual open enrollment periods for the FF-SHOP will be finalized as proposed to create a uniform enrollment timeline. We continue to believe that the effective dates for special enrollment periods should be standardized for all SHOPs to

ensure a minimum standard for special enrollment periods. We note that pursuant to § 155.420, SHOPs have existing authority to set earlier effective dates for certain special enrollment periods.

Comment: We received several comments on the timeline for an employee to select a SHOP plan as it relates to employee waiting periods. Some commenters supported our proposed policy on employee enrollment periods and waiting period rules. One commenter noted that a scenario could arise where an employee would need to select a SHOP plan on a timeline that does not align with the waiting period.

Response: We are finalizing our provision as proposed. SHOPs should ensure that an employee waiting period does not exceed the duration permitted under § 147.116. State-based SHOPs may continue to set their own rules regarding enrollment timelines for newly qualified employees so long as such rules comply with § 147.116.

Comment: We received comments supporting the proposed enrollment process for newly qualified employees. These commenters stated the process provides sufficient time for employees to select a plan. One commenter stated that an employee election period of more than 30 days may cause confusion to consumers and may cause significant IT modifications for issuers.

Response: We are finalizing the provision as proposed. We note that while the rule sets a 30-day minimum for a newly qualified employee's enrollment period, it does not require a SHOP to provide an enrollment period in excess of 30 days to newly qualified employees. A longer enrollment period might, however, be mandated by State law or permitted under the terms of the plan. Because this rule provides only for a minimum length, which already constitutes common market practice, finalizing this rule is not expected to cause consumer confusion or necessitate IT modifications.

Comment: We received several comments on our proposed policies to harmonize our provision on rolling enrollment in a merged market. We received a comment supporting rolling enrollment in States with a merged market. Some commenters stated they believed our proposed policies would be disruptive to States with merged markets. One commenter asked HHS to develop a more targeted set of policy solutions to address the specific issues associated with enrollment timelines in States with merged markets. One commenter asked HHS to clarify whether States with markets that are

merged only for purposes of State law, but not Federal law, are subject to these proposed rules.

Response: We are finalizing our provision as proposed. We continue to believe that rolling enrollment in States with merged markets provides employers an opportunity to offer health insurance through the SHOP at any point during the year, pursuant to our policies on guaranteed availability. We are not limiting small employer groups in States with a merged market to the individual market enrollment periods or otherwise prohibiting them from seeking coverage at any point during the year. However, to align with the requirements to offer plans in the merged market on a calendar year basis pursuant to § 147.104(f), as moved from § 147.104(b)(2) by this rule, SHOP coverage with a plan year starting at any time during the year would have the plan year end on December 31 and renew effective January 1 of the following year. Rolling enrollment in the SHOP, as it aligns with this policy, would allow for plan years shorter than 12 months. For coverage that has an effective date after January 1, a 12-month plan year would not align with the requirement for coverage to be offered on a calendar year basis, and is therefore not permitted in States with merged markets. We note that the additional language finalized in this rule at § 155.725(b) is only applicable in States that have merged their markets under section 1312(c)(3) of the Affordable Care Act. This language does not apply in States with markets that are not considered to be merged for purposes of Federal law.

Comment: Several commenters supported the proposal permitting automatic renewal of employers' offers of coverage. One commenter asked HHS to specify what it means to become ineligible for SHOP coverage and to specify whether an employer may be eligible for automatic renewal if the employer group falls below one non-owner full-time equivalent employee. We also received a comment asking HHS to specify if States may renew an employer's coverage if the employer's Employee Identification Number (EIN) changes provided that the employer retains the same legal identity. We also received a comment opposing automatic renewals and requests that HHS streamline processes to allow employer groups to quickly update only necessary information for a more simplified re-enrollment process. It was also recommended that agents and brokers be provided with an opt-in or opt-out choice for employees rather than an automatic renewal.

Response: We are finalizing our provision as proposed. We do not believe that a streamlined process to allow employer groups to update information about their group is necessary because qualified employers are already required to update this information to the SHOP throughout the plan year. *See* § 157.205(f). We believe our broad provision regarding SHOP coverage renewal will provide employer groups and their employees and enrollees an efficient way to renew and avoid any gaps in their coverage. Because not all groups work with an agent or broker, we believe that providing agents and brokers with an opt-in or opt-out choice for employees will not cover the universe of renewals that will occur.

An employer is considered eligible to participate in the SHOP if it is a “small employer” as defined in § 155.20 and if it meets the requirements set forth at § 155.710(b). To qualify, employers must have at least one employee who is not the owner or the spouse of the owner.⁴⁴ With one limited exception, if a group fails to meet any of these eligibility criteria, including if it no longer has at least one employee who is not the owner or the owner’s spouse, it may not renew coverage through the SHOP. The limited exception applies, under § 155.710(d), to employers that cease to be small employers solely by reason of an increase in the number of employees, so long as they otherwise meet the eligibility criteria and continue to purchase coverage for qualified employees through the SHOP. For purposes of renewing coverage, if an employer’s EIN changes, but it retains the same legal identity, then the group can renew their coverage as long as they continue being eligible for coverage, if permitted by applicable State law. HHS considers an employer to have the same legal identity if the group maintains all other identifiable information including the business ownership structure and State in which the business operates.

Comment: We received some comments related to the calculation of and enforcement of minimum participation rates, but we did not receive specific comments on the proposed policy at § 155.725(k).

Response: We are finalizing the provision as proposed, and note that applicable minimum participation rates are calculated and enforced at the time of initial group enrollment or renewal, subject to § 147.104(b)(1)(B).

f. Termination of SHOP Enrollment or Coverage (§ 155.735 and § 156.285)

In § 155.735, we proposed to amend paragraph (c)(2)(ii) to specify that in the FF–SHOP, a termination of coverage due to non-payment of premiums would be effective on the last day of the month for which the FF–SHOP received full payment. Prior to this proposal, the effective date of such a termination was not specified in the rule. We are finalizing this policy as proposed.

In paragraph (c)(2)(iii), we proposed to specify that, in the FF–SHOP, a qualified employer whose coverage was terminated for non-payment of premiums could be reinstated in its prior coverage only once per calendar year. We are finalizing this provision as proposed.

Paragraphs (c)(2)(iv) and (c)(3) are added in light of comments related to COBRA continuation coverage, as discussed in the preamble discussion of § 155.705.

In paragraphs (d)(1)(iii) and (g) of § 155.735 and in § 156.285(d)(1)(ii), we proposed to amend certain existing notice requirements by transferring them from QHP issuers to the SHOP. Under current § 156.285(d)(1)(ii), a QHP issuer must notify an enrollee and a qualified employer if the enrollee or employer is terminated due to a loss of eligibility, due to a qualified employer’s non-payment of premiums, due to a rescission of coverage for fraud or misrepresentation of material fact in accordance with § 147.128, or because the QHP issuer elects not to seek recertification with the Exchange for its QHP. We proposed to transfer two of these notice requirements to the SHOP. At § 155.735(g)(1), we proposed that the SHOP be required to provide notice to the enrollee if an enrollee is terminated due to non-payment of premium or a loss of eligibility for participation in the SHOP, including when an enrollee loses eligibility due to a qualified employer’s loss of eligibility. We also proposed at § 155.735(g)(2) that the SHOP be required to provide notice to qualified employers for termination due to nonpayment of premiums or where applicable, due to loss of the employer’s eligibility. Proposed § 155.735(g)(2) would apply to terminations for a reason other than the employer reporting information to the SHOP resulting in a loss of eligibility.

Through the proposed amendments to the definition of “enrollee” discussed above, we also proposed to expand the class of people who would receive notices under the proposed amendments to § 155.735 and § 156.285(d)(1)(ii). Additionally, we

proposed that QHP issuers in the SHOP would continue to be required to provide notice to qualified employers and enrollees when an enrollee’s coverage is terminated due to a rescission in accordance with § 147.128, and when an enrollee’s coverage is terminated due to an election by a QHP issuer not to seek recertification with the Exchange for its QHP. We proposed to amend § 155.735(d)(1)(iii), which currently refers to terminations of SHOP coverage due to a QHP’s termination or decertification, by adding a reference to terminations of SHOP coverage due to the non-renewal of a QHP’s certification. By proposing to include a cross-reference to § 155.735(d)(1)(iii) in § 156.285(d)(1)(ii), we also proposed to expand the notice a QHP issuer must provide regarding the discontinuation of a product in which a qualified employee is enrolled to include circumstances where the QHP is terminated or is decertified as described in § 155.1080. We are finalizing the provisions with modifications noted below.

We also proposed that each notice required under § 155.735(g) and the proposed amendments to § 156.285(d)(1)(ii) would have to be provided by the SHOP or QHP issuer promptly and without undue delay. We explained that we would consider an electronic notice that was sent no more than 24 hours after the SHOP or QHP issuer determined coverage was to be terminated to have been provided “promptly and without undue delay.” In the case of paper notices, we would consider notices that were mailed no later than 48 hours after the SHOP determined coverage was to be terminated to have been provided “promptly and without undue delay.” We have revisited these deadlines in light of comments received, and are finalizing the proposal with a modification to allow 3 business days for electronic notices and 5 business days for mailed notices. New paragraph § 155.735(g) and the corresponding amendments related to issuer notice requirements at § 156.285(d)(1)(ii) are effective on January 1, 2016.

We are also finalizing amendments to § 155.735 and § 156.285 to conform with our interpretation of the guaranteed availability and guaranteed renewability requirements. For a discussion of these revisions, please see the preamble for § 155.430 in this final rule.

Comment: We received several comments in support of HHS codifying the termination effective date for non-payment of premiums as the last day of the month for which the FF–SHOP received a full payment.

⁴⁴ See Exchange Establishment Rule, 77 FR 18310 at 18399.

Response: We are finalizing the provision as proposed regarding termination effective dates for the FF-SHOP due to non-payment of premiums.

Comment: We received a comment recommending HHS provide a more “robust approach” to reinstatements for a given employer. The commenter stated that costs resulting from those that fail to pay premiums on time are ultimately borne by other insurers. However, the commenter did not discuss any alternative approach. We also received a comment asking HHS to specify that this provision only applies to the FF-SHOP.

Response: We are finalizing our provision as proposed to discourage employers from repeatedly failing to make timely payments in the FF-SHOP. We note that to be reinstated, an employer must pay its premium in full and, generally, in order for new coverage to be effectuated, the FF-SHOP would require an employer to pay its first month’s premium in full. Therefore, we do not believe that in this case, an employer’s failure to make timely payments will impact another issuer. We note this policy, like all the policies set forth at § 155.735(c)(2), only applies in the FF-SHOP. HHS is not regulating the number of reinstatements that State-based SHOPS may choose to enforce.

Comment: We received several comments on the transfer of certain notice requirements from QHP issuers to the SHOP. Many commenters supported our proposed policies because the SHOP has better information regarding the timing of non-payment of premiums and why an enrollee or employer lost his or her eligibility. Some commenters stated that the notices should only be provided to qualified employees and adult dependents, while others stated that the notices should be provided to qualified employees and their dependents if the last known address for the dependent is different from the subscriber. Additionally, we also received a comment requesting HHS specify that the notice requirement also applies to SADP issuers. One commenter recommended employers that actively provide to the SHOP information which indicates a loss of eligibility also receive a notice. We received a comment stating issuers should not be required to send any notices of termination to individual employees as it is not common market practice.

Response: We have modified the final notice requirement to specify that when a primary subscriber and his or her dependents live at the same address, a separate notice need not be sent to each

dependent at that address, so long as the notice sent to each primary subscriber at that address contains all the required information about the termination for that primary subscriber and each of his or her dependents at that address. We note that when dependents live at a different address from the primary subscriber, a separate notice must be sent to those dependents. We note the broad language of the notice requirement applies to both medical and dental coverage sold through the SHOP. We do not believe a notice to the employer is necessary when an employer reports to the SHOP that it no longer meets the SHOP eligibility criteria. The SHOP eligibility criteria are sufficiently simple that we believe that under such circumstances the loss of eligibility would be self-evident to the employer.

HHS believes that these notices of termination should be sent to all individual, qualified employees affected by the termination of coverage or enrollment. By communicating directly with qualified employees through a notice of termination, the SHOP or the issuer can provide more timely notice regarding termination of coverage or enrollment, allowing employers and enrollees to seek other coverage and reduce gaps in coverage.

Comment: A commenter recommended that in a State that operates its own SHOP, the SHOP should provide the notice unless State law requires that the notice be provided by the issuer. We also received a comment requesting that sending these notices should be at the discretion of issuers so that issuers can communicate and maintain relationships that they have with employer groups and their enrollees.

Response: We appreciate the commenters’ concern regarding unnecessary duplication of notices. As such, we are finalizing the proposal with a modification that provides that if a State law requires such notices be provided by the issuer, then the SHOP is not required to also send these notices. In a State with no such law, if an issuer would like to send these notices to maintain its relationships with employer groups and enrollees, it may do so. But the fact that the issuer sent the notice would not exempt a SHOP from the notice requirement.

Comment: We received a comment asking HHS to provide specific information on the required termination notices about how employer groups can maintain coverage or obtain other coverage, reinstatement rights and processes, how to reapply for coverage,

and information about other coverage options.

Response: When sending these notices in States with an FF-SHOP, HHS intends to provide additional information about how to avoid a gap in coverage and other coverage options. However, we do not believe that this content is necessary for the notice requirement to be met, and are therefore not requiring that it be included in the notices sent by all SHOPS and issuers.

Comment: Some commenters support a SHOP sending termination notices to enrollees and employer groups “promptly and without undue delay.” However, one commenter requested flexibility to issuers to ensure notices are provided consistent with existing State criteria. We also received comments requesting that the standard for timing be broader, and recommending delivery of termination notices occur at least 30 days prior to the termination effective date, rather than timing the notice as proposed. One commenter recommended that HHS specify that the timing of sending notices be expressed in business days.

Response: We recognize that the timeline described as a safe harbor in the preamble to the proposed rule might not give QHP issuers sufficient time to mail notices. We therefore are modifying the proposal to specify that SHOPS and issuers should send the required notices within 3 business days where notice is provided electronically and within 5 business days when hard copy notices are mailed.

We are also making minor changes to the wording of the proposed requirements at § 155.735(g) and at § 156.285(d)(1)(ii), so that the final rule refers to a requirement to “notify” new enrollees, rather than to “provide” them “with a notice.” We are also finalizing new § 155.735(g) and the amendments to § 156.285(d)(1)(ii) with an effective date of January 1, 2016.

7. Exchange Functions: Certification of Qualified Health Plans

a. Certification Standards for QHPs (§ 155.1000)

In § 155.1000, we proposed to add paragraph (d) to harmonize QHP certification with rolling enrollment in the SHOP. Under the proposal, where a SHOP certifies QHPs on a calendar year basis, a QHP’s certification will be in effect for the duration of any employer’s plan year that began in the calendar year for which the plan was certified.

We are finalizing as proposed with the modification noted below.

Comment: We received some comments supporting the proposed

policy for QHPs in SHOPs that certify QHPs on a calendar year basis to retain their certification for the duration of any employer's plan year that began in the calendar year for which the plan was certified. We also received one comment recommending that we specify that this proposed policy applies with the exception provided in § 155.1080.

Response: In light of comments received, we are amending the proposed language to specify that § 155.1000(d) does not apply when there is a decertification by the Exchange of QHPs, pursuant to § 155.1080.

b. Recertification of QHPs (§ 155.1075)

We are making a conforming amendment to align the date by which an Exchange must complete the QHP recertification process with the date finalized in this rule at § 155.410(e)(2) for the beginning of the open enrollment period for the benefit year beginning on January 1, 2016. In the Exchange Establishment Rule, we finalized § 155.1075(b) to state that the Exchange must complete the QHP recertification process on or before September 15 of the applicable calendar year. In that rule, we also finalized the open enrollment periods for years other than the 2014 benefit year as running from October 15 through December 7 of the preceding year (77 FR 18462). This gave Exchanges until 1 month before the beginning of the open enrollment period to complete the recertification process.

In the proposed rule, we proposed that the beginning of the open enrollment period for the benefit year beginning on or after January 1, 2016, would begin on October 1, 2015—approximately 2 weeks after the QHP recertification deadline. As discussed elsewhere in this final rule, we are finalizing an open enrollment period for coverage beginning in 2016 that would begin 1 month later, on November 1. To align the date by which an Exchange must complete recertification and the beginning of the open enrollment period in a manner that provides issuers, State regulators, and Exchanges additional time to complete the plan review and certification processes without placing any substantive burden on consumers, we are amending § 155.1075(b) to require Exchanges to complete recertification of QHPs no later than 2 weeks prior to the beginning of open enrollment.

F. Part 156—Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges

1. General Provisions

a. Definitions (§ 156.20)

In § 156.20, we proposed that for purposes of part 156, the term “plan” have the meaning given the term in § 144.103, as proposed to be amended in this rulemaking. Please refer to section III.A.1 for a discussion of the term “plan,” which is being finalized as proposed.

b. FFE User Fee for the 2016 Benefit Year (§ 156.50(c))

Section 1311(d)(5)(A) of the Affordable Care Act contemplates an Exchange charging assessments or user fees to participating health insurance issuers to generate funding to support its operations. If a State does not elect to operate an Exchange or does not have an approved Exchange, section 1321(c)(1) of the Affordable Care Act directs HHS to operate an Exchange within the State. In addition, 31 U.S.C. 9701 permits a Federal agency to establish a charge for a service provided by the agency. Accordingly, at § 156.50(c), we specified that a participating issuer offering a plan through an FFE must remit a user fee to HHS each month that is equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year and the monthly premium charged by the issuer for each policy under the plan where enrollment is through an FFE.

OMB Circular No. A–25 Revised (Circular No. A–25R) establishes Federal policy regarding user fees, and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public. As in benefit year 2015, issuers seeking to participate in an FFE in benefit year 2016 will receive two special benefits not available to the general public: (1) The certification of their plans as QHPs; and (2) the ability to sell health insurance coverage through an FFE to individuals determined eligible for enrollment in a QHP. Activities performed by the Federal government that do not provide issuers participating in an FFE with a special benefit will not be covered by this user fee.

Circular No. A–25R further states that user charges should generally be set at a level so that they are sufficient to recover the full cost to the Federal

government of providing the service when the government is acting in its capacity as sovereign (as is the case when HHS operates an FFE). We proposed to set the 2016 user fee rate for all participating issuers at 3.5 percent of the monthly premium charged by the issuer. This rate is the same as the 2015 user fee rate. We are finalizing the 2016 user fee rate as proposed. Circular No. A–25R allows for exceptions to this policy, with OMB approval. An exception was in place for establishing the 2015 user fee rate. To ensure that FFEs can support many of the goals of the Affordable Care Act, we received an exception to this policy again for 2016.

Comment: We received one comment on the underlying structure of the FFE user fee, recommending that HHS establish broad-based financing for FFEs, such as an assessment on all health care industry entities. If the existing fee structure is kept, the commenter stated that it should be paid by consumers and small employers that purchase coverage through an FFE. The commenter also stated that the user fee should not be set as a percent of premium, as the cost to run an Exchange is not related to the cost of coverage.

Response: We will continue to assess the FFE user fee as a percent of the monthly premium charged by issuers participating in an FFE. In accordance with Circular No. A–25R, issuers are charged the user fee in exchange for receiving special benefits beyond those that accrue to the general public. Setting the user fee as a percent of premium ensures that the user fee generally aligns with the business generated by the issuer as a result of participation in an FFE.

Comment: One commenter recommended that HHS publish cost estimates for the FFEs, disclose how funds will be spent, and develop performance metrics for the FFEs. The commenter stated that any increase in an issuer's aggregate liability for FFE user fees should be capped at changes in the Consumer Price Index, and that total user fee collections across all issuers should be capped at the level of expended costs. The commenter urged that if user fee collections exceed FFE costs, issuers should receive a rebate or credit against future fees.

Response: HHS will continue to publish cost estimates through the Federal budget process, and publish periodic performance measures, such as HHS reports on Marketplace call center wait times, and Web site visits and rates of eligibility determinations through HealthCare.gov. We will also continue to set the user fee rate based on the expected costs to the Federal

government of providing the special benefits to issuers; however, for 2016 as noted above, we received an exception to this policy because we wish to ensure that the FFEs can support many of the goals of the Affordable Care Act. Because we set the user fee rate below that which is expected to cover full Federal costs (as in 2014 and 2015), we do not see the need at this time to address a situation in which user fee collections exceed costs.

2. Essential Health Benefits Package

a. State Selection of Benchmark (§ 156.100)

We proposed to amend paragraph (c) of § 156.100 to delete the language regarding the default base-benchmark plan in the U.S. Territories of Guam, the U.S. Virgin Islands, American Samoa, and the Northern Mariana Islands. The change reflects HHS's determination, described in more detail in section III.A.1.b of this final rule, that certain provisions of the PHS Act enacted in title I of the Affordable Care Act that apply to health insurance issuers are appropriately governed by the definition of "State" set forth in that title. Therefore, the rules regarding EHB (section 2707 of the PHS Act) do not apply to health insurance issuers in the U.S. Territories. We also proposed to make a technical change to this section by replacing "defined in § 156.100 of this section" with "described in this section." We note that this has no effect on Medicaid and CHIP programs and that Alternative Benefit Plans will still have to comply with the essential health benefit requirements.

We did not receive any comments regarding this proposal. We are finalizing the provisions as proposed.

b. Provision of EHB (§ 156.115)

(1) Habilitative Services

One of the 10 categories of benefits that must, under section 1302(b)(1)(G) of the Act, be included under the Secretary's definition of EHB is rehabilitative and habilitative services and devices. If a benchmark plan does not include habilitative services, § 156.110(c)(6) of the current EHB regulations requires the issuer to cover habilitative services as specified by the State under § 156.110(f) or, if the State does not specify, then the issuer must cover habilitative services in the manner specified in § 156.115(a)(5). Section 156.115(a)(5) states that a health plan may provide habilitative coverage by covering habilitative services benefits that are similar in scope, amount, and duration to benefits covered for rehabilitative services or otherwise

determine which services are covered and report the determination to HHS. In some instances, those options have not resulted in comprehensive coverage for habilitative services. Therefore, we proposed amending § 156.115(a)(5) to establish a uniform definition of habilitative services that may be used by States and issuers. In addition, we proposed to remove § 156.110(c)(6) because that provision gives issuers the option to determine the scope of habilitative services.

We believe that adopting a uniform definition of habilitative services would minimize the variability in benefits and lack of coverage for habilitative services versus rehabilitative services. Defining habilitative services clarifies the difference between habilitative and rehabilitative services. Habilitative services, including devices, are provided for a person to attain, maintain, or prevent deterioration of a skill or function never learned or acquired due to a disabling condition. Rehabilitative services, including devices, on the other hand, are provided to help a person regain, maintain, or prevent deterioration of a skill or function that has been acquired but then lost or impaired due to illness, injury, or disabling condition.

We proposed adopting the definition from the Glossary of Health Coverage and Medical Terms⁴⁵: Health care services that help a person keep, learn, or improve skills and functioning for daily living. Examples include therapy for a child who is not walking or talking at the expected age. These services may include physical and occupational therapy, speech-language pathology and other services for people with disabilities in a variety of inpatient and/or outpatient settings.

We did not propose any changes to § 156.110(f), which allows States to determine services included in the habilitative services and devices category if the base-benchmark plan does not include coverage. Several States have made such a determination following benchmark selection for the 2014 plan year, and we wish to continue to defer to States on this matter as long as the State definition complies with EHB policies, including non-discrimination. If the State does not supplement missing habilitative services or does not supplement the services in an EHB-compliant manner, issuers should cover habilitative services and devices as defined in § 156.115(a)(5)(i).

⁴⁵ <http://www.cms.gov/CCIIO/Resources/Files/Downloads/uniform-glossary-final.pdf>.

We also proposed to revise current § 156.115(a)(5)(ii) to provide that plans required to provide EHB cannot impose limits on coverage of habilitative services that are less favorable than any such limits imposed on coverage of rehabilitative services. Since the statutory category includes both rehabilitative and habilitative services and devices, we interpret the statute to require coverage of each. Therefore, issuers that previously excluded habilitative services, but subsequently added them, would be required under our proposal to impose separate limits on each service rather than retaining the rehabilitative services visit limit and having habilitative services count toward the same visit limit. Because we proposed to establish a uniform definition of habilitative services in new § 156.115(a)(5)(i), we also proposed to delete § 156.110(c)(6), which would remove the option for issuers to determine the scope of the habilitative services. In § 156.110 we proposed to make a technical change to amend the list structure of paragraph (c) by replacing the "and" in (c)(5) with a period and adding an "and" at the end of (c)(4).

We are finalizing our policy as proposed, adopting the definition of habilitative services from the Uniform Glossary in its entirety, to be effective beginning with the 2016 plan year and requiring separate limits on habilitative and rehabilitative services beginning with the 2017 plan year. We are codifying this final policy in revised § 156.115(a)(5) and removing § 156.110(c)(6).

Comment: Several commenters requested more State flexibility, even in cases where the benchmark plan includes habilitative services; they sought assurance that a Federal definition will not supersede a State law, and that State-required benefits that could be considered habilitative services would be treated as EHB.

Response: States are required to supplement the benchmark plan if the base benchmark plan does not include coverage of habilitative services as defined in this final rule. We are codifying the definition of habilitative services as a minimum for States to use when determining whether plans cover habilitative services. State laws regarding habilitative services are not pre-empted so long as they do not prevent the application of the Federal definition. State laws enacted in order to comply with § 156.110(f) are not considered benefits in addition to the EHB; such laws ensure compliance with § 156.110(a) which requires coverage of all EHB categories. Therefore, there is

no obligation to defray the cost of such State-required benefits.

Comment: Several commenters objected to imposing separate limits on rehabilitative and habilitative services and devices, claiming issuers do not have operational capacity to differentiate between habilitative and rehabilitative services and devices based on enrollee diagnosis or whether the enrollee is seeking to maintain or achieve function.

Response: We are finalizing the requirement to ensure coverage of each with separate limits, but the requirement will not become effective until 2017. This delay is intended to provide issuers with the opportunity to resolve operational issues with their claims systems.

Comment: Several commenters asked that “devices” be included in the definition of habilitative services.

Response: We originally omitted devices because the term is already included in the statutory description of this category of EHB. In response to comments, however, we have added “devices” to our regulatory definition. We remind issuers that the statute requires coverage of devices for both rehabilitative and habilitative services.

Comment: Several commenters requested that we require issuers to have an exceptions process similar to the process required by OPM for multi-State plans, in case a patient needs treatment that exceeds the visit limits allowed by the plan.

Response: Enrollees wishing to appeal an adverse benefit determination, including denial of habilitative services, should follow the process established in § 147.136, which implements section 2719 of the PHS Act for internal claims and appeals and external review processes.

Comment: Commenters offered many suggestions for specific services and devices, such as orthotics and prosthetics, which they stated should be required to be covered as habilitative services and devices by all issuers.

Response: We are not codifying such a list at this time, as we continue to allow States to maintain their traditional role in defining the scope of insurance benefits, but we encourage issuers to cover additional services and devices beyond those covered by the benchmark plan.

(2) Pediatric Services

In the preamble of the EHB Rule, we stated that pediatric services should be provided until at least age 19 (78 FR 12843). States, issuers, and stakeholders requested clarification on this standard. To provide this clarification, we

proposed amending § 156.115(a) to add paragraph (6), specifying that EHB coverage for pediatric services should continue until the end of the plan year in which the enrollee turns 19 years of age. This was proposed as a minimum requirement.

This age limit is consistent with section 1201 of the Affordable Care Act,⁴⁶ which phased in the prohibition on preexisting conditions exclusions by first prohibiting them for children under age 19, as well as the age limit for eligibility to enroll in CHIP. In addition, as noted in the EHB Rule, this proposed policy aligns with Medicaid rules (78 FR 12843), which require States to cover children up to age 19 with family incomes up to 100 percent of the FPL as a mandatory eligibility category.

Comment: Many commenters requested that pediatric services continue only until the end of the month in which the enrollee turns 19, stating that this is the industry standard.

Response: Although we proposed to require pediatric services until the end of the plan year in which the enrollee turns 19, we recognize these commenters’ concerns. Accordingly, we are finalizing a policy in § 156.115(a)(6), under which issuers must provide coverage for pediatric services until at least the end of the month in which the enrollee turns 19. We encourage issuers to cover services under the pediatric services EHB category beyond the 19th birthday month if non-coverage of those services after that time would negatively affect care.

c. Collection of Data To Define Essential Health Benefits (§ 156.120)

In the Patient Protection and Affordable Care Act; Data Collection to Support Standards Related to Essential Health Benefits; Recognition of Entities for the Accreditation of Qualified Health Plans final rule (EHB Data Collection Rule),⁴⁷ we required issuers in each State to submit certain data regarding the three largest health insurance products by enrollment (as of March 31, 2012) to HHS by September 4, 2012. These data, gathered from 2012 plans, were used to determine, for each State, the benefits and limitations of the three

largest small group products by enrollment, which were used to establish potential benchmark plans. The EHB Rule unintentionally deleted § 156.120, which included the data submission requirement.

We proposed to allow each State to select a new base-benchmark plan for the 2017 plan year, allowing States to choose a 2014 plan that meets the requirements of § 156.110 as the new EHB-benchmark plan, so that issuers can design substantially equal EHB-compliant products for the 2017 plan year. We believe that this would ultimately create efficiencies for issuers in designing plans. As stated in § 156.115(a), provision of EHB means that a health plan provides benefits that are substantially equal to the EHB-benchmark plan. Therefore, health plans offering EHB in the 2017 plan year will be required to provide benefits substantially equal to the benefit amounts, duration and scope of benefits covered by the 2014 EHB-benchmark plan (supplemented as necessary).

If a category of base-benchmark plans under § 156.100(a)(1)–(4) does not include a plan that meets the requirements of § 156.110, we considered permitting the State to select a base-benchmark plan that does not meet the requirements of § 156.110 in that category and supplement its base-benchmark plan as provided in § 156.110(b) to ensure that all 10 categories of benefits are covered in a benchmark plan.

We proposed re-codifying part of § 156.120, in a manner similar to that which appeared in our regulations prior to the effective date of the EHB Rule. We proposed to require a State that chooses a new benchmark plan in the State or, if a State does not choose a new benchmark plan, the issuer of the default benchmark plan, to provide benchmark plan data as of a date specified by HHS. We anticipate collection of new benchmark plan data for the 2017 plan year and the data discussed in § 156.120(b), including administrative data and descriptive information pertaining to all health benefits in the plan, treatment limitations, drug coverage, and exclusions. We believe that this information is already included in the issuer’s form filing that the issuer submitted to the State regulator. The definitions previously adopted in § 156.120(a) for the terms health benefits, health plan, State, and treatment limitations are still applicable and would be codified as previously defined. However, we are not finalizing the definitions for “health insurance market” or “small group market” in

⁴⁶ Section 1201 of the Affordable Care Act added section 2704 of the PHS Act, which prohibited preexisting condition exclusions. Section 1255 of the Affordable Care Act states that the provisions of section 2704 of the PHS Act, as they apply to enrollees who are under 19 years of age, shall become effective for plan years beginning on after September 23, 2010.

⁴⁷ Patient Protection and Affordable Care Act; Data Collection to Support Standards Related to Essential Health Benefits; Recognition of Entities for the Accreditation of Qualified Health Plans, 77 FR 42658 (July 20, 2013) (codified at part 156).

§ 156.120(a), as they are not used in this section.

Comment: Some commenters requested use of a 2014 plan as the benchmark for 2016 rather than 2017. Several commenters suggested we use a 2015 plan as the benchmark for 2017, noting that the final regulations pertaining to the Mental Health Parity and Addiction Equity Act will not be effective until 2015.

Response: For the 2016 plan year, HHS expects to begin the certification process for QHPs in the FFEs in early spring of 2015. Because issuers are required to design QHP plans that provide EHB that are substantially equal to the EHB-benchmark plan, based on the base-benchmark plan chosen and supplemented as necessary by the State, it is not operationally possible for us to collect and publish new EHB-benchmark plans prior to the QHP certification process for the 2016 plan year if we allow States to choose a 2014 plan as their new base-benchmark plan and supplement if necessary. As codified in § 156.115(a)(3), an EHB-compliant plan must provide mental health and substance use disorder services, including behavioral health treatment services in compliance with MHPAEA and its corresponding regulations. While we agree that it would be easier for issuers to design plans if the base-benchmark plan chosen by the State were compliant with MHPAEA (that is, based on a 2015 plan), nothing in this rule negates the current requirement that EHB-compliant plans comply with MHPAEA and any associated regulatory requirements in effect at the time. Based on the timelines needed for issuers to design plans, if we permitted States to select 2015 plans as new base-benchmark plans, we do not believe that issuers would be able to design substantially equal EHB-compliant products until the 2018 plan year, based on those benchmarks, which we believe is not in consumers' best interest. Therefore, we are finalizing the re-codification of part of § 156.120 as proposed, as well as our proposal to allow issuers to design a plan that is substantially equal to the newly selected 2014 benchmark plan for the 2017 plan year.

Comment: Several States and other commenters requested more details on the process for selection and reassurance that they can supplement their benchmark plan.

Response: We did not propose to make changes to § 156.100(a) or (b); therefore, the options from which a base-benchmark plan may be selected remain the same. HHS issued a PRA package regarding collection of

benchmark information on November 26, 2014.⁴⁸ As stated there, HHS proposes to obtain the certificate of coverage and other plan documents that describe covered services, exclusions, limitations, cost sharing, and all other terms and conditions of plan benefits that are provided to enrollees. States that select, or issuers in States that default to a benchmark due to lack of selection, would submit the documents securely via email. HHS intends to work collaboratively with States to identify responsive documents and to secure such documents during the second quarter of 2015. HHS then intends to publish selected and default benchmark plans and supporting documents. States retain the ability to supplement the base-benchmark plan, as codified in § 156.110(b)(1), and retain the ability to determine whether the base-benchmark plan covers the EHB category or whether supplementation is warranted. We also reiterate that supplementation is the addition of the entire category of such benefits to satisfy § 156.110(a), while substitution is the removal of one particular item or service for another actuarially-equivalent item or service within the same category. Supplementation ensures that all EHB categories are covered. Substitution, which is permitted within an EHB category at the issuer's discretion, allows for greater variety of plan designs.

Comment: Several States and other commenters requested further clarification regarding how new benchmark plan selection will affect our policy at § 155.170 pertaining to State-required benefits.

Response: We did not propose any changes to § 155.170. Therefore, only new State-required benefits enacted on or prior to December 31, 2011 are included as EHB, and States are expected to continue to defray the cost of State-required benefits enacted on or after January 1, 2012 unless those State-required benefits were required in order to comply with new Federal requirements. HHS intends to continue to publish a list of non-EHB State-required benefits on its Web site on an annual basis.

Comment: Some commenters expressed their desire for HHS to abandon the benchmark policy in the future, and specify a list of services that issuers must cover in each EHB category instead.

Response: To maintain State flexibility while ensuring comprehensive coverage, we believe that the benchmark policy continues to be the most appropriate at this time. Therefore, the benchmark policy will continue to establish EHBs through plan year 2017. Since the first EHB plan year just ended, we will examine how the policy affected enrollees and what changes, if any, should be made in the future. We believe that it is important to have a more complete sense of how EHB policy is working before proposing changes to the benchmark approach.

d. Prescription Drug Benefits (§ 156.122) i. § 156.122(a)

Under our regulations at § 156.122(a), EHB plans are required to cover the greater of one drug per United States Pharmacopeia (USP) category and class or the same number of drugs in each USP category and class as the State's EHB-benchmark plan. In the proposed rule, we proposed several revisions to this policy. First, we proposed to retain § 156.122(a)(2), with one modification to change "drug list" to "formulary drug list" for uniformity purposes for this section, and to renumber this paragraph from § 156.122(a)(2) to § 156.122(a)(1). Due to some concerns detailed in the proposed rule about the drug count standard under current § 156.122(a)(1), we proposed an alternative to the drug count standard. Specifically, we proposed that plans have a pharmacy and therapeutics (P&T) committee and use that committee to ensure that the plan's formulary drug list covers a sufficient number and type of prescription drugs. We proposed that the P&T committee standards must be met for the prescription drug coverage to be considered EHB. We stated our belief that the use of a P&T committee in conjunction with other standards that we proposed would ensure that an issuer's formulary drug list covers a broad array of prescription drugs. We noted that standards defined by the Medicare Part D Prescription Drug Program (Medicare Part D), the NAIC,⁴⁹ and other stakeholders, and we solicited comments on these standards and whether we should adopt them in lieu of or in addition to the standards we are proposing.

In the proposed rule, we proposed to specify P&T committee standards on

⁴⁸ CMS-10448; <http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10448.html>.

⁴⁹ Medicare Part D plans are required to maintain P&T committees by the Social Security Act section 1860D-4(b)(3)(G) codified at 42 CFR 423.120(b), 42 CFR 423.272(b)(2). NAIC has a Model Act entitled Health Carriers Prescription Drug Benefit Management Model Act (July 2003) that includes P&T Committee provisions at: <http://www.naic.org/store/free/MDL-22.pdf>.

membership, meetings, and establishment and development of a formulary drug list. For P&T committee membership, we proposed requiring the P&T committee to include members from a sufficient number of clinical specialties to adequately represent the needs of enrollees. For instance, we would expect that the P&T committee members include experts in chronic diseases and in the care of individuals with disabilities. We proposed that the majority of members be practicing physicians, practicing pharmacists, and other practicing health care professionals. Additionally, we proposed to require that members of the P&T committee that have a conflict of interest with the issuer or a pharmaceutical manufacturer would be permitted to sit on the P&T committee but would be prohibited from voting on matters for which the conflict exists. We also proposed that at least 20 percent of the P&T committee's membership have no conflict of interest with respect to either the issuer or to any pharmaceutical manufacturer. Under these standards, a member who holds more than one health care license, for example as a nurse practitioner and a pharmacist, would only count as one person. We also solicited comments on the percentage of committee members that should have no conflict of interest, and the proposed requirement that the members of the P&T committee with conflicts of interest should be permitted to sit on the P&T committee but would be prohibited from voting on matters for which the conflict exists. We considered requiring a set number of participants to be independent and have no conflicts of interest, but we were concerned that absent a limitation on the total number of committee members, requiring a specific number of committee members to be independent and not have a conflict of interest would have a variable impact, depending on the size of the P&T committee. We also proposed that the P&T committee would be responsible for defining a reasonable definition of conflict of interest and for managing the conflicts of interest of its committee members. As part of this standard, the P&T committee would require its P&T committee members to sign a conflict of interest statement revealing economic or other relationships with entities, including the issuer and any pharmaceutical manufacturers, affected by drug coverage decisions that could influence committee decisions. We solicited comments on this proposed standard, including the implementation of this

conflict of interest standard, whether there are additional conflict of interest standards that should apply and what would constitute a conflict of interest. In particular, we sought comments on what could be considered a permissible relationship with respect to the issuer or a pharmaceutical manufacturer. We stated that we would consider providing further guidance regarding conflicts of interest.

We also proposed that the P&T committee must meet at least quarterly, and maintain written documentation of all decisions regarding development and revision of formulary drug lists. For formulary drug list establishment and management, we proposed that the P&T committee must develop and document procedures to ensure appropriate drug review and inclusion on the formulary drug list, as well as make clinical decisions based on scientific evidence, such as peer-reviewed medical literature, and standards of practice, such as well-established clinical practice guidelines. The P&T committee would be required to consider the therapeutic advantages of prescription drugs in terms of safety and efficacy when selecting formulary drugs and making recommendations for their formulary tier. The P&T committee would be required to review both newly FDA-approved drugs and new uses for existing drugs. We also proposed that the P&T committee would be required to ensure that an issuer's formulary drug list covers a range of drugs across a broad distribution of therapeutic categories and classes and recommended drug treatment regimens that treat all disease states and does not discourage enrollment by any group of enrollees.

Lastly, we proposed to require that issuers' formularies provide appropriate access to drugs that are included in broadly accepted treatment guidelines and which are indicative of and consistent with general best practice formularies in widespread use. Broadly accepted treatment guidelines and general best practices could be based on industry standards or other appropriate guidelines that are issued by expert organizations that are current at the time. For instance, broadly accepted treatment guidelines could include guidelines provided in the National Guideline Clearinghouse (NGC), which is a publicly available database of evidence-based clinical practice guidelines and related documents. As a result of this proposed policy, we would expect that a health plan's formulary drug list would ensure that appropriate

access is being afforded to drugs in widely accepted national treatment guidelines and which are indicative of general best practices at the time. Given our proposal to use broadly accepted treatment guidelines and best practices, we would also expect that plans' formulary drug lists be similar to those formulary drug lists then currently in widespread use. We also noted that States have primary responsibility for enforcing EHB requirements and, if finalized, States would be responsible for the oversight and enforcement of the P&T committee standards. We sought comment on these proposed revisions to § 156.122(a), including on the oversight and enforcement of these standards, and whether other standards are needed for P&T committees.

As an alternative to, or in combination with, the above-proposed P&T committee requirements, we considered whether to replace the USP standard with a standard based on the American Hospital Formulary Service (AHFS). We sought comments on the proposed P&T committee standard, and whether we should consider adopting AHFS or another drug classification system, as well as on any other standards that may be appropriate for this purpose. For instance, for the AHFS system, we considered amending the minimum standard established in the EHB Final Rule that requires coverage of at least the greater of one drug in every USP category and class or the same number of drugs in each USP category and class as the State's EHB-benchmark plan to require at least the greater of one drug in each AHFS class and subclass or the same number of drugs in each AHFS class and subclass as the State's EHB-benchmark plan. We explained that if we were to finalize a P&T committee process in combination with a drug count standard based on either the AHFS system or the USP system, we would expect the health plan to establish and maintain its formulary drug list in compliance with the P&T committee standards, and in addition, the resulting health plan's formulary drug list would also need to comply with the drug count standard. We discussed continuing to use the existing USP drug count standard, and updating the USP drug count system to a more current version. We proposed to implement proposed § 156.122(a)(2) to start in the 2017 plan year, seeking comments on this proposed timing of implementation. Based on comments

received, as described in detail below, we are finalizing an approach that combines the use of a P&T committee (satisfying standards largely as proposed) with the current drug count standard that requires coverage of at least the greater of one drug per USP category and class or the same number of drugs in each USP category and class as the State's EHB benchmark plan.

Comment: Some commenters supported replacing the current drug standard with the P&T committee approach only, and some commenters recommended that we defer to a health plan's accreditation by the National Committee for Quality Assurance (NCQA) or URAC, or use Medicare Part D standards. Some commenters did not support the P&T committee approach because they were concerned it could result in plans with widely varying formularies, leading to consumer confusion. They also had concerns about oversight and enforcement. Several commenters supported combining the P&T committee with a drug count standard. Of those who commented on the drug count standard, some supported USP, some supported AHFS, and others supported the creation of a new standard. Some commenters recommended changes to the manner in which the drug count is calculated. For example, some commenters suggested that the drug count metric change to the greater of two drugs per category and class or the number of drugs in the benchmark. Other commenters sought clarification on the counting of chemically distinct drugs and the modes of delivery.

Response: We are finalizing an approach that combines the use of a P&T committee with the current drug count standard that requires coverage of at least the greater of one drug per USP category and class or the same number of drugs in each USP category and class as the State's EHB benchmark plan. We believe that a combination of a qualitative and quantitative approach will best ensure robust formulary design, because the two standards can complement each other. For instance, the requirement of the P&T committee to review new drugs addresses one of our concerns that the current drug count system does not incentivize coverage of new drugs. However, the drug count standard can provide a minimum standard for coverage.

For the P&T committee requirements, we considered deferring to other standards, such as those established by NCQA, URAC and Medicare Part D. However, § 156.122 establishes a market-wide standard, and not all plans are required to be accredited by those

organizations. We also do not believe that some accreditation standards are as transparent as Medicare Part D standards—for example, some accreditation standards are proprietary and could be costly and burdensome for an issuer to implement. Further, stakeholders are already familiar with Medicare Part D's P&T committee standards and we believe that these standards will best ensure the P&T committee is able to ensure a robust formulary. For these reasons, we are finalizing P&T committee standards modeled on Medicare Part D's P&T committee standards that have been modified, as explained below, to better address the private health plan population and the needs of plans required to cover EHB. We also believe that adopting P&T committee standards that generally align with the existing Medicare Part D standards and guidance, where possible, will better ensure uniformity between standards to help reduce the burden on issuers. As explained below, we are finalizing the proposed conflict of interest standards. Although these standards are different than those adopted by Medicare Part D, we believe that these standards are similar to practices in the private insurance market.

We are retaining the USP drug count standard because stakeholders are now familiar with the USP system after using it for 2 years, and we were persuaded by the comments supporting the continued use of USP. Issuers have already developed 2 years of formularies based on it, States have already developed systems to review those formularies, and stakeholders are familiar with the system. Thus, while AHFS had the benefit of being updated more frequently and incorporating a broader set of classes and subclasses, commenters did not uniformly support its use because of several issues, including a lack of transparency, the need to supplement certain classes when compared with USP, and the complexity of the AHFS system. We also believe that retaining USP will reduce the administrative burden and costs on States and issuers in implementing a combined P&T committee process with a drug count standard. In implementing the revised § 156.122(a), we intend to use the most up-to-date version of the USP system available at the time that we build our formulary review tools for each plan year, starting with the 2017 plan year, and will refer to the version number in

the methodology document that we update each year.⁵⁰

To codify our final policy, we are retaining § 156.122(a)(1) (with one technical change to delete the “and”), we are retaining current § 156.122(a)(2) (with one technical correction to replace “drug list” with “formulary drug list” and to add an “and”), and we are adding a new § 156.122(a)(3). Under the new § 156.122(a)(3), a health plan must establish and maintain its formulary drug list in compliance with the P&T committee standards. These standards are in addition to the requirement that the health plan's formulary drug list comply with the drug count standard under § 156.122(a)(1) as the minimum standard of coverage, and the requirement that the health plan submit its formulary drug list to the Exchange, the State, or OPM. While issuers must have a P&T committee, nothing under § 156.122(a) precludes issuers from using the same P&T committee across multiple issuers. However, we recognize that using the same P&T committee across multiple issuers may be complex to administer. Because States are primarily responsible for enforcing EHB requirements, States will be responsible for the oversight and enforcement of the P&T committee standards and the drug count standard. We intend to work with States to implement these provisions and may consider developing additional tools and resources to assist States in reviewing formulary drug lists. New § 156.122(a)(3) will apply starting with the 2017 plan year to give States, issuers, and PBMs time to implement the new P&T committee standards.

Comment: Many commenters wanted the P&T committee membership to include certain types of representatives. Some commenters also wanted membership on the P&T committee to be limited to a certain number. Commenters supported limiting the P&T committee membership category for “other practicing health professionals” to “other practicing health care professionals that can prescribe.” Comments sought clarification that a practicing provider on the committee could be practicing part-time, and clarification on the P&T committee's documentation of its decisions. Some commenters supported the proposed conflict of interest standards, while other commenters were concerned it would be difficult to meet the standards. Others recommended other conflict of interest standards. Some commenters

⁵⁰ See the Essential Health Benefits (EHB) Rx Crosswalk Methodology at: <https://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/ehb-rx-crosswalk.pdf>.

supported the conflict of interest percentage of 20 percent, and others recommended that it be 50 percent. Some commenters recommended implementing the Office of Inspector General's recommendations on conflicts of interest for Medicare Part D P&T committees,⁵¹ and others sought transparency requirements for the operation and management of the P&T committee.

Response: We are finalizing the requirement that the P&T committee must be comprised of members that represent a sufficient number of clinical specialties to adequately meet the needs of enrollees. We would expect that the P&T committee membership include experts in chronic diseases and in the care of individuals with disabilities and that it would be composed of a diverse set of experts. We have established certain minimum standards for membership to ensure the integrity of the P&T committee and to allow flexibility to issuers in designing the P&T committee. However, we also expect the P&T committee would consult with experts in management of the relevant condition for each drug being considered. The P&T committee's membership is also required to include a majority of practicing physicians, practicing pharmacists, and other practicing health care professionals. The other practicing health care professionals on the P&T committee, excluding pharmacists, must be licensed to prescribe drugs. The practicing physicians, pharmacists, and other health care professionals on the P&T committee may be practicing part-time. However, under these standards, a member who holds more than one health care license, for example, as a nurse practitioner and a pharmacist, only counts as one member of the P&T committee.

We are finalizing the conflict of interest requirements as proposed. These conflict of interest standards are not the same as Medicare Part D's standards, but we believe that issuers are currently using similar practices in the private health insurance market. Members of the P&T committee that have a conflict of interest with respect to the issuer or a pharmaceutical manufacturer are permitted to sit on the P&T committee but are prohibited from voting on matters for which the conflict exists. We would expect that in implementing this standard, if a particular member of a P&T committee

has to abstain from a majority of votes, that the P&T committee should consider removal of the member from the P&T committee. Additionally, at least 20 percent of the P&T committee's membership must have no conflicts of interest with respect to either the issuer or to any pharmaceutical manufacturer. We considered the comments we received on other P&T committee standards and on the requirements for the number and percentage of conflict free members. However, due to concerns about issuers' ability to meet a requirement with a higher threshold and concerns about setting a fixed number of members required to be conflict free when we did not also set the limit on the number of participants on the P&T committee, we believe that requiring 20 percent of the P&T committee's membership to be conflict free is a reasonable threshold in combination with § 156.122(a)(3)(i)(C). As part of this standard, the P&T committee members must sign a conflict of interest statement at least annually revealing economic or other relationships with entities affected by the committee's drug coverage decisions, including the issuer and any pharmaceutical manufacturers. The P&T committee is responsible for establishing a reasonable definition of conflict of interest and for managing the conflicts of interest of its committee members. We will consider providing further guidance regarding the P&T committee's management and oversight, including its operation and management of conflicts of interest, in the future.

Comment: Commenters generally supported the requirements regarding the establishment and management of the formulary drug list, and recommended specifying the timing of reviews for new drugs as well as other specified guidelines or best practices. Some commenters wanted the P&T committees' decisions to be binding on the plan, and others wanted the P&T committee's decisions to be advisory. Some commenters opposed the use of treatment guidelines or best practices, and some wanted clarification that the P&T committee can use pharmacoeconomic studies in formulary development. Commenters were concerned about the documentation requirements of P&T committees' decisions and others wanted additional standards, such as to require the P&T committee to have an appeals process for a consumer or provider to request a drug to be placed on the formulary.

Response: To ensure better uniformity of P&T committee practice, we are finalizing new § 156.122(a)(3)(iii), which generally aligns with the Medicare Part D standards and guidance

on this subject. Under § 156.122(a)(3)(iii)(A), the P&T committee must develop and document procedures to ensure appropriate drug review and inclusion. This includes documentation of decisions regarding formulary development and revision and utilization management activities. P&T committee recommendations regarding which drugs are placed on the plan's formulary are binding on the plan. This clarification reflects practices by Medicare Part D. We also encourage P&T committees to be transparent about their operation and function, and while we are not requiring that P&T committees publicly post information on the P&T committee, we encourage issuers to consider providing this level of transparency to consumers. We are also finalizing a new § 156.122(a)(3)(iii)(B), which is consistent with Medicare Part D standards at 42 CFR 423.120(b)(1)(iv) and which requires the P&T committee to base clinical decisions on the strength of scientific evidence and standards of practice, and requires the P&T committee to assess peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other such information as it determines appropriate. Formulary management decisions must be based on scientific evidence, and may also be based on pharmacoeconomic considerations that achieve appropriate, safe, and cost-effective drug therapy. Under § 156.122(a)(3)(ii)(C), drugs' therapeutic advantages in terms of safety and efficacy must be considered when selecting formulary drugs. We are finalizing this provision, except we are not finalizing the requirement that drugs' therapeutic advantages be considered when placing the drugs on formulary tiers, to better align with 42 CFR 423.120(b)(1)(v).

We are also adding new § 156.122(a)(3)(iii)(D) through (F), which are consistent with Medicare Part D standards at 42 CFR 423.120(b)(1)(vi), (vii), and (ix), respectively. The new standard in § 156.122(a)(3)(iii)(D) will require the P&T committee to review policies that guide exceptions and other utilization management processes, including drug utilization review, quantity limits, and therapeutic interchange. The purpose of finalizing these reviews, which is a typical practice by P&T committees, is to ensure that formulary management techniques do not undermine access to covered drugs.

The new standard in § 156.122(a)(3)(iii)(E) requires the P&T committee to evaluate and analyze treatment protocols and procedures

⁵¹ See the Department of Health and Human Services' Office of the Inspector General Report on Gaps in Overview of Conflicts of Interest in Medicare Prescription Drug Decisions at: <http://oig.hhs.gov/oei/reports/oei-05-10-00450.pdf>.

related to the plan's formulary at least annually, which is also a typical practice of P&T committees today. Furthermore, under § 156.122(a)(3)(iii)(F), the P&T committee must review and approve all clinical prior authorization criteria, step therapy protocols, and quantity limit restrictions applied to each drug. P&T committee recommendations, with respect to a P&T committee's clinical appropriateness review of the practices and policies for formulary management activities, such as prior authorizations, step therapies, quantity limitations, and other drug utilization activities that affect access, are advisory only and not binding on the issuer, a standard that we believe reflects current practice in both the private health insurance and Medicare Part D markets. However, issuers must take the recommendations into good faith consideration. Similar to the new standards in § 156.122(a)(3)(iii)(D), the purpose of finalizing these reviews is to better ensure that formulary management techniques do not undermine access to covered drugs.

Under § 156.122(a)(3)(iii)(G), which was proposed as § 156.122(a)(3)(iii)(D), the P&T committee must review all new FDA-approved drugs and new uses for existing drugs. To implement this requirement, the P&T committee must make a reasonable effort to review a new FDA approved drug product (or new FDA approved indication) within 90 days, and make a decision on each new FDA approved drug product (or new FDA approved indication) within 180 days of its release onto the market, or a clinical justification must be documented if this timeframe is not met.

A health plan's formulary drug list, under § 156.122(a)(3)(iii)(H), must cover a range of drugs across a broad distribution of therapeutic categories and classes and recommended drug treatment regimens that treat all disease states and must not discourage enrollment by any group of enrollees. The formulary drug list must also ensure appropriate access to drugs in accordance with widely accepted national treatment guidelines and general best practices at the time. To comply with § 156.122(a)(3)(iii)(H), broadly accepted treatment guidelines and general best practices could be based on industry standards or other appropriate guidelines that are issued by expert organizations that are current at the time. For instance, broadly accepted treatment guidelines could include guidelines provided in the National Guideline Clearinghouse (NGC), which is a publicly available

database of evidence-based clinical practice guidelines and related documents.

ii. Section 156.122(c)

Section 156.122(c) currently requires issuers of EHB plans to have procedures in place that allow an enrollee to request and gain access to clinically appropriate drugs not covered by the plan. This requirement, commonly referred to as the "exceptions process," applies to drugs that are not included on the plan's formulary drug list. As established in the EHB Final Rule (78 FR 12834) and the Market Standards Rule (79 FR 30240), such procedures must include a process that allows an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber) to request an expedited review based on exigent circumstances. Exigent circumstances exist when an enrollee is suffering from a serious health condition that may seriously jeopardize the enrollee's life, health, or ability to regain maximum function, or when an enrollee is undergoing a current course of treatment using a non-formulary drug. A health plan must make its coverage determination on an expedited review request based on exigent circumstances, and notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage determination no later than 24 hours after it receives the request. A health plan that grants an exception based on exigent circumstances must provide coverage of the non-formulary drug for the duration of the exigency.

In the proposed rule, we proposed to build on the expedited exception process by proposing to also adopt similar requirements for the standard exception process. We also proposed to adopt standards for a secondary external review process if the first exception request is denied by the plan (regardless of whether the exception is requested using the standard process or the expedited process).

We proposed at § 156.122(c), that a health plan providing EHB must have certain exception processes in place that allow an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber) to request and gain access to clinically appropriate drugs not covered by the health plan, and when an exception requested under one of these processes is granted, the plan must treat the excepted drug as EHB for all purposes, including accrual to the annual limitation on cost sharing. Proposed § 156.122(c)(1) sets forth the standard exception process. Under this process,

we proposed that a health plan have a process for an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber) to request a standard review of a coverage decision for a drug that is not covered by the plan. We proposed that the health plan must make its coverage determination on a standard exception request and notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage determination no later than 72 hours after it receives the request. We proposed to require a health plan that grants an exception based on the standard review process to provide coverage of the non-formulary drug for the duration of the prescription, including refills, and we stated that in such a case the excepted drug would be considered EHB for all purposes, including for counting towards the annual limitation on cost sharing. As stated in the EHB Rule, plans are permitted to go beyond the number of drugs offered by the benchmark without exceeding EHB. Therefore, if the plan is covering drugs beyond the number of drugs covered by the benchmark, all of these drugs are EHB and must count towards the annual limitation on cost sharing.

We proposed moving the language regarding the expedited exceptions process from § 156.122(c)(1) to new § 156.122(c)(2) and to replace "Such procedures must include" with "A health plan must have" in current (c)(1) proposed as a new paragraph (c)(2)(i).

In § 156.122(c)(3), we proposed that if the health plan denies an exception request for a non-formulary drug, the issuer must have a process for an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber, as appropriate) to request that an independent review organization review the exception request and the denial of that request by the plan. For this external exception review, we proposed to apply the same timing that applied to the initial review. Thus, if the enrollee requested the drug under the proposed standard process and the request was denied, then the independent review organization would have to make its determination and the health plan would have to notify the enrollee or enrollee's designee and the prescribing physician (or other prescriber, as appropriate) no later than 72 hours after the time it receives the external exception review request. Likewise, if the initial exception request is for an expedited review and that request is denied by the plan, then the independent review organization would

have to make its coverage determination and provide appropriate notification no later than 24 hours after the time it receives the external exception review request. We are finalizing the updated standards in § 156.122(c) as proposed, with an addition to clarify the duration of coverage of the excepted drug when accessed through the external review process.

Comment: Many commenters supported revising § 156.122(c), relating to the exceptions process. Some commenters wanted the same standards as Medicare Part D, and others wanted the same standards as the appeals process codified at § 147.136. Other commenters had concerns about conflict with State requirements, the definitions of expedited review and the current course of treatment, and the administrative cost of the exceptions process. Some commenters were concerned about time limits and wanted clarification on when the time limits begin, recommending that the time limits should be measured in business days instead of hours, or be different for the external review process. Others sought additional requirements related to the operation of the exception process such as requiring coverage of the non-formulary drug during the review process, requiring issuers to begin the external review if the original exception request is denied, and requiring issuers to submit or release information on its consideration of exception requests. Although some commenters recommended using a separate review organization for the external review, several commenters supported allowing issuers to use the same independent review organization for the external review as for the final external review decision under § 147.136. Commenters also supported requiring coverage of the excepted drug for the duration of the prescription, including refills, and others supported permitting the issuer to determine and notify the enrollees of the duration of the coverage for the excepted drug.

Response: The purpose of revising § 156.122(c) was to establish a more uniform exceptions process across plans and issuers providing EHB to help reduce consumer confusion in accessing, understanding, and using the exception process. We believe that uniform standards in this area will better ensure consumers' ability to understand and access this consumer protection. Because of the importance of this process in ensuring enrollee access to clinically appropriate medications, we are finalizing the 72-hour review period for the standard exception review, continuing the 24-hour review

period for an expedited review, and applying the related timing standards to the external review periods. This exceptions process applies to drugs that are not included on the plan's formulary drug list, and § 147.136 applies if an enrollee receives an adverse benefit determination for a drug that is included on the plan's formulary drug list. Because these two processes serve different purposes, we believe they are not duplicative. Furthermore, while our exception process standards are not the same as those under Medicare Part D, they have similar elements. Since issuers that provide EHB are already required under our regulations to have formulary exceptions processes and procedures in place that allow an enrollee to request and gain access to clinically appropriate drugs not covered by the plan, we do not expect that these new requirements will significantly increase the administrative cost burden on issuers. Furthermore, to permit flexibility in implementing this policy for issuers, we have declined to establish additional requirements at this time, such as requiring issuers to begin the external review absent an enrollee request if the original exception request is denied, and requiring issuers' to submit or release information on its consideration of exception requests.

The 24-hour timing policy for the expedited review was adopted in the final rule on the Market Standards Rule (79 FR 30240), and we are finalizing the 72-hour standard review, as well as the timing for the external reviews, in this final rule. All of these timeframes begin when the issuer or its designee receives a request. An enrollee or the enrollee's prescribing physician (or other prescriber) should strive to submit a completed request; however, issuers should not fail to commence review if they have not yet received information that is not necessary to begin review. Therefore, we interpret new § 156.122(c) to mean that the review must begin following the receipt of information sufficient to begin review. Issuers should not request irrelevant or overly burdensome information. Issuers must be equipped to accept these requests in writing, electronically, and telephonically.

As part of the request for a standard review, the prescribing physician or other prescriber should support the request by including an oral or written statement that provides a justification supporting the need for the non-formulary drug to treat the enrollee's condition, including a statement that all covered formulary drugs on any tier will be or have been ineffective, would not

be as effective as the non-formulary drug, or would have adverse effects.

Following a favorable decision on the standard or external review, the enrollee must be provided access to the prescribed drug without unreasonable delay. Therefore, issuers need to be prepared to communicate rapidly with pharmacies and pharmacy benefit managers, as applicable. At a minimum, we expect issuers to update certificates of coverage to reflect the availability of this process, and to be able to provide instruction to enrollees or their designees and providers or their designees on how to use the process.

For the external exception review, we are finalizing a standard under which the independent review organization that conducts the external review must be accredited by a nationally recognized private accrediting organization. As part of this process, the issuer should provide the independent review organization with all relevant information to conduct the review, including the initial denial of the exception request. The issuer may use the same independent review organization for the external review for the drug exception process under § 156.122(c)(3) that the plan contracts with for the final external review decision under § 147.136. As established in revised § 156.122(c), any drug covered through the exception process must be treated as an EHB, including by counting any cost sharing towards the plan's annual limitation on cost sharing and when calculating the plan's actuarial value. We believe that ensuring that an enrollee has the option to request an external review of a denied exception request and that a drug covered through the exception process count towards the plan's annual limitation on cost sharing are important consumer protections that help ensure enrollees' access to clinically appropriate medications.

We do not believe that enrollees should have to continue to make requests under § 156.122(c) to access a refill of the same clinically appropriate drugs that they initially obtained through the exceptions process. Therefore, we are finalizing a standard under which non-grandfathered health plans in the individual and small group markets that must provide coverage of the essential health benefit package under section 1302(a) of the Affordable Care Act must cover a drug accessed through the standard exception process for the duration of the prescription, including refills. To provide further clarification on the operation of the external review process, we are also finalizing a new standard under which,

if a health plan providing EHB grants an external exception review of a standard exception request, the health plan must provide coverage of the non-formulary drug for the duration of the prescription, including refills. Likewise, if a health plan grants an external exception review of an expedited exception request, the health plan must provide coverage of the non-formulary drug for the duration of the exigency. Nothing under this policy precludes a State from requiring stricter standards in this area. Issuers will be required to comply with the new standard exception process and external review process requirements starting with the 2016 plan year.

iii. Section 156.122(d)

Under § 156.122(d), we proposed adding a requirement to the EHB prescription drug benefit that a health plan must publish an up-to-date, accurate, and complete list of all covered drugs on its formulary drug list, including any tiering structure that it has adopted and any restrictions on the manner in which a drug can be obtained, in a manner that is easily accessible to plan enrollees, prospective enrollees, the State, the Exchange, HHS, OPM, and the general public. We also solicited comment on whether the formulary tiering information should include cost sharing information, such as the enrollee's applicable pharmacy deductible (for example, \$100), copayment (for example, \$20), or cost-sharing percentage for the enrollee (for example, 20 percent). We proposed that a formulary drug list be considered easily accessible when the general public is able to view the formulary drug list on the plan's public Web site through a clearly identifiable link or tab and without creating or accessing an account or entering a policy number. The general public should be able to easily discern which formulary drug list applies to which plan if the issuer maintains multiple formularies, and the plan associated with each formulary drug list should be clearly identified on the plan's Web site. As a result of this proposed requirement, we would expect the issuers' formulary drug list to be up-to-date, meaning that the formulary drug list must accurately list all of the health plan's covered drugs at that time. We solicited comments on this timing. Also, the formulary drug list URL link under this section should be the same direct formulary drug list URL link for obtaining information on prescription drug coverage in the Summary of Benefits and Coverage, in accordance with § 147.200(a)(2)(i)(K). We proposed that this requirement would be effective beginning with the 2016 plan year. We

solicited comments on these proposed requirements, including whether we should require that additional types of information be included in the formulary drug list.

As part of this proposed requirement that issuers' formulary drug list must be made available to the general public, we considered requiring issuers to make this information publicly available on their Web sites in a machine-readable file and format specified by HHS. The purpose of establishing machine-readable files with the formulary drug list data would be to provide the opportunity for third parties to create resources that aggregate information on different plans. As an alternative, we considered whether the formulary drug list information could be submitted to HHS through an HHS-designed standardized template, while recognizing that there could be challenges with keeping this type of template information updated. We solicited comments on these options. We are finalizing these requirements largely as proposed, with language to clarify that the requirement to publish an up-to-date, accurate and complete list of all covered drugs applies beginning with the 2016 plan year, and to require that QHPs in the FFEs make available this information to HHS in a format and at times determined by HHS beginning with the 2016 plan year.

Comment: Most commenters generally supported the proposed standards regarding the ease with which consumers should be able to view formulary drug lists on issuers' Web sites, and some recommended requirements on the format for the formulary drug list on the Web site. Many commenters wanted detailed cost-sharing information to be included on the formulary drug list, including deductible, copay, and specific coinsurance dollar amounts. Others opposed providing that level of detail on the formulary drug list because of difficulties in keeping the formulary drug list up to date and potential consumer confusion because every plan design, including each silver plan variant, would need a separate formulary drug list. Other commenters sought clarification on definitions, including all covered drugs and any restrictions on the manner in which the drug can be obtained. Others supported or opposed the proposed definition of "up to date."

Response: The purpose of § 156.122(d) is to improve the transparency of formulary drug lists for plans required to cover the essential health benefits by requiring accurate, complete and up-to-date information on

the drugs that the plan covers to assist consumers. Thus, while we recognize the value in providing consumers with detailed cost-sharing information on the formulary drug list (such as the enrollee's applicable pharmacy deductible, copayment, or cost-sharing percentage for the enrollee), our goal with this provision is to ensure that the formulary drug list is accurate, complete, and up-to-date. Providing detailed cost-sharing information on the formulary drug list is not a typical practice in the private health insurance market. Therefore, we are finalizing § 156.122(d) as proposed at this time. Issuers' formulary drug lists must include any tiering structure that it has adopted and any restrictions on the manner in which a drug can be obtained, and while we are not requiring detailed cost-sharing information under § 156.122(d) at this time, we encourage issuers to provide this level of transparency on the formulary drug list where feasible to help consumers make more informed decisions about their health insurance coverage. In general, consumers should be able to use the formulary drug list in conjunction with the summary of benefits and coverage or other plan documents to determine their applicable cost sharing. For example, a formulary drug list would list which drugs are in Tier 1 (or similar category of prescription drug coverage), and the SBC would indicate that drugs in Tier 1, or similar category, have a \$20.00 copayment. While the SBC must list any applicable coinsurance and major limitations or exceptions, an issuer's SBC would not list the specific dollar amounts an enrollee would pay for a drug that is subject to coinsurance, given that the SBC is only a summary of cost-sharing features. For the purpose of this section, references to the URL have been removed to clarify that our standards apply to the actual formulary drug list, not the Web address.

For the purpose of § 156.122(d), for a formulary drug list to be considered complete, the formulary drug list must list all drugs that are EHB and when the formulary drug list specifies all drug names that are currently covered by the plan at that time. This requirement means that issuers are prohibited from listing only the most commonly prescribed medications. The formulary drug list does not have to list every covered formulation for each covered drug, but the issuer should be prepared to provide information on the specific formulations upon request to the plan's enrollees, prospective enrollees, the State, the Exchange, HHS, OPM, and the

general public. Issuers must also include accurate information on any restrictions on the manner in which the drug can be obtained in the formulary drug list, including prior authorization, step therapy, quantity limits, and any access restrictions related to obtaining the drug from a brick and mortar retail pharmacy, such as only being accessible through a mail-order pharmacy because the drug requires special handling. The formulary drug list must be up-to-date, which means that the formulary drug list must accurately list all of the health plan's covered drugs at that time. To meet this requirement, we would expect that the issuer would make any coverage changes simultaneously with updating the formulary drug list and therefore, if an issuer makes a change to its formulary, it would not implement the change until the issuer has posted the change to the formulary drug list on its Web site. We understand that our standard for updating the formulary drug list is stricter than is the case for the typical private market plan, but we believe that the value of increased transparency to consumers is critically important to ensuring that consumers are making informed decisions about their health care. Issuers are prohibited from limiting the updates to their formulary drug list to only formulary changes that negatively impact enrollees, such as removal of drugs from the formulary drug list. Also, the URL that takes a consumer to the issuer's formulary drug list on its Web site must be the same direct formulary drug list URL link for obtaining information on prescription drug coverage in the SBC, in accordance with § 147.200(a)(2)(i)(K), and for QHPs on the Exchanges, this link must be the same link displayed to prospective enrollees on the applicable Exchange Web site. As discussed in the preamble to § 156.250, in addition to the requirements imposed by § 156.250, QHP issuers may also have duties to make this information accessible to individuals with disabilities and individuals with LEP under Federal civil rights laws that also might apply, including section 1557 of the Affordable Care Act, section 504 of the Rehabilitation Act of 1973, and Title VI of the Civil Rights Act. For the FFEs, this URL must be the one that issuers provide through the QHP application for display on HealthCare.gov. While these regulations do not prohibit issuers from providing their drug lists in a searchable or dynamic format on their Web sites, consumers should not have to create an account, be an enrollee in the plan, or navigate multiple Web pages to view the formulary drug list. Specifically, the

link needs to be the direct link to the formulary drug list. Further, if an issuer has multiple formulary drug lists, consumers should be able to easily discern which formulary drug list applies to which plan. Also, the Web page should clearly list which plans the formulary drug list applies to using the marketing name for the plan, which for Marketplace plans would be the marketing name used on HealthCare.gov. The revised § 156.122(d) is effective beginning with the 2016 plan year, and we expect that most issuers already have a formulary drug list available via a URL link and will only need to make certain minor modifications to its link to be in compliance with the new § 156.122(d)(1).

Comment: Several commenters supported the proposal for issuers to make the formulary drug list information available in a machine-readable file or a format specified by HHS, stating that this would improve transparency and foster development of additional tools to help consumers make informed decisions about their coverage. Commenters recommended types of information that should be included and the development of tools similar to tools developed by the Medicare Part D program. Others supported allowing various options on how to search for covered drugs, such as by the drug name or listing alphabetically. Conversely, some commenters opposed the proposal, expressing concerns about data integrity, accuracy, confidentiality, and managing third parties' use of this data. Some commenters were concerned that the machine-readable data collection would be duplicative, and noted that implementing any standard would be time-consuming and requested the opportunity to provide additional stakeholder feedback. Some commenters suggested use of an application programming interface (API) to support making formulary drug list information more transparent.

Response: We believe a machine-readable file or a format specified by HHS will increase transparency by allowing software developers to access this information and create innovative and informative tools to help enrollees better understand plans' formulary drug lists. Based on the comments received asking us to make formulary drug list information more transparent and accessible to consumers, HHS is finalizing this rule by adding § 156.122(d)(2) to require QHPs in the FFEs to make available the information on the formulary drug list on its Web site in a HHS specified format and also submit this information to HHS, in a

format and at times determined by HHS. We agree with commenters that creating a vehicle for consumers to easily determine which plans cover which drugs will help consumers select QHPs that best meet their needs. We recognize that this will require issuer resources, and will provide further details about the specific data elements, frequency of updates, file types, and other crucial information in future guidance.

iv. Section 156.122(e)

Under § 156.122(e), we proposed to require that enrollees be provided with the option to access their prescription drug benefit through retail (brick-and-mortar or non-mail order) pharmacies. This requirement would mean that a health plan that is required to cover the EHB package cannot have a mail-order only prescription drug benefit. This proposed requirement would still allow a health plan to charge a different cost-sharing amount when an enrollee obtains a drug at an in-network retail pharmacy than he or she would pay for obtaining the same covered drug at a mail-order pharmacy. However, as a part of these requirements, we proposed to clarify that this additional cost sharing for the covered drug would count towards the plan's annual limitation on cost sharing under § 156.130 and would need to be taken into account when calculating the actuarial value of the health plan under § 156.135. Additionally, under this proposed policy, issuers would still retain the flexibility to charge a lower cost-sharing amount when obtaining the drug at an in-network retail pharmacy. While this proposal requires coverage of a drug at an in-network retail pharmacy, for plans that do not have a network, the enrollee would be able to go to any pharmacy to access their prescription drug benefit and those plans would, therefore, be in compliance with this proposed standard.

As part of this proposed policy, we proposed that the health plan may restrict access to a particular drug when: (1) The FDA has restricted distribution of the drug to certain facilities or practitioners (including physicians); or (2) appropriate dispensing of the drug requires special handling, provider coordination, or patient education that cannot be met by a retail pharmacy. If the health plan finds it necessary to restrict access to a drug for either of the two reasons listed above, we proposed that it must indicate this restricted access on the formulary drug list under § 156.122(d). We are finalizing these policies as proposed with a technical edit to § 156.122(e)(2) to replace

“higher” cost sharing with “different” cost sharing.

Comment: Several commenters supported proposed § 156.122(e) as helping to ensure that plans do not discourage enrollment by, and thus discriminate against, transient individuals and individuals who have conditions that they wish to keep confidential and discussed other cases in which obtaining a prescription from a mail-order pharmacy is difficult for an enrollee, such as cases where an enrollee with a serious health condition may be unable to wait for the prescription to be filled via a mail-order pharmacy. Other commenters opposed these requirements, stating that it would be costly, limit consumer choice of plans that use mail-order benefits, be contrary to specialty drug market practices, not account for the quality standards used by specialty pharmacies, be contrary to precedent from other Federal programs, and be duplicative. Some commenters were concerned that the issue is outside the scope of EHB, is not reflective of a typical employer plan, does not take into account existing privacy laws, and should require additional rulemaking that, for instance, takes into account the NAIC’s pending model act on network adequacy. Other commenters wanted clarification that preventive services drugs must be covered at no cost sharing at retail pharmacies, and other commenters discussed similar and overlapping State requirements. Several commenters wanted additional exceptions, such as an exclusion related to specialty drugs and pharmacies, and some commenters supported implementing this provision in 2016 while others supported a 2017 implementation date.

Response: The intention of § 156.122(e) is to ensure all enrollees in plans required to cover EHB are able to use the prescription drug benefit if needed, and is intended to expand options for these enrollees. Thus, the purpose of this policy is not to limit the ability of issuers to use mail-order pharmacies—issuers can continue to influence consumer choice through cost sharing. The issuers need only provide enrollees with the option to access drugs that are not exempted under § 156.122(e)(1)(i) and (ii) at an in-network retail pharmacy. There are instances in which obtaining a drug through a mail-order pharmacy may not be a viable option, such as when an individual does not have a stable living environment and does not have a permanent address, or when a retail pharmacy option better ensures that consumers can access their EHB prescription drug benefit on short

notice. In such cases, we do not believe that making drugs available only by mail order constitutes fulfilling the obligation under section 1302(b)(1)(F) of the Affordable Care Act to provide prescription drug coverage as part of EHB. We also believe that making drugs available only by mail order could discourage enrollment by, and thus discriminate against, transient individuals and individuals who have conditions that they wish to keep confidential. We also believe that this provision is important to ensure uniformity in benefit design and consumer choice. Therefore, we are finalizing § 156.122(e) as proposed and with a clarification that this policy will be effective beginning with the 2017 plan year.

Issuers retain the ability to charge different cost sharing for drugs obtained at a retail pharmacy, but for non-grandfathered health plans in the individual and small group markets that must provide coverage of the essential health benefit package under section 1302(a) of the Affordable Care Act, all cost sharing, including any difference between the cost sharing for mail order and the cost sharing for retail, must count towards the plan’s annual limitation on cost sharing in accordance with § 156.130(a) and must be taken into account when calculating the actuarial value of the health plan in accordance with § 156.135. We are clarifying that these issuers can apply higher or lower cost sharing, that is, nothing requires an issuer to use higher cost sharing for drugs obtained from a retail pharmacy. As a result, some or all of the costs associated with this option may be passed on to the consumer who chooses to use it. However, nothing in this provision supersedes State law that may apply other cost sharing standards to mail-order pharmacies. For plans that do not have a network, enrollees should be able to go to any pharmacy to access their prescription drug benefit, and those plans would, therefore, be in compliance with this standard. In addition, this requirement is not intended to disrupt or supersede the rules regarding cost sharing for preventive service benefits when such coverage includes drugs.

In response to comments, we considered an exceptions process under which an enrollee could make a request to obtain the prescription at a brick and mortar retail pharmacy. However, we are concerned that if we allow an exception process, the issuer would retain the option to deny the request, and such a process could be seen as burdensome on the enrollee. In particular, an exception process could

be burdensome for enrollees with complex health conditions if they had to seek an exception request for each of their prescription drugs that they take.

We understand that specialty pharmacies provide more integrated services, aimed at improving clinical outcomes while limiting costs relating to the delivery and management of the product, than a typical mail-order pharmacy or a brick and mortar retail pharmacy. We understand that drugs on the specialty tier of a formulary are not necessarily the same drugs that a specialty pharmacy would provide. Our intention with this policy was not to disrupt the specialty pharmacy market, and we understand that exceptions will be needed for many drugs that are only accessible via a specialty pharmacy. For these reasons, we are finalizing the exceptions that allow a health plan to restrict access to certain drugs in limited circumstances. As part of this requirement, a health plan may restrict access to mail order, which may include specialty pharmacies, for a particular drug when: (1) The FDA has restricted distribution of the drug to certain facilities or practitioners (including physicians); or (2) appropriate dispensing of the drug requires special handling, provider coordination, or patient education that cannot be met by a retail pharmacy. For instance, certain drugs have a Risk Evaluation and Mitigation Strategy (REMS) that includes Elements to Assure Safe Use that may require that pharmacies, practitioners, or health care settings that dispense the drug be specially certified and that may limit access to the drugs to certain health care settings.⁵² If the health plan finds it necessary to restrict access to a drug for either of the reasons listed above, it must indicate this restricted access on the formulary drug list that plans must make publicly available under § 156.122(d). The provisions at § 156.122(e)(1)(i) and (ii) allow an issuer to restrict access to certain drugs at a retail pharmacy for the specific reasons noted in those paragraphs. Although issuers may subject these drugs to reasonable utilization management techniques, the fact that these drugs have restricted access should not in and of itself be a justification for applying these techniques to these drugs.

Issuers must implement the revised § 156.122(e) no later than for the start of

⁵² FDA requires a Risk Evaluation and Mitigation Strategies (REMS) for certain drugs to ensure that the benefits of a drug or biological product outweigh its risks. The following is FDA’s list of currently approved REMS at: <http://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm111350.htm>.

the 2017 plan year, and we have added this clarification to the regulation.

v. Other Comments on the Preamble to § 156.122

In addition to the proposed provisions above, we urged issuers to temporarily cover non-formulary drugs (including drugs that are on an issuer's formulary but require prior authorization or step therapy) as if they were on formulary (or without imposing prior authorization or step therapy requirements) during the first 30 days of coverage. We encouraged plans to adopt this policy to accommodate the immediate needs of enrollees, while allowing the enrollee sufficient time to go through the prior authorization or drug exception processes.

Comment: Some commenters sought clarification about coverage of medical drugs and preventive service drugs. Others recommended requiring limits to formulary changes during the plan year. Several commenters recommended that we require issuers to temporarily cover non-formulary drugs during the first 30 days of coverage or longer and other commenters were against this policy, stating that it is not a typical requirement in the private market, and that it is costly and counterintuitive to formulary transparency. Other commenters supported transition policies, but acknowledged the importance of flexibility for issuers in developing these policies.

Response: Preventive services, including preventive service drugs, are required to be covered as part of EHB. Non-grandfathered group health plans and health insurance coverage must provide benefits for preventive health services, including preventive service drugs, without cost sharing, consistent with the requirements of section 2713. Similarly, the rules set forth under § 156.122 are specific to coverage of drugs under the prescription drug EHB category. Issuers could cover drugs administered as part of another service (such as during an inpatient hospitalization or a physician service) under the EHB category that covers that service, in addition to covering the drug under the prescription drug EHB category. We believe this clarification reflects the current practice of issuers.

We are also concerned about issuers making mid-year formulary changes, especially changes that negatively affect enrollees. We are monitoring this issue to consider whether further standards are needed. We also note that, under guaranteed renewability requirements and the definitions of “product” and “plan,” issuers generally may not make plan design changes, including changes

to drug formularies, other than at the time of plan renewal. We recognize that certain mid-year changes to drug formularies related to the availability of drugs in the market may be necessary and appropriate.

We are not requiring coverage of a transitional fill at this time. As stated in the proposed rule, we will consider whether additional requirements may be needed in this area. We remain concerned that new enrollees may be unfamiliar with what is covered on their new plan's formulary drug list and the process and procedures under the plan. Further, some new enrollees whose drugs are covered by the plan's formulary may need to obtain prior authorization or go through step therapy to have coverage for their drugs, and others may need time to work with their provider to determine which formulary drug the individual should be transitioned to. For these reasons, we urge issuers to temporarily fill drugs that are not on the formulary (or are on an issuer's formulary but require prior authorization or step therapy) as if they were on formulary (or without imposing prior authorization or step therapy requirements) during the first 30 days of coverage. We encourage plans to adopt this policy to accommodate the immediate needs of enrollees, while allowing the enrollee sufficient time to go through the prior authorization or drug exception processes.

Comment: Some commenters recommended that we implement the prescription benefit requirements in 2017 or later. Others recommended that all of the prescription drug benefit changes be implemented in 2016. Some had separate recommendations for the timing or only commented on the timing for certain requirements.

Response: We recognize that certain prescription benefit changes under § 156.122 will be easier to implement than others. For that reason, we are finalizing our proposal effective dates for § 156.122(c) and new § 156.122(d), such that they are effective for plan years beginning on or after January 1, 2016. These requirements are typical of the current market and would require updating and modifying of systems and procedures to align with the finalized policy. We are finalizing our proposed effective dates for the revisions to § 156.122(a) and new § 156.122(e) such that they are effective for plan years beginning on or after January 1, 2017 to better ensure a smooth transition in implementing these policies.

e. Prohibition on Discrimination (§ 156.125)

Section 1302(b)(4) of the Affordable Care Act directs the Secretary to address certain standards in defining EHB, including elements related to balance, discrimination, the needs of diverse sections of the population, and denial of benefits. We have interpreted this provision, in part, as a prohibition on discrimination by issuers providing EHB. Under § 156.125, which implements the prohibition on discrimination provisions, an issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions.

As described in the proposed rule, since we finalized § 156.125, we have become aware of benefit designs that we believe would discourage enrollment by individuals based on age or based on health conditions, in effect making those plan designs discriminatory, thus violating this prohibition. Some issuers have maintained limits and exclusions that were included in the State EHB benchmark plan. As we have previously stated in guidance, EHB-benchmark plans may not reflect all requirements effective for plan years starting on or after January 1, 2014. Therefore, when designing plans that are substantially equal to the EHB-benchmark plan, issuers should design plan benefits, including coverage and limitations, to comply with requirements and limitations that apply to plans beginning in 2014.⁵³

In the proposed rule, we discussed three examples of potentially discriminatory practices: (1) Attempts to circumvent coverage of medically necessary benefits by labeling the benefit as a “pediatric service,” thereby excluding adults; (2) refusal to cover a single-tablet drug regimen or extended-release product that is customarily prescribed and is just as effective as a multi-tablet regimen, absent an appropriate reason for such refusal; and (3) placing most or all drugs that treat a specific condition on the highest cost tiers.

In this final rule, CMS adopts the same approach as described in the proposed rule. As we indicated in the proposed rule and the 2014 Letter to Issuers, we will notify an issuer when we see an indication of a reduction in the generosity of a benefit in some

⁵³ Guide to Reviewing EHB Benchmark Plans—http://www.cms.gov/CCIIO/Resources/Data-Resources/ehb.html#review_benchmarks.

manner for subsets of individuals that is not based on clinically indicated, reasonable medical management practices.⁵⁴ We conduct this examination whenever a plan subject to the EHB requirement reduces benefits for a particular group. Issuers are expected to impose limitations and exclusions based on clinical guidelines and medical evidence, and are expected to use reasonable medical management. Issuers may be asked to submit justification with supporting documentation to HHS or the State explaining how the plan design is not discriminatory.

We note that other nondiscrimination and civil rights laws may apply, including the Americans with Disabilities Act, section 1557 of the Affordable Care Act, Title VI of the Civil Rights Act of 1964, the Age Discrimination Act of 1975, section 504 of the Rehabilitation Act of 1973 and State law. Compliance with § 156.125 is not determinative of compliance with any other applicable requirements, and § 156.125 does not apply to the Medicaid and CHIP programs, but a parallel provision applies to EHBs furnished by Medicaid Alternative Benefit Plans.

Comment: Many commenters requested that we clarify that the examples provided are only examples and not *per se* discriminatory. Other commenters requested that we codify the examples and suggested additional examples of discriminatory practices that should be codified as well.

Response: We are not prohibiting certain practices in regulatory text at this time. Several factors must be taken into consideration during benefit design, and a discrimination determination is often dependent on the specific facts and circumstances. However, the examples identified in the proposed rule contain indications that they are discriminatory, and therefore further investigation by the enforcing entity may be required. We strongly caution issuers that the examples cited appear discriminatory in their application when looking at the totality of the circumstances, and may therefore be prohibited.

Additionally, as described later in this preamble, section 1302(b) of the Affordable Care Act requires that the definition of EHB be based on the scope of benefits provided under a typical employer plan, subject to requirements under the joint interpretive jurisdiction

of the Departments of HHS, Labor, and the Treasury.⁵⁵ Because the nondiscrimination provisions are related to many other such requirements, HHS will consult with relevant Federal agencies, such as the Departments of Labor and the Treasury, as necessary, in developing new guidance related to discriminatory benefit designs.

Comment: Some commenters asked whether discrimination would be identified during certification or approval and therefore a finding of discrimination would be prospective only.

Response: As provided under § 156.125(a), an issuer does not provide EHB if the implementation of a benefit design discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions. Some discriminatory practices might not be discovered until an enrollee files a complaint with the appropriate body. Once a discriminatory practice is identified, the issuer may be asked to submit a justification with supporting documentation to HHS or the State explaining why the practice is not discriminatory.

Comment: Some commenters expressed concern regarding the example of placing most or all drugs for a certain condition on a high cost tier. They noted that drug tiering reflects current realities of the drug market and is based on costs. The commenters asked CMS to clarify that having a specialty tier is not discriminatory.

Response: The examples provided in the proposed rule are potentially discriminatory if there is no appropriate non-discriminatory reason for the noted practice. Having a specialty tier is not on its face discriminatory; however, placing most or all drugs for a certain condition on a high cost tier without regard to the actual cost the issuer pays for the drug may often be discriminatory in application when looking at the totality of the circumstances, and therefore prohibited. When CMS or the

State requests a justification for such a practice, issuers should be able to identify an appropriate non-discriminatory reason that supports their benefit design, including their formulary design.

Comment: Several commenters requested more detailed information regarding how CMS and States monitor and enforce discrimination.

Response: Enforcement of the requirement to cover EHB is governed by section 2723 of the PHS Act, which looks first to States for enforcement, then to the Secretary where a State informs CMS that it is not enforcing the requirement, or CMS finds that the State has failed to substantially enforce. Therefore the State, or CMS in States that are not substantially enforcing market-wide standards, is responsible for enforcing EHB standards, including the non-discrimination standard. In an FFE, CMS notifies an FFE issuer when we see an indication of a reduction in the generosity of a benefit for a subset of individuals and it is not apparent that the reduction is based on a clinical indication or reasonable medical management practices.⁵⁶ We conduct this examination whenever a plan on an FFE reduces benefits for a particular group. Limitations and exclusions are expected to be based on clinical guidelines and medical evidence, and medical management standards are expected to be reasonable. Issuers may be asked to submit a justification with supporting documentation to CMS or the State explaining how the plan design is not discriminatory.

HHS's Office for Civil Rights (OCR) has independent authority to enforce section 1557 of the Affordable Care Act (42 U.S.C. 18116), which prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in any health program or activity, any part of which receives Federal financial assistance. OCR also enforces Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d, *et seq.*), section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), and the Age Discrimination Act of 1975 (42 U.S.C. 6101, *et seq.*) and their respective implementing regulations, which prohibit discrimination on the basis of race, color, national origin, disability, or age in health programs and activities that receive Federal financial assistance.

f. Cost-Sharing Requirements (§ 156.130)

We proposed to amend § 156.130 to clarify how the annual limitation on

⁵⁴ Letter to Issuers on Federally-facilitated and State Partnership Exchanges, April 5, 2013, page 15 and 2015 Letter to Issuers in the Federally facilitated Marketplaces, March 14, 2014, page 29.

⁵⁵ To inform the determination as to the scope of a typical employer plan, section 1302(b)(2)(A) of the Affordable Care Act requires the Secretary of Labor to conduct a survey of employer-sponsored coverage to determine the benefits typically covered by employers, and to provide a report to the Secretary of HHS. These provisions suggest that, while detailed requirements for EHB in the individual and small group health insurance markets were deemed necessary, the benefits covered by typical employer plans providing primary coverage at the time the Affordable Care Act was enacted were seen as sufficient to satisfy the Act's objectives for the breadth of benefits needed for health plan coverage and, in fact, to serve as the basis for determining EHB.

⁵⁶ Letter to Issuers on Federally-facilitated and State Partnership Exchanges, April 5, 2013, page 15 and 2015 Letter to Issuers in the Federally-facilitated Marketplaces, March 14, 2014, page 29.

cost sharing applies to plans that operate on a non-calendar year, and to make a technical correction to the special rule for network plans. First, we proposed to add new § 156.130(b), which would provide that non-calendar year plans that are subject to the annual limitation on cost sharing in section 1302(c)(1) must adhere to the annual limitation that is specific to the calendar year in which the plan begins. That annual limitation amount would serve as the maximum for the entire plan year. The purpose of this proposal is to ensure that the enrollee would only be required to accumulate cost sharing that applies to one annual limit per year. We also stated that under section 1302(c)(3) of the Affordable Care Act, the term “cost sharing” includes deductibles, coinsurance, copayments, or similar charges, and any other expenditure required of an individual that is a qualified medical expense (within the meaning of section 223(d)(2) of the Code) for EHB covered under the plan. Expenditures that meet this definition of cost sharing must, under section 1302(c) of the Affordable Care Act, count toward the annual limitation on cost sharing incurred under a health plan that is required to cover EHB. Cost sharing does not include premiums, balance billing amounts for non-network providers, or spending for non-covered services. This definition was codified in § 155.20.

Additionally, we proposed to make a technical correction to the text at § 156.130(c) on the special rule for network plans to replace “shall not” with “is not required to.” This proposed amendment was intended to clarify that issuers have the option to count the cost sharing for out-of-network services towards the annual limitation on cost sharing, but are not required to do so. This out-of-network cost sharing would not count toward the calculation of actuarial value under § 156.135(b)(4) or meeting a given level of coverage under § 156.140.

Lastly, in the proposed rule, we proposed clarifying that the annual limitation on cost sharing for self-only coverage applies to all individuals regardless of whether the individual is covered by a self-only plan or is covered by a plan that is other than self-only. In both of these cases, an individual’s cost sharing for EHB may never exceed the self-only annual limitation on cost sharing. For example, under the proposed 2016 annual limitation on cost sharing, if an other than self-only plan has an annual limitation on cost sharing of \$10,000 and one individual in the family plan incurs \$20,000 in expenses from a hospital stay, that particular

individual would only be responsible for paying the cost sharing related to the costs of the hospital stay covered as EHB up to the annual limit on cost sharing for self-only coverage (assuming an annual limitation of \$6,850 for 2016, the maximum for that year). We sought comments on these proposed requirements and clarifications as well as whether other requirements and clarifications were needed. We are finalizing our proposal that the annual limitation on cost sharing for self-only coverage applies to all individuals regardless of whether the individual is covered by a self-only plan or is covered by a plan that is other than self-only and the technical correction we proposed to make to the text at § 156.130(c).

Comment: Several commenters were supportive of the proposed § 156.130(b) as ensuring that cost sharing for non-calendar plans accrues for a 12-month period, and ensuring that an enrollee only has to accumulate cost sharing towards one annual limitation on cost sharing. Other commenters opposed the proposed § 156.130(b) because small employer plans typically operate on a non-calendar year basis, but accumulate towards a calendar year annual limitation on cost sharing. These commenters saw the proposed requirements as disruptive, confusing to consumers, and difficult to implement. Commenters asked for an exception from the new § 156.130(b) for large and self-funded group health plans and indicated that issuers would need time to implement the rules, and would require a clear transitional policy.

Response: The purpose of proposed § 156.130(b) was to ensure that issuers could not reset the annual limitation on cost sharing more frequently than once a year and was not intended to disrupt the employer group health insurance market. After careful consideration of comments received, we are not finalizing this policy at this time. At this time, we believe it is important to retain flexibility in the employer health insurance market on the timeframe under which the employer sets the annual limitation on cost sharing, but we do maintain that the annual limitation cost sharing is to apply on an annual basis regardless of whether it is a calendar year or a non-calendar year plan.

Comment: Some commenters were supportive of the proposed technical correction to § 156.130(c) to replace “shall not” with “is not required to.” Some commenters recommended that we expand this requirement to require the counting of out-of-network services toward the annual limit on cost sharing, including in cases where the issuer is

failing to meet network adequacy standards or in cases of emergency services, or to expand the types of cost sharing that must count towards the annual limitation on cost sharing.

Response: The purpose of this correction was to better align this regulation with the Affordable Care Act Implementation FAQs (Set 18) that were prepared jointly by the Departments of Labor, HHS, and the Treasury.⁵⁷ In this final rule, we do not intend to expand this requirement to require counting of out-of-network services toward the annual limitation on cost sharing and believe that requiring coverage of out-of-network services for cases where an enrollee is unable to access an in-network provider for covered services is beyond the scope of the regulation related to cost sharing requirements, which applies in different ways in a broad range of markets, some of which may be subject to varying network adequacy requirements. However, revised § 156.130(c) ensures that an issuer has the option to count the cost sharing for these out-of-network services towards the annual limitation on cost sharing. In addition, issuers’ obligations under § 156.130(g) and § 147.138(b)(3) regarding coverage of emergency services are applicable. Accordingly, we are finalizing these changes to § 156.130(c) as proposed.

Comment: Several commenters supported the clarification in the preamble that the self-only coverage limit for the annual limitation on cost sharing applies to all individuals regardless of whether the individual has other than self-only coverage, as a step toward greater consistency in consumer protections. Commenters who opposed this clarification were primarily concerned that this provision would limit the ability of issuers to offer high deductible health plans with a health savings account. Other commenters raised concerns about whether this clarification was within the Congressional intent of the statute, and whether this policy would be more generous than other Federal programs. Other commenters wanted additional clarification on how the annual limitation on cost sharing may be applied for other than self-only coverage.

Response: We believe that this clarification is an important consumer protection, as we are aware that some consumers have been confused by the applicability of the annual limitation on cost sharing in other than self-only

⁵⁷ http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs18.html. (January 8, 2014).

plans. Therefore, we are finalizing this clarification. The annual limitation on cost sharing for self-only coverage applies to all individuals regardless of whether the individual is covered by a self-only plan or is covered by a plan that is other than self-only.

Section 156.130 is specific to the annual limitation on cost sharing. While cost sharing incurred towards the deductible must count towards the annual limitation on cost sharing for EHB, the deductible limit is not regulated in the same manner as the annual limitation on cost sharing. Therefore, family high deductible health plans that count the family's cost sharing to the deductible limit can continue to be offered under this policy. The only limit will be that the family high deductible health plan cannot require an individual in the family plan to exceed the annual limitation on cost sharing for self-only coverage. We also note that this policy, that the annual limitation on cost sharing for self-only coverage applies to all individuals regardless of whether the individual is covered by a self-only plan or is covered by a plan that is other than self-only, would also apply to catastrophic plans under § 156.155 and that plans are required to comply with reduced maximum annual limitation on cost sharing under § 156.420. We note that 2016 plans must comply with this policy.

g. Premium Adjustment Percentage (§ 156.130)

Section 1302(c)(4) of the Affordable Care Act directs the Secretary to determine an annual premium adjustment percentage, which is used to set the rate of increase for three parameters detailed in the Affordable Care Act: The maximum annual limitation on cost sharing (defined at § 156.130(a)), the required contribution percentage by individuals for minimum essential health coverage the Secretary may use to determine eligibility for hardship exemptions under section 5000A of the Code, and the assessable payment amounts under section 4980H(a) and (b) of the Code (finalized at 26 CFR 54.4980H in the "Shared Responsibility for Employers Regarding Health Coverage," published in the February 12, 2014 **Federal Register** (79 FR 8544)). Section 156.130(e) provides that the premium adjustment percentage is the percentage (if any) by which the average per capita premium for health insurance coverage for the preceding calendar year exceeds such average per capita premium for health insurance for 2013, and that this percentage will be

published annually in the HHS notice of benefit and payment parameters.

We established a methodology for estimating average per capita premium for purposes of calculating the premium adjustment percentage in the 2015 Payment Notice. Under that methodology, the premium adjustment percentage is calculated based on the projections of average per enrollee employer-sponsored insurance (ESI) premiums from the NHEA, which is calculated by the CMS Office of the Actuary.

Accordingly, using the ESI data, the premium adjustment percentage for 2016 is the percentage (if any) by which the most recent NHEA projection of per enrollee ESI premiums for 2015 (\$5,744) exceeds the most recent NHEA projection of per enrollee ESI premiums for 2013 (\$5,303).⁵⁸ We are finalizing the proposed premium adjustment percentage for 2016 at 8.316047520 percent. We note that the 2013 premium used for this calculation has been updated to reflect the latest NHEA data. We are also finalizing the following cost-sharing parameters for calendar year 2016, based on our finalized premium adjustment percentage for 2016.

Maximum Annual Limitation on Cost Sharing for Calendar Year 2016. Under § 156.130(a)(2), for the 2016 calendar year, cost sharing for self-only coverage may not exceed the dollar limit for calendar year 2014 increased by an amount equal to the product of that amount and the premium adjustment percentage for 2016, and for other than self-only coverage, the limit is twice the dollar limit for self-only coverage. Under § 156.130(d), these amounts must be rounded down to the next lowest multiple of 50. Using the premium adjustment percentage of 8.316047520 for 2016 we established above, and the 2014 maximum annual limitation on cost sharing of \$6,350 for self-only coverage, which was published by the IRS on May 2, 2013,⁵⁹ we are finalizing the proposed 2016 maximum annual limitation on cost sharing at \$6,850 for self-only coverage and \$13,700 for other than self-only coverage.

Comment: Two commenters expressed concern with the increase in the maximum limitation on cost

sharing, and asked HHS to consider alternative factors to those that make up the methodology or an alternate methodology to protect patients from increasing out-of-pocket costs. One commenter stated that the proposed increase of \$500 for self-only and \$1,000 for family policies over the 2014 maximums will deter enrollees from using drugs, and continual annual increases of this magnitude would nullify the protection afforded patients from limits on out-of-pocket expenses. Another commenter stated that the proposed percentage increase far exceeds any recent percentage increase in the maximum annual limit on deductibles proposed by the Internal Revenue Service for High Deductible Health Plans, the index used to establish maximum annual limits on cost sharing in the first year of the Affordable Care Act. The commenter stated that consumers do not commonly experience both annual premium increases and significant increases in the cost of benefits.

Response: We are finalizing the 2016 maximum annual limit on cost sharing as proposed. As discussed above, section 1302(c)(4) of the Affordable Care Act directs the Secretary to set the maximum limitation on cost sharing using an annual premium adjustment percentage. Other indices may use different factors. HHS recognizes that significant annual increases in out-of-pocket expenses would have a deleterious effect on consumers' ability to access health care. The methodology to establish the maximum annual limitation on cost sharing was finalized in the 2015 Payment Notice, and as stated there, we will consider adjusting the methodology in 2017 as additional data on health insurance premiums become available through the Exchanges and other sources.

h. Reduced Maximum Annual Limitation on Cost Sharing (§ 156.130)

Sections 1402(a) through (c) of the Affordable Care Act direct issuers to reduce cost sharing for EHBs for eligible individuals enrolled in a silver level QHP. In the 2014 Payment Notice, we established standards related to the provision of these cost-sharing reductions. Specifically, in part 156 subpart E, we specified that QHP issuers must provide cost-sharing reductions by developing plan variations, which are separate cost-sharing structures for each eligibility category that change how the cost sharing required under the QHP is to be shared between the enrollee and the Federal government. At § 156.420(a), we detailed the structure of these plan variations and specified that QHP

⁵⁸ See <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ProjectionsMethodology2012.pdf> and Table 17 in <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Proj2012.pdf> for additional information.

⁵⁹ See <http://www.irs.gov/pub/irs-drop/rp-13-25.pdf>.

issuers must ensure that each silver plan variation has an annual limitation on cost sharing no greater than the applicable reduced maximum annual limitation on cost sharing specified in the annual HHS notice of benefit and payment parameters. Although the amount of the reduction in the maximum annual limitation on cost sharing is specified in section 1402(c)(1)(A) of the Affordable Care Act, section 1402(c)(1)(B)(ii) of the Affordable Care Act states that the Secretary may adjust the cost-sharing limits to ensure that the resulting limits do not cause the AVs of the health plans to exceed the levels specified in section 1402(c)(1)(B)(i) (that is, 73 percent, 87 percent or 94 percent, depending on the income of the enrollee(s)). Accordingly, we proposed to use a method we established in the 2014 Payment Notice for determining the appropriate reductions in the maximum annual limitation on cost sharing for cost-sharing plan variations. As finalized above, the 2016 maximum annual limitation on cost sharing is \$6,850 for self-only coverage and \$13,700 for other than self-only coverage. We analyzed the effect on AV of the reductions in the maximum annual limitation on cost sharing described in the statute to determine whether to adjust the reductions so that the AV of a silver plan variation will not exceed the AV specified in the statute. Below, we describe our analysis for the 2016 benefit year and the results described in the proposed rule, which are being finalized as proposed.

Reduced Maximum Annual Limitation on Cost Sharing for Benefit Year 2016. Consistent with our analysis in the 2014 and 2015 Payment Notices, we developed three model silver level QHPs, and analyzed the impact on AV

of the reductions described in the Affordable Care Act to the estimated 2016 maximum annual limitation on cost sharing for self-only coverage (\$6,850). The model plan designs are based on data collected for 2015 plan year QHP certification to ensure that they represent a range of plan designs that we expect issuers to offer at the silver level of coverage through the Exchange. For 2016, the model silver level QHPs included a PPO with a typical cost-sharing structure (\$6,850 annual limitation on cost sharing, \$2,000 deductible, and 20 percent in-network coinsurance rate), a PPO with a lower annual limitation on cost sharing (\$4,600 annual limitation on cost sharing, \$2,550 deductible, and 20 percent in-network coinsurance rate), and an HMO (\$6,850 annual limitation on cost sharing, \$2,700 deductible, 20 percent in-network coinsurance rate, and the following services with copays that are not subject to the deductible or coinsurance: \$500 inpatient stay per day, \$350 emergency department visit, \$25 primary care office visit, and \$50 specialist office visit). All three model QHPs meet the AV requirements for silver level health plans.

We then entered these model plans into the proposed 2016 AV calculator developed by HHS and observed how the reductions in the maximum annual limitation on cost sharing specified in the Affordable Care Act affected the AVs of the plans. We found that the reduction in the maximum annual limitation on cost sharing specified in the Affordable Care Act for enrollees with a household income between 100 and 150 percent of the FPL ($\frac{2}{3}$ reduction in the maximum annual limitation on cost sharing), and 150 and 200 percent of the FPL ($\frac{2}{3}$ reduction), would not cause the AV of any of the

model QHPs to exceed the statutorily specified AV level (94 and 87 percent, respectively). In contrast, the reduction in the maximum annual limitation on cost sharing specified in the Affordable Care Act for enrollees with a household income between 200 and 250 percent of the FPL ($\frac{1}{2}$ reduction), would cause the AVs of two of the model QHPs to exceed the specified AV level of 73 percent. As a result, we are finalizing our proposal that the maximum annual limitation on cost sharing for enrollees in the 2016 benefit year with a household income between 200 and 250 percent of the FPL be reduced by approximately $\frac{1}{5}$, rather than $\frac{1}{2}$. We are further finalizing as proposed a requirement that the maximum annual limitation on cost sharing for enrollees with a household income between 100 and 200 percent of the FPL be reduced by approximately $\frac{2}{3}$, as specified in the statute, and as shown in Table 10. These reductions in the maximum annual limitation on cost sharing should adequately account for unique plan designs that may not be captured by our three model QHPs. We also note that selecting a reduction for the maximum annual limitation on cost sharing that is less than the reduction specified in the statute will not reduce the benefit afforded to enrollees in aggregate because QHP issuers are required to further reduce their annual limitation on cost sharing, or reduce other types of cost sharing, if the required reduction does not cause the AV of the QHP to meet the specified level.

We note that for 2016, as described in § 156.135(d), States are permitted to submit for approval by HHS State-specific data sets for use as the standard population to calculate AV. No State submitted a data set by the September 1 deadline.

TABLE 10—REDUCTIONS IN MAXIMUM ANNUAL LIMITATION ON COST SHARING FOR 2016

Eligibility category	Reduced maximum annual limitation on cost sharing for self-only coverage for 2016	Reduced maximum annual limitation on cost sharing for other than self-only coverage for 2016
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(i) (that is, 100–150 percent of FPL)	\$2,250	\$4,500
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(ii) (that is, 150–200 percent of FPL)	2,250	4,500
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(iii) (that is, 200–250 percent of FPL)	5,450	10,900

Comment: We received one comment supporting the proposed reductions in the maximum annual limitation on cost sharing for 2016 for enrollees with a household income between 200 and 250

percent of the FPL, with the caveat that HHS design policies in future plan years to lower up-front cost sharing, such as through lower deductibles. Other commenters stated that HHS should

consider reducing the cost-sharing limits for individuals with a household income between 200 and 400 percent of the FPL as the proposed cost-sharing limits may pose significant financial

challenge for enrollees with significant expenditures. One commenter urged HHS to systematically analyze the reduced annual limitation on cost sharing provided by cost-sharing reduction plans in each State or rating area for their impact on people with chronic illnesses.

Response: As discussed in the proposed rule, selecting a reduction for the maximum annual limitation on cost sharing that is less than the reduction specified in the statute will not reduce the benefit afforded to enrollees in aggregate, because QHP issuers are required to further reduce their annual limitation on cost sharing, or other types of cost sharing, to meet the specified AV for the plan variation. Therefore, we are finalizing the reductions to the maximum annual limitation on cost sharing for 2016 as proposed.

i. Minimum Value (§ 156.145)

Section 1401(a) of the Affordable Care Act added a new section 36B to the Code, providing a premium tax credit for certain individuals with household incomes between 100 percent and 400 percent of the FPL who enroll in, or who have one or more family members enrolled in an individual market QHP through an Exchange, who are not otherwise eligible for MEC. An employer-sponsored plan is MEC, but for purposes of the premium tax credit under section 36B(c)(2)(C)(ii) of the Code, an employee is generally treated as not eligible for MEC under an employer-sponsored plan unless the plan is affordable and provides minimum value (MV). An employer-sponsored plan provides MV if the plan's share of the total allowed costs of benefits provided under the plan is greater than or equal to 60 percent of the costs. An employee who is eligible for coverage under an employer-sponsored plan that is both affordable and provides MV to the employee may not receive a premium tax credit under section 36B of the Code for the employee's coverage in a QHP. If the employer coverage does not provide MV, the employee may be entitled to a premium tax credit even if the coverage is affordable.

Section 1513 of the Affordable Care Act added a new section 4980H to the Code providing for shared responsibility for employers regarding health coverage. An applicable large employer that does not offer coverage that is affordable and provides MV may be liable for an employer shared responsibility payment under section 4980H of the Code if one or more of its full-time employees receives a premium tax credit.

Under our regulations, the MV standard of 60 percent of the total

allowed costs of benefits provided under the plan is based on an amount equivalent to the plan's share of total allowed costs required for a bronze level QHP offered on an Exchange. Section 1302(d)(2)(C) of the Affordable Care Act provides that regulations promulgated by the Secretary of HHS under section 1302(d)(2), addressing actuarial value, apply in determining under this title, the Public Health Service Act, and the Internal Revenue Code . . . the percentage of the total allowed costs of benefits provided under a group health plan or health insurance coverage that are provided by such plan or coverage. Accordingly, HHS regulations under section 1302(d) implementing actuarial value requirements, which an insurer offering essential health benefits (EHB) must meet for a non-grandfathered individual market or small group health insurance plan to be considered a bronze plan under section 1302(d)(1)(3) of the Affordable Care Act, also form the basis for determining the percentage of the total allowed costs of benefits provided for purposes of whether the value of coverage meets the MV standard under section 36B(c)(2)(C)(ii) of the Code.

HHS published final regulations implementing section 1302(d)(2) on February 25, 2013 (78 FR 12834). The regulations at § 156.20 define the percentage of the total allowed costs of benefits as (1) the anticipated covered medical spending for EHB coverage paid by a health plan for a standard population, (2) computed in accordance with the plan's cost sharing, and (3) divided by the total anticipated allowed charges for EHB coverage provided to the standard population. HHS regulations at § 156.145(b)(2) apply this definition in the context of MV by taking into account benefits a plan provides that are included in any one of the State EHB benchmarks.

The IRS and Treasury Department published proposed regulations on May 3, 2013 (78 FR 25909), applying the HHS regulations in defining MV for employer-sponsored plans. The proposed regulations provide that the MV percentage is determined by dividing a plan's anticipated medical spending (based on the plan's cost-sharing) for plan benefits that are EHB covered under a particular EHB benchmark plan for the MV standard population by the total allowed charges for EHB coverage for the standard population and converting the result to a percentage. Proposed 26 CFR 1.36B-6(c). Taxpayers may apply the proposed regulations for taxable years ending before January 1, 2015.

The final HHS regulations and proposed Treasury regulations allow plans to determine the MV percentage by using the MV Calculator published by HHS. It came to our attention that certain group health plan designs that provide no coverage of inpatient hospital services were being promoted, and that representations were being made, based on the MV Calculator, that these plan designs would cover 60 percent of the total allowed costs of benefits provided, and thus provide MV under the test in the current regulations. We understand that these designs have been promoted as a way of both minimizing the cost of the plan to the employer (a consequence not only of excluding inpatient hospitalization benefits but also of making an offer of coverage that a substantial percentage of employees will not accept) and avoiding potential liability for employer shared responsibility payments. By offering coverage that is affordable to the employee and that purports to provide MV, employers adopting these plan designs were seeking, to deny their employees the ability to obtain a premium tax credit that could result in the employer becoming subject to a section 4980H employer shared responsibility payment.

In Notice 2014-69 (2014-48 IRB, November 24, 2014), released on November 4, 2014, HHS and Treasury advised that regulations would be proposed providing that plans that fail to provide substantial coverage of inpatient hospital or physician services do not provide MV. Allowing these designs to be treated as providing MV not only would allow an employer to avoid the shared responsibility payment that the statute imposes when an employer does not offer its full-time employees adequate health coverage, but would adversely affect employees (particularly those with significant health risks) who understandably would find this coverage unacceptable, by denying them access to a premium tax credit for individual coverage purchased through an Exchange. Plans that omit critical benefits used disproportionately by individuals in poor health will enroll far fewer of these individuals, effectively driving down employer costs at the expense of those who, because of their individual health status are discouraged from enrolling.

That the MV standard may be interpreted to require that employer-sponsored plans cover critical benefits is evident in the structure of the Affordable Care Act, the context in which the grant of the authority to the Secretary to prescribe regulations under section 1302 was enacted, and the

policy underlying the legislation. Section 1302(b) authorizes the Secretary of HHS to define EHB to be offered by individual market and small group health insurance plans, provided that this definition include at least 10 specified categories of benefits, and that the benefits be equal to the scope of benefits provided under a typical employer plan. To inform this determination as to the scope of a typical employer plan, section 1302(b)(2)(A) provides that the Secretary of Labor shall conduct a survey of employer-sponsored coverage to determine the benefits typically covered by employers, including multiemployer plans, and provide a report on such survey to the Secretary [of HHS].⁶⁰ These provisions suggest that, while detailed requirements for EHB in the individual and small group health insurance markets were deemed necessary, the benefits covered by typical employer plans providing primary coverage at the time the Affordable Care Act was enacted were seen as sufficient to satisfy the Act's objectives for the breadth of benefits needed for health plan coverage and, in fact, to serve as the basis for determining EHB. They also suggest that any meaningful standard of minimum coverage may require providing certain critical benefits.

Employer-sponsored plans in the large group market and self-insured employers continue to have flexibility in designing their plans. They are not required to cover all EHB. Providing flexibility, however, does not mean that these plans can offer whatever benefits they choose and automatically meet MV requirements. A plan that excludes substantial coverage for inpatient hospital and physician services is not a health plan in any meaningful sense and is contrary to the purpose of the MV requirement to ensure that an employer-sponsored plan, while not required to cover all EHB, nonetheless must offer coverage with minimum value at least roughly comparable to that of a bronze plan offered on an Exchange.

For these reasons, the Secretary has concluded that the provisions of section 1302(d)(2) of the Affordable Care Act—requiring that the regulations for determining the percentage of the total allowed costs of benefits that apply to plans that must cover all EHB also be applied as a basis for determining minimum value—reflect a statutory design to provide basic minimum

standards for health benefits coverage through the MV requirement, without requiring large group market plans and self-insured plans to meet all EHB standards. Given the scope of benefits covered by typical employer plans, the MV requirement is properly viewed as a means of ensuring that employer-sponsored plans satisfy basic minimum standards while also accommodating flexibility in the design of those plans.

Employers have been able to claim that plans without coverage of inpatient hospital services provide MV under the current quantitative MV test by designing a benefit package that, based on standardized actuarial assumptions used in the MV calculator, offsets the absence of actuarial value derived from spending on inpatient hospital coverage with increased spending on other benefits. Accordingly, some plan designs may pass the current quantitative test without offering a critical benefit universally understood to be included in any minimally acceptable employer health plan coverage, and which the Department of Labor study determined was included in all employer plans it surveyed.

As noted previously, we have concluded that the quantitative test for MV is not exclusive. Accordingly, we are finalizing our proposal to amend § 156.145 to require that, to provide MV, an employer-sponsored plan not only must meet the quantitative standard of the actuarial value of benefits, but also must provide a benefit package that meets a minimum standard of benefits. Specifically, we are finalizing as proposed the policy to revise § 156.145 to provide that, to satisfy MV, an employer plan must provide substantial coverage of both inpatient hospital services and physician services.

We are not requiring that large employer or self-insured employer group health plans provide all EHB as defined under section 1302 of the Affordable Care Act. Rather, we are only requiring that, to provide MV, employer-sponsored plans provide substantial coverage of the two types of benefits that we believe were envisioned for health plan coverage meeting the MV standard. We have concluded that plans that omit these types of coverage fail to meet universally accepted minimum standards of value expected from, and inherent in the nature of, any arrangement that can reasonably be called a health plan intended to provide the primary health coverage for employees.

Consistent with Notice 2014–69, we are finalizing our proposal that these changes to our regulations on MV will apply to employer-sponsored plans,

including plans that are in the middle of a plan year, immediately on the effective date of the final regulations. However, because some employers adopted plans prior to publication of Notice 2014–69, we are finalizing our proposal that the final regulations not apply before the end of the plan year (as in effect under the terms of the plan on November 3, 2014) to plans that before November 4, 2014, entered into a binding written commitment to adopt, or began enrolling employees into, the plan, so long as that plan year begins no later than March 1, 2015. For these purposes, a binding written commitment exists when an employer is contractually required to pay for an arrangement, and a plan begins enrolling employees when it begins accepting employee elections to participate in the plan. The Department of the Treasury and the IRS are expected to publish proposed regulations making clear that this delayed applicability date applies solely for purposes section 4980H of the Code. At no time will any employee be required to treat a plan that fails to provide substantial coverage of inpatient hospital services or physician services as providing MV for purposes of eligibility for the premium tax credit under section 36B of the Code.

Comment: We received several comments supporting our proposal and urging HHS to broaden the MV requirement to include outpatient services, emergency services and prescription coverage. Several commenters recommended establishing a clear standard for “substantial coverage” to determine whether an employer has met the requirements: One commenter suggested conducting a survey of employer-sponsored plans to establish a benchmark, three commenters suggested using the Federal Employees Health Benefits (FEHB) plan as a benchmark, and one commenter suggested using 4 days of minimum hospital stays coverage as a threshold based on an analysis of hospital stays among individuals in employer-sponsored plans. Several commenters requested that HHS establish a good faith compliance standard for plans offering coverage with inpatient hospital and physician services for the 2015 plan year.

Response: We are finalizing the policy as proposed. As discussed in the proposed rule, because under the terms of the statute large employers are not required to offer EHB as defined by the Secretary, we are not requiring that large employer or self-insured employer group health plans provide all EHB as defined under section 1302 of the Affordable Care Act. Rather, we are only

⁶⁰ See Department of Labor, Special Report: Selected Medical Benefits: A Report from the Department of Labor to the Department of Health and Human Services, <http://www.bls.gov/ncs/ebs/sp/selmedbensreport.pdf>.

requiring that, to provide MV, employer-sponsored plans provide substantial coverage of the two types of benefits that we believe were envisioned as essential to health plan coverage meeting the MV standard. We have concluded that plans that omit these types of coverage fail to meet universally accepted minimum standards of value expected from, and inherent in, the nature of any arrangement that can reasonably be called a health plan intended to provide the primary health coverage for employees. We intend to provide further clarity on the requirement to provide “substantial coverage,” as circumstances warrant.

Comment: Several commenters raised concerns that the Affordable Care Act only requires coverage of 60 percent of costs of benefits and HHS is imposing other benefits requirements without statutory basis. One of the commenters recommended HHS create a safe harbor for plans establishing coverage designs based on good faith belief that the plan meets the 60 percent actuarial value threshold.

Response: As discussed above, we believe that section 1302(d)(2) of the Affordable Care Act—requiring that the regulations for determining the percentage of the total allowed costs of benefits that apply to plans that must cover all EHB also be applied as a basis for determining minimum value—reflect a statutory design to incorporate basic minimum standards for health benefits coverage similar in scope to EHB through the MV requirement, without requiring large group market plans and self-insured plans to meet all EHB standards. Given the scope of benefits covered by typical employer plans, the MV requirement is properly viewed as a means of ensuring that employer-sponsored plans that prevent employees from accessing the premium tax credit for comprehensive coverage in the Marketplace satisfy basic minimum standards while also accommodating flexibility in the design of those plans. We believe that our rules on effective dates adequately address transition issues. As described above, for purposes of section 4980H of the Code, the changes to our regulations on MV requirements will not apply before the end of the plan year for employers that adopted plans prior to November 4, 2014, so long as the plan begins no later than March 1, 2015. However, under no circumstances will an employee be denied the premium tax credit under section 36B of the Code for a plan that does not cover at least 60 percent of the total allowed costs of benefits, and/or fails to provide substantial coverage of

inpatient hospital services or physician services.

Comment: Several commenters raised the concern that the MV requirements will increase the number of plans affected by the excise tax on high-cost employer-sponsored health coverage, and that many employers have limited benefits to avoid the tax or are considering passing off the excise tax costs to individuals.

Response: Our analysis shows plans likely to be affected by these clarifications of the MV requirements generally have annual costs far below the thresholds above which the excise tax will apply in 2018; \$10,200 for self-only and \$27,500 for other-than-self-only coverage. Pursuant to the statute, the thresholds may be increased for excess growth in health care costs through 2018 and based on inflation annually thereafter. We thus do not believe that this policy will affect the number of employer plans affected by the excise tax and are finalizing the policy as proposed.

3. Qualified Health Plan Minimum Certification Standards

a. QHP Issuer Participation Standards (§ 156.200)

We proposed to revise § 156.200(b)(7) to require that a QHP issuer comply with the standards under part 153 and not just the standards related to the risk adjustment program. This amendment clarifies that a QHP issuer must maintain responsibility for its compliance and, under § 156.340, the compliance of any of its delegated or downstream entities with the standards set forth in part 153, not just those specifically pertaining to risk adjustment. We received no comments on this proposal. We are finalizing this provision as proposed.

b. Transparency in Coverage (§ 156.220)

The transparency in coverage standards established under section 1311(e)(3) of the Affordable Care Act, as implemented at § 155.1040(a) and § 156.220, require health insurance issuers that offer a QHP in accordance with a certification from an Exchange to provide specified information to HHS, the Exchange, and the State insurance commissioner and to make this information available to the public in “plain language.” In a frequently asked question dated April 29, 2013,⁶¹ HHS clarified that, to comply with section 1311(e)(3), issuers offering QHPs

certified by an Exchange would be required to begin submitting this information only after QHPs have been certified for one benefit year.⁶² We noted in the proposed rule (79 FR 70726) that because a full year of claims data will be available, we anticipate the collection and public display of the required information listed in § 156.220 from QHP issuers offering coverage through Exchanges beginning in 2016. We requested comments to inform future policies, regarding the data elements, format, and timeframe for the data submission, as well as the manner in which HHS, the Exchanges, and QHPs should publicly display the collected information. We also sought feedback on how to minimize duplication with information that issuers must already submit to HHS, States, or other entities (for example, accreditation organizations). Finally, we requested feedback on whether State Exchanges should display the same information and in the same format and manner as in the FFEs.

Comment: One commenter asked whether the transparency in coverage standards are applicable to stand-alone dental plans.

Response: The transparency in coverage reporting standards, established at § 156.220, are applicable to all QHPs offered on Exchanges, including stand-alone dental plans.

Comment: Several commenters recommended that HHS narrow any data elements it collects to reflect only information that would be useful to consumers as they select a QHP. Commenters were concerned with duplication of collections that are already required by States or HHS. Some commenters suggested that data collection should rely on what is already publicly available when possible. Some commenters expressed concerns regarding protection of proprietary information and suggested that HHS should not request or display data that could have unintended, anticompetitive consequences. A few

⁶² The FAQ also states that because section 2715A of the PHS Act simply extends the transparency provisions set forth in section 1311(e)(3) of the Affordable Care Act to group health plans and health insurance issuers offering group and individual health insurance coverage, the Departments clarified that the reporting requirements under section 2715A of the PHS Act will become applicable to group health plans and health insurance issuers offering group and individual health insurance coverage no sooner than when the reporting requirements under section 1311(e)(3) of the Affordable Care Act become applicable. Nothing in these proposed regulations would apply any transparency reporting requirements related to section 2715A of the PHS Act, incorporated into section 715(a)(1) of ERISA and section 9815(a)(1) of the Code.

⁶¹ Affordable Care Act Implementation Set 15, available at: http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs15.html.

commenters suggested examples of data elements, the frequency of collection, the format of display, and data sources that could be used to meet the requirements for specific elements.

Response: We intend to provide detail regarding the referenced data collection and display at a future date. We will take the commenters' suggestions into account when we do so. We intend to collect and display information in a standardized manner to minimize burden on issuers and maximize utility for consumers.

Comment: Some commenters recommended that transparency of coverage standards not be implemented for 1 year following issuance of the final guidance operationalizing them. These commenters were concerned about having sufficient time to put resources in place to submit and display data. Commenters also suggested that issuers be given an opportunity to comment on the specific elements that will be collected, the definition of those elements, and how the data will be used. One commenter suggested that HHS conduct beta testing before the requirements are fully implemented. In contrast, a few commenters were concerned with the 2016 implementation date for transparency requirements and recommended that HHS collect and display the required information as soon as possible.

Response: We believe a 2016 date will allow sufficient time for HHS to provide detailed guidance regarding the data collection, review, and public display of transparency elements and will allow HHS and Exchanges to collect a full set of data reflecting post-2014 experience. We intend to solicit additional comments on the specific approach before it is finalized.

c. Network Adequacy Standards (§ 156.230)

In § 156.230, we established the minimum network adequacy criteria that health and dental plans must meet to be certified as QHPs, under the Secretary's authority in section 1311(c)(1)(B) of the Affordable Care Act. In this rule, we proposed modifying § 156.230(a) to specify that this section only applies to QHPs that use a provider network and that a provider network includes only providers that are contracted as in-network. This means that the general availability of out-of-network providers will not be counted for purposes of meeting network adequacy requirements.

We believe that networks that provide sufficient access to benefits are a priority for issuers and consumers. HHS continues to take great interest in

ensuring strong network access, particularly for QHPs that must meet the standards in § 156.230. As stated in the proposed rule, HHS is aware that the NAIC has formed a workgroup that is drafting a model act relative to network adequacy and will await the results of this workgroup before proposing significant changes to network adequacy policy. For 2016, HHS expects to continue the reasonable access standard adopted in the 2015 Letter to Issuers in the Federally-facilitated Marketplaces⁶³ and assess the provider networks information submitted as part of the QHP certification process. We urge State-based Exchanges to employ the same standard when examining network adequacy.

In addition to the changes above, we are also cognizant that new enrollees in QHPs may need a transition period to switch to a provider that is in-network in their new plan. We encourage QHP issuers that use a network of providers to offer new enrollees transitional care for an ongoing course of treatment. We suggest that this begin with the effective date of coverage of a new enrollee and last for at least 29 days thereafter (for a minimum of 30 days). These benefits would extend to health care services furnished by any provider to the new enrollee, regardless of whether the provider is in the plan's network, as long as the enrollee received health services from that provider under an ongoing course of treatment in the 90 days prior to the effective date of coverage. Because different plans may have different provider networks, when an individual enrolls in a new health plan, he or she may be undergoing a course of treatment with a provider that is not in the new issuer's provider network. In such a case, it may take time for the new enrollee to select a new in-network provider and to meet with the new provider to ensure that there is no disruption in treatment. We encourage issuers to adopt this policy to accommodate the immediate needs of enrollees, while allowing the enrollee sufficient time to go through the process of selecting an in-network provider in their new plan. As we stated in the proposed rule, we are considering whether requirements may be needed in this area in the future.

We are renumbering § 156.230(b), to (b)(1) and adding (b)(2) to strengthen the provider directory requirement effective for plan years beginning on or after January 1, 2016. Specifically, we

proposed that a QHP issuer must publish an up-to-date, accurate, and complete provider directory, including information on which providers are accepting new patients, the provider's location, contact information, specialty, medical group, and any institutional affiliations, in a manner that is easily accessible to plan enrollees, prospective enrollees, the State, the Exchange, HHS, and OPM. As part of this requirement, we proposed that a QHP issuer must update the directory information at least once a month, and that a provider directory will be considered easily accessible when the general public is able to view all of the current providers for a plan on the plan's public Web site through a clearly identifiable link or tab without having to create or access an account or enter a policy number. The general public should be able to easily discern which providers participate in which plan(s) and provider network(s) if the health plan issuer maintains multiple provider networks, and the plan(s) and provider network(s) associated with each provider, including the tier in which the provider is included, should be clearly identified on the Web site and in the provider directory. We solicited comments on this proposal, including comments regarding how often updating should occur. We are finalizing this policy as proposed, retaining the monthly timeline.

We also finalize the requirement for issuers to make this information publicly available on their Web sites in a machine-readable file and format specified by HHS. The purpose of establishing machine-readable files with this data would be to provide the opportunity for third parties to create resources that aggregate information on different plans. We believe this will increase transparency by allowing software developers to access this information and create innovative and informative tools to help enrollees better understand the availability of providers in a specific plan. To facilitate this change, we proposed adding § 156.230(c) to require QHP issuers to make available and submit to HHS information about providers in its provider networks.

We specifically solicited comments on this requirement and other options, including the technical requirements for developing a machine-readable file and format for a provider directory, as well as other technical considerations, such as processes and considerations that should be taken into account. We have established these requirements to enhance transparency of QHP provider directories and to help consumers make

⁶³ 2015 Letter to Issuers in the Federally-facilitated Marketplaces, March 14, 2014, available at: <http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2015-final-issuer-letter-3-14-2014.pdf>.

more informed decisions about their health care coverage. We solicited comments on these proposed requirements, including how frequently provider data should be updated, and whether additional types of information should be required to be included in the provider directory. We understand the complexity of this undertaking, and recognize that this will require issuer resources. Therefore, HHS intends to provide additional details about the data submission requirements.

We also requested comments on the feasibility and merits of incorporating information on physical accessibility for individuals with disabilities, including accessibility information regarding facilities and equipment, or other information that would be important to enrollees and potential enrollees, as a part of network adequacy standards in the future.

Comment: A number of commenters supported stronger network adequacy standards. Commenters were divided between supporting our proposal to wait for NAIC recommendations before taking further action, and urging us to act immediately and implement stronger network adequacy standards. Commenters suggested a wide range of network adequacy criteria for HHS to adopt, including provider to patient ratios; time and distance metrics; geographic-based metrics; minimum numbers of specialty providers; specific criteria for areas of concern including pediatric, dialysis centers, and autoimmune and rare disorders; monitoring of plans; and secret shopping. One commenter requested increased transparency regarding evaluation of network adequacy. This commenter suggested that HHS should modify the provider data template for QHP issuers in the FFEs to allow greater flexibility, and should clarify how reasonable access will be determined in situations where a sufficient number of providers are not willing to contract with the issuer.

Response: We are finalizing the rule without making any additional changes to the network adequacy general requirements at this point as the NAIC finishes its work on the network adequacy model act. We expect that the final product of the NAIC work will reflect the viewpoints of the various stakeholders. This reflects our general position that network adequacy is an area subject to significant State regulation and oversight. We agree with commenters that QHP networks should provide access to a range of health care providers, and we continue to require all QHP issuers to provide reasonable access to all covered services in

accordance with § 156.230(a) of this rule. We are also planning changes to the template used to collect network data to improve the collection process for QHP issuers in the FFE during the QHP certification process.

Comment: A number of commenters support the clarification that only in-network providers will be considered when determining if a plan's medical network meets reasonable access requirements, and urged CMS to clarify that issuers must be able to provide reasonable access with the providers available in their lowest cost tier. Other commenters also urged CMS to require issuers to have an internal exceptions or appeals process to obtain out-of-network services at in-network cost when adequate access is not available, while others stressed that out-of-network referrals should be rare. Similarly, several commenters voiced concerns about consumers being charged out-of-network charges while being treated in an in-network hospital because not all of the treating providers were in-network. In such circumstances, commenters urged that the consumer only be charged in-network costs, and that in-network hospitals should be required to have sufficient in-network providers to furnish all covered services. Some commenters raised concerns about the standard use of out-of-network providers for dental networks and the lack of availability of dentists who will contract with issuers.

Response: In light of the general support of the proposed change, we intend to finalize the regulation as proposed. We understand the concern about confusion created when a hospital is listed as in-network and has providers that are out-of-network for particular in-house services. We remind issuers that all covered services must be reasonably accessible, and in accordance with this regulatory change, must be available in-network. We urge issuers to evaluate their in-network hospitals to make certain that all required services are accessible without unreasonable delay from in-network providers. We appreciate the concerns voiced regarding coverage of dental providers and are contemplating whether further guidance is warranted.

Comment: A number of commenters strongly supported the transition policy allowing new enrollees to have access to providers from whom they received services before they joined their new plan. Some commenters urged HHS to require the transition policies, and some advocated for longer transition periods, such as 60 or 90 days or 6 months with reassessment, to determine if continued care is necessary at the end of the set

time period. Some commenters suggested expanding transitional policies to include current enrollees whose in-network providers become out-of-network providers mid-year due to network changes. Conversely, some commenters expressed that clear and accurate provider directories make transitional policies unnecessary, and some believe the policy would negatively impact care management and that many States already have requirements for transitional care. Similarly, some suggested that transitional policies should have specific limits, including specific situations and types of care, to reduce the impact on premiums. Many commenters expressed concern about what payment rates would be if there is no contract with the out-of-network provider and suggested HHS should require plans to reimburse providers the reasonable and customary value for out-of-network services and prohibit balance billing of consumers for anything above what they would have been charged for the services in-network. Commenters also stated that this is an area that many States already regulate closely.

Response: There are strong opinions supporting and opposing a requirement for a transitional policy, as well as varying opinions about the amount of time transitional policies should cover. We continue to encourage issuers to adopt appropriate transitional policies and to pay close attention to issues around continuity of care for both new enrollees and enrollees whose current providers become unavailable. We expect to continue to analyze this area and may propose standards concerning this topic in the future.

Comment: Commenters generally supported the proposal to strengthen provider directory requirements and agreed that provider data should be updated at least monthly, especially for on-line directories. Some commenters urged more frequent updates and urged CMS to move towards requiring "real time" updates in the future. Concerns were raised about penalizing issuers if there were errors in the directories because providers may fail to notify the issuer of changes, and the administrative burden and costs associated with strengthened provider directory requirements. Conversely, other commenters urged that issuers be required to honor what is listed in the provider directory even if it erroneous, and that plans be required to monitor data for accuracy.

Response: We are finalizing the regulation as proposed. We are requiring that directories be updated at least

monthly and encourage more frequent updating when possible. We also understand and appreciate the concern about issuers being held accountable for errors in directories and encourage issuers to work with their providers to ensure that their directories are as current and accurate as possible. We understand that there may be some administrative burden associated with updating directories, but believe it is necessary for consumers to be fully informed about network access. Similarly, we appreciate commenters who stated that issuers should honor what is listed in their directories even if there are errors, and while we are not requiring that at this time, we strongly encourage that practice.

Comment: Some commenters supported the inclusion of the proposed data elements in provider directories, including indicating if the provider is accepting new patients. Conversely, some commenters were concerned about being required to list if the provider is accepting new patients, citing the administrative burden because that status can frequently change. There was also concern about consumer confusion that could be caused by the requirement to indicate whether specialists are “accepting new patients.” Some commenters noted that in the case of specialists for whom a referral is needed, indicating the specialist is “accepting new patients” could be misleading to consumers, who may understand that to mean that they can request an appointment directly with the specialist. To alleviate confusion about referrals, it was suggested that another column or notation be included that indicates if a referral is needed, and it was also suggested that issuers retain flexibility in what is included in their directories.

Response: We are finalizing all of these requirements as proposed, including the requirement that issuers must indicate if providers are accepting new patients. All of the required data, including information on whether providers are accepting new patients, are critical for consumers to make educated decisions about their health coverage.

Comment: Some commenters suggested that additional data should be required as part of provider directories to make it easier for consumers to compare plans. Some of the specific data elements suggested included: hours physician traditionally practices at referenced practices, board certification(s), sub-specialties practiced, language spoken by each provider, interpreter services or communication and language assistance

services that are available at the provider’s facilities and information about how enrollees can obtain such services, publication date of directory, and a field for providing advance notice that the provider will be leaving the network. Commenters also urged requiring plans to provide a dedicated email address to be used to notify the plan of inaccuracies in the plan directory, and holding the issuer accountable for making changes when notified. Similarly, it was suggested that plans should monitor provider directories to determine if they are accurate.

Response: We are finalizing our proposal requiring the issuer to publish an up-to-date, accurate, and complete provider directory, including information on which providers are accepting new patients, the provider’s location, contact information, specialty, medical group, and any institutional affiliations, in a manner that is easily accessible to plan enrollees, prospective enrollees, the State, the Exchange, HHS, and OPM. We believe the new requirements will greatly strengthen provider directory requirements and provide consumers with valuable information to help them determine which QHP best meets their needs. We encourage issuers to continuously evaluate the data they include in their directories and aim to provide all of the information that will help consumers understand their network. We appreciate the suggestion that issuers have a dedicated email address for enrollees and providers to submit changes or inaccuracies, and while we are not requiring it at this time, we encourage the practice.

Comment: There was some concern raised that including items such as location, contact information, and specialty type on a real time basis could conflict with what is in National Plan and Provider Enumeration System (NPPES), which providers may fail to update, and would result in confusion. To alleviate possible NPPES confusion, it was suggested that issuers only include information from the previous month’s information in the NPPES database.

Response: We appreciate this concern but are finalizing the regulation as proposed. The requirement for issuers to publish an up-to-date, accurate, and complete provider directory takes into account the issuers’ obligation to develop a system to ensure that the information about providers that they publish in the provider directory is accurate and up-to-date, including ensuring it is consistent with what is listed in the NPPES database.

Comment: Some commenters supported the requirement that issuers provide access to provider directories through the issuer’s public Web site without the need to create an account or enter policy information, and HHS was asked to clarify the term “user-friendly” when used to describe the location of provider directories on issuer Web sites.

Response: We are finalizing this policy as proposed. In response to requests for clarification about the term “user friendly,” we suggest issuers adopt common industry standards for publishing the provider directory in an area of their Web site where it will be easy for enrollees to find and that enrollees will be able to access without the need for an account or policy number as stated in this rule at § 156.230(b)(2)(i). To reiterate, consumers should not have to create a user ID, log on, enter a policy number, or be enrolled in a plan to view the network. The URL that issuers provide to HHS for publication on HealthCare.gov for QHPs in an FFE should link directly to the applicable provider directory. If it does not, it should link to a list of the issuer’s provider directories, and it should be readily discernible to a consumer which directory applies to which QHP.

Comment: Some commenters supported the proposal for issuers to make available provider information in a machine-readable file and format specified by HHS, citing that this would improve transparency and support informed consumer decision-making without burdening issuers. Conversely, some commenters opposed the proposal and voiced concerns about data accuracy, including how HHS would hold third parties accountable for data errors, and cost. Some commenters stated that if data are not frequently updated, consumers could receive inaccurate information, upon which they might rely to select a QHP, while other commenters were concerned that frequent updating would be burdensome to issuers. Some commenters also noted that implementing any standard could be time-consuming and requested the opportunity to provide additional feedback. A number of commenters provided suggestions regarding the format, structure, file type, and content of the data they believe should be collected. Some commenters also suggested that any machine-readable databases should be accessible through an API.

Response: We believe a machine-readable file or a format specified by HHS will increase transparency by allowing software developers to access

this information and create innovative and informative tools to help enrollees better understand the plan's provider network. Based on the comments received asking us to make provider information more transparent and accessible to consumers, HHS is finalizing this rule by adding § 156.230(c), to require QHP issuers in the FFEs to make available the information on the provider list on its Web site in a HHS specified format and also submit this information to HHS, in a format and at times determined by HHS. We agree with commenters that creating a vehicle for consumers to easily determine which providers are in which networks will help consumers select QHPs that best meet their needs. We recognize that this will require issuer resources, and will provide further details about the specific data elements, frequency of updates, file types, and other crucial information in future guidance.

Comment: Commenters supported having issuers list detailed information in provider directories about physical accessibility for individuals with disabilities to help consumers choose plans and providers. Some sought information about exam table access, transfer assistance, and wheelchair access. One commenter urged caution in this area out of concern that including information on accessibility features for certain providers could be read to imply that other providers need not offer such features, even though they are legally obligated to do so pursuant to the Americans with Disabilities Act and section 504 of the Rehabilitation Act.

Response: We appreciate the complexity of this topic, and do not intend to issue additional regulation on this topic at this time. We urge all issuers and providers to continue to ensure that they are providing full and equal access to all covered services to all enrollees, including those people with disabilities, and we remind them of the obligation to adhere to the requirements of the Americans with Disabilities Act and section 504 of the Rehabilitation Act. Issuers are

encouraged to consult relevant Department of Justice guidance on accessibility of medical providers and effective communications at www.ada.gov. We will continue to monitor this issue.

d. Essential Community Providers (§ 156.235)

At § 156.235, we proposed to strengthen the essential community provider (ECP) standard in accordance with section 1311(c)(1)(C) of the Affordable Care Act, which requires that a QHP's network include ECPs, where available, that serve predominantly low-income and medically underserved populations. As established in section 1311(c)(1)(C) of the Affordable Care Act, ECPs include entities defined in section 340B(a)(4) of the PHS Act and providers described in section 1927(c)(1)(D)(i)(IV) of the Act as set forth by section 211 of Pub. L. 111–8. Additionally, we proposed that ECPs may include not-for-profit or State-owned providers that would be entities described in section 340B of the PHS Act but do not receive Federal funding under the relevant section of law, as these providers satisfy the same 340B requirements and therefore meet the definition of ECPs by virtue of the following description in section 1311(c)(1)(C) of the Affordable Care Act—health care providers defined in section 340B(a)(4) of the PHS Act and providers in section 1927(c)(1)(D)(i)(IV) of the Act. For the same reasons described above, we proposed that such providers also include not-for-profit or governmental family planning service sites that do not receive a grant under Title X of the PHS Act. Other providers that provide health care to populations residing in low-income zip codes or Health Professional Shortage Areas could also be considered ECPs. We proposed that the above proposals apply to benefit years 2016 and thereafter.

To assist issuers in ensuring that, in future QHP certification years, they are providing sufficient consumer access to ECPs to satisfy the requirement in section 1311(c)(1)(C) of the Affordable Care Act, we also proposed in new

paragraph (a)(2)(i) of this section that, for QHP certification cycles beginning with the 2016 benefit year, a health plan seeking certification to be offered through an FFE must satisfy the general ECP standard described in paragraph (a)(1) of this section by demonstrating in its applications for QHP certification that a sufficient percentage, as determined annually by HHS and specified in HHS guidance, of available ECPs in the plan's service area have a contractual agreement to participate in the plan's provider network. For purposes of this general ECP standard, we proposed that multiple providers at a single location would count as a single ECP toward the issuer's satisfaction of the proposed ECP participation standard. Any update to the general ECP inclusion standards would be based on HHS's post-certification assessments of the adequacy of ECP participation, and geographic distribution of such providers, and evidence of contractual negotiation efforts provided by issuers in the ECP supplemental response forms.

In addition, we proposed in paragraph (a)(2)(ii) of this section that, to satisfy the general ECP standard, the issuer of the plan seeking certification as a QHP in an FFE would be required to offer contracts for participation in the plan for which a certification application is being submitted to the following: (1) All available Indian health providers in the service area, applying the special terms and conditions necessitated by Federal law and regulations as referenced in the recommended model QHP addendum for Indian health providers developed by HHS; and (2) at least one ECP in each ECP category (see Table 11) in each county in the service area, where an ECP in that category is available and provides medical or dental services that are covered by the issuer plan type. We expect that issuers will offer contracts in good faith. A good faith contract offer should offer the same rates and contract provisions as other contracts accepted by or offered to similarly situated providers that are not ECPs.

TABLE 11—ECP CATEGORIES AND TYPES IN FFEs

Major ECP category	ECP provider types
Federally Qualified Health Centers (FQHC).	FQHC and FQHC “Look-Alike” Clinics, ⁶⁴ Outpatient health programs/facilities operated by tribes, tribal organizations, programs operated by Urban Indian Organizations.
Ryan White Providers	Ryan White HIV/AIDS Providers.
Family Planning Providers	Title X Family Planning Clinics and Title X “Look-Alike” Family Planning Clinics. ⁶⁵
Indian Health Care Providers	Tribes, Tribal Organization and Urban Indian Organization Providers, Indian Health Service Facilities.
Hospitals	Disproportionate Share Hospital (DSH) and DSH-eligible Hospitals, Children's Hospitals, Rural Referral Centers, Sole Community Hospitals, Free-standing Cancer Centers, Critical Access Hospitals.

TABLE 11—ECP CATEGORIES AND TYPES IN FFEs—Continued

Major ECP category	ECP provider types
Other ECP Providers	STD Clinics, TB Clinics, Rural Health Clinics, Black Lung Clinics, Community Mental Health Centers, Hemophilia Treatment Centers, and other entities that serve predominantly low-income, medically underserved individuals.

We proposed to add paragraph (a)(3) to this section to specify that if an issuer's QHP certification application to the FFE does not satisfy the ECP standard described in paragraph (a)(2) of this section, the issuer must include as part of its application a narrative justification describing how the provider network(s) of the plans for which certification applications have been submitted provides an adequate level of service for individuals residing in low-income zip codes or Health Professional Shortage Areas within the plan's service area and how the plan's provider network will be strengthened toward satisfaction of the ECP standard prior to the start of the benefit year. The narrative justification should include the following: The number of contracts offered to ECPs for the benefit year; the number of additional contracts the issuer expects to offer for the benefit year and the timeframe of planned negotiations; the names of the ECP hospitals FQHCs, Ryan White providers, family planning providers, Indian health providers, and other ECPs to which the issuer has offered contracts, but with whom an agreement has not yet been reached; and contingency plans for how the issuer's provider network(s), as currently designed, will provide adequate care to enrollees who might otherwise be cared for by relevant ECPs. Through HHS's post-certification assessments, HHS may examine an issuer's progress toward satisfying the applicable ECP standard to ensure that the issuer continues to qualify for offering its plan on the Exchange, while OPM would retain this responsibility for issuers of multi-State plans, acting in coordination with HHS as may be appropriate.

We proposed to redesignate current paragraph (a)(3) as paragraph (a)(4), in which we clarify that nothing in the requirements under paragraphs (a)(1) through (a)(3) of this section requires any QHP to provide coverage for any specific medical procedure. We also

proposed to redesignate current paragraph (a)(2) as paragraph (a)(5).

We proposed in paragraph (b)(1) that the alternate ECP standard described in § 156.235(a)(5) will apply to issuers with plans that provide a majority of covered professional services through physicians employed by the issuer or through a single contracted medical group that offer QHPs in any Exchange. Additionally, for plans seeking QHP certification in FFEs, we proposed that a QHP issuer described in paragraph (a)(5) of this section be determined to have a sufficient number and geographic distribution of employed or contracted providers by demonstrating in its QHP application that the number of its providers in the following locations meets a percentage specified in HHS guidance of the number of available ECPs in the service area: (i) Located within a Health Professional Shortage Areas; or (ii) located within five-digit zip codes in which 30 percent or more of the population falls below 200 percent of the Federal Poverty Line. For purposes of this alternate ECP standard, multiple providers at a single location will count as one ECP toward the available ECPs in the plan's service area and toward the issuer's satisfaction of the proposed ECP participation standard to ensure a sufficient number and geographic distribution of ECPs as required under § 156.235(a). Any modification to the alternate ECP inclusion standard in future benefit years would be based on HHS's post-certification assessments of the adequacy of ECP participation and geographic distribution of such providers to ensure reasonable and timely access to such ECPs for low-income, medically underserved individuals.

Furthermore, we proposed in new paragraph (b)(3) of this section that if a QHP certification application of a plan for the FFE does not satisfy the alternate ECP standard described in paragraph (b)(2) of this section, the issuer must include as part of its QHP application a narrative justification describing how the issuer's provider network(s) provides an adequate level of service for low-income and medically underserved enrollees. When assessing whether an issuer has provided a satisfactory narrative justification under either the

general or alternate ECP standard, as applicable, HHS will take into account factors and circumstances identified in the ECP Supplemental Response Form,⁶⁶ along with an explanation of how the issuer will provide access for individuals residing in low-income zip codes or Health Professional Shortage Areas within the plan's service area and how the plan's provider network will be strengthened toward satisfaction of the ECP standard prior to the start of the benefit year. Additionally, justifications that include verification of contracts offered in good faith, that include terms that a willing, similarly-situated, non-ECP provider would accept or has accepted, would be considered toward satisfaction of the ECP standard.

Finally, we proposed in paragraph (c) of this section to remove the language defining ECPs as meeting the criteria on the initial date of the regulation's publication. We proposed this change in recognition of the fact that the universe of ECPs, as well as the databases we use to delineate this universe, may vary over time for many reasons, including demographic and provider characteristics. We requested comment on these proposed changes. We are now finalizing these changes with modifications. The final rule specifies in regulation text that entities that could receive funding under Title X and 340B are ECPs, clarifies the application to SADPs, clarifies standards related to covered services, and clarifies the standard for integrated delivery systems.

Comment: A number of commenters supported the clarification that ECPs include not-for-profit or State-owned providers that would be entities described in section 340B of the PHS Act but do not receive Federal funding under the relevant section of law, including not-for-profit or governmental family planning service sites that do not receive a grant under Title X of the PHS Act. These commenters urged that HHS include this clarification in the regulation text. Some commenters recommended that we provide clear language to States and issuers indicating that Indian health providers are among

⁶⁴ For more information on FQHC "Look-Alike" Clinics, see <http://bphc.hrsa.gov/about/lookalike/index.html> and section 1861(a)(4) and section 1905(l)(2)(B) of the Act.

⁶⁵ For more information on Title X "Look-Alike" Clinics, see section 1927(c)(1)(D)(i)(IV) of the Social Security Act.

⁶⁶ More information on the supplemental response can be found on the CCIIO Web site at: <http://www.cms.gov/ccio/programs-and-initiatives/health-insurance-marketplaces/qhp.html>.

the ECP groups to which issuers must extend contract offers in good faith to satisfy § 156.235(a) of the ECP standard.

Response: Based on the comments received, we are codifying the inclusion of the following entities in the definition of an ECP in § 156.235(c): Not-for-profit or State-owned providers that would be entities described in section 340B of the PHS Act but do not receive Federal funding under the relevant section of law; not-for-profit or governmental family planning service sites that do not receive a grant under Title X of the PHS Act; and Indian health care providers. Effective January 1, 2016, we are making this modification to emphasize that these providers are among the ECP groups to which issuers must extend contract offers in good faith to satisfy § 156.235(a).

Comment: Several commenters recommended that HHS clarify that providers located in low-income zip codes or HPSAs must also serve predominately low-income, medically underserved individuals to satisfy the definition of an ECP.

Response: We agree with commenters. In alignment with the regulatory definition of an ECP at § 156.235(c), we emphasize that a provider must actually serve predominantly low-income, medically underserved individuals to be considered an ECP, and not simply be located in low-income zip codes or HPSAs.

Comment: We received a few comments expressing concern that removal of the language defining ECPs as meeting the criteria on the initial date of the regulation's publication risks the stability in the number and scope of ECPs and carries the risk that States, Exchanges, and other entities will attempt to limit the providers identified as an ECP.

Response: While we understand the commenters' desire for providers to retain a designated ECP status as of the initial date of the regulation's publication, such a policy could conflict with the statutory definition of an ECP if interpreted to extend past the reexamination period for determining continued eligibility of such providers on the list. To avoid any such misinterpretation, we proposed removing this language from § 156.235(c) to clarify that such providers must continue to qualify each benefit year as providers that serve predominantly low-income, medically underserved individuals to retain their ECP status on the list each year. Therefore, we are finalizing this provision as proposed, effective January 1, 2016.

Comment: We received a number of comments in support of our proposal that a health plan seeking QHP certification to be offered through an FFE must satisfy the general ECP standard by demonstrating in its applications for QHP certification that a sufficient percentage, as determined annually by HHS and specified in HHS guidance, of available ECPs in the plan's service area have a contractual agreement to participate in the plan's provider network. Some of these commenters urged that we increase the percentage each year beyond the existing 30 percent requirement. Some commenters urged that we set a minimum percentage requirement in the regulation text and encourage plans to include a greater number of ECPs in their networks as a part of ensuring access and continuity of care. One commenter pointed out that some States have implemented much higher ECP inclusion percentage standards.

In contrast, one commenter stated that the QHPs lack complete information to adequately identify the universe of ECPs. Furthermore, the commenter stated that the ECP lists provided to issuers in the past have included providers that either do not provide medical services or include inaccurate provider information. The commenter recommended that HHS improve the utility of ECP information by including National Provider Identifiers (NPIs) in their database of ECPs, and by publishing any revised ECP lists prior to the anticipated QHP application submission deadline and with any modifications made apparent to allow issuers to easily reconcile the HHS ECP list with their internal records. Some commenters recommended that SADP issuers be exempt from the ECP inclusion standard given that certain elements of the ECP requirements are less suited for dental issuers than medical issuers, and suggested that CMS instead require SADPs to provide evidence of offering meaningful access to lower income enrollees in their service areas.

Response: Based on our QHP certification reviews for the 2015 benefit year and the ongoing strengthening of our ECP list, we believe that specifying the ECP inclusion percentage in HHS guidance for the 2016 benefit year provides desirable flexibility at this time for HHS to further examine the adequacy of this inclusion standard for ensuring access to care for low-income, medically underserved individuals for future years. Furthermore, we agree with the recommendation that the accuracy of the ECP list be improved prior to increasing the ECP inclusion

percentage standard. To this effect, we have recently published a draft ECP list for the 2016 benefit year⁶⁷ and solicited public comments in an effort to make corrections to the list and publish the list prior to the anticipated QHP application submission deadline. In response to comments, we also intend to make apparent the modifications to the list to allow issuers to easily reconcile the HHS ECP list with their internal records. We will further examine the feasibility of the commenter's recommendation to add NPIs to the ECP list in future years in coordination with our Federal partners from whom we collect the provider data.

Regarding the commenters' recommendation to exempt SADPs from the ECP inclusion standard, we proposed to modify the ECP requirement at § 156.235(a)(2)(ii)(B) to clarify that only the providers in the ECP categories that provide dental services would be considered available for an SADP's offering of a contract. In other words, we have added "and provides medical or dental services that are covered by the issuer plan type" to the end of that paragraph to ensure the applicability of this provision to SADPs. Given that this was the only ECP provision unsuited for SADPs, we believe we have addressed the need for its suitability by making this proposed modification, and are finalizing this language as proposed, effective January 1, 2016.

Comment: We received comments in support of our proposal that an issuer's satisfaction of the ECP inclusion percentage of available ECPs in the plan's service area be calculated based on multiple providers at a single location counting as a single ECP toward both the available ECPs in the plan's service area and the issuer's satisfaction of the ECP participation standard, stating that the proposal would help ensure access to a broad range of provider types and geographic distribution of ECPs for low-income, medically underserved individuals. However, several commenters suggested that counting multiple providers at a single location as only a single ECP may overlook availability of different services, and recommended that HHS count multiple providers at a single location as multiple ECPs toward satisfaction of the ECP inclusion percentage standard. One commenter contended that such a policy would undermine the ability of integrated

⁶⁷ http://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Description-and-Purpose-of-Draft-HHS-List-of-ECPs-for-PY-2016_12-24-14.pdf.

delivery systems to provide high levels of consistent, quality care.

Response: We believe it is important to clarify the underlying rationale for this proposed provision. At § 156.235(a)(1) and (b)(1), we have established that a QHP issuer that satisfies the ECP inclusion standard must include a sufficient number and geographic distribution of ECPs in its provider network, or through its employed providers and hospital facilities if the issuer qualifies for the alternate ECP standard described at § 156.235(b). Therefore, we believe that our proposed provision is critical for ensuring that issuers satisfy both the sufficient number and geographic distribution requirements by not concentrating the majority of its providers at only one or a few locations. Furthermore, such an accounting of multiple providers at a single location aligns with the crediting of an issuer's inclusion of provider facilities on the available HHS ECP list, which includes practices and clinics, which generally consist of multiple providers at a single location. While such a policy may reduce the number of credited ECPs for an issuer, to the extent that multiple provider types practice at a given location and may map to different ECP categories, these different provider types could contribute to satisfying the requirement that an issuer offer a contract to at least one ECP in each category in each county in the plan's service area for multiple ECP categories. In response to issuers that qualify for the alternate ECP standard, as defined at § 156.235(a)(5), and commenters' concern that such a policy might be disruptive to an integrated delivery system, the narrative justification provision at § 156.235(b)(3) ensures that such issuers comply with the ECP inclusion standard by describing how the plan's provider networks provide an adequate level of service for low-income enrollees or individuals residing in HPSAs within the plan's service area. After careful consideration of the public comments applicable to issuers that qualify for both the general and alternate ECP standards, we are finalizing our proposal that an issuer's satisfaction of the ECP inclusion percentage of available ECPs in the plan's service area be calculated based on multiple providers at a single location counting as a single ECP toward both the available ECPs in the plan's service area and the issuer's satisfaction of the ECP participation standard, effective January 1, 2016.

Comment: One commenter recommended that HHS require that issuers that qualify for the alternate ECP

standard, as defined at § 156.235(a)(5), that are unable to provide all of the categories of services provided by entities in each of the ECP categories in each county in the service area as outlined in the general ECP standard, be required to contract with outside providers or facilities that can provide those services to low-income, medically underserved individuals. In contrast, another commenter expressed concern that HHS's methodology for assessing the adequacy of ECP inclusion for issuers that provide the majority of their covered professional services through physicians employed by the issuer or through a single contracted medical group does not fit well for plans with well-established integrated care delivery systems. The commenter expressed concern that requirements to contract with outside providers that use different clinical protocols and thus have incomplete patient information and lack linkages for patients with chronic conditions, would fundamentally change how integrated delivery systems provide care to their patients and would undermine the ability of integrated care teams to provide high levels of consistent, quality care. The commenter contended that counting multiple providers at a single location as only one provider toward satisfaction of the alternate ECP standard is problematic for an entity that serves its members with large facilities and has systems in place (for example, telemedicine, etc.) that can serve members in a broad geographic area. This commenter urged CMS to better assess effectiveness of networks at delivering quality care, and rapid access.

Response: While we recognize the challenges for alternate ECP standard issuers that offer an integrated health care delivery system, we believe that consumers should experience equal access to covered benefits, regardless of whether they are enrolled in plans offered by issuers that qualify for the general or the alternate ECP standard. To ensure such equal access, issuers that qualify for the alternate ECP standard must provide access to the same categories of services provided by entities in each of the ECP categories in each county in the plan's service area as issuers that qualify for the general ECP standard. Therefore, effective January 1, 2016, we have modified our proposed provision at § 156.235(b)(2)(ii) to require issuers to provide within the issuer's integrated delivery system all of the categories of services provided by entities in each of the ECP categories in each county in the plan's service area as outlined in the general standard; or

otherwise offer a contract to at least one ECP outside of the issuer's integrated delivery system per ECP category in each county in the plan's service area that can provide those services to low-income, medically underserved individuals.

Comment: We received several comments recommending that CMS retain the requirement that QHP issuers offer contracts to all Indian health care providers in the QHP's service area. These commenters also urged that CMS require QHP issuers to use the recommended model QHP addendum, rather than our proposal to require that contract offers apply the special terms and conditions necessitated by Federal law and regulations as referenced in the recommended model QHP addendum. These commenters expressed concern that not requiring use of the actual model QHP addendum could result in loss of the following provisions in the executed QHP-Indian health care provider (ICHP) contracts: (1) A listing of each Indian-specific provision in Federal law that is applicable to the provider contract; and (2) a clear statement of the meaning of each applicable Indian-specific provision.

Response: We believe the requirement that issuers apply the special terms and conditions necessitated by Federal law and regulations as referenced in the recommended model QHP addendum, along with encouraging issuer use of the recommended model QHP addendum in guidance, strikes the desirable balance between allowing the minimal flexibility that issuers have requested while ensuring inclusion of the fundamental provisions of the model QHP addendum within the issuer contractual offers to the Indian health providers. Therefore, while we strongly encourage issuers to use the model QHP Addendum, we are not requiring that they do so. We are finalizing, effective January 1, 2016, our proposal requiring that health plans seeking certification as a QHP in an FFE offer contracts for participation in the plan for which a certification application is being submitted to all available Indian health providers in the service area, applying the special terms and conditions necessitated by Federal law and regulations as referenced in the recommended model QHP addendum for Indian health providers developed by HHS.

Comment: One commenter recommended that if issuers met the ECP standard in the previous year, issuers not be required every year to offer contracts to all Indian health care providers in the service area and to at

least one ECP in each ECP category in each county in the service area.

Response: We share the commenter's interest in minimizing contracting burden on both issuers and providers; however, given the dynamic nature of the health insurance industry, we believe that a contract denial the previous year should not carry over to future years. Therefore, we are finalizing, effective January 1, 2016, our proposal that health plans seeking certification as a QHP in an FFE offer contracts for participation in the plan for which a certification application is being submitted to all available Indian health providers in the service area. Satisfaction of this requirement in previous years does not exempt a QHP from satisfying the requirement for future QHP application years.

Comment: Several commenters urged CMS to encourage application of the ECP inclusion requirement, including the requirement that issuers offer contracts to all Indian health providers, to issuers operating in State Exchanges, as well to issuers operating in the FFEs.

Response: We urge State Exchanges to employ the same standard when examining adequacy of ECPs as outlined in § 156.235, including the requirement that issuers offer contracts to all Indian health providers in the plan's service area.

Comment: A number of commenters urged that we require issuers to actually contract, as opposed to offer a contract, with at least one ECP in each ECP category in each county in the service area, where an ECP in that category is available and provides medical or dental services that are covered by the issuer plan type. Several commenters urged that we require issuers to offer contracts to all available ECPs in the plan's service area. A few commenters suggested that we require that issuers offer contracts to at least two ECPs in each ECP category in each county in the service area, where an ECP in that category is available and provides medical or dental services that are covered by the issuer plan type.

Several commenters supported the inclusion of Rural Health Clinics (RHCs) and Community Mental Health Centers in the ECP category listing in Table 11 of the preamble. Commenters expressed concern, though, that the requirement that QHPs offer contracts to at least one ECP in each ECP category in each county in the plan's service area is a county-based requirement, and suggested that the requirement be based on time and distance within the county.

A few commenters urged that we add freestanding birth centers located in medically underserved and rural areas

as a new ECP category. Several commenters recommended that we list Hemophilia Treatment Centers as a separate ECP category, rather than grouped in the "Other ECP Providers" category. Another commenter suggested that we add migrant and community health centers as an ECP category. One commenter urged that HHS require issuers to offer a contract to any willing Ryan White provider. One commenter suggested adding dental providers, substance abuse and mental health providers, children's hospitals, and essential pediatric providers to the list of ECP categories.

Several commenters suggested that HHS disaggregate the providers listed in the "Hospitals" ECP category and the "Other ECP Providers" category. These commenters expressed concern that by grouping together providers such as Hemophilia Treatment Centers, Community Mental Health Centers, and Rural Health Clinics into one ECP category such that issuers are only required to offer a contract to one of these and other types of providers in a given county, HHS runs the risk that low-income, underserved enrollees will have inadequate access to key providers that are uniquely suited to meet their specialized health needs. Another commenter urged that HHS identify Nurse Managed Clinics within the providers listed in the ECP categories in Table 11 of the preamble, stating that they are primary care clinics similar to the FQHCs, but with a different funding source.

One commenter recommended that we remove Indian health care providers as a major ECP category due to the overlapping requirement that issuers offer contracts to all Indian health providers in the service area.

Numerous commenters urged HHS to continually monitor for issuer maintenance of their networks throughout the year to ensure that issuers do not discriminate against ECPs through contract negotiations, and to make sure contracts are offered in good faith. One commenter urged that HHS consider not just the number of ECPs included and their geographic distribution, but also the breadth of services they provide and the type of ECP providers and facilities that the networks include.

Response: Given the ongoing strengthening of the non-exhaustive HHS List of ECPs (available at <http://www.cms.gov/ccio/programs-and-initiatives/health-insurance-marketplaces/qhp.html>), we intend to revisit this requirement to offer contracts in good faith and may

consider a stronger requirement in future benefit years.

In response to comments regarding the groupings of provider types in the ECP categories, we agree with the need to disaggregate several of these categories over time to ensure better access to a wider variety of health care services. More specifically, we considered modifying the ECP category listing to include a total of 11 ECP categories, by creating a separate ECP category each for children's hospitals and free-standing cancer centers, and disaggregating hemophilia treatment centers, community mental health centers, and rural health clinics from the "Other ECP Providers" category. However, because we recognize that issuers are in the process of finalizing their networks for 2016, we intend to propose this reclassification for 2017. We are not removing the Indian health care providers as a major ECP category, notwithstanding the overlapping requirement that issuers offer contracts to all Indian health care providers in the service area, because many providers and issuers rely on Table 11 to identify the universe of ECP types. In response to public comments supporting the inclusion of rural health clinics and Community Mental Health Centers as ECP provider types within the "other ECP providers" category, we are finalizing our proposal to include these provider types in our ECP category listing in Table 11, although we will not disaggregate them into their own separate ECP categories at this time.

For purposes of inclusion on the non-exhaustive HHS list of ECPs, we are clarifying that only those Medicare-certified rural health clinics that meet the following two requirements qualify: (1) Based on attestation, the clinic accepts patients regardless of ability to pay and offers a sliding fee schedule, or is located in a primary care Health Professional Shortage Area (whether geographic, population, or automatic⁶⁸);

⁶⁸ As of January 1, 2014, more than 1,000 rural health clinics (RHCs) were designated as an automatic Health Professional Shortage Area (HPSA), the criteria for which include accepting patients regardless of ability to pay; offering a sliding fee schedule based on ability to pay (income); and accepting Medicare, Medicaid, CHIP and private health insurance patients. To receive the automatic HPSA designation, each RHC is required to complete an attestation form, which is available at: <http://bhpr.hrsa.gov/shortage/hpsas/certofeligibility.pdf>. CMS intends to include RHCs that are not listed on the current non-exhaustive ECP list and complete the attestation form to receive an automatic HPSA designation through the Health Resources and Services Administration in future non-exhaustive ECP lists. More information about the HPSA designation requirements and process is also available at: <http://bhpr.hrsa.gov/shortage/hpsas/ruralhealthhpsa.html>.

and (2) accepts patients regardless of coverage source (whether Medicare, Medicaid, CHIP, private health insurance, or other source). HHS has determined that all rural health clinics included on the non-exhaustive HHS list of ECPs satisfy these standards.

Lastly, we agree with commenters regarding the importance of monitoring issuer compliance with this important provision of our ECP standard, and intend to continue our post-certification monitoring activities to help ensure that consumers have access to the essential health benefits guaranteed to them under the Affordable Care Act. Therefore, we are finalizing our proposal, effective January 1, 2016, that a health plan seeking certification as a QHP in an FFE be required to offer contracts for participation in the plan for which a certification application is being submitted to at least one ECP in each ECP category in each county in the service area, where an ECP in that category is available and provides medical or dental services that are covered by the issuer plan type.

Comment: Some commenters recommended that we eliminate the option for an issuer to submit a narrative justification in cases where a plan's network does not meet the minimum ECP percentage requirement. Many of these commenters expressed concern that the narrative justification might be accepted in lieu of issuer compliance with the ECP inclusion percentage requirement specified by HHS. Commenters suggested that the narrative justification is inadequate in cases where an issuer fails to meet the minimum ECP percentage standard and suggested that issuers be required to contract with all available ECPs. These commenters also recommended that HHS make publicly available the narrative justifications submitted when issuers do not meet the minimum ECP percentage standard or other requirements of the ECP standard.

Some commenters stated that if HHS permits issuers to continue submitting narrative justifications when unable to satisfy the statutory ECP requirements, HHS should only allow the justifications in extremely rare circumstances, and issuers should be required to provide a reason for why the plan has failed to satisfy the standard to discourage plans from seeking an exemption when unwarranted.

Several commenters supported the requirement that QHPs not meeting the ECP standard must submit a justification describing how the plan's provider network is adequate for low-income enrollees in HPSAs. One of these commenters suggested that HHS

clarify that this requirement extends to SADPs, as well.

Response: Based on our QHP certification reviews for the 2015 benefit year and the ongoing strengthening of our ECP list, we believe that the narrative justification provides desirable flexibility at this time for HHS to further assess the adequacy of our ECP inclusion standard, given the need to provide issuers with the flexibility to develop networks that deliver benefits at an affordable price to low-income, medically underserved individuals. At the same time, the vast majority of issuers are complying with the requirements without submission of a narrative justification, and therefore we believe this option is being used under relatively rare circumstances. Regarding the suggestion to make publicly available the narrative justifications submitted when issuers do not meet the ECP inclusion percentage, HHS will consider the feasibility of providing such increased transparency over the next year. We expect the need for issuers to submit such justifications to decrease over time as issuers further develop their networks in adherence to HHS standards. Lastly, we clarify that the narrative justification standard applies to SADPs as well as QHPs that provide medical services.

Comment: One commenter expressed concern that the language under § 156.235(a)(4) (that is, "Nothing in paragraphs (a)(1) through (a)(3) of this section requires any QHP to provide coverage for any specific medical procedure provided by an ECP") might be interpreted by issuers as permitting discrimination regarding which covered services among those provided by an ECP it will contract with the ECP to provide. The commenter pointed out that section 1311(c)(1)(C) of the Affordable Care Act regarding the inclusion of ECPs in QHP networks states that nothing in this subparagraph shall be construed to require any health plan to provide coverage for any specific medical procedure. The commenter expressed concern that our proposed regulation adds the additional language "provided by an ECP" that could permit issuers to contract with ECPs for only some, but not all, of the services for which they are licensed and otherwise fully able to provide in accordance with the same standards that the QHP applies to other non-ECP providers. This commenter urged HHS to remove the additional language from the regulatory text and clarify that, when contracting with ECPs, QHPs must do so for the full scope of services that the ECPs are licensed to provide.

Response: We agree with the commenter in part, and so we are removing the additional language "provided by an ECP" from § 156.235(a)(4), effective January 1, 2016. However, we emphasize that we are not requiring that QHPs contract with ECPs for the full scope of services that the ECPs are licensed to provide; rather, we are continuing to require only that they offer the same contract provisions as other contracts accepted by or offered to similarly situated providers.

Comment: One commenter recommended that HHS modify the language at § 156.235(d) to reflect the language used in the preamble to ensure that issuers offer ECPs rates comparable to other providers. Specifically, the commenter suggested that we replace the language ". . . if such provider refuses to accept the generally applicable payment rates of such issuer," and replace it with language that reads ". . . if such provider refuses to accept the same rates and contract provisions as included in contracts accepted by similarly situated providers that are not ECPs." The commenter noted that this would provide a clearer definition of an issuer's "generally applicable payment rates" and would prevent issuers from discriminating against ECPs in their payment rates.

Response: We agree with the commenter that such clarification would help prevent issuers from discriminating against ECPs in their payment rates and would align with the language used in our preamble. Therefore, we are making this change at § 156.235(d), effective January 1, 2016.

Comment: Several commenters urged that we retain the requirement that QHP issuers offer contracts in good faith. However, these commenters urged that HHS clarify that a minimum payment rate provision be required rather than expected, and that we include such a requirement in the regulation rather than in only the preamble.

Response: We do not intend to prescribe such specificity regarding contract negotiations between parties. Therefore, we are not requiring a minimum payment rate provision, and instead reiterate our expectation that QHP issuers offer contracts in good faith.

e. Meaningful Access to Qualified Health Plan Information (§ 156.250)

In the proposed rule, we proposed to amend § 156.250 to replace the cross-reference to the Exchange application and notices provision at § 155.230(b) with a cross-reference to § 155.205(c). We also proposed to change the title of

the provision to “Meaningful access to qualified health plan information” for improved clarity. As discussed above, amendments to § 155.205(c) for oral interpretation services were also proposed.

We also proposed to extend the requirements of § 156.250 so that not only applications and notices to enrollees, but all information that is critical for obtaining health insurance coverage or access to health care services through the QHP to qualified individuals, applicants, qualified employers, qualified employees, and enrollees, would be provided in a manner consistent with § 155.205(c). In addition, using the summary of benefits and coverage (SBC) disclosure required under § 147.200 as an example, we proposed that information would be deemed to be critical for obtaining health insurance coverage or access to health care services if the issuer were required by State or Federal law or regulation to provide the document to a qualified individual, applicant, qualified employer, qualified employee, or enrollee. We also indicated that, based on our proposed standard, we would consider information that is critical for obtaining health coverage or access to health care services to include: Applications; consent, grievance, appeal, and complaint forms; notices pertaining to the denial, reduction, modification, or termination of services, benefits, non-payment, or coverage; a plan’s explanation of benefits or similar claim processing information; QHP ratings information; rebate notices; correspondence containing information about eligibility and participation criteria; notices advising individuals of the availability of free language assistance; and letters or notices that require a signature or response from the qualified individual, applicant, qualified employer, qualified employee, or enrollee. We stated that we would not consider marketing materials that are available for advertising purposes only and not otherwise required by law to be critical for obtaining health insurance coverage or access to health care services through the QHP, and therefore an issuer would not be required to be make such materials accessible to individuals with disabilities or limited English proficiency.

We are finalizing this provision as proposed.

Comment: Commenters expressed general support for our proposal, including our proposed standard for determining whether a document was “critical” such that an issuer would be required to provide meaningful access to it in accordance with the standards

set forth in § 155.205(c). A few commenters requested that we specifically acknowledge other documents, such as evidences of coverage, or information needed to understand coverage, provider networks, or enrollment or re-enrollment processes, as meeting the standard. One commenter expressed concern that our identification in preamble of certain documents that we would consider to meet the standard was misplaced. The commenter stated that certain documents we had identified, such as “rebate notices” (concerning medical loss ratio requirements) and “any letter or notice requiring a signature or response,” were not inherent to obtaining services through the QHP or accessing health coverage.

Response: We are finalizing the provision as proposed. Therefore, QHP issuers must provide all information that is critical for obtaining health insurance coverage or access to health care services through the QHP, including applications, forms, and notices, to qualified individuals, applicants, qualified employers, qualified employees, and enrollees in accordance with the standards described in § 155.205(c). Information will be deemed to be critical for obtaining health insurance coverage or access to health care services if the issuer is required by Federal or State law or regulation to provide the document to a qualified individual, applicant, qualified employer, qualified employee, or enrollee. We agree that evidences of coverage, group certificates of coverage, contracts of insurance, benefits summaries, policies, formulary drug lists, provider directories, and other similar documents that are relied upon by individuals to understand their benefits and the full terms of coverage of the QHP are critical for obtaining health care services through the QHP and therefore must be provided by the issuer in a manner that satisfies the requirements in § 155.205(c). In addition, given the general significance of information, such as an MLR rebate notice, that a QHP issuer is required by Federal or State law or regulation to communicate to consumers, we believe it is appropriate to require a QHP issuer to provide meaningful access to such legally required information to all consumers in a manner that conforms to § 155.205(c) so that all consumers serviced by the QHP issuer can access and understand the legal rights or duties that are frequently discussed in such communication. With respect to our interpretation stated in the preamble to

the proposed rule that our proposed standard would include any document provided by the issuer that requires a response or signature from the qualified individual, applicant, qualified employer, qualified employee, or enrollee, in our view, these documents, by requiring a signature or response, typically confer an agreement or important acknowledgement regarding benefits or claims payment which an individual must be able to access and affirmatively understand. Thus, we believe consumers receiving such documents from a QHP issuer should have meaningful access to this information within the meaning of § 155.205(c).

As we noted in the preamble to the proposed rule, we consider the SBC to be a document subject to § 156.250 for which a QHP issuer must provide meaningful access in accordance with the standards of § 155.205(c). As such, like any document that is considered to be “critical” within the meaning of § 156.250, in accordance with § 155.205(c)(2)(iii)(A), beginning no later than the first day of the Exchange individual market open enrollment period for the 2017 benefit year, a QHP issuer is required to include taglines with any SBC that reflects a QHP option or plan variation of a standard QHP option in the top 15 languages spoken by the LEP population in the applicable State. An issuer may satisfy this requirement if it includes a cover letter or other additional pages provided along with the SBC that contains all required taglines. In addition, in accordance with § 155.205(c)(2)(i), beginning when this rule takes effect, a QHP issuer is required to provide telephonic interpreter services in at least 150 languages with respect to any SBC that reflects a QHP option or plan variation of a standard QHP option. Because the requirements with respect to oral interpretation and taglines that are finalized in this rule are different in substance than those that apply generally to the SBC under § 147.200(a)(5) (which cross-references the internal claims and appeals and external review processes standards at § 147.136(e)), we clarify that these additional specific standards supplement the existing “ten percent county-level” language access standards in § 147.200(a)(5).⁶⁹ For example,

⁶⁹ Under § 147.200(a)(5), a plan or issuer is considered to provide the SBC in a culturally and linguistically appropriate manner if the thresholds and standards of § 147.136(e), implementing standards for the form and manner of notices related to internal claims appeals and external review, are met as applied to the SBC. When we

whereas the existing standards under § 147.136(e) require QHP issuers to provide taglines and oral language services with respect to an applicable non-English language spoken by a given LEP population that comprises ten percent or more of the total population residing in the applicable county, QHP issuers must also provide taglines on the SBC (or in a cover letter or other additional pages included with the SBC) in the top 15 non-English languages spoken by the LEP population in the relevant State as well as provide telephonic interpreter services in at least 150 languages with respect to any SBC that reflects a QHP option or plan variation of a standard QHP option. We note that based on an analysis of current data, the top 15 languages Statewide standard described in § 155.205(c)(2)(iii) will yield any language that is triggered by the county-level standards in § 147.136(e)(3).⁷⁰ In addition, under § 147.136(e)(2)(ii), a QHP issuer is still required to provide, upon request, a translated version of the SBC in an applicable non-English language if at least ten percent of the population in the applicable county is comprised of an LEP population that is literate in the same non-English language.

We make one clarification regarding our reference to “QHP ratings information.” By using this term, we intended to refer to the Quality Rating System and QHP Enrollee Experience Survey results established under sections 1311(c)(3) and (c)(4) of the Affordable Care Act. However, we recognize that this information, when available, is required to be displayed by Exchanges on the Exchange Web site, rather than by a QHP issuer directly. Therefore, unless a QHP issuer is required by other Federal or State law or regulation to provide QHP ratings information directly to consumers, that information would not be subject to § 156.250. A QHP issuer voluntarily providing the information to consumers is encouraged, but not required, to provide it in a manner that conforms to § 155.205(c).

Finally, though we do not consider marketing materials that are available

for advertising purposes only and not otherwise required by law to be critical for obtaining health insurance coverage or access to health care services through the QHP, we remind issuers that they might have duties to make these materials accessible to individuals with disabilities and individuals with LEP under Federal civil rights laws that also might apply, including section 1557 of the Affordable Care Act, section 504 of the Rehabilitation Act of 1973, and Title VI of the Civil Rights Act of 1964.

f. Enrollment Process for Qualified Individuals (§ 156.265)

Sections 155.240 and 155.400 explicitly authorize Exchanges to establish certain requirements related to premium payment for enrollment in QHPs through the Exchange. Section 156.265 currently only cross-references § 155.240. To clarify that both sets of requirements apply to QHPs, we proposed that a QHP issuer must follow the premium payment process established by the Exchange in accordance with § 155.240 and the payment rules established in § 155.400(e).

We did not receive comments concerning the proposed enrollment process provisions. We are finalizing the provisions proposed in § 156.265 of the proposed rule without any modifications.

g. Termination of Coverage or Enrollment for Qualified Individuals (§ 156.270)

We are finalizing revisions in this section to conform to our interpretation of the guaranteed availability and guaranteed renewability requirements. For a discussion these revisions, please see the preamble for § 155.430.

h. Segregation of Funds for Abortion Services (§ 156.280)

Section 1303 of the Affordable Care Act and § 156.280 specify accounting and other standards for issuers of QHPs through the Exchange in the individual market that cover abortion services for which public funding is prohibited (also referred to as non-excepted abortion services). The statute and regulations establish that unless otherwise prohibited by State law, a QHP issuer may elect to cover such services. If an issuer elects to cover such services under a QHP sold through the individual market Exchange, the issuer must ensure that no premium tax credit or cost-sharing reduction funds are used to pay claims for abortion services for which public funding is prohibited.

In the proposed rule, we provided guidance on individual market

Exchange issuer's responsibilities for requirements related to QHP coverage of abortion services for which public funding is prohibited. HHS works with stakeholders, including States and issuers, to help them fully understand and follow the statutes and regulations governing the provision of health insurance coverage under a QHP through the Exchange. As is the case with many provisions in the Affordable Care Act, States and State insurance commissioners are the entities primarily responsible for implementing and enforcing the provisions in section 1303 of the Affordable Care Act related to individual market QHP coverage of non-excepted abortion services. OPM may issue guidance related to these provisions for multi-State plan issuers.

Under section 1303(b)(2)(B) of the Affordable Care Act, as implemented in § 156.280(e)(2)(i), individual market Exchange issuers must collect a separate payment from each enrollee, for an amount equal to the AV of the coverage for abortions for which public funding is prohibited. However, section 1303 of the Affordable Care Act and § 156.280 do not specify the method an issuer must use to comply with the separate payment requirement. As we described in the proposed rule, this provision may be satisfied in a number of ways. Several such ways include: Sending the enrollee a single monthly invoice or bill that separately itemizes the premium amount for non-excepted abortion services; sending a separate monthly bill for these services; or sending the enrollee a notice at or soon after the time of enrollment that the monthly invoice or bill will include a separate charge for such services and specify the charge. Section 1303 of the Affordable Care Act permits, but does not require, a QHP issuer to separately identify the premium for non-excepted abortion services on the monthly premium bill to comply with the separate payment requirement. A consumer may pay the premium payment for non-excepted abortion services and the separate payment for all other services in a single transaction, with the issuer depositing the two separate payments into the issuer's two separate allocation accounts as required by section 1301(b)(2)(C) of the Affordable Care Act, as implemented in § 156.280(e)(2)(ii) and (e)(3).

Section 1303(b)(2)(D) of the Affordable Care Act, as implemented in § 156.280(e)(4), establishes requirements for individual market Exchange issuers for how much they must charge each QHP enrollee for coverage of abortions for which public funding is prohibited. A QHP issuer must estimate the basic

refer to the “ten percent county-level” standards, we are referring to the standards set forth under § 147.136(e)(3), which states that with respect to an address in any United States county to which a notice is sent, a non-English language is an applicable non-English language if ten percent or more of the population residing in the county is literate only in the same non-English language, as determined in guidance published by the Secretary.

⁷⁰In the counties for which the ten percent threshold triggers an applicable non-English language, Spanish is triggered in the vast majority of cases. In a few counties, Tagalog, Navajo, or Chinese are also triggered. 79 FR 78587 (Dec. 30, 2014).

per enrollee, per month cost, determined on an average actuarial basis, for including coverage of non-excepted abortion services. In making this estimate, a QHP issuer may not estimate the basic cost of coverage for non-excepted abortion services to be less than \$1 per enrollee, per month. In the proposed rule and past guidance, we clarified that this means an issuer must charge each QHP enrollee a minimum premium of \$1 per month for coverage of non-excepted abortion services.

Comment: Some commenters supported enrollees paying premiums in one single transaction for both non-excepted abortion services and other health care services. Commenters requested clarification on the guidance provided in the proposed rule so enrollees will not receive multiple notices regarding separate premium amounts. These commenters stated that a single payment transaction without notice to the consumer would minimize administrative complexity for issuers. Other commenters requested that QHP issuers be prohibited from collecting the two separate payments for coverage for non-excepted abortion services and other health care services, respectively, in a single transaction (for example, having them combined in a single check), and instead require that they be separated by the enrollee. Commenters also recommended HHS clarify the guidance regarding itemizing the two premium amounts on monthly invoices and provide additional technical guidance on maintaining separate allocation accounts for non-excepted abortion services and all other services, along with enforcement mechanisms.

Response: The discussion of § 156.280 in the proposed rule of the separate payment requirement constituted clarifying guidance, and did not propose to modify existing requirements under section 1303 of the Affordable Care Act and § 156.280. We affirm the guidance in the proposed rule. This guidance offers QHP issuers several ways to comply with the requirements, while minimizing burden on QHP issuers and consumers.

i. Non-Renewal and Decertification of QHPs (§ 156.290)

We are finalizing revisions in this section to conform with our interpretation of the guaranteed availability and guaranteed renewability requirements. For a discussion of these revisions, please see the preamble for § 155.430. We are also correcting a typographical error by inserting the words “adhere to the” in § 156.290(a)(1).

4. Health Insurance Issuer Responsibility for Advance Payments of the Premium Tax Credit and Cost-Sharing Reductions

a. Plan Variations (§ 156.420)

In the proposed rule, we proposed to amend § 156.420 to add § 156.420(h) and require QHP issuers to provide SBCs that accurately represent plan variations in a manner consistent with the requirements set forth at § 147.200 to ensure that consumers have access to SBCs that accurately represent cost-sharing responsibilities for all coverage options, including plan variations, and are provided adequate notice of the plan variations.

We proposed that QHP issuers would be required to provide SBCs for plan variations no later than the first day of the next Exchange open enrollment period for the individual market for the 2016 benefit year, in accordance with § 155.410(e). We sought comments on whether the proposed applicability date would present implementation challenges for QHP issuers as well as on other aspects of the proposal. We also noted that QHP issuers would be required to provide the SBC in a manner that is consistent with the meaningful access requirements under § 155.205(c).

We are finalizing this provision as proposed, with one modification to specify that this standard will apply no later than November 1, 2015, which is the first day of the individual market open enrollment period for the 2016 benefit year.

Comment: Commenters expressed support for the proposal. Some commented that the proposal would better enable consumers who are eligible for cost-sharing reductions to take into account the overall out-of-pocket costs of a given QHP benefit package, rather than focusing primarily on premiums.

Response: We agree that requiring the provision of plan variation SBCs for individual market QHP options will increase the likelihood that consumers will select a plan option that is appropriate for both their financial and health care needs.

Comment: Commenters supported an implementation date of no later than the open enrollment period for the 2016 benefit year. Some commenters stated that issuers are already providing plan variation SBCs to enrollees and did not express opposition to our proposed implementation timeline. However, one commenter opposed the proposed implementation date because it did not believe issuers could receive State approval of their form filings, including

plan variation SBCs, in time to make such SBCs available.

Response: We are finalizing the applicability date as proposed. We expect that States and issuers will continue to work collaboratively to ensure that the applicable form filing approvals are received sufficiently in advance of the open enrollment period for the 2016 benefit year.

b. Changes in Eligibility for Cost-Sharing Reductions (§ 156.425)

In the proposed rule, we proposed to amend § 156.425 to clarify when a QHP issuer would be required to provide an SBC if an individual's assignment to a standard plan or plan variation of the QHP changes in accordance with § 156.425(a). We proposed that a QHP issuer must provide an SBC that accurately represents a new plan variation (or the standard plan variation) as soon as practicable after receiving notice from the Exchange of the individual's change in eligibility, but in no case later than 7 business days following receipt of notice. We proposed that this requirement would be effective beginning on January 1, 2016.

We are finalizing these provisions as proposed.

Comment: Commenters generally expressed support. Some commenters requested that an additional notice, beyond the SBC, be sent to consumers whose eligibility for cost-sharing variations changes which would explain the change to the consumer, the reason for the change, and how many cost-sharing amounts already incurred by the consumer during the benefit year would be applied toward the new deductible(s) and out-of-pocket limit(s).

Response: While issuers are encouraged to develop health literacy tools and provide consumer-friendly explanatory information to enrollees when their eligibility for cost-sharing reductions changes, we are not requiring issuers to send an additional notice beyond the SBC at this time. We will continue to monitor the extent to which consumers understand cost-sharing reductions eligibility and whether other information should be provided to consumers in this context.

Comment: Some commenters requested additional time to send an SBC to an enrollee whose eligibility for cost-sharing reduction changes. One commenter requested as many as 14 business days from the date the issuer effectuates the assignment into a plan variation (or standard plan without cost-sharing reductions), while the other commenter requested 14 calendar days to send the SBC.

Response: We are finalizing the timing requirement to send the SBC as proposed, that is, 7 business days from the date the issuer receives notice of the change in the enrollee's eligibility from the Exchange. Virtually all issuers subject to this requirement have already incurred one-time costs to develop systems necessary to generate and provide SBCs in an automated and efficient fashion to meet the timing requirements specified in § 147.200. Further, in accordance with § 147.200(a)(1)(iv)(D), QHP issuers must already send an SBC when an individual requests an SBC as soon as practicable, but no later than 7 business days following the receipt of the request.

c. Cost-Sharing Reductions Reconciliation (§ 156.430)

Sections 1402(a) through (c) of the Affordable Care Act provide for cost-sharing reductions for EHB provided by a QHP. Cost-sharing reductions are advanced to issuers throughout the benefit year, and reconciled following the benefit year against actual cost-sharing amounts provided by issuers to enrollees.

The reconciliation process requires QHP issuers to submit to HHS the total allowed costs for EHB charged for each plan variation policy, the amounts paid by the issuer, and the amounts paid by or on behalf of the enrollee (other than by the Federal government under section 1402 of the Affordable Care Act), as well as the amounts that would have been paid by the enrollee under the standard plan. Under the standard methodology described at § 156.430(c)(2), costs paid by the issuer under the standard plan are calculated by applying actual cost-sharing requirements for the standard plan to the allowed costs for EHB under the enrollee's policy for the benefit year. The difference is the amount of cost-sharing reductions provided.

In the proposed Payment Notice, we reiterated that issuers will not be reimbursed for reductions in out-of-pocket spending for benefits other than EHB. However, we explained that because of technology challenges in these early years of the cost-sharing reduction program, some issuers are presently unable to differentiate on a policy level between EHB claims and non-EHB claims, as required by HHS when applying the standard cost-sharing reduction reconciliation methodology. The difficulty occurs in plan designs that allow enrollee out-of-pocket spending for EHB and non-EHB claims alike to accumulate toward deductibles and the reduced annual

limit on cost sharing. Such plan designs benefit enrollees by allowing them to reach their spending limits sooner. As a result, for the purpose of cost-sharing reduction reconciliation, we proposed to allow QHP issuers to submit percentage estimates of the portion of claims attributable to non-EHB for the 2014 benefit year, and to reduce the total claims amount by that percentage, to arrive at an estimated total EHB amount. The percentage estimate would be the estimate of expected non-EHB claims costs previously submitted for each plan variation on the Uniform Rate Review Template (URRT)⁷¹ and which HHS used to calculate 2014 advance cost-sharing reduction payments. An issuer using this procedure would be required to do so for all plan variations for which the criteria below are met.

As described in proposed § 156.430(c)(2)(i), this exception to permit QHP issuers to use plan-specific URRT estimates of non-EHB claims would be limited to plan designs in which out-of-pocket expenses for non-EHB benefits accumulate toward the deductible and reduced annual limitation on cost sharing, but for which copayments and coinsurance rates for non-EHB are not reduced. This limitation helps assure that the estimated percentage, which is calculated based on the proportion of claims attributable to EHB, does not overstate the proportion of reduced out-of-pocket spending associated with EHB. In addition, the exception would apply only when non-EHB estimated percentages account for less than 2 percent of total claims, helping assure that any inaccuracies in the estimate are unlikely to result in significant inaccuracies in total cost-sharing reduction reimbursement.

Comment: We received comments in support of our proposal to permit estimates of non-EHB cost sharing based on the URRT. One commenter asked HHS to make this exception permanent. Another commenter asked HHS to extend the exception to the simplified method of cost-sharing reduction reconciliation since it, too, requires comparison of standard plan cost sharing to the total allowed EHB costs for a plan variation, and issuers face similar problems identifying EHB. Another commenter asked us to clarify

what we mean by reducing total claims amount by the percentage of non-EHB, and specifically whether issuers must reduce every claim before re-adjudication. Finally, a commenter asked HHS to permit issuers to use the simplified method of cost-sharing reduction reconciliation permanently, stating that the double adjudication required under the standard methodology is too complex for the variety of plan designs on the individual market.

Response: We are finalizing the exception proposed in § 156.430(c)(2)(i) to permit QHP issuers to use plan-specific URRT estimates of non-EHB claims, with two modifications. We are expanding this exception to include issuers using the simplified methodology for cost-sharing reduction reconciliation, since they are equally affected by technology challenges, and we are extending it to the 2015 benefit year. We also clarify that issuers should reduce total claims at the policy-level before re-adjudication. Finally, we believe the standard methodology will provide the most accurate permanent method of reconciling advanced cost-sharing reduction payments—the simplified methodology is an interim step.⁷²

5. Minimum Essential Coverage

a. Other Coverage That Qualifies as Minimum Essential Coverage (§ 156.602)

Under § 156.602, State high risk pool coverage is designated as minimum essential coverage for a plan or policy year beginning on or before December 31, 2014, for a one-year transition period. However, many State high risk pools have continued into the 2015 policy year. The proposed rule would designate as minimum essential coverage any qualified high risk pool (as defined by section 2744(c)(2) of the PHS Act) established in any State as of the publication date of the proposed rule. This would provide States additional time to evaluate State-administered high risk pools and facilitate the transition of State high risk pool enrollees into QHPs through the Exchange or into other forms of minimum essential coverage. We sought comment on whether the designation should be permanent or time-limited (for example, for 2015 only). We also sought comment on the cut-off date for formation of State high

⁷¹ Percentage of the total allowed costs of benefits as defined at § 156.20 means the anticipated covered medical spending for EHB coverage (as defined in § 156.110(a) of the subchapter) paid by a health plan for a standard population, computed in accordance with the plan's cost-sharing, divided by the total anticipated allowed charges for EHB coverage provided to a standard population, and expressed as a percentage.

⁷² "Timing of Reconciliation of Cost-Sharing Reductions for the 2014 Benefit Year." February 13, 2015. https://www.regtap.info/uploads/library/APTC_CSR_Recon_timing_guidance_5CR_021315.pdf.

risk pools that will qualify for recognition under the regulations.

Comment: Several commenters favored the proposal to permanently designate State high risk pool coverage as minimum essential coverage. One commenter suggested the designation should apply only through the 2016 plan year. Another commenter stated that State high risk pools must at least be required to provide minimum value to be recognized as minimum essential coverage after 2015.

Response: We believe States are in the best position to assess the unique circumstances in each State and determine when it is in the best interest of consumers to close State-administered high risk pools. While a one-year designation as minimum essential coverage would allow adequate time for some States to phase out high risk pools, many State laws require the retention of State high risk pools after 2015. Additionally, since the benefits are generally statutorily mandated, many States may not be able to easily alter the State high risk pool benefits to provide minimum value. Imposing a timeline that is not tailored to the unique circumstances of a particular State potentially disadvantages a vulnerable population that has significant health costs and that may be uninformed about the Exchanges and the availability of financial help to purchase health coverage. We received no comments on the cut-off date for formation for State high risk pools. Therefore we are establishing a permanent minimum essential coverage designation for any State high risk pool in existence as of November 26, 2014, the publication date of the proposed rule. The IRS has indicated that as long as HHS designates qualified high risk pool coverage as minimum essential coverage, an individual that is eligible but not enrolled in a qualified high risk pool will be treated as eligible for QHP coverage and the premium tax credit.⁷³

6. Enforcement Remedies in Federally-Facilitated Exchanges

a. Available Remedies; Scope (§ 156.800)

In the first Program Integrity Rule,⁷⁴ HHS finalized § 156.800(c), which established a good faith compliance policy for QHP issuers offering coverage through an FFE for the 2014 calendar year. Specifically, the first Program Integrity Rule provides that HHS will not impose sanctions under subpart I of

part 156 against a QHP issuer in an FFE if the QHP issuer has made good faith efforts to comply with applicable Exchange requirements. HHS adopted the good faith compliance policy to help QHP issuers become familiar with the standards unique to the FFEs during the initial stage of operations.

HHS is committed to ensuring that QHP issuers have the opportunity to learn from their experiences in 2014 without undue concern about being subject to formal enforcement actions when the QHP issuer has made reasonable efforts to comply with applicable standards. While immediate formal enforcement actions may be appropriate in some cases, we continue to prefer resolving most compliance issues by providing technical assistance. Accordingly, in the proposed rule we proposed extending the good faith compliance standard under § 156.800(c) through the end of calendar year 2015. We also noted, that irrespective of the good faith compliance standard, QHP issuers are required to comply with all applicable FFE standards (and any applicable Federal or State laws regarding privacy, security and fraud) at the time of certification and on an ongoing basis.

We are finalizing the provision as proposed.

Comment: Commenters generally supported the proposed extension of the good faith compliance standard. One commenter did not support the proposal, stating that the extension of the standard may impede HHS's efforts to enforce FFE standards. Some commenters also requested that HHS clarify that the good faith compliance policy would apply to non-compliance occurring during the 2015 benefit year that is identified after calendar year 2015.

Response: We note that issuers seeking to avoid enforcement actions under subpart I of part 156 through the good faith compliance standard may do so only by demonstrating that they exercised good faith efforts at complying with FFE standards. Consistent with the good faith compliance standard for the 2014 calendar year, HHS will determine whether the good faith compliance standard applies based on an evaluation of various factors surrounding the issuer's participation in the FFEs, including past instances of non-compliance, the gravity or severity of non-compliance, and the presence or absence of HHS guidance on the matter. We further clarify that the good faith compliance standard would apply to conduct occurring during the 2015 calendar year even if the activity is identified after 2015 calendar year. It

would not apply to conduct that occurs in 2016 or later, even if that conduct was related to coverage provided in the 2015 calendar year.

b. Plan Suppression (§ 156.815)

In § 156.815(a), we proposed a definition of suppression, which would mean that a suppressed QHP temporarily would not be available for enrollment through the FFEs. In § 156.815(b), we proposed the bases for suppression of a QHP in the FFEs. Our first proposed basis for suppression, § 156.815(b)(1), is the issuer notifying HHS of its withdrawal of the QHP from the FFEs when one of the exceptions to guaranteed renewability of coverage related to discontinuing a particular product or discontinuing all coverage under § 147.106(c) or (d) applies. In § 156.815(b)(2), we proposed as a basis to suppress a QHP submission of data for the QHP that is incomplete or inaccurate. For example, incorrect rates submitted by a QHP issuer generally would lead to the suppression of the QHP until the rating data are corrected. In § 156.815(b)(3), we proposed as a basis to suppress a QHP that is undergoing decertification under § 156.810 or the appeal of a decertification under subpart J of part 156. In § 156.815(b)(4), we proposed as a basis to suppress a QHP pending, ongoing, or final State regulatory or enforcement action against the QHP that could affect the issuer's ability to enroll consumers or that otherwise relates to the issuer's ability to offer QHPs in the FFEs. In § 156.815(b)(5), we proposed as a basis for suppression of a QHP application of the special rule for network plans under § 147.104(c) or the financial capacity limits provision under § 147.104(d). In § 156.815(c), we proposed a basis for suppression of a QHP that is a multi-State plan upon notification by OPM of certain findings. We solicited comments on this proposal, including whether the proposed bases for suppression were appropriate and whether an appeals process should be available following suppression decisions.

We are finalizing the provision as proposed.

Comment: Some commenters supported the proposed provisions. Commenters requested that HHS clarify that QHP suppression would not be implemented in violation of State law. One commenter did not support QHP suppression, stating that it would conflict with HIPAA and one State's law on guaranteed renewability. Another commenter recommended that HHS clarify that, when the QHP continues to offer coverage through the FFEs but is

⁷³ See Notice 2013–41, 2013–29 I.R.B. 60.

⁷⁴ Patient Protection and Affordable Care Act; Program Integrity: Exchange, SHOP, and Eligibility Appeals, 78 FR 54074 (August 30, 2013).

being suppressed, consumers should be notified of the suppression. One commenter asked if the proposed process and reasons for QHP suppression would apply to QHPs in the SHOP.

Response: We envision suppressing a QHP when continuing to allow new enrollment in the QHP through an FFE is not in the interest of qualified individuals and employers, such as when the QHP has withdrawn from an FFE, when there is incorrect data being displayed about the QHP, and when the QHP will be decertified. Our experience shows that by removing QHPs subject to the suppression from an FFE Web site, it will minimize confusion by consumers, agents and brokers, and assist about the QHPs that are available during plan selection. Federal regulations on guaranteed renewability at § 147.106(c) and (d) provide for circumstances under which an issuer may discontinue a particular product or discontinue all coverage in an applicable market. We intend to implement QHP suppression in coordination with States to ensure that conflicts with State law can be avoided and adverse effects minimized. We note that suppression does not affect re-enrollments into the plan, but temporarily restricts the availability of the plan for new enrollments through an FFE. We further note that if suppression of a plan ultimately leads to the plan being no longer available through an FFE, the issuer may be required to offer the same plan outside an FFE under §§ 147.104 and 147.106. We further clarify that the process and reasons for QHP suppression would also apply to QHPs in the FF-SHOP.

7. Quality Standards

a. Quality Improvement Strategy (§ 156.1130)

In § 156.1130(a), we proposed that a QHP issuer participating in an Exchange for at least 2 years must implement and report information regarding a quality improvement strategy (QIS), that is a payment structure that provides increased reimbursement or other market-based incentives in accordance with the health care topic areas in section 1311(g)(1) of the Affordable Care Act, for each QHP offered in an Exchange, consistent with the guidelines developed by HHS under section 1311(g)(2) of the Affordable Care Act. We noted that the statutory QIS requirements, similar to the other Exchange quality standards, extend to all Exchange types, including a State

Exchange and the FFEs.⁷⁵ For the QIS standards, we proposed to provide State Exchanges flexibility to establish the timeline, format, validation, and other requirements related to the annual submission of QIS data by QHP issuers that participate in their respective Exchanges. Under this proposal, the establishment and implementation of such standards and other requirements by State Exchanges would support compliance with § 155.200(d), which requires the Exchange to evaluate and oversee implementation of the QIS (among other QHP issuer quality initiatives for coverage offered through Exchanges). We noted that we envisioned the standards that will be used for the FFEs would provide the minimum requirements for State Exchanges to build upon.

We proposed to phase in QIS implementation standards and reporting requirements to provide QHP issuers the necessary time to understand the populations enrolling in a QHP offered through the Exchange and to build quality performance data on their respective QHP enrollees. We believe that implementation of a QIS should be a continuous improvement process for which QHP issuers define the health outcome needs of their enrollees, set goals for improvement, and provide increased reimbursement to their providers or other market-based incentives to reward achievement of those goals. This approach is consistent with other QHP issuer quality standards for coverage offered through an Exchange including implementation and reporting for the patient safety standards, the Quality Rating System (QRS), and the Enrollee Satisfaction Survey (ESS). We further noted that, consistent with existing regulations at § 156.200(h), QHP issuers participating in Exchanges would be required to attest to compliance with QIS standards, along with the other QHP issuer quality initiatives for coverage offered through Exchanges established under subpart L of part 156, as part of the QHP application process.

In paragraph (b), we proposed to direct a QHP issuer to submit validated data in a form, manner, and reporting frequency specified by the Exchange to support evaluation of quality improvement strategies in accordance with § 155.200(d) and § 156.200(b)(5). We noted that we anticipate using the data collected as part of information used to evaluate and oversee compliance of QHP issuers in FFEs with

the Exchange QIS standards and encourage State Exchanges to adopt a similar approach. State Exchanges would maintain the flexibility to add to the Federal minimum QIS standards and would also have the ability to establish their own form, manner, and reporting frequency. We proposed that beginning in 2016, a QHP issuer participating in an Exchange for at least 2 years would submit a QIS implementation plan for the 2017 plan year to the applicable Exchange, followed by annual progress updates. We noted that we anticipate that the implementation plan for a QHP issuer's proposed QIS would reflect a payment structure that provides increased reimbursement or other market-based incentives for addressing at least one of the topics in section 1311(g)(1) of the Affordable Care Act.

We proposed requesting information from QHP issuers regarding percentage of payments to providers that is adjusted based on quality and cost of health care services as this would promote transparency and assist Exchanges to make better informed QHP certification decisions. We also proposed that 1 year after submitting the QIS implementation plan, the QHP issuer would submit information including an annual update including a description of progress of QIS implementation activities, analysis of progress using proposed measures and targets, and any modifications to the QIS.

We noted that we believe that the implementation and reporting for the QIS over time would provide meaningful QIS data from QHP issuers by minimizing administrative effort while also allowing for flexibility and innovation. In the proposed rule, we explained that we anticipate issuing technical guidance in the future that will provide operational details including data validation, other data submission processes, timeframes and potential minimum enrollment size threshold for coverage offered through an FFE. We anticipate that this guidance would be updated on an annual basis (or more frequently as may be necessary). We proposed to allow State Exchanges to establish the data validation and submission requirements for QIS data from QHP issuers that participate in their respective Exchanges.

In paragraph (c), we proposed to direct a QHP issuer to submit data annually for activities that are conducted related to implementation of its QIS, in a manner and timeframe specified by the Exchange. For example, an issuer that participates in an FFE for

⁷⁵ Unless indicated otherwise, references in this section to the "FFE" include States performing plan management functions.

2 consecutive years for coverage beginning in January 2014 and January 2015 would submit a QIS implementation plan to an FFE during the fall 2016 post-certification period, and in a format specified by HHS. A progress update on the QHP issuer's QIS activities would be required the following year. Similarly, an issuer participating in an FFE for the first time during the 2015 open enrollment period for the 2016 coverage year and also offering coverage in the 2017 plan year would submit an implementation plan in the 2018 post-certification period to align with our proposed approach of phasing in the QIS over time and allowing a QHP issuer 2 years to collect data and develop quality improvement strategies for its QHPs offered through an Exchange, before the submission of an implementation plan is required. A progress update on the QHP issuer's QIS activities would be required the following year. We proposed to allow State Exchanges to establish the specific timeline and format requirements for the annual submission of QIS data by QHP issuers that participate in their respective Exchanges.

We noted that multi-State plans, as defined in § 155.1000(a), are subject to reporting QIS data for evaluation, as described in paragraph (b). In the proposed rule, we proposed to codify this general requirement at § 156.1130(d). We noted that we anticipate that OPM will provide guidance on QIS reporting to issuers with whom it holds multi-State plan contracts.

We sought comment on all aspects of this proposal, including whether the standard should apply to all types of QHPs offered through the Exchanges (for example, stand-alone dental plans, QHPs providing child-only coverage, and health savings accounts) or if different standards should be developed for the different types of QHPs. We also solicited feedback on: whether there should be a minimum enrollment size threshold to trigger the applicability of the QIS standards, what information should be included to effectively monitor and evaluate a QIS, and whether the information collected should be publically displayed to encourage transparency, support comparison of QHP issuer QIS activities, and align with other quality standards for QHP issuers participating in Exchanges.

We are finalizing these provisions as proposed, with the following modifications. For the initial years of implementation, QHPs that are stand-alone dental plans, provide child-only coverage, or are compatible with health

savings accounts will not be subject to the QIS. Additionally, HHS intends to establish a minimum enrollment size that triggers the QIS obligations in alignment with the other Exchange quality initiatives (for example, the QRS and ESS) and will do so through technical guidance. Further, we clarify that, in the initial years of QIS implementation, HHS will not require QHP issuers to select measures from a set of standardized or uniform performance measures established by HHS for inclusion in their respective QIS implementation plans. HHS anticipates requiring QHP issuers to provide information regarding their payment structure that provides increased reimbursement or other incentives such as the percentage of payments made across various categories including fee-for-service with no link of payment to quality; fee-for-service with a link of payment to quality; alternative payment models built on fee-for-service architecture; and population-based payments, to promote transparency and align this approach with other current CMS and HHS payment reform initiatives. As detailed above, we intend to issue future technical guidance that will provide more information regarding these and other QIS data collection and submission details for QHP issuers participating on an FFE.

Comment: Several commenters supported requiring QIS compliance from QHP issuers that have been participating in an Exchange for at least 2 years. A few commenters agreed the phased-in approach of the QIS program would allow for the necessary preparations and knowledge building, while other commenters recommended a delay based on concerns that the timeline was too aggressive. While one commenter urged HHS to postpone its QIS proposals and requirements for the private sector until it has had time to evaluate lessons learned from the public sector, others recommended that HHS require all QHP issuers—not only those that have been participating in the Exchange for 2 or more consecutive years—to submit a QIS implementation plan, with one stating that QHP issuers will have sufficient information at the outset to design their quality improvement strategies.

Response: We maintain in the final rule the approach outlined in the proposed rule that QHP issuers participating in an Exchange for at least 2 consecutive years must implement and report information regarding a QIS, followed by annual progress updates. We believe that 2 years is an appropriate time period for QHP issuers to

understand their populations who have enrolled through Exchanges, and develop relevant quality improvement strategies to meet the needs of that population. We anticipate requiring compliance with the QIS reporting requirements beginning in 2016 for the 2017 coverage year and will be issuing future guidance that addresses this, as well as other QIS operational and data submission details, for QHP issuers participating in the FFEs.

Comment: Some commenters suggested that a minimum QHP enrollment size that aligns with the minimum threshold requirements of the 2015 QRS beta test requirement and the QHP Enrollee Experience Survey should be required to trigger the applicability of the QIS certification standard. Other commenters suggested that all QHP issuers, regardless of enrollment size, should be required to develop and implement a quality improvement strategy.

Response: We considered the feedback regarding the applicability of a minimum enrollment size. In an effort to maintain consistency with other Exchange quality standards in the initial years, we will direct QHP issuers to comply with the QIS certification standard and report QIS data if they meet the minimum enrollment size threshold. We intend to include additional details regarding the applicability of the minimum enrollment threshold to the QIS standards in future technical guidance.

Comment: Some commenters suggested that the QIS should align with existing quality standards required as part of Exchange participation standards to be accredited by a recognized accrediting entity and that the accreditation certification standard should satisfy the QIS standards provided in § 156.1130(a).

Response: We note that the existing accreditation standards do not include the use of market-based incentives as outlined in § 156.1130(a) and required by section 1311(g) of the Affordable Care Act for QHP issuers participating in Exchanges. However, we would not restrict a QHP issuer from using quality improvement strategy information submitted to a recognized accrediting entity for QIS purposes as long as the information otherwise satisfies the QIS requirements included in this final rulemaking and future technical guidance.

Comment: Commenters expressed general support for the QIS principles and goal of improving quality of care delivered to Exchange enrollees through quality improvement strategies that provide for increased reimbursements,

benefit designs, and other market-based incentives. Commenters supported QIS alignment of priorities, performance measures, and reporting requirements with the National Quality Strategy, the CMS Quality Strategy, and other national and regional efforts to improve the quality of healthcare to reduce both QHP issuer and provider burden. Commenters remarked on the importance of leveraging quality improvement efforts in the public and private sectors to hasten achievement of better patient outcomes and lower costs.

Response: We made extensive efforts to incorporate similar standards and requirements from other quality initiatives into the QIS, and believe that the QIS requirements will align as consistently as possible with other quality initiatives. At this time, we do not intend to require QHP issuers to select specific measures from a set required by HHS.

Comment: Comments related to whether all QHP types (SADPs, child only coverage, and health savings accounts) should be required to implement a QIS fell into two categories. The first category of commenters noted that all types of QHPs should meet the QIS certification standard and be subject to the same QIS standards. The second category of commenters noted that the QIS should apply to all QHPs, but the standards should be directly relevant to the population(s) covered by the QHP (that is, different standards for SADPs, QHPs with rural enrollees, integrated delivery systems, etc.). Some commenters suggested that QHP issuers be allowed to target specific populations within their network when implementing a QIS instead of targeting all their QHP enrollees. Others recommended that QHP issuers be provided the flexibility to address the needs of specific enrollee populations while recommending HHS review QIS submissions to ensure that the strategies do not exclude any particular group, either by design or effect. Other commenters stressed the need to review quality improvement strategies to ensure that such strategies do not discriminate, either by design or by effect, against any one group of individuals. Some commenters also recommended excluding SADPs, noting that SADPs do not have the same ability to implement and track measures, and therefore should be exempt from the QIS requirements.

Response: We clarify in the final rule that the Federal QIS standards will apply to same QHP types that are required to comply with the QIS certification standard across all Exchange types. However, a QHP

issuer's QIS does not need to apply to all populations covered by its QHPs, and the issuer has the option of developing multiple strategies to ensure that each QHP is covered by a QIS. We agree that it would be premature at this point in time to require all QHP types (for example, SADPs, child only coverage plans, or QHPs compatible with health savings accounts) to develop, implement, and track a QIS. We therefore clarify in the final rule that in the initial years of the QIS, SADPs, child only coverage plans, and QHPs that are compatible with health savings accounts will be exempt from the QIS certification and reporting requirements. This approach aligns with our current approach for other Exchange and QHP issuer quality requirements, allows the program to mature, and allows for additional measures for other QHP types to be developed for reporting. Consistent with the nondiscrimination prohibition in § 156.225, QIS implementation plans will be reviewed to ensure that they are not designed and do not have the effect of discouraging the enrollment of individuals with significant health needs.

Comment: We solicited comments on whether to require information relating to provider payment models, such as an issuer's minimum target or goal set with regards to the percentage of provider payments adjusted for quality and cost, to be submitted for compliance with QIS standards proposed in § 156.1130. While one commenter agreed with the concept, other commenters recommended that QHP issuers be required to indicate specifically to providers how payment is tied to performance or questioned the need for QHP issuers to report on the details of their proprietary contracts with providers, and encouraged HHS to let market factors drive quality improvements.

Response: We believe that understanding how QHP issuers participating in Exchanges are adjusting provider payments for quality and cost is important and directly aligns with the statutory definition of a QIS. As such, this type of information is subject to the periodic reporting of QIS information under section 1311(g)(3) of the Affordable Care Act. We anticipate requiring QHP issuers participating in Exchanges to establish and share with the applicable Exchange performance measure improvement targets and report on progress against those targets as they relate to QIS implementation. We anticipate alignment of QIS information collection requirements with current payment reform data collection efforts, including the adoption of safeguards to

protect confidential or proprietary information. The goal is to collect issuer QIS information from QHP issuers participating in Exchanges that demonstrates compliance with 1311(g) of the Affordable Care Act and facilitates understanding of the issuer's payment structure framework that provides increased reimbursement or other market-based incentives for the implementation of activities related to the topics specified in section 1311 (g). We anticipate the display of a subset of this information to promote transparency and will provide additional details through future guidance. We do not intend that the public display of payment structure information will include information that is considered confidential or proprietary.

Comment: Commenters provided feedback on the definition of a quality improvement strategy as a payment structure. Various commenters recommended not linking incentives to cost, including cost-independent protections, and suggested that HHS recognize different types of provider incentives, and emphasize the importance of capturing outcome variations within a provider's control.

Response: We clarify that the description of a strategy described in 1311(g) of the Affordable Care Act is a payment structure that provides increased reimbursement or other market-based incentives. The purpose of soliciting comments was to understand the types of market-based incentives that are currently in use by issuers to reward quality and value. HHS intends to issue technical guidance to assist QHP with compliance with the QIS standards and reporting requirements.

Comment: Some commenters expressed concern with HHS's proposal that a QHP issuer could meet the QIS requirements by focusing on only one of the five topic areas in the Section 1311(g) of the Affordable Care Act. These commenters suggested requiring QHP issuers to focus on more than one topic area, with some commenters suggesting a requirement of at least three topic areas be addressed.

Response: While we agree that ideally QHP issuers participating in Exchanges would focus on more than one topic area as part of their QIS, we are cognizant that this could be difficult for issuers to accomplish immediately. Therefore, consistent with the phase in approach to implementation, for the initial years of the QIS, QHP issuers will have to address at least one of the topic areas included in section 1311(g) of the Affordable Care Act.

Comment: Some commenters expressed concern over the impact the QIS will have on providers if each QHP issuer is allowed to have extensive flexibility in designing its quality improvement strategies, in particular the performance measures used to track implementation progress. One commenter recommended that QHP issuers be required to use quality measures already in use by existing quality programs and for HHS to require QHP issuers to select their QIS quality measures from a limited subset of existing measures.

Response: Based on input from experts and stakeholders, we anticipate allowing QHP issuers to select their own performance measures and establish targets designed to measure the impact of their respective QIS plans. Our concern is that imposing specific performance measures on QHP issuers would limit their ability to target their strategies to their specific populations and possibly limit innovation. However, we will take these comments into consideration as we assess whether changes are warranted in the future.

Comment: Commenters strongly supported the proposal that QIS standards be developed in a public, accessible, and transparent manner that seeks and incorporates stakeholder feedback. Some commenters further recommended that HHS explicitly state that “stakeholder feedback” must include both consumer advocates and public and private purchasers, while another recommended that HHS reach out directly to State consumer health advocates, patient advocates, and case managers who represent consumer health perspectives.

Response: Consistent with the statutory directive at section 1311(g)(2) of the Affordable Care Act that requires consultation with experts in health care quality and stakeholders, HHS conducted numerous activities to seek feedback and develop the proposed approach to the QIS, including meetings with a QIS Technical Expert Panel and engagement of stakeholders through activities such as key informant interviews, listening sessions, discussions, and a pilot test. We will continue to engage a variety of public and private stakeholders, and will seek to incorporate their feedback to help inform the further development and evolution of the QIS.

Comment: Some commenters suggested we develop specific formats for data collection and reporting to ensure consistency, reliability in the data, and to reduce provider’s data reporting burden. Other commenters encouraged HHS to develop a uniform

standardized reporting format for use by QHP issuers in both the FFEs and the State Exchanges to allow QHP issuers to implement consistent quality improvement strategies, as well as enable fair comparison between QHP issuers operating in State Exchanges and the FFEs. Others urged HHS to allow for flexibility to ensure that QHP issuers can develop various strategies across their populations and across their provider contracts.

Response: We appreciate the feedback and clarify that we plan on establishing a standardized format for which QIS data must be submitted for those QHP issuers operating in the FFEs. We expect that the exact format and the validation process will be released as part of the operational details in technical guidance that will be issued later in 2015. State Exchanges will have the flexibility to add reporting requirements beyond the minimum Federal requirements, determine how they will communicate the process for submission, establish the timeframe and validation approach for the data submission, and any additional quality improvement requirements they may require beyond the minimum Federal requirements.

Comment: Some commenters felt that QIS data should not be made publicly available at all, adding that QHP issuers may be encouraged to take on more challenging or innovative strategies if the data are not made public. Other commenters suggested that if QIS data would be publicly available, HHS should create a uniform format for displaying the data using consumer-tested language, as well as provide evidence of effectiveness of different payment structures for QHP issuers’ use. Some commenters urged HHS to make QIS data publicly available and require evaluation against benchmark data, allowing the data to be used for decision making by multiple stakeholder groups such as State Exchanges, health plans, consumers, employers, providers and provider organizations.

Response: We clarify in the final rule that HHS seeks to encourage transparency and align with other Exchange quality standards and data collection for QHP issuers, while protecting information that may be misinterpreted or misused if made publicly available. Similar to other quality standards and CMS programs collecting data from QHP issuers in the Exchanges, we do not anticipate publicly displaying information that is considered confidential or proprietary. As noted above, HHS anticipates the display of a subset of this information to promote transparency and will

provide additional details through future guidance.

Comment: Many commenters recommended that HHS require the use of specific performance measures in the QIS, specifically those from the following organizations: NCQA (HEDIS); URAC; the Pediatric Quality Measurement Program; and the Dental Quality Alliance (DQA). There was also strong support for use of National Quality Forum (NQF)-endorsed measures, and measures that align with the National Quality Strategy. Commenters noted that requiring QHP issuers to include commonly used measures in their quality improvement strategies would minimize the data collection burden on QHP issuers as well as providers. Some comments supported inclusion of process-level and plan-level data and measures of improvement when evaluating a QIS. Some commenters stated that defining the health outcomes that will be the focus of interventions, setting goals for improvement, and the approach for linking improvement to payment incentives should be detailed in the QHP issuer’s quality improvement strategy. They also suggested that these elements be fully disclosed so that regulators and other interested parties can properly evaluate a QHP issuer’s quality improvement strategy. Other commenters supported collection of information such as the rationale for the targeted population, proposed performance measures, approaches to reducing health care disparities, and a description of the mitigation strategy.

Response: HHS will not require QHP issuers to include specific performance measures in a QIS. Instead, we have outlined the elements that should be included as part of a QIS, including a rationale that describes its relevance to the QHP’s enrollee population, proposed performance measures and targets, a description of activities conducted to implement the strategy, a description of activities conducted to reduce health and health care disparities, as well as other chosen topics, goals, timeline, and information about challenges, barriers, and mitigation planning. As noted above, we anticipate requiring QHP issuers to include information in their respective QIS implementation plan regarding percentage of payments to providers that is adjudicated based on quality and cost of services as a range within categories of provider payments.

Comment: Several commenters provided comments specifically on evaluation. Commenters supported the evaluation of QHP issuers’ quality improvement strategies, as long as the

purpose of the evaluation is to drive improvement in the strategies being implemented, and to create a national set of performance data against which to assess the strategies. Some commenters noted that evaluating the quality improvement strategies could be challenging, due to QHP issuers changing, removing, or adding QHPs, and enrollee movement across plans both within and outside of the Exchange. Additional challenges noted by commenters included aligning evaluation requirements with other State and Federal requirements and ensuring that QHP issuers have sufficient time to understand changing rules and regulations to meet compliance requirements.

Response: This final rule adopts a phased-in approach to implementation of the QIS and accompanying reporting requirements to provide QHP issuers the necessary time to understand the population enrolling in their respective QHPs offered through the Exchanges and to build quality performance data on its QHP enrollees. We also finalize an approach that requires a QHP issuer participating in the FFEs for at least 2 years to submit a QIS implementation plan for each QHP offered in the Exchange, followed by annual progress updates. The purpose of requiring a QHP issuer to submit an annual progress update on its QIS implementation plan is to evaluate progress. As detailed in the proposed rule (79 FR 70735), we believe that implementation of a QIS should be a continuous process under which QHP issuers define the health outcome needs of their enrollees, set goals for improvement, and use increased reimbursement to their providers or other market-based incentives as a reward for quality improvement and to stimulate achievement of those goals. As such, we anticipate that QHP issuers will be engaged in a continuous process of evaluating the populations enrolling in their respective QHPs offered through Exchanges, modifying or otherwise adjusting their QIS plan as may be appropriate, and building quality performance data on its QHP enrollees. This approach is designed to account for the changes with respect to QHP offerings, as well as enrollee movement across plans both within and outside of Exchanges. We further note that since QHP issuers will not be penalized if the implementation is not demonstrating an effect on the performance targets set out in the implementation plan, we believe that these challenges are not a barrier to performing an annual evaluation review. Additional details on the timing

of the submission of the initial QIS implementation plan and the annual progress reports will be included in technical guidance.

Comment: Some commenters suggested that we provide additional technical guidance on the QIS requirements in § 156.1130(b), specifically those related to data validation and which entity will be reviewing data submissions for accuracy prior to public display.

Response: HHS intends to publish QIS technical guidance in 2015 that will establish the minimum enrollment size threshold to trigger the applicability of the QIS standards, as well as data validation, data submission, and evaluation requirements for QHP issuers participating in the FFEs. We anticipate that State Exchanges will be issuing similar guidance to their respective QHP issuers.

8. Qualified Health Plan Issuer Responsibilities

a. Administrative Appeals (§ 156.1220(c))

In the 2015 Payment Notice, we established an administrative appeals process designed to address unresolved discrepancies regarding advance payments of the premium tax credit, advance payments of cost-sharing reductions, FFE user fee payments, payments and charges for the premium stabilization programs, cost-sharing reduction reconciliation payments and charges, and assessments of default risk adjustment charges. We established a three-tier appeals process: a request for reconsideration under § 156.1220(a); a request for an informal hearing before a CMS hearing officer under § 156.1220(b); and a request for review by the Administrator of CMS under § 156.1220(c).

Under § 156.1220(a), we provided that an issuer may file a request for reconsideration of a processing error by HHS, HHS's incorrect application of the relevant methodology, or HHS's mathematical error only for advance payments of the premium tax credit, advance payments of cost-sharing reductions, FFE user fee payments, payments and charges for the premium stabilization programs, cost-sharing reduction reconciliation payments and charges, and assessments of default risk adjustment charges for a benefit year. In § 156.1220(a)(6), we stated that a reconsideration decision would be final and binding for decisions regarding the advance payments of the premium tax credit, advance payments of cost-sharing reductions, and FFE user fees. A reconsideration decision for other

matters would be subject to the outcome of a request for informal hearing filed in accordance with § 156.1220(b).

Under § 156.1220(b), an issuer that elects to challenge the reconsideration decision may request an informal hearing before a CMS hearing officer. The CMS hearing officer's decision would be final and binding, but subject to any Administrator's review initiated in accordance with § 156.1220(c).

We stated in § 156.1220(c)(1) that if the CMS hearing officer upholds the reconsideration decision, the issuer is permitted to request a review by the Administrator of CMS within 15 calendar days of the date of the CMS hearing officer's decision. We proposed a modification to this process to also permit CMS the opportunity to request review of the CMS hearing officer's decision, and to permit the Administrator of CMS to decline to review the CMS hearing officer's decision. Specifically, we proposed to amend § 156.1220(c)(1) to permit either the issuer or CMS to request review by the Administrator of the CMS hearing officer's decision. We proposed to provide that any request for review of the hearing officer's decision must be submitted to the Administrator of CMS within 15 calendar days of the date of the hearing officer's decision, and must specify the findings or issues that the issuer or CMS challenges. We proposed that the issuer or CMS be permitted to submit for review by the Administrator a statement supporting the decision of the CMS hearing officer.

We also proposed to amend § 156.1220(c)(2) to provide the Administrator of CMS with the discretion to review or not review the decision of the CMS hearing officer after receiving a request for review under § 156.1220(c)(1). We believe such discretion will permit the Administrator to focus resources on the priority matters, including disputes with implications for other issuers. In keeping with our current process set forth in § 156.1220(c), we proposed that if the Administrator elects to review the CMS hearing officer's decision, the Administrator will review the statements of the issuer and CMS, and any other information included in the record of the CMS hearing officer's decision, and will determine whether to uphold, reverse, or modify the CMS hearing officer's decision. We proposed that the issuer or CMS be required to prove its case by clear and convincing evidence for issues of fact, and that the Administrator will send the decision and the reasons for the decision to the issuer. As established in

§ 156.1220(c)(3), the Administrator's decision will be final and binding.

We received no comments on this proposal. We are finalizing these amendments as proposed.

F. Part 158—Issuer Use of Premium Revenue: Reporting and Rebate Requirements

1. Treatment of Cost-Sharing Reductions in MLR Calculation (§ 158.140)

The Premium Stabilization rule (77 FR 17220) aligned the definition of “allowable costs” under the risk corridors program at § 153.500 with the definition of incurred claims under the MLR program at § 158.140 and expenditures for health care quality and health information technology under § 158.150–§ 158.151. In the 2014 Payment Notice, we additionally specified that allowable costs under risk corridors must be reduced by the amount of cost-sharing reduction payments received by the issuer, to the extent not reimbursed to the provider. To align the calculations between the two programs, we proposed to specify that cost-sharing reduction payments should be deducted from incurred claims under the MLR program just as they are deducted from allowable costs under the risk corridors program. As we explained in the proposed rule, it is our understanding that in capitated arrangements, issuers will generally retain the cost-sharing reduction payments, and in such circumstances cost-sharing reduction payments should be accounted for as a reduction to incurred claims because capitation payments (which are reflected directly in an issuer's incurred claims) will be raised to account for the reductions in the providers' cost-sharing income. In contrast, in most fee-for-service arrangements, issuers will pass the cost-sharing reduction payments through to providers, and therefore no adjustment to incurred claims for cost-sharing reduction payments would be required in such situations.

We are finalizing this provision as proposed.

Comment: Several commenters supported our proposal as drafted, while one commenter opposed it. Several commenters expressed concern that the proposal could disadvantage issuers in capitated arrangements that do pass through the cost-sharing reduction payments to the providers.

Response: We agree with the commenters that issuers who pursue innovative cost containment practices involving capitation and cost-sharing reduction payments should not be treated differently than issuers in fee-

for-service arrangements. However, we note that our proposed regulation text did not distinguish between capitation and fee-for-service arrangements. Under our proposal, issuers in either type of arrangement must deduct cost-sharing reduction payments from incurred claims, to the extent such payments are not reimbursed to the provider furnishing the item or service. Therefore, we are finalizing the clarification of the definition of incurred claims in § 158.140 as proposed.

2. Reporting of Federal and State Taxes (§ 158.162)

The MLR December 1, 2010 interim final rule (75 FR 74864) broadly describes Federal and State taxes and assessments that are excluded from premiums in the MLR and rebate calculations, and Federal and State taxes and assessments not excluded from premium in MLR and rebate calculations. In the proposed rule (79 FR 70737), we proposed to further clarify for future MLR reporting years the treatment of Federal and State employment taxes. Specifically, we proposed to amend the provisions for the reporting of Federal and State taxes in § 158.162(a)(2) and (b)(2) to provide that Federal and State employment taxes (such as the Federal Insurance Contributions Act (FICA) and the Railroad Retirement Tax Act (RRTA) taxes, the Federal Unemployment Act (FUTA) and State unemployment taxes, and other similar taxes) should not be excluded from premium in the MLR and rebate calculations.

Comment: Several commenters supported our proposal. One commenter noted that our proposal reflected their understanding of Congressional intent, as evidenced by the 2010 letter to the Secretary from six congressional committee chairs involved in drafting the Affordable Care Act.⁷⁶ In contrast, other commenters opposed our proposal, questioning our authority to amend the definition of taxes. These commenters stated that the reference to “excluding Federal and State taxes” in section 2718 of the PHS Act does not require clarification. These commenters alternatively asserted that to the extent the statute requires interpretation, only the NAIC has the authority to do so. Consequently, a subset of these commenters recommended that we obtain an official recommendation from the NAIC before adopting any modifications to the definition of taxes. Some commenters additionally

expressed concern regarding the effective date of the proposed provision.

Response: We disagree that there is no need to clarify the statutory reference to taxes or that the NAIC, rather than HHS, has the authority to clarify it. Our review of the MLR reports submitted by issuers identified this issue as one that would benefit from further clarification for future reporting years due to the fact that there appeared to be inconsistent treatment among issuers. While most issuers do not exclude employment taxes from premium, others have adopted the opposite approach and exclude such taxes from premium. Further, as some of the commenters point out, section 2718 of the PHS Act directed the NAIC to develop the uniform definitions and standardized methodologies with regard to the MLR provisions. It directed the NAIC to develop such definitions and methodologies no later than December 31, 2010, and subjected all such definitions and methodologies to the certification of the Secretary. As a Federal agency, HHS retains the authority to implement the statute and interpret the statutory terms where necessary, including the authority to adjust the MLR definitions after 2010. Furthermore, the NAIC's recommendation to the Secretary provided that certain Federal and State taxes should not be excluded from premiums in MLR and rebate calculations, supporting our belief that the phrase “excluding Federal and State taxes” requires clarification and does not mean all taxes of any kind. This approach—the identification of those Federal and State taxes that must be excluded from premium and those that cannot be excluded—was codified in our regulations at § 158.162 as part of the MLR December 1, 2010 interim final rule. The use of uniform definitions and standardized methodologies when calculating the MLR and associated rebates (including the treatment of employment taxes) is critical to both ensuring a level playing field across issuers and to deliver to consumers the protections promised by the statute. Therefore, we are finalizing the amendment to the definition of Federal and State taxes that may be deducted from premium in § 158.162(a)(2) and (b)(2) as proposed. In recognition of commenters' concerns regarding the effective date of this provision, we note that this provision will become effective for the 2016 reporting year, and therefore must be reflected in reports submitted to the Secretary by July 31, 2017. This should provide adequate time for those issuers that previously

⁷⁶ Available at http://www.politico.com/static/PPM170_100811_taxes.html.

interpreted the regulation differently to adjust their financial planning. We also reiterate that this is simply a clarification to explicitly require inclusion, as our data indicate most issuers have been doing.

3. Distribution of Rebates to Group Enrollees in Non-Federal Governmental Plans (§ 158.242)

The December 7, 2011 MLR Rebate Requirements for Non-Federal Governmental Plans interim final rule (76 FR 76596) directs issuers to distribute rebates to the group policyholders of non-Federal governmental plans. Under CMS's direct enforcement authority over non-Federal governmental plans, the interim final rule further directs the group policyholders of such plans to use the portion of the rebate attributable to the amount of premium paid by subscribers of such plans for the benefit of subscribers in one of three prescribed ways. These provisions were put in place to ensure that rebates are used for the benefit of enrollees of non-Federal governmental plans, who do not receive the protections of Employee Retirement Income Security Act of 1974 (ERISA), as amended. Under ERISA and implementing regulations, most plan participants are assured that the rebate (when the rebate is determined to be a plan asset) is applied for their benefit within 3 months of receipt by the policyholder.

To afford similar protection to subscribers of non-Federal governmental plans, we proposed to amend the provisions for distribution of rebates in § 158.242(b) to require group policyholders of non-Federal governmental plans to use the subscribers' portion of the rebate for the subscribers' benefit within 3 months of receipt of the rebate by the group policyholder. Under the proposal, plans would continue to be able to use the rebate to reduce the subscribers' portion of premium for the subsequent policy year (including by spreading it over the 12 months of the policy year) as long as the subsequent policy year commences within 3 months of receipt of the rebate by the group policyholder. If the subsequent policy year commences outside this 3-month window, the group policyholder of a non-Federal governmental plan must distribute the subscribers' portion of the rebate within 3 months in the form of a cash refund or by applying a mid-policy year premium credit to the subscriber's portion of the premium. We also noted that, because under § 158.242(b)(3) group health plans that are not governmental plans and are not subject

to ERISA (such as church plans) must follow the same rebate distribution rules in order to receive the rebate directly, the same distribution deadline would apply to such plans.

We are finalizing the amendments as proposed. In addition, we are finalizing the December 7, 2011 interim final rule (76 FR 76596) with minor changes after consideration of the comments received on that rule as noted below.

Comment: We received one comment supporting the requirement that policyholders that are non-Federal governmental or other group health plans not subject to ERISA apply or distribute rebates within 3 months of receipt, or pay interest on the rebates.

Response: We appreciate the comment regarding the distribution of rebates to group enrollees in non-Federal governmental and other group health plans not subject to ERISA. Policyholders that are non-Federal governmental or other group health plans not subject to ERISA that do not apply or distribute rebates within 3 months of receipt will be required to pay interest on the rebates, much the same as an issuer is required to do if they do not disburse the rebate to the policyholder by the due date.

Comment: We received several comments supporting the rules governing the distribution of rebates to subscribers of non-Federal governmental and other group health plans not subject to ERISA, which were set forth in the December 7, 2011 MLR Rebate Requirements for Non-Federal Governmental Plans interim final rule (76 FR 76596). Other commenters requested that we clarify the deadline for rebate distribution by such plans. One commenter expressed concern that the regulation does not afford such plans adequate time to use the rebate to reduce the subscribers' portion of premium or enhance benefits for a subsequent policy year. One commenter requested that such plans be permitted to distribute rebates directly to subscribers in situations where the policyholder has modified or ceased to offer group coverage.

Response: We agree with the commenters regarding the need for clarification of the rebate distribution deadline for policyholders that are non-Federal governmental or other group health plans not subject to ERISA. As noted above, we believe that requiring such policyholders to use the rebate for the benefit of subscribers no later than 3 months of receipt of the rebate by the policyholder ensures that consumers in group health plans not subject to ERISA receive the benefit of MLR rebates in a timely manner. Accordingly, we have

clarified the deadline in this final rule, as described in more detail above. In addition, we agree that policyholders that are non-Federal governmental or other group health plans not subject to ERISA should be allowed to distribute rebates directly to subscribers in situations where the policyholder does not offer the same plan(s) or has ceased to offer group coverage. Therefore, we are amending the provisions in § 158.242(b)(1)(iii) to specify that as an alternative to providing a cash rebate to the subscribers enrolled in the plan option at the time the policyholder receives the rebate, the group policyholder may instead provide a cash rebate to the subscribers who were enrolled in the plan option during the MLR reporting year that generated the rebate.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. This final rule contains information collection requirements (ICRs) that are subject to review by OMB. A description of these provisions is given in the following paragraphs with an estimate of the annual burden, summarized in Table 12.

In the November 26, 2014 (79 FR 70674) proposed rule, we requested public comment on each of the collection of information requirements contained in the proposed rule. The comments and our responses to them are discussed below:

A. ICRs Regarding Standards for Notification of Change of Ownership (§ 147.106(g))

When an issuer that offers a QHP, a plan otherwise subject to risk corridors, a risk adjustment covered plan, or a reinsurance-eligible plan experiences a change of ownership as recognized by the State in which the plan is offered, the issuer is required to notify HHS in a manner to be specified by HHS and provide the legal name, Health Insurance Oversight System (HIOS) plan identifier,⁷⁷ tax identification number of the original and post-transaction issuers, as applicable, and the effective date of the change of ownership, and the summary description of transaction. The information must be submitted by the latest of (1) the date the transaction is entered into; or (2) the 30th day prior to

⁷⁷ OMB Control Number: 0938-1086.

the effective date of the transaction. The burden associated with this requirement is the time and effort for the issuer to notify HHS of a change of ownership. We estimate that it will take an insurance operations analyst 30 minutes (at an hourly wage rate of \$56.63) to prepare the data related to the change of ownership, and 10 minutes for a senior manager (at an hourly wage rate of \$103.95) to review the data and transmit it electronically to HHS. We estimate that it will cost an issuer \$45.65 to comply with this reporting requirement. Although at this time we cannot precisely estimate the number of issuers that will be reporting changes of ownership, we expect that no more than 20 issuers will be subject to this reporting requirement annually, for a total burden of \$913.

B. ICRs Regarding Effective Rate Review Programs (§ 154.301)

Under § 154.301(b)(2), if a State intends to make the information contained in Parts I, II, and III of the rate filing justification regarding proposed rate increases subject to review available to the public prior to the date specified in guidance by the Secretary, or if it intends to make the information contained in Parts I, II, and III of the rate filing justification regarding final rate increases available to the public prior to the first day of the annual open enrollment period in the individual market for the applicable calendar year, the State must notify CMS in writing of its intent to publish this information at least 30 days before it makes the information public and the date it intends to make the information public. We intend to seek OMB approval and solicit public comment on this information collection requirement, in accordance with the Paperwork Reduction Act of 1995, at a future date.

C. ICRs Regarding Standards for HHS-Approved Vendors of Federally-Facilitated Exchange Training and Information Verification for Agents and Brokers (§ 155.222)

In § 155.222, we describe the information collection and disclosure requirements that pertain to the approval of vendors' FFE agent and broker training programs, including information verification and administration of identity proofing. The burden estimate associated with these disclosure requirements includes the time and effort required for vendors to develop, compile, and submit the application information and any documentation or agreement necessary to support oversight in the form and manner required by HHS. We estimate

that HHS will receive applications from nine or fewer vendors, and that it will take each vendor approximately 10 hours to complete an application and the agreement, at a cost of \$24.10 per hour. Therefore, we estimate a total burden of approximately 90 hours and a cost of \$2,169 as a result of this requirement. HHS will develop a model vendor application that will include data elements necessary for HHS review and approval. HHS will estimate the burden on vendors for complying with this provision of the regulation, and submit the application for OMB approval in the future. For vendors that choose to charge for their training, HHS will consider current training costs for State-licensed agents and brokers for comparable training to comparable audiences when reviewing vendor applications with proposed fee structures.

In § 155.222(d), we establish a process through which HHS will monitor approved vendors for ongoing compliance. HHS may require additional information from approved vendors to be submitted periodically to ensure continued compliance related to the obligations described in this section. We estimate that HHS will receive applications from nine or fewer vendors. We estimate that it will take no longer than 10 hours (at a cost of \$24.10 per hour) for each vendor to comply with any additional monitoring by HHS. Therefore, we estimate a total annual burden of 90 hours for all vendors for a total cost burden estimate of \$2,169. In § 155.222(e), we establish a process by which a vendor whose application is not approved or whose approval is revoked by HHS can appeal HHS's determination. We discuss the costs associated with the appeals process in the Regulatory Impact Analysis (RIA) section of this rule.

This section establishes a new method by which agents and brokers may complete training and information verification components of the registration process to be authorized to assist with enrollment in individual market and SHOP coverage through the FFE. The information collection associated with the current process by which agents and brokers may be authorized to assist with enrollment through the Exchange is approved under OMB Control Number 0938-1204. We intend to revise the current collection request to incorporate this new method by which agents and brokers may complete training and information verification components of the registration process. Based on information not available when the current collection request was

developed in 2013, we also expect a significant reduction in the overall burden, both in terms of the total number of respondents and the time required for each response. We intend to seek OMB approval and solicit public comment on this information collection requirement in accordance with the Paperwork Reduction Act of 1995.

D. ICRs Regarding Notification of Effective Date for SHOP (§ 155.720(e))

Section § 155.720(e) has been amended to refer to enrollees and not qualified employees. This amendment establishes that issuers must provide a coverage effective date notice to anyone who enrolled in coverage through a SHOP under the new definition of "enrollee," including dependents (including a new dependent of the employee, when the dependent separately joins the plan), former employees of a qualified employer, and certain business owners, who might be enrolled in coverage through a SHOP. We specify that when a primary subscriber and his or her dependents live at the same address, a separate notice need not be sent to each dependent at that address, so long as the notice sent to each primary subscriber at that address contains all the required information about the coverage effective date for the primary subscriber and each of his or her dependents at that address. When dependents live at a different address from the primary subscriber, a separate notice must be sent to those dependents. We note that the notices required under this proposal could be incorporated into existing notifications that QHPs provide to their new customers, for example in a welcome document. We are also making a conforming amendment to § 156.285(c)(3) to ensure that QHP issuers participating in a SHOP provide notice to a new enrollee of the enrollee's effective date of coverage. We note that the effective date for this notice requirement will take effect in plan years beginning on or after January 1, 2017 for enrollees that are not qualified employees. Issuers have already been providing these notices to qualified employees and are expected to continue sending these notices under the current rule. This final rule also expands issuers' obligation to send notices to former employees under the amended definition of a qualified employee.

The burden estimate associated with this requirement includes the time and effort needed to develop the notice and to distribute it through an automated process to enrollees, as appropriate. We estimate that approximately 445 QHP issuers (including dental issuers) will

participate on the SHOPS in all States. We estimate that it will take approximately 35 hours annually to develop and transmit this notice, including 4 hours for a health policy analyst (at an hourly wage rate of \$58.05), 3 hours for an operations analyst (at an hourly wage rate of \$56.63), 25 hours for a computer programmer (at an hourly wage rate of \$48.61), 2 hours for a fulfillment manager (at an hourly wage rate of \$27.00), and 1 hour for a senior manager (at an hourly wage rate of \$103.95). Therefore, we estimate an aggregate burden of 15,575 hours and \$790,004 for QHP issuers participating in a SHOP as a result of this requirement. We describe this burden in more detail in our discussion of the Information Collection Reporting section for § 156.285(d) in this final rule.

E. ICRs Regarding Collection of Data To Define Essential Health Benefits (§ 156.120)

In § 156.120, we require States that select a base-benchmark plan or an issuer that offers a default base-benchmark plan to submit to HHS certain information in a form and manner, and by a date, determined by HHS. We are also finalizing our proposal to allow each State to select a new base-benchmark plan and supplement if necessary for the 2017 plan year. The information collection associated with State or issuer submission of benchmark plan data is currently approved under OMB Control Number 0938–1174. We expect to collect less information for the 2017 plan year than we previously collected for this purpose, and therefore we have revised our current burden estimate to reflect the reduced burden on issuers. The burden estimate associated with this requirement includes the time and effort needed for issuers and States to file an electronic submission describing the benefits, limits, and exclusion of the plan chosen as the State benchmark for the 2017 benefit year. We estimate that approximately 51 entities are subject to the reporting requirements and that it will take approximately 1.5 hours annually to identify and submit the responsive records to CMS, including 1.5 hours for an issuer or health policy analyst (at an hourly wage rate of \$58.05). Therefore, we estimate an aggregate burden of 76.5 hours and \$4,440.83 for issuers and States as a result of this requirement.

We released information regarding this data collection requirement, in accordance with the Paperwork Reduction Act of 1995, on November 26,

2014 in CMS–10448,⁷⁸ for a 60-day comment period.⁷⁹ We did not receive any comments in relation to that release. This final rule serves to provide notice of a 30-day public comment period in relation to this proposed information collection which will be available on our Web site.⁸⁰

F. ICRs Regarding Prescription Drug Benefits (§ 156.122)

In § 156.122, we require health plans that are required to comply with EHB, as part of a committee that meets the standards established in that section. We expect that health plans have already established P&T committees that meet these standards and follow these processes. These processes include recordkeeping requirements for the P&T committee. Because we believe that issuers are already required to maintain such documentation, such as for accreditation purposes, and that issuers tend to use the same formulary drug list for multiple plans, we believe that the recordkeeping requirement will only impose a minimal additional burden on issuers. Therefore, we estimate that it will take a compliance officer approximately 8 hours (at an hourly wage rate of \$43.34) to prepare for and attend meetings on a quarterly basis, and maintain the required documentation. Therefore, for approximately 2,400 plans in the individual and small group market that would be subject to this requirement, we estimate an aggregate annual burden of 76,800 hours and \$3,328,512.

G. ICRs Regarding Transparency in Coverage (§ 156.220)

In the proposed rule, we solicited comment regarding the type of information that QHP issuers would be required to provide and make available to the public in plain language under § 156.220. We intend to provide further detail regarding the proposed implementation approach in the future. We believe that the 2016 implementation date finalized in this rule will allow sufficient time for HHS to provide details regarding the data collection, review, and public display of transparency elements. We intend to seek public comments on a proposed information collection detailing the

specific data elements, frequency of updates, file types, and other crucial information for OMB approval at a future date.

H. ICRs Regarding Termination Notices for SHOP (§ 156.285(d)(1)(iii)) and § 155.735(d)(1)(iii) and (g)

In § 156.285(d)(1)(ii) and § 155.735(d)(1)(iii) and (g) we require QHP issuers participating in the SHOP to provide notices to qualified employers and enrollees related to terminations of enrollment or coverage through the SHOP due to rescission in accordance with § 147.128 and due to the QHP's termination, decertification, or non-renewal of certification, while shifting the burden of notifying qualified employers and enrollees of terminations due to loss of eligibility or nonpayment of premiums to the SHOP. The amendments to § 156.285(d)(1)(ii) and new § 155.735(g) will take effect January 1, 2016. We note that, while our current rules require issuers to provide notice of terminations when coverage through the SHOP is rescinded in accordance with § 147.128, or when the issuer elects not to seek recertification for a QHP offered through the SHOP, this provision will expand QHP issuers' notice requirements to circumstances in which the QHP terminates or is decertified in accordance with § 155.1080. The notices must inform the enrollee and qualified employer of the termination effective date and the reason for the termination. We specify that when a primary subscriber and his or her dependents live at the same address, a separate notice need not be sent to each dependent at that address, so long as the notice sent to each primary subscriber at that address contains all the required information about the termination of coverage for the primary subscriber and each of his or her dependents at that address. We note that when dependents live at a different address from the primary subscriber, a separate notice must be sent to those dependents. The burden estimate associated with this requirement includes the time and effort needed to develop the notice and to distribute it through an automated process to qualified employer and the enrollee, as appropriate. We estimate that approximately 445 QHP issuers (including dental issuers) will participate on the SHOPS in all States. We estimate that it will take approximately 35 hours annually to develop and transmit this notice, including 4 hours for a health policy analyst (at an hourly wage rate of \$58.05), 3 hours for an operations analyst (at an hourly wage rate of

⁷⁸ <http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10448.html?DLPage=2&DLSort=1&DLSortDir=descending>.

⁷⁹ <http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10448.html?DLPage=2&DLSort=1&DLSortDir=descending>.

⁸⁰ <http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

\$56.63), 25 hours for a computer programmer (at an hourly wage rate of \$48.61), 2 hours for a fulfillment manager (at an hourly wage rate of \$27.00), and 1 hour for a senior manager (at an hourly wage rate of \$103.95). Therefore, we estimate an aggregate burden of 15,575 hours across and \$790,004 for QHP issuers participating in the SHOP as a result of this requirement. HHS intends to seek public comment on a proposed information collection at a later date. We note that amendments to the definition of “enrollee” that are set forth in this final rule and that take effect sooner than January 1, 2016, may expand the universe of individuals who must receive these notices under both the current rule and the amendments that take effect January 1, 2016. As part of developing and proposing the information collection for this ICR, HHS will estimate the effect of the modified definition of “enrollee” on the information collection burden.

Based on the above per-notice development wage rates and hours, we believe that each State-based SHOP will spend roughly 70 hours annually to prepare the two termination notices (35 hours per notice), for a total cost of \$3,550 to design and implement the notices proposed under § 155.735(g). We estimate that there will be approximately 18 State-based SHOPS, and that all State-based SHOPS will be subject to this requirement. Therefore, we estimate an aggregate burden of 1,260 hours and \$63,900 for State-based SHOPS as a result of this requirement.

I. ICRs Regarding Plan Variation Notices and Changes in Eligibility for Cost-Sharing Reductions (§ 156.420 and § 156.425)

In § 156.420(h), we require an issuer to provide a summary of benefits and coverage (SBC) for each plan variation of a QHP it offers in accordance with the rules set forth under § 156.420 (referred to in this section as a “plan variation SBC”), in a manner that is consistent with the standards set forth in § 147.200. In § 156.425(c), we provide that if an individual’s assignment to a plan variation or standard plan without cost-sharing reductions changes in the course of a benefit year (in accordance with § 156.425(a)), an issuer must provide an SBC in a manner consistent with the standards set forth in § 147.200, as soon as practicable after receiving notice from the Exchange of the individual’s change in eligibility and no later than 7 business days following receipt of notice. The burden associated with this requirement is the time and effort for an issuer to create

and provide plan variation SBCs to affected individuals under § 156.420.

Nearly all issuers affected by this requirement have already incurred one-time start-up costs related to implementing the SBC requirements established under § 147.200, and are already providing SBCs that reflect the standard QHPs they offer.⁸¹ We believe that QHP issuers will leverage existing processes to generate and distribute plan variation SBCs under § 156.420(h). We estimate that issuers would incur additional burden to produce and distribute plan variation SBCs under the proposed §§ 156.420(h) and 156.425(c). The additional burden will be associated with three tasks: (1) Producing plan variation SBCs; (2) distributing plan variation SBCs; and (3) distributing a plan variation SBC (or standard QHP without cost-sharing reductions) after a change in eligibility in the course of a benefit year. We intend to revise the information collection approved under OMB Control Number 0938–1187 to reflect this additional burden.

1. Producing Plan Variation SBCs

Because stand-alone dental plans are not required to complete SBCs, we exclude these plans from the number of QHPs that we estimate are required to comply with the requirement. We estimate that approximately 575 issuers participate in the Exchange, and that each issuer offers one QHP per metal level, with four zero cost-sharing plan variations and four limited cost-sharing plan variations (two per metal level per QHP) and three silver plan variations.⁸²

⁸¹ Summary of Benefits and Coverage and Uniform Glossary Final Rule (“SBC Final Rule”), 77 FR 8690 (Feb. 14, 2012). We have already received OMB approval under OMB control number 0938–1146 for the collection of information requirements related to the SBC provisions as finalized under current rules.

⁸² Under § 156.420(a), for each of its silver health plans that an issuer offers, the issuer must offer three variations of the standard silver plan that reflect, in addition to the applicable annual limitation on cost-sharing, the following: (1) A silver plan variation with cost-sharing reductions such that the actuarial value (AV) of the variation is 94 percent plus or minus the de minimis variation for a silver plan variation; (2) a silver plan variation with cost-sharing reductions such that the AV of the variation is 87 percent plus or minus the de minimis variation for a silver plan variation; and (3) a silver plan variation with cost-sharing reductions such that the AV of the variation is 73 percent plus or minus the de minimis variation for a silver plan variation. Under § 156.420(b), for each QHP at any metal level that an issuer offers, the issuer must offer two variations to American Indians/Alaska Natives that reflect the following: (1) A variation of the QHP with all cost sharing eliminated; and (2) a variation of the QHP with no cost-sharing on any item or service that is an essential health benefit furnished directly by the Indian Health Service, an Indian Tribe, Tribal

Therefore, we estimate that each issuer offers 11 plan variations, and would produce 11 SBCs to reflect each plan variation, for a total of 6,325 plan variation SBCs annually. We estimate that it will take up to 1 hour to produce each plan variation SBC, for an annual time burden of 11 hours for each issuer. We estimate that it would take an information technology (IT) professional 5 hours (at an hourly wage rate of \$54.39), a benefits/sales professional 5.5 hours (an hourly wage rate of \$44.9) per hour, and an attorney 30 minutes (at an hourly wage rate of \$84.96) to comply with the requirements. Therefore, we estimate a total annual cost burden of \$561.44 per issuer, and \$322,828 (6,325 hours) for all issuers affected by this requirement.

2. Distributing Plan Variation SBCs

We are unable to estimate the number of cost-sharing reduction-eligible enrollees at this time and the related burden on issuers to provide for these disclosures. We expect that the vast majority (approximately 95 percent) of the total number of plan variation SBCs provided in accordance with § 156.420(h) would be sent prior to enrollment and electronically at minimal cost, under the timing and form requirements set forth in § 147.200(a)(1)(iv) and (a)(4)(iii). Of the remaining number of plan variation SBCs, we estimate that approximately 4 percent of these disclosures will be sent in other instances, in accordance with the other timing requirements that may apply, including, requests for a plan variation SBC made by a consumer in the course of the benefit year. We expect that the vast majority of these disclosures will be provided electronically at minimal cost. We assume that there are costs for paper disclosures, but no costs for electronic disclosures.⁸³ We expect that up to 1 percent of plan variation SBCs will be provided in paper form. We estimate that the labor costs associated with distributing each SBC will be \$1.63 (3 minutes for an administrative assistant at an hourly wage rate of \$32.59), and that printing, mailing, and supply costs will be \$0.69 per SBC (\$0.05 to print each page and \$0.49 for first class postage), for a total cost of \$2.32 per SBC. We estimate an annual burden of \$331 for each QHP issuer and an aggregate burden of \$190,240 for all issuers that are subject to the requirement.

Organization, or Urban Indian Organization, or through referral under contract health services.

⁸³ SBC Final Rule, 77 FR 8691 (Feb. 14, 2012).

3. Notice After Changes in Eligibility for Cost-Sharing Reductions

In § 156.425(c), we require an issuer to provide adequate notice to the individual about the availability of the SBC that accurately reflects the applicable plan variation of the QHP (or the standard QHP without cost-sharing reductions) if an enrollee's eligibility for cost-sharing reductions changes in the course of a benefit year. Similarly, if an enrollee changes QHPs as the result of a special enrollment period in accordance with § 155.420(d)(6), the issuer of the new QHP will be required to provide the individual with an SBC that accurately reflects the new QHP. We are unable to estimate the number of cost-sharing reduction-eligible enrollees who would experience a change in eligibility for cost-sharing reductions at this time and the related burden on issuers to provide for these disclosures. We expect that the vast majority (approximately 99 percent) of

the total number of SBCs provided in accordance with § 156.425(c) will be sent electronically at minimal cost. We estimate that the labor costs associated with producing each SBC will be approximately \$1.63 (3 minutes for an administrative assistant at an hourly wage rate of \$32.59), and that printing, and mailing costs will be \$0.69 (\$0.05 to print each page and \$0.49 for first class postage), for a total cost of \$2.32 per SBC. We estimate a total annual cost of \$165 for each QHP issuer and \$95,120 for all QHP issuers that are subject to this requirement.

J. ICRs Regarding the Collection and Reporting of Quality Improvement Strategies (§ 156.1130)

In § 156.1130, we established requirements for QHP issuers related to data collection and submission of information regarding a quality improvement strategy (QIS). QIS standards will establish the minimum

requirements for the FFEs, States with plan management functions and that State-based Exchanges must follow. State-based Exchanges can, if desired, build additional reporting requirements in accordance with their needs.

Because SADPs will not be included in the initial years, this estimate assumes 575 QHP issuers (all issuers in all Marketplaces excluding SADPs) and covers the annual costs for a QHP issuer over a 3-year period (2016–2018). The burden associated with submitting initial attestations as part of the QHP certification process is currently accounted for under OMB Control Number 0938–1187. We estimate that it will take each QHP issuer 48 hours (at a cost of \$3,372) to collect this QIS data and to submit this information to the Exchange. Therefore, we estimate an aggregate burden of 27,600 hours and \$1,938,900 for 575 QHP issuers as a result of these requirements.

TABLE 12—ANNUAL REPORTING, RECORDKEEPING AND DISCLOSURE BURDEN

Regulation section(s)	Number of respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting (\$)	Total labor cost of reporting (\$)	Total capital/maintenance costs (\$)	Total cost (\$)
§ 147.106(g)	20	20	0.67	13.4	68.17	913	0	913
§ 155.222(a)	9	9	10.00	90	24.10	2,169	0	2,169
§ 155.222(d)	9	9	10.00	90	24.10	2,169	0	2,169
§ 155.720(e) and § 156.285(c)(3)	445	445	35.00	15,575	50.72	790,004	0	790,004
§ 155.735(g)	18	36	35.00	1,260	50.71	63,900	0	63,900
§ 156.120	51	51	1.5	76.5	58.05	4,480.83	0	1,480.28
§ 156.122	2,400	2,400	32.00	76,800	43.34	3,328,512	0	3,328,512
§ 156.285(d)(1)(ii)	445	445	35.00	15,575	50.72	790,004	0	790,004
§ 156.420	575	6,325	1.00	6,325	51.04	322,828	0	322,828
§ 156.420(h)	575	81,000	0.05	4,050	32.59	131,990	58,250	190,240
§ 156.425	575	41,000	0.05	2,025	32.59	65,995	29,125	95,120
§ 156.1130	575	575	48	27,600	70.25	1,938,900	0	1,938,900
Total	2,400			149,504.9		7,441,865	87,375	7,529,240

Copies of the supporting statement and any related forms for information collections identified above can be found at: <http://www.cms.hhs.gov/PaperworkReductionActof1995> or can be obtained by emailing your request, including your address, phone number, OMB number, and CMS document identifier, to: Paperwork@cms.hhs.gov, or by calling the Reports Clearance Office at 410–786–1326. If you comment on these proposed information collection, please reference the CMS document identifier and the OMB control number. To be assured consideration, comments and recommendations must be received in one of the following ways prior to the public comment deadline: 1. Electronically. You may submit your

comments electronically to <http://www.regulations.gov>. Follow the instructions for “Comment or Submission” or “More Search Options” to find the information collection document(s) accepting comments. 2. By regular mail. You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier (CMS–10523), Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850, and, OMB Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: 202–395–6974.

V. Regulatory Impact Analysis

A. Statement of Need

This final rule sets forth standards related to the premium stabilization programs (risk adjustment, reinsurance, and risk corridors) for the 2016 benefit year, as well as certain modifications for the 2015 benefit year, that will protect issuers from the potential effects of adverse selection and protect consumers from increases in premiums due to issuer uncertainty. The Premium Stabilization Rule and the 2014 and 2015 Payment Notices provided detail on the implementation of these programs, including the specific parameters for the 2014 and 2015 benefit years applicable to these programs. This final rule sets forth

additional standards related to essential health benefits, meaningful access in the Exchange, consumer assistance tools and programs of an Exchange, non-Navigator assistance personnel, cost-sharing parameters and cost-sharing reduction notices, quality improvement strategy standards for issuers of QHPs participating in Exchanges, guaranteed availability, guaranteed renewability, minimum essential coverage, the rate review program, the medical loss ratio program, the Small Business Health Options Program, and FFE user fees.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects (\$100 million or more in any 1 year).

OMB has determined that this final rule is “economically significant” within the meaning of section 3(f)(1) of Executive Order 12866, because it is likely to have an annual effect of \$100 million in any 1 year. Accordingly, we have prepared an RIA that presents the costs and benefits of this rule.

Although it is difficult to discuss the wide-ranging effects of these provisions in isolation, the overarching goal of the premium stabilization, market standards, and Exchange-related provisions and policies in the Affordable Care Act is to make

affordable health insurance available to individuals who do not have access to affordable employer-sponsored coverage. The provisions within this final rule are integral to the goal of expanding access to affordable coverage. For example, the premium stabilization programs help prevent risk selection and decrease the risk of financial loss that health insurance issuers might otherwise expect in 2016 and the advance payments of the premium tax credit and cost-sharing reduction programs assist low- and moderate-income consumers and American Indians/Alaska Natives in purchasing health insurance. The combined impacts of these provisions affect the private sector, issuers, and consumers, through increased access to health care services including preventive services, decreased uncompensated care, lower premiums, establishment of quality improvement strategy standards, and increased plan transparency. Through the reduction in financial uncertainty for issuers and increased affordability for consumers, these provisions are expected to increase access to affordable health coverage.

HHS anticipates that the provisions of this final rule will help further the Department’s goal of ensuring that all consumers have access to quality, affordable health care and are able to make informed choices, that Exchanges operate smoothly, that premium stabilization programs work as intended, that SHOPs are provided flexibility, and that employers and consumers are protected from fraudulent and criminal activities. Affected entities such as QHP issuers will incur costs to comply with the provisions specified in the final rule, including administrative costs related to notices, quality improvement strategy requirements, training and recertification requirements, and, in some cases, establishing a larger provider network. In accordance with Executive Order 12866, HHS believes that the benefits of this regulatory action justify the costs.

C. Impact Estimates of the Payment Notice Provisions and Accounting Table

In accordance with OMB Circular A–4, Table 13 below depicts an accounting statement summarizing HHS’s assessment of the benefits, costs, and transfers associated with this regulatory action.

This final rule implements standards for programs that will have numerous effects, including providing consumers with affordable health insurance coverage, reducing the impact of adverse selection, and stabilizing premiums in the individual and small group health insurance markets and in an Exchange. We are unable to quantify certain benefits of this rule—such as improved health outcomes and longevity due to continuous quality improvement and increased insurance enrollment—and certain costs—such as the cost of providing additional medical services to newly-enrolled individuals. The effects in Table 13 reflect qualitative impacts and estimated direct monetary costs and transfers resulting from the provisions of this final rule for reinsurance contributing entities and health insurance issuers. The annualized monetized costs described in Table 13 reflect direct administrative costs to these entities as a result of these provisions, and include administrative costs related to notices, quality improvement strategy requirements, and training and recertification requirements that are estimated in the Collection of Information section of this final rule. The annual monetized transfers described in Table 13 include costs associated with the reinsurance contribution fee, FFE user fees, and the risk adjustment user fee paid to HHS by issuers, and additional MLR rebate payments from issuers to consumers. We also note that reinsurance administrative expenses, included in the reinsurance contribution rate, will increase slightly from 2015 to 2016. In addition, as a result of HHS’s increased contract costs related to risk adjustment operations and risk adjustment data validation, we will collect a total of \$50 million in risk adjustment user fees or \$1.75 per enrollee per year from risk adjustment issuers, which is greater than the \$0.96 per-enrollee-per-year risk adjustment user fee amount established for benefit year 2015. This increase is due in large part to risk adjustment data validation costs that will occur in 2016. The increase in FFE user fee collections is a result of a constant user fee rate from 2015 to 2016 (3.5 percent) but expected growth in enrollment in the FFEs. We are also including costs associated with administrative appeals under § 156.1220 in the RIA of this final rule.

TABLE 13—ACCOUNTING TABLE

Benefits:

Qualitative:

TABLE 13—ACCOUNTING TABLE—Continued

* Increased enrollment in the individual market leading to improved access to health care for the previously uninsured, especially individuals with medical conditions, which will result in improved health and protection from the risk of catastrophic medical expenditures. * Encourage continuous quality improvement among QHP issuers to improve health outcomes at lower costs. * Allow Exchanges to make informed QHP certification decisions. * Increasing coverage options for small businesses and their employees while mitigating the effect of adverse selection. * Ensure that consumers in group health plans not subject to ERISA receive the benefit of MLR rebates in a timely manner.				
Costs:				
	Estimate (million)	Year dollar	Discount rate (percent)	Period covered
Annualized Monetized (\$/year)	6.77	2015	7	2015–2018
	6.77	2015	3	2015–2018
Quantitative:				
* Costs incurred by issuers and contributing entities to comply with provisions in the rule.				
* Costs incurred by States for complying with audits of State-operated reinsurance programs.				
Transfers:				
	Estimate (million)	Year dollar	Discount rate (percent)	Period covered
Annualized Monetized (\$/year)	418.61	2015	7	2015–2018
	418.52	2015	3	2015–2018
* Transfers reflect incremental cost increases from 2015–2016 for reinsurance administrative expenses, FFE user fees, and the risk adjustment user fee, which are transfers from contributing entities and health insurance issuers to the Federal government. FFE user fees are newly included in the estimated transfers as collections are now projected for the period covered. Transfers also reflect annual transfer from shareholders or nonprofit stakeholders to enrollees of rebates paid by issuers for coverage in the individual and group markets, resulting from clarification regarding MLR methodology to account for Federal and State employment taxes.				
* Unquantified: Lower premium rates in the individual market due to the improved risk profile of the insured, competition, and pooling risk.				

This RIA expands upon the impact analyses of previous rules and utilizes the Congressional Budget Office's (CBO) analysis of the Affordable Care Act's impact on Federal spending, revenue collection, and insurance enrollment. Table 14 summarizes the effects of the risk adjustment and reinsurance programs on the Federal budget from fiscal years 2015 through 2018, with the additional, societal effects of this proposed rule discussed in this RIA. We do not expect the provisions of this final rule to significantly alter CBO's estimates of the budget impact of the risk adjustment, reinsurance, and risk

corridors programs that are described in Table 14. For this RIA, we are shifting the estimates for the risk adjustment and reinsurance programs to reflect the 4-year period from fiscal years 2015 through 2018, because these payments and charges will begin in the 2015 calendar year for the 2014 benefit year. We note that transfers associated with the risk adjustment and reinsurance programs were previously estimated in the Premium Stabilization Rule; therefore, to avoid double-counting, we do not include them in the accounting statement for this final rule (Table 13).

In addition to utilizing CBO projections, HHS conducted an internal analysis of the effects of its regulations on enrollment and premiums. Based on these internal analyses, we anticipate that the quantitative effects of the provisions finalized in this rule are consistent with our previous estimates in the 2015 Payment Notice for the impacts associated with the cost-sharing reduction program, the advance payments of the premium tax credit program, the premium stabilization programs, and FFE user fee requirements.

TABLE 14—ESTIMATED FEDERAL GOVERNMENT OUTLAYS AND RECEIPTS FOR THE RISK ADJUSTMENT, REINSURANCE, AND RISK CORRIDORS PROGRAMS FROM FY 2014–2018

[In billions of dollars]

Year	2015	2016	2017	2018	2019	2015–2019
Risk Adjustment, Reinsurance, and Risk Corridors Program Payments	17	17.5	19.5	15	17	86
Risk Adjustment, Reinsurance, and Risk Corridors Program Collections	18	16.5	19.5	15	17	86

Source: Congressional Budget Office. Updated Estimates of the Insurance Coverage Provisions of the Affordable Care Act, January 2015.

1. Rate Review

The final rule will trigger review of rate increases that meet or exceed the

applicable review threshold when such increases happen at the “plan” level rather than at the “product” level. This

will protect consumers against unreasonable rate increases for their plans, since, under current regulations,

it is possible for a plan to experience a rate increase higher than the threshold and still avoid review because the average rate increase for the product does not meet or exceed the threshold. States may have to review more submissions and experience an increase in related costs. The establishment of a uniform timeframe by which issuers in every State must submit a completed Rate Filing Justification to CMS and the applicable State for all rate increases, including both QHPs and non-QHPs, will provide timely information to consumers and other stakeholders and ensure that State and Federal regulators have adequate time for review prior to implementation of a rate increase. The amendment to specify the timing for States to make proposed and final rate increase information available to the public will ensure that consumers have timely access to this information. These provisions will also reduce the potential for anti-competitive behavior and promote fair market competition between issuers inside and outside of the Exchange.

2. Change of Ownership Notification Requirement

This final rule provides that when an issuer of a QHP, a plan otherwise subject to risk corridors, a risk adjustment covered plan, or a reinsurance-eligible plan, experiences a change in ownership as recognized by the State in which the plan is offered, the issuer must notify HHS in a manner specified by HHS, by the latest of (1) the date the transaction is entered into; or (2) the 30th day prior to the effective date of the transaction. We expect that upon notification, issuers may need to work with HHS to clarify operational processes related to the HHS-administered programs, and will follow with guidance related to such operational processes. We estimate the administrative costs associated with the notification requirement in the Collection of Information section of this final rule.

3. Appeals Process for HHS-Approved Vendors for FFE Training and Information Verification for Agents and Brokers

In § 155.222, we proposed information collection and disclosure requirements that pertain to the approval of vendors to have their FFE agent and broker training and information verification programs recognized as sufficient for agents and brokers to satisfy the training requirement to assist or facilitate enrollment in individual market or SHOP coverage through the FFEs. We

also establish a monitoring and appeals process for such HHS-approved vendors. We estimate that five vendors that apply may not have their application approved, and one vendor may have their approval revoked, and all of those vendors will appeal HHS's determination and submit additional documentation to HHS. We estimate that filing an appeal with HHS will take no longer than 1 hour. Therefore, at an hourly wage rate of \$24.10, we estimate a total cost of \$144.60 as a result of this appeals process.

4. Risk Adjustment

The risk adjustment program is a permanent program created by the Affordable Care Act that transfers funds from lower risk, non-grandfathered plans to higher risk, non-grandfathered plans in the individual and small group markets, inside and outside the Exchanges. We established standards for the administration of the risk adjustment program in subparts D and G of part 45 of the CFR.

A State approved or conditionally approved by the Secretary to operate an Exchange may establish a risk adjustment program, or have HHS do so on its behalf. As described in the 2014 and 2015 Payment Notices, if HHS operates risk adjustment on behalf of a State, it will fund its risk adjustment program operations by assessing a risk adjustment user fee on issuers of risk adjustment covered plans. For the 2016 benefit year, we estimate that the total cost for HHS to operate the risk adjustment program on behalf of States for 2016 will be approximately \$50 million, and that the risk adjustment user fee would be approximately \$1.75 per enrollee per year. The increased risk adjustment user fee for 2016 is the result of the increased contract costs to support the risk adjustment data validation process.

5. Reinsurance

The Affordable Care Act directs that a transitional reinsurance program be established in each State to help stabilize premiums for coverage in the individual market by helping to pay the cost of treating high-cost enrollees. In the 2014 and 2015 Payment Notices, we expanded upon the standards set forth in subparts C and E of the Premium Stabilization Rule and established the 2014 and 2015 uniform reinsurance payment parameters and national contribution rate. In this rule, we finalize the 2016 uniform reinsurance payment parameters and contribution rate and a modification to the 2015 benefit year attachment point.

Section 153.220(c) provides that HHS will publish the uniform per capita reinsurance contribution rate for the upcoming benefit year in the annual HHS notice of benefit and payment parameters. Section 1341(b)(3)(B)(iii) of the Affordable Care Act specifies that \$10 billion for reinsurance contributions is to be collected from contributing entities for the 2014 benefit year (the reinsurance payment pool), \$6 billion for the 2015 benefit year, and \$4 billion for the 2016 benefit year. Additionally, sections 1341(b)(3)(B)(iv) and 1341(b)(4) of the Affordable Care Act direct that \$2 billion in funds is to be collected for contribution to the U.S. Treasury for the 2014 benefit year, \$2 billion for the 2015 benefit year, and \$1 billion for the 2016 benefit year. Finally, section 1341(b)(3)(B)(ii) of the Affordable Care Act allows for the collection of additional amounts for administrative expenses. Taken together, these three components make up the total dollar amount to be collected from contributing entities for 2014, 2015 and 2016 benefit years for the reinsurance program under the uniform per capita contribution rate.

In the 2015 Payment Notice, we estimated that the Federal administrative expenses of operating the reinsurance program would be \$25.4 million, based on our estimated contract and operational costs. We used the same methodology to estimate the administrative expenses for the 2016 benefit year. We estimate this amount to be approximately \$32 million for the 2016 benefit year. This estimate increased for the 2016 benefit year due to increased audit and data validation contract costs. We believe that this figure reflects the Federal government's significant economies of scale, which helps to decrease the costs associated with operating the reinsurance program. Based on our estimate of covered lives for which reinsurance contributions are to be made for 2016, we are finalizing a uniform reinsurance contribution rate of \$0.17 annually per capita for HHS administrative expenses. If a State establishes its own reinsurance program, HHS would transfer \$0.085 of the per capita administrative fee to the State for purposes of administrative expenses incurred in making reinsurance payments, and retain the remaining \$0.085 to offset the costs of collecting contributions. We note that the administrative expenses for reinsurance payments will be distributed to those States that operate their own reinsurance program in proportion to the State-by-State total requests for reinsurance payments made

under the uniform reinsurance payment parameters.

6. Risk Corridors

The Affordable Care Act creates a temporary risk corridors program for the years 2014, 2015, and 2016 that applies to QHPs, as defined in § 153.500. Section 1342 of the Affordable Care Act directs the Secretary to establish a temporary risk corridors program that protects issuers against inaccurate rate setting from 2014 through 2016. The Affordable Care Act establishes the risk corridors program as a Federal program; consequently, HHS will operate the risk corridors program under Federal rules with no State variation.

We finalize a clarification to the risk corridors transitional adjustment for benefit year 2014. We clarify that we intend to implement the risk corridors transitional adjustment for transitional plans only, as stated in the 2015 Payment Notice. This clarification does not affect the impact of the risk corridors transitional adjustment.

For benefit year 2016, we are finalizing the treatment of excess risk corridors collections that may remain after the 3-year duration of the program. We will adjust the allowable administrative cost ceiling and profit floor so that any excess risk corridors collections that remain in benefit year 2016 are paid out to eligible QHP issuers. We anticipate that collections will fully offset payments over the 3-year duration of the program. Consequently, we do not believe that this provision will have a monetary impact on QHP issuers or the Federal government.

7. SHOP

The SHOP facilitates the enrollment of eligible employees of small employers into small group health insurance plans. A qualitative analysis of the costs and benefits of establishing a SHOP was included in the RIA published in conjunction with the Exchange Establishment Rule.⁸⁴

Please see the Collection of Information section of this proposed rule for the costs expected to be incurred by State-based SHOPS and QHP issuers participating in the SHOP related to the notification requirements related to terminations of coverage or enrollment through the SHOP and the notification requirement for the coverage effective date under the new definition of an enrollee. We believe the cost associated with termination notices is justified because SHOPS are best

positioned to provide meaningful notice regarding terminations due to loss of eligibility and nonpayment of premiums in a timely manner, while issuers are best positioned to provide meaningful notice when coverage or enrollment through the SHOP is terminated due to a rescission in accordance with § 147.128 or when the QHP is terminated, decertified, or its certification is not renewed, as well as notices of the effective date of coverage. We believe expanding the notice requirement under § 155.720(e) benefits all individuals with coverage, including dependents, former employees of a qualified employer, and certain business owners, with a notification of effective date of coverage.

8. User Fees

To support the operation of FFEs, we require in § 156.50(c) that a participating issuer offering a plan through an FFE must remit a user fee to HHS each month equal to the product of the user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year and the monthly premium charged by the issuer for each policy under the plan where enrollment is through an FFE. For the 2016 benefit year, we are finalizing a monthly user fee rate equal to 3.5 percent of the monthly premium. As described in the Budget of the United States Government, Fiscal Year 2016, we expect approximately \$1.514 billion in user fee collections would be obligated in fiscal year 2016. For the user fee charge assessed on issuers in the FFE, we received an exception to OMB Circular No. A–25R, which requires that the user fee charge be sufficient to recover the full cost to the Federal government of providing the special benefit. This exception ensures that the FFEs can support many of the goals of the Affordable Care Act, including improving the health of the population, reducing health care costs, and providing access to health coverage as advanced by § 156.50(d).

9. Essential Health Benefits, Cost Sharing, and Actuarial Value

Issuers may incur minor administrative costs associated with altering benefits, cost-sharing and/or AV parameters of their plan designs to ensure compliance with the EHB requirements in this rule. For example, issuers that do not currently meet the standards for EHB prescription drug coverage will incur contracting and one-time administrative costs to bring their prescription drug benefits into compliance. HHS expects that the

process for compliance with the revised EHB requirements will not significantly add to existing compliance costs because issuers have extensive experience in offering products with various benefits and levels of cost sharing and these modifications are expected to be relatively minor for most issuers.

In addition, we are adding standards for a health plan's formulary exception process that includes an external review. We believe that issuers that provide EHB already have formulary exceptions processes and procedures in place that allow an enrollee to request and gain access to clinically appropriate drugs not covered by the plan. We do not expect these requirements to significantly increase the volume of reviews conducted under issuers' contracts with Independent Review Organizations. Therefore, we do not anticipate that these requirements would result in any significant new cost for issuers.

10. Network Adequacy

Issuers may incur minor administrative costs associated with updating their provider directory to ensure compliance with the requirements under this final rule. Since issuers already maintain a directory and the expected modification is to re-locate that directory to a more user-friendly location on the issuer Web site, HHS expects that compliance will not demand any additional resources.

11. Downstream Entities

We revised § 156.200(b)(7), to clarify that a QHP issuer is required to comply with the standards under part 153 and not just the standards related to the risk adjustment program. Under § 156.340, notwithstanding any relationship(s) that a QHP issuer may have with delegated and downstream entities, a QHP issuer maintains responsibility for its compliance and the compliance of any of its delegated or downstream entities, as applicable, with all applicable standards, including the standards of subpart C of part 156 for each of its QHPs on an ongoing basis. Because we believe that QHP issuers have existing agreements with downstream entities that define responsibilities, we do not believe that this requirement will impose an additional burden on QHP issuers.

12. Provisions Related to Cost Sharing

The Affordable Care Act provides for the reduction or elimination of cost sharing for certain eligible individuals enrolled in QHPs offered through the Exchanges. This assistance will help

⁸⁴ Available at: <http://ccio.cms.gov/resources/files/Files2/03162012/hie3r-ria-032012.pdf>.

many low- and moderate-income individuals and families obtain health insurance—for many people, cost sharing is a barrier to obtaining needed health care.⁸⁵

To support the administration of the cost-sharing reduction program, we set forth in this final rule the reductions in the maximum annual limitation on cost sharing for silver plan variations. Consistent with our analysis in the 2014 and 2015 Payment Notices, we developed three model silver level QHPs and analyzed the impact on their AVs of the reductions described in the Affordable Care Act to the estimated 2016 maximum annual limitation on cost sharing for self-only coverage (\$6,850). We do not believe these changes will result in a significant economic impact.

We are also finalizing the premium adjustment percentage for the 2016 benefit year. Section 156.130(e) provides that the premium adjustment percentage is the percentage (if any) by which the average per capita premium for health insurance coverage for the preceding calendar year exceeds such average per capita premium for health insurance for 2013. The annual premium adjustment percentage sets the rate of increase for three parameters detailed in the Affordable Care Act: The annual limitation on cost sharing (defined at § 156.130(a)), the required contribution percentage by individuals for minimum essential health coverage the Secretary may use to determine eligibility for hardship exemptions under Section 5000A of the Code, and the section 4980H(a) and section 4980H(b) assessable payment amounts (finalized at 26 CFR 54.4980H in the “Shared Responsibility for Employers Regarding Health Coverage,” published in the *Federal Register* on February 12, 2014 (79 FR 8544)). We believe that the 2016 premium adjustment percentage of 8.316047520 percent is well within the parameters used in the modeling of the Affordable Care Act, and we do not expect that these proposed provisions will alter CBO’s January 2015 baseline estimates of the budget impact.

13. Minimum Essential Coverage

The final rule provides continued recognition of State high risk pools as minimum essential coverage. This will

facilitate the transition of State high risk pool enrollees into QHPs through the Exchange or into other forms of minimum essential coverage, while ensuring continued access to coverage. It will also help ensure that this vulnerable population will not be subject to the shared responsibility payment during this transition, and thereby avoid an increase in out-of-pocket costs.

14. Quality Improvement Strategy

The standards requiring QHP issuers participating in Exchanges to establish and submit information regarding a quality improvement strategy will encourage continuous quality improvement among QHP issuers to help strengthen system-wide efforts to improve health outcomes at lower costs, promote provider payment models that link quality and value of services, allow for flexibility and innovation of diverse market-based incentive approaches, encourage meaningful improvements as well as provide regulators and stakeholders with information to use for monitoring and evaluation purposes. We discuss the administrative costs associated with submitting this information in the Collection of Information section of this proposed rule.

15. Administrative Appeals

In § 156.1220, we establish an administrative appeals process to address unresolved discrepancies for advance payments of the premium tax credit, advance payment and reconciliation of cost-sharing reductions, FFE user fees, and the premium stabilization programs, as well as any assessment of a default risk adjustment charge under § 153.740(b). We estimated the burden associated with the administrative appeals process in the 2015 Payment Notice, and in the Supporting Statement approved under OMB Control Number 0938–1155. We will revise the information collection currently approved OMB Control Number 0938–1155 with an October 31, 2015 expiration date. We do not believe that the provisions in this final rule will alter the economic impact of this requirement that was estimated in the 2015 Payment Notice.

16. Medical Loss Ratio

This final rule clarifies the treatment of cost-sharing reductions in the MLR calculations. This final rule also ensures timely distribution of rebates for the benefit of subscribers of group health plans not subject to ERISA. Specifically, the amendments to the MLR provisions governing the distribution of rebates to

group enrollees in non-Federal governmental and other group health plans not subject to ERISA ensure that group policyholders of such plans do not withhold the benefit of rebates from the enrollees for longer than 3 months. This final rule also provides an additional option for distribution of rebates by such policyholders. We do not anticipate that these provisions will have any significant effect on MLR program estimates. This final rule also amends the MLR regulations to provide that premium in MLR and rebate calculations should not be reduced by the amount of Federal and State employment taxes. Based on MLR data for the 2013 MLR reporting year, the clarification regarding the treatment of such taxes in the MLR and rebate calculations may result in additional rebate payments to consumers of approximately \$35 million from issuers that previously interpreted the MLR December 1, 2010 interim final rule to permit the reduction of premium by the amount of such taxes.

D. Regulatory Alternatives Considered

When considering the final 2016 reinsurance payment parameters we also considered a set of uniform reinsurance payment parameters that would have substantially lowered the reinsurance cap, but believe those uniform reinsurance payment parameters would have raised the complexity of estimating the effects of reinsurance for issuers.

We also considered expanding the risk corridors transitional adjustment to apply to early renewal plans. This approach would have increased the impact of the risk corridors adjustment and altered the impact analysis related to the risk corridors transitional adjustment that was published in the 2015 Payment Notice. However, we decided not to propose or finalize this alternate policy.

We considered for the 2016 benefit year requiring issuers to separate visit limits for rehabilitative and habilitative services and devices. However, we determined that issuers’ claims systems are unable to distinguish rehabilitative and habilitative services and devices at this time. Therefore, we determined that this requirement should not be effective until 2017 to allow issuers to modify their claims systems.

We considered ending the good faith compliance policy for QHP issuers. However, we determined that subjecting QHP issuers to increased punitive actions in the early years of the Exchange would be less effective than working with issuers to address compliance issues. We also considered

⁸⁵ Brook, Robert H., John E. Ware, William H. Rogers, Emmett B. Keeler, Allyson Ross Davies, Cathy D. Sherbourne, George A. Goldberg, Kathleen N. Lohr, Patricia Camp and Joseph P. Newhouse. *The Effect of Coinsurance on the Health of Adults: Results from the RAND Health Insurance Experiment*. Santa Monica, CA: RAND Corporation, 1984. Available at: <http://www.rand.org/pubs/reports/R3055>.

a more expansive good faith compliance policy, but believe that 2 years is a sufficient transition period.

We considered not suppressing QHPs on the FFE, but this approach would have resulted in less flexibility for the FFE to address situations that could affect consumers' interests. For example, this alternative could cause disruption by requiring consumers to select a new QHP mid-year if their QHP was decertified rather than just suppressed for new enrollments.

We also considered not recognizing vendors as an alternative avenue for FFE training and information verification of agents and brokers. However, we believe that recognizing vendors will make it easier for agents and brokers to identify appropriate vendors who meet HHS standards for training and registration.

Additionally, we considered not requiring QIS reporting for QHP issuers. However, we decided to finalize the policy in this rule because we believe that QIS reporting will result in higher quality QHPs being offered in the Exchange and make it easier for consumers to select a high-quality QHP.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*) (RFA) requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of the proposed rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The RFA generally defines a "small entity" as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of "small entity." HHS uses a change in revenues of more than 3 to 5 percent as its measure of significant economic impact on a substantial number of small entities.

In this final rule, we set forth standards for the risk adjustment, reinsurance, and risk corridors programs, which are intended to stabilize premiums as insurance market reforms are implemented and Exchanges facilitate increased enrollment. Because we believe that insurance firms offering comprehensive health insurance policies generally exceed the size thresholds for "small entities" established by the SBA, we do not believe that an initial regulatory flexibility analysis is required for such firms.

For purposes of the RFA, we expect the following types of entities to be affected by this rule:

- Health insurance issuers.
- Group health plans.
- Reinsurance entities.

We believe that health insurance issuers and group health plans would be classified under the North American Industry Classification System (NAICS) code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of \$35.5 million or less would be considered small entities for these NAICS codes. Issuers could possibly be classified in 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard would be \$32.5 million or less.

In this final rule, we set forth standards for employers that choose to participate in a SHOP Exchange. Until 2017, the SHOPS are limited by statute to employers with at least one but not more than 100 employees. For this reason, we expect that many employers who would be affected by these requirements would meet the SBA standard for small entities. We do not believe that these provisions impose requirements on employers offering health insurance through the SHOP that are more restrictive than the current requirements on small businesses offering employer-sponsored insurance. We believe the processes that we have established constitute the minimum amount of requirements necessary to implement the SHOP program and accomplish our policy goals, and that no appropriate regulatory alternatives could be developed to further lessen the compliance burden.

Based on data from MLR annual report submissions for the 2013 MLR reporting year, approximately 141 out of 500 issuers of health insurance coverage nationwide had total premium revenue of \$38.5 million or less. This estimate may overstate the actual number of small health insurance companies that may be affected, since 77 percent of these small companies belong to larger holding groups, and many if not all of these small companies are likely to have non-health lines of business that would result in their revenues exceeding \$38.5 million. Only 16 of these small entities owed a rebate for the 2013 reporting year, and none of these small entities are estimated to experience a rebate increase of more than 0.1 percent of total premium revenue under the MLR provisions of this final rule. None of the small entities that did not previously owe rebates are expected to owe rebates as a result of the provisions of this final rule. Based on data from MLR annual

report submissions for the 2013 MLR reporting year, approximately 286,750 out of 1.6 million small group policyholders and 13,500 out of 228,000 large group policyholders nationwide were owed rebates for the 2013 reporting year. It is uncertain how many of the group policyholders obtaining coverage from health insurance issuers subject to MLR are both (a) small entities that fall below the size thresholds set by the SBA for various industries, and (b) enrolled in group health plans not subject to ERISA, and would therefore be subject to the proposed provisions related to MLR. However, the provisions of this final rule only establish a deadline for the use of MLR rebates by certain policyholders similar to the deadline that is already followed by most group policyholders, and do not otherwise alter the requirements for rebate use by such policyholders. In addition, the clarification regarding how health insurance issuers must treat cost-sharing reductions in their MLR calculations simply aligns the MLR regulatory language with the risk corridors program.

F. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a rule that includes any Federal mandate that may result in expenditures in any 1 year by a State, local, or Tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. In 2015, that threshold is approximately \$141 million. Although we have not been able to quantify all costs, the combined administrative cost and user fee impact on State, local, or Tribal governments and the private sector may be above the threshold. Earlier portions of this RIA constitute our UMRA analysis.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications. Because States have flexibility in designing their Exchange and Exchange-related programs, State decisions will ultimately influence both administrative expenses and overall premiums. States are not required to establish an Exchange or risk adjustment or reinsurance program. For States electing to operate an Exchange, risk adjustment

or reinsurance program, much of the initial cost of creating these programs will be funded by Exchange Planning and Establishment Grants. After establishment, Exchanges will be financially self-sustaining, with revenue sources at the discretion of the State. Current State Exchanges may charge user fees to issuers.

In HHS's view, while this rule would not impose substantial direct requirement costs on State and local governments, this regulation has Federalism implications due to direct effects on the distribution of power and responsibilities among the State and Federal governments relating to determining standards relating to health insurance that is offered in the individual and small group markets. Each State electing to establish an Exchange must adopt the Federal standards contained in the Affordable Care Act and in this rule, or have in effect a State law or regulation that implements these Federal standards. However, HHS anticipates that the Federalism implications (if any) are substantially mitigated because under the statute, States have choices regarding the structure and governance of their Exchanges and risk adjustment and reinsurance programs. Additionally, the Affordable Care Act does not require States to establish these programs; if a State elects not to establish any of these programs or is not approved to do so, HHS must establish and operate the programs in that State.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have Federalism implications or limit the policy making discretion of the States, HHS has engaged in efforts to consult with and work cooperatively with affected States, including participating in conference calls with and attending conferences of the National Association of Insurance Commissioners, and consulting with State insurance officials on an individual basis.

Throughout the process of developing this proposed rule, HHS has attempted to balance the States' interests in regulating health insurance issuers, and Congress' intent to provide access to Affordable Insurance Exchanges for consumers in every State. By doing so, it is HHS's view that we have complied with the requirements of Executive Order 13132.

H. Congressional Review Act

This rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5

U.S.C. 801, *et seq.*), which specifies that before a rule can take effect, the Federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report containing a copy of the rule along with other specified information, and has been transmitted to Congress and the Comptroller General for review.

List of Subjects

45 CFR Part 144

Health care, Health insurance, and Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, and State regulation of health insurance.

45 CFR Part 153

Administrative practice and procedure, Adverse selection, Health care, Health insurance, Health records, Organization and functions (Government agencies), Premium stabilization, Reporting and recordkeeping requirements, Reinsurance, Risk adjustment, Risk corridors, Risk mitigation, State and local governments.

45 CFR Part 154

Administrative practice and procedure, Claims, Health care, Health insurance, Health plans, Penalties, Reporting and recordkeeping requirements.

45 CFR Part 155

Administrative practice and procedure, Health care access, Health insurance, Reporting and recordkeeping requirements, State and local governments, Required Contribution Percentage, Cost-sharing reductions, Advance payments of the premium tax credit, Administration and calculation of advance payments of the premium tax credit, Plan variations, Actuarial value.

45 CFR Part 156

Administrative appeals, Administrative practice and procedure, Administration and calculation of advance payments of the premium tax credit, Advertising, Advisory Committees, American Indian/Alaska Natives, Brokers, Conflict of interest, Consumer protection, Cost-sharing reductions, Grant programs-health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Individuals with disabilities, Loan programs-health, Organization and

functions (Government agencies), Medicaid, Payment and collections reports, Public assistance programs, Reporting and recordkeeping requirements, State and local governments, Sunshine Act, Technical assistance, Women, and Youth.

45 CFR Part 158

Administrative practice and procedure, Claims, Health care, Health insurance, Health plans, Medical loss ratio, Penalties, Premium revenues, Rebating Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR parts 144, 147, 153, 154, 155, 156, and 158 as set forth below.

PART 144—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

■ 1. The authority citation for part 144 continues to read as follows:

Authority: Secs. 2701 through 2763, 2791, and 2792 of the Public Health Service Act, 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92.

■ 2. Section 144.103 is amended by revising the definitions of “Plan” and “State” to read as follows:

§ 144.103 Definitions.

* * * * *

Plan means, with respect to an issuer and a product, the pairing of the health insurance coverage benefits under the product with a particular cost-sharing structure, provider network, and service area. The product comprises all plans offered with those characteristics and the combination of the service areas for all plans offered within a product constitutes the total service area of the product. With respect to a plan that has been modified at the time of coverage renewal consistent with § 147.106 of this subchapter—

(1) The plan will be considered to be the same plan if it:

(i) Has the same cost-sharing structure as before the modification, or any variation in cost sharing is solely related to changes in cost or utilization of medical care, or is to maintain the same metal tier level described in sections 1302(d) and (e) of the Affordable Care Act;

(ii) Continues to cover a majority of the same service area; and

(iii) Continues to cover a majority of the same provider network. For this purpose, the plan's provider network on the first day of the plan year is compared with the plan's provider

network on the first day of the preceding plan year (as applicable).

(2) The plan will not fail to be treated as the same plan to the extent the modification(s) are made uniformly and solely pursuant to applicable Federal and State requirements if—

(i) The modification is made within a reasonable time period after the imposition or modification of the Federal or State requirement;

(ii) The modification is directly related to the imposition or modification of the Federal or State requirement.

(3) A State may permit greater changes to the cost-sharing structure, or designate a lower threshold for maintenance of the same provider network or service area for a plan to still be considered the same plan.

* * * * *

State means each of the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands; except that for purposes of part 147, the term does not include Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

* * * * *

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 3. The authority citation for part 147 continues to read as follows:

Authority: Secs 2701 through 2763, 2791 and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

■ 4. Section 147.104 is amended by—

■ a. Revising paragraphs (b)(1)(i)(C), (b)(2), and (b)(4).

■ b. Redesignating paragraphs (f) through (h) as paragraphs (g) through (i), respectively.

■ c. Adding new paragraph (f).

The revisions and addition read as follows:

§ 147.104 Guaranteed availability of coverage.

* * * * *

(b) * * *

(1) * * *

(i) * * *

(C) With respect to coverage in the small group market, and in the large group market if such coverage is offered through a Small Business Health Options Program (SHOP) in a State, coverage must become effective consistent with the dates described in § 155.725 of this subchapter, except as

provided in paragraph (b)(1)(iii) of this section.

* * * * *

(2) *Limited open enrollment periods.*

A health insurance issuer in the individual market must provide a limited open enrollment period for the events described in § 155.420(d) of this subchapter, excluding § 155.420(d)(3) of this subchapter (concerning citizenship status), § 155.420(d)(8) of this subchapter (concerning Indians), and § 155.420(d)(9) of this subchapter (concerning exceptional circumstances).

* * * * *

(4) *Length of enrollment periods.* (i) In the group market, enrollees must be provided 30 calendar days after the date of the qualifying event described in paragraph (b)(3) of this section to elect coverage.

(ii) In the individual market, enrollees must be provided 60 calendar days after the date of an event described in paragraph (b)(2) and (3) of this section to elect coverage, as well as 60 calendar days before certain triggering events as provided for in § 155.420(c)(2) of this subchapter.

* * * * *

(f) *Calendar year plans.* An issuer that offers coverage in the individual market, or in a merged market in a State that has elected to merge the individual market and small group market risk pools in accordance with section 1312(c)(3) of the Affordable Care Act, must ensure that such coverage is offered on a calendar year basis with a policy year ending on December 31 of each calendar year.

* * * * *

■ 5. Section 147.106 is amended by—

■ a. Redesignating paragraphs (g) through (j) as paragraphs (h) through (k), respectively.

■ b. Adding new paragraph (g).

The addition reads as follows:

§ 147.106 Guaranteed renewability of coverage.

* * * * *

(g) *Notification of change of ownership.* If an issuer of a QHP, a plan otherwise subject to risk corridors, a risk adjustment covered plan, or a reinsurance-eligible plan experiences a change of ownership, as recognized by the State in which the plan is offered, the issuer must notify HHS in a manner specified by HHS, by the latest of—

(1) The date the transaction is entered into; or

(2) The 30th day prior to the effective date of the transaction.

* * * * *

PART 153—STANDARDS RELATED TO REINSURANCE, RISK CORRIDORS, AND RISK ADJUSTMENT UNDER THE AFFORDABLE CARE ACT

■ 6. The authority citation for part 153 continues to read as follows:

Authority: Secs. 1311, 1321, 1341–1343, Pub. L. 111–148, 24 Stat. 119.

■ 7. Section 153.100 is amended by revising paragraph (c) to read as follows:

§ 153.100 State notice of benefit and payment parameters.

* * * * *

(c) *State notice deadlines.* If a State is required to publish an annual State notice of benefit and payment parameters for a particular benefit year, it must do so by the later of March 1 of the calendar year prior to the applicable benefit year, or by the 30th day following the publication of the final HHS notice of benefit and payment parameters for that benefit year.

* * * * *

■ 8. Section 153.400 is amended by revising paragraph (a)(1)(iii) and adding paragraph (c) to read as follows:

§ 153.400 Reinsurance contribution funds.

(a) * * *

(1) * * *

(iii) Such plan or coverage is expatriate health coverage, as defined by the Secretary, or for the 2015 and 2016 benefit years only, is a self-insured group health plan with respect to which enrollment is limited to participants who reside outside of their home country for at least 6 months of the plan year, and any covered dependents; or

* * * * *

(c) *Determination of a debt.* Any amount owed to the Federal government by a self-insured group health plan (including a group health plan that is partially self-insured and partially insured, where the health insurance coverage does not constitute major medical coverage) and its affiliates for reinsurance is a determination of a debt.

■ 9. Section 153.405 is amended by—

■ a. Revising paragraphs (b), (c)(1), (d) introductory text, (g)(4)(i) introductory text, and (g)(4)(ii) introductory text.

■ b. Removing paragraph (c)(2).

■ c. Redesignating paragraph (c)(3) as paragraph (c)(2).

■ d. Revising newly designated paragraph (c)(2).

The revisions read as follows:

§ 153.405 Calculation of reinsurance contributions.

* * * * *

(b) *Annual enrollment count.* No later than November 15 of benefit year 2014,

2015, or 2016, as applicable, or, if such date is not a business day, the next business day, a contributing entity must submit an annual enrollment count of the number of covered lives of reinsurance contribution enrollees for the applicable benefit year to HHS. The count must be determined as specified in paragraphs (d) through (g) of this section, as applicable.

(c) * * *

(1) Following submission of the annual enrollment count described in paragraph (b) of this section, HHS will notify the contributing entity of the reinsurance contribution amount allocated to reinsurance payments, administrative expenses, and the U.S. Treasury to be paid for the applicable benefit year.

(2) A contributing entity must remit reinsurance contributions to HHS no later than January 15, 2015, 2016, or 2017, as applicable, or, if such date is not a business day, the next business day, if making a combined contribution or the first payment of the bifurcated contribution, and no later than November 15, 2015, 2016, or 2017, as applicable, or, if such date is not a business day, the next business day, if making the second payment of the bifurcated contribution.

(d) *Procedures for counting covered lives for health insurance issuers.* A health insurance issuer must use the same method in a benefit year for all of its health insurance plans in the State (including both the individual and group markets) for which reinsurance contributions are required. To determine the number of covered lives of reinsurance contribution enrollees under all health insurance plans in a State for a benefit year, a health insurance issuer must use one of the following methods:

* * * * *

(g) * * *

(4) * * *

(i) *Multiple group health plans including an insured plan.* If at least one of the multiple plans is an insured plan, the average number of covered lives of reinsurance contribution enrollees must be calculated using one of the methods specified in either paragraph (d)(1) or (2) of this section, applied across the multiple plans as a whole. The following information must be determined by the plan sponsor:

* * * * *

(ii) *Multiple group health plans not including an insured plan.* If each of the multiple plans is a self-insured group health plan, the average number of covered lives of reinsurance contribution enrollees must be

calculated using one of the methods specified either in paragraph (e)(1) or (2) of this section, applied across the multiple plans as a whole. The following information must be determined by the plan sponsor:

* * * * *

■ 10. Section 153.500 is amended by revising the definition of “Adjustment percentage” to read as follows:

§ 153.500 Definitions.

* * * * *

Adjustment percentage means, with respect to a QHP:

(1) For benefit year 2014—

(i) For a QHP offered by a health insurance issuer with allowable costs of at least 80 percent of after-tax premium in a transitional State, the percentage specified by HHS for such QHPs in the transitional State; and otherwise

(ii) Zero percent.

(2) For benefit year 2015, for a QHP offered by a health insurance issuer in any State, 2 percent.

(3) For benefit year 2016—

(i) For a QHP offered by a health insurance issuer with allowable costs of at least 80 percent of after-tax premium, the percentage specified by HHS; and otherwise

(ii) Zero percent.

* * * * *

■ 11. Section 153.740 is amended by revising paragraph (a) and adding paragraph (c) to read as follows:

§ 153.740 Failure to comply with HHS-operated risk adjustment and reinsurance data requirements.

(a) *Enforcement actions.* If an issuer of a risk adjustment covered plan or reinsurance-eligible plan fails to establish a dedicated distributed data environment in a manner and timeframe specified by HHS; fails to provide HHS with access to the required data in such environment in accordance with § 153.700(a) or otherwise fails to comply with the requirements of §§ 153.700 through 153.730; fails to adhere to the reinsurance data submission requirements set forth in § 153.420; or fails to adhere to the risk adjustment data submission and data storage requirements set forth in §§ 153.610 through 153.630, HHS may impose civil money penalties in accordance with the procedures set forth in § 156.805 of this subchapter. Civil monetary penalties will not be imposed for non-compliance with these requirements during the 2014 or 2015 calendar years under this paragraph if the issuer has made good faith efforts to comply with these requirements.

* * * * *

(c) *Information sharing.* HHS may consult with and share information about issuers of risk adjustment covered plans and reinsurance-eligible plans with other Federal and State regulatory and enforcement entities to the extent the consultation or information is necessary for purposes of Federal or State oversight and enforcement activities.

PART 154—HEALTH INSURANCE ISSUER RATE INCREASES: DISCLOSURE AND REVIEW REQUIREMENTS

■ 12. The authority citation for part 154 continues to read as follows:

Authority: Section 2794 of the Public Health Service Act (42 U.S.C. 300gg–94).

■ 13. Section 154.102 is amended by—

■ a. Revising the definitions of “Individual market”, “Rate increase”, “Small group market”, and “State”.

■ b. Adding a definition of “Plan” in alphabetical order.

The revisions and addition read as follows:

§ 154.102 Definitions.

* * * * *

Individual market has the meaning given the term in § 144.103 of this subchapter.

* * * * *

Plan has the meaning given the term in § 144.103 of this subchapter.

* * * * *

Rate increase means, with respect to rates filed—

(1) For coverage effective prior to January 1, 2017, any increase of the rates for a specific product offered in the individual or small group market.

(2) For coverage effective on or after January 1, 2017, any increase of the rates for a specific product or plan within a product offered in the individual or small group market.

* * * * *

Small group market has the meaning given the term in § 144.103 of this subchapter.

State means each of the 50 States and the District of Columbia.

* * * * *

■ 14. Section 154.200 is amended by revising paragraphs (a) and (c) to read as follows:

§ 154.200 Rate increases subject to review.

(a) A rate increase filed in a State, or effective in a State that does not require a rate increase to be filed, is subject to review if:

(1) The rate increase is 10 percent or more applicable to a 12-month period

that begins on January 1, as calculated under paragraph (c) of this section; or

(2) The rate increase meets or exceeds a State-specific threshold applicable to a 12-month period that begins on January 1, as calculated under paragraph (c) of this section, determined by the Secretary. A State-specific threshold shall be based on factors impacting rate increases in a State to the extent that the data relating to such State-specific factors is available by August 1. States interested in proposing a State-specific threshold for approval are required to submit a proposal to the Secretary by August 1.

* * * * *

(c) A rate increase meets or exceeds the applicable threshold set forth in paragraph (a) of this section if—

(1) For rates filed for coverage beginning before January 1, 2017, the average increase for all enrollees weighted by premium volume meets or exceeds the applicable threshold.

(2) For rates filed for coverage beginning on or after January 1, 2017, an increase in the plan-adjusted index rate (as described in § 156.80 of this subchapter) for any plan within the product meets or exceeds the applicable threshold.

* * * * *

■ 15. Section 154.215 is amended by revising paragraph (a) to read as follows:

§ 154.215 Submission of rate filing justification.

(a) If any plan within a product is subject to a rate increase, a health insurance issuer must submit a Rate Filing Justification for all products in the single risk pool, including new or discontinuing products, on a form and in a manner prescribed by the Secretary.

* * * * *

■ 16. Section 154.220 is revised to read as follows:

§ 154.220 Timing of providing the rate filing justification.

A health insurance issuer must submit a Rate Filing Justification for all rate increases that are filed in a State, or effective in a State that does not require the rate increase to be filed, as follows:

(a) For rate increases for coverage effective prior to January 1, 2016:

(1) If a State requires that a proposed rate increase be filed with the State prior to the implementation of the rate, the health insurance issuer must submit to CMS and the applicable State the Rate Filing Justification on the date on which the health insurance issuer submits the proposed rate increase to the State.

(2) For all other States, the health insurance issuer must submit to CMS

and the State the Rate Filing Justification prior to the implementation of the rate increase.

(b) For rate increases for coverage effective on or after January 1, 2016, the health insurance issuer must submit to CMS and the applicable State a Rate Filing Justification by the earlier of the following:

(1) The date by which the State requires that a proposed rate increase be filed with the State; or

(2) The date specified in guidance by the Secretary.

■ 17. Section 154.301 is amended by revising paragraph (b) to read as follows:

§ 154.301 CMS's determinations of Effective Rate Review Programs.

* * * * *

(b) *Public disclosure and input.* (1) In addition to satisfying the provisions in paragraph (a) of this section, a State with an Effective Rate Review Program must provide:

(i) For proposed rate increases subject to review, access from its Web site to at least the information contained in Parts I, II, and III of the Rate Filing Justification that CMS makes available on its Web site (or provide CMS's Web address for such information), and have a mechanism for receiving public comments on those proposed rate increases, no later than the date specified in guidance by the Secretary.

(ii) Beginning with rates filed for coverage effective on or after January 1, 2016, for all final rate increases (including those not subject to review), access from its Web site to at least the information contained in Parts I, II, and III of the Rate Filing Justification (as applicable) that CMS makes available on its Web site (or provide CMS's Web address for such information), no later than the first day of the annual open enrollment period in the individual market for the applicable calendar year.

(2) If a State intends to make the information in paragraph (b)(1)(i) of this section available to the public prior to the date specified by the Secretary, or if it intends to make the information in paragraph (b)(1)(ii) of this section available to the public prior to the first day of the annual open enrollment period in the individual market for the applicable calendar year, the State must notify CMS in writing, no later than 30 days prior to the date it intends to make the information public, of its intent to do so and the date it intends to make the information public.

(3) A State with an Effective Rate Review Program must ensure the information in paragraphs (b)(1)(i) and (ii) of this section is made available to the public at a uniform time for all

proposed and final rate increases, as applicable, in the relevant market segment and without regard to whether coverage is offered through or outside an Exchange.

* * * * *

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

■ 18. The authority citation for part 155 continues to read as follows:

Authority: Title I of the Affordable Care Act, sections 1301, 1302, 1303, 1304, 1311, 1312, 1313, 1321, 1322, 1331, 1332, 1334, 1402, 1411, 1412, 1413, Pub. L. 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18033, 18041–18042, 18051, 18054, 18071, and 18081–18083).

■ 19. Section 155.20 is amended by—

■ a. Revising paragraph (2) of the definition of “Applicant.”

■ b. Revising the definitions of “Enrollee” and “Qualified employee.”

The revisions read as follows:

§ 155.20 Definitions.

* * * * *

Applicant * * *

(2) An employer, employee, or former employee seeking eligibility for enrollment in a QHP through the SHOP for himself or herself, and, if the qualified employer offers dependent coverage through the SHOP, seeking eligibility to enroll his or her dependents in a QHP through the SHOP.

* * * * *

Enrollee means a qualified individual or qualified employee enrolled in a QHP. Enrollee also means the dependent of a qualified employee enrolled in a QHP through the SHOP, and any other person who is enrolled in a QHP through the SHOP, consistent with applicable law and the terms of the group health plan. Provided that at least one employee enrolls in a QHP through the SHOP, enrollee also means a business owner enrolled in a QHP through the SHOP, or the dependent of a business owner enrolled in a QHP through the SHOP.

* * * * *

Qualified employee means any employee or former employee of a qualified employer who has been offered health insurance coverage by such qualified employer through the SHOP for himself or herself and, if the qualified employer offers dependent coverage through the SHOP, for his or her dependents.

* * * * *

■ 20. Section 155.205 is amended by revising paragraphs (c)(2)(i) and (iii) and

adding paragraph (c)(2)(iv) to read as follows:

§ 155.205 Consumer assistance tools and programs of an Exchange.

* * * * *

(c) * * *
(2) * * *

(i) For all entities subject to this standard, oral interpretation.

(A) For Exchanges and QHP issuers, this standard also includes telephonic interpreter services in at least 150 languages.

(B) For an agent or broker subject to § 155.220(c)(3)(i), beginning November 1, 2015, or when such entity been registered with the Exchange for at least 1 year, whichever is later, this standard also includes telephonic interpreter services in at least 150 languages.

* * * * *

(iii) For all entities subject to this standard, taglines in non-English languages indicating the availability of language services.

(A) For Exchanges and QHP issuers, beginning no later than the first day of the individual market open enrollment period for the 2017 benefit year, this standard also includes taglines on Web site content and any document that is critical for obtaining health insurance coverage or access to health care services through a QHP for qualified individuals, applicants, qualified employers, qualified employees, or enrollees. A document is deemed to be critical for obtaining health insurance coverage or access to health care services through a QHP if it is required to be provided by law or regulation to a qualified individual, applicant, qualified employer, qualified employee, or enrollee. Such taglines must indicate the availability of language services in at least the top 15 languages spoken by the limited English proficient population of the relevant State, as determined in guidance published by the Secretary.

(B) For an agent or broker subject to § 155.220(c)(3)(i), beginning on the first day of the individual market open enrollment period for the 2017 benefit year, or when such entity has been registered with the Exchange for at least 1 year, whichever is later, this standard also includes taglines on Web site content and any document that is critical for obtaining health insurance coverage or access to health care services through a QHP for qualified individuals, applicants, qualified employers, qualified employees, or enrollees. A document is deemed to be critical for obtaining health insurance coverage or access to health care services through a QHP if it is required to be provided by law or regulation to

a qualified individual, applicant, qualified employer, qualified employee, or enrollee. Such taglines must indicate the availability of language services in at least the top 15 languages spoken by the limited English proficient population of the relevant State, as determined in guidance published by the Secretary.

(iv) For Exchanges, QHP issuers, and an agent or broker subject to § 155.220(c)(3)(i), Web site translations.

(A) For an Exchange, beginning no later than the first day of the individual market open enrollment period for the 2017 benefit year, content that is intended for qualified individuals, applicants, qualified employers, qualified employees, or enrollees on a Web site that is maintained by the Exchange must be translated into any non-English language that is spoken by a limited English proficient population that reaches 10 percent or more of the population of the relevant State, as determined in guidance published by the Secretary.

(B) For a QHP issuer, beginning no later than the first day of the individual market open enrollment period for the 2017 benefit year, if the content of a Web site maintained by the QHP issuer is critical for obtaining health insurance coverage or access to health care services through a QHP, within the meaning of § 156.250 of this subchapter, it must be translated into any non-English language that is spoken by a limited English proficient population that reaches 10 percent or more of the population of the relevant State, as determined in guidance published by the Secretary.

(C) For an agent or broker subject to § 155.220(c)(3)(i), beginning on the first day of the individual market open enrollment period for the 2017 benefit year, or when such entity has been registered with the Exchange for at least 1 year, whichever is later, content that is intended for qualified individuals, applicants, qualified employers, qualified employees, or enrollees on a Web site that is maintained by the agent or broker must be translated into any non-English language that is spoken by a limited English proficient population that reaches 10 percent or more of the population of the relevant State, as determined in guidance published by the Secretary.

* * * * *

■ 21. Section 155.215 is amended by revising paragraph (h) to read as follows:

§ 155.215 Standards applicable to Navigators and Non-Navigator Assistance Personnel carrying out consumer assistance functions under §§ 155.205(d) and (e) and 155.210 in a Federally-facilitated Exchange and to Non-Navigator Assistance Personnel funded through an Exchange Establishment Grant.

* * * * *

(h) *Physical presence.* All non-Navigator entities carrying out consumer assistance functions under § 155.205(d) and (e) in an Exchange operated by HHS during the exercise of its authority under § 155.105(f) and all non-Navigator entities funded through an Exchange Establishment Grant under section 1311(a) of the Affordable Care Act must maintain a physical presence in the Exchange service area, so that face-to-face assistance can be provided to applicants and enrollees. In a Federally-facilitated Exchange, no individual or entity shall be ineligible to operate as a non-Navigator entity or as non-Navigator assistance personnel solely because its principal place of business is outside of the Exchange service area.

* * * * *

■ 22. Section 155.220 is amended by revising paragraph (i) to read as follows:

§ 155.220 Ability of States to permit agents and brokers to assist qualified individuals, qualified employers, or qualified employees enrolling in QHPs.

* * * * *

(i) *Use of agents' and brokers' Internet Web sites for SHOP.* For plan years beginning on or after January 1, 2015, in States that permit this activity under State law, a SHOP may permit agents and brokers to use an Internet Web site to assist qualified employers and facilitate enrollment of enrollees in a QHP through the Exchange, under paragraph (c)(3) of this section.

■ 23. Section 155.222 is added to read as follows:

§ 155.222 Standards for HHS-approved vendors of Federally-facilitated Exchange training and information verification for agents and brokers.

(a) *Application for approval.* (1) A vendor must be approved by HHS, in a form and manner to be determined by HHS, in order to have its training and information verification program recognized for agents and brokers assisting with or facilitating enrollment in individual market or SHOP coverage through the Exchanges consistent with § 155.220.

(2) As part of the training program, the vendor must require agents and brokers to provide identifying information and proof of valid State licensure, and successfully complete the

required curriculum and identity proofing.

(3) HHS will approve vendors on an annual basis for a given plan year, and each vendor must submit an application for each year that approval is sought.

(b) *Standards.* To be approved by HHS and maintain its status as an approved vendor for plan year 2016 and future plan years, a vendor must meet each of the following standards:

(1) Submit a complete and accurate application by the deadline established by HHS, which includes demonstration of the following:

(i) Prior experience with successfully conducting online training, verification of valid State license, as well as providing technical support to a large customer base; and

(ii) The ability to conduct identity proofing.

(2) Adhere to HHS specifications for content, format, and delivery of training and information verification, which include offering continuing education units (CEUs) for at least five States in which a Federally-facilitated Exchange is operating.

(3) Collect, store, and share with HHS all data from agent and broker users of the vendor's training and information verification in a manner, format, and frequency specified by HHS, and protect the data in accordance with applicable privacy and security laws and regulations.

(4) Execute an agreement with HHS, in a form and manner to be determined by HHS, which requires the vendor to comply with HHS guidelines for interfacing with HHS data systems, the implementation of the training and information verification processes, and the use of all data collected.

(5) Permit any individual who holds a valid State license or equivalent State authority to sell health insurance products to access the vendor's training and information verification.

(c) *Approved list.* A list of approved vendors will be published on an HHS Web site.

(d) *Monitoring.* HHS may periodically monitor and audit vendors approved under this subpart, and their records related to the training and information verification functions described in this section, to ensure ongoing compliance with the standards in paragraph (b) of this section. If HHS determines that an HHS-approved vendor is not in compliance with the standards required in paragraph (b) of this section, the vendor may be removed from the approved list described in paragraph (c) of this section and may be required by HHS to cease performing the training

and information verification functions described under this subpart.

(e) *Appeals.* A vendor that is not approved by HHS after submitting the application described in paragraph (a) of this section, or an approved vendor whose agreement is revoked under paragraph (d) of this section, may appeal HHS's decision by notifying HHS in writing within 15 days from receipt of the notification of not being approved and submitting additional documentation demonstrating how the vendor meets the standards in paragraph (b) of this section and (if applicable) the terms of its agreement with HHS. HHS will review the submitted documentation and make a final approval determination within 30 days from receipt of the additional documentation.

■ 24. Section 155.400 is amended by revising paragraph (e) to read as follows:

§ 155.400 Enrollment of qualified individuals into QHPs.

* * * * *

(e) *Premium payment.* Exchanges may, and the Federally-facilitated Exchange will, require payment of the first month's premium to effectuate an enrollment. Exchanges may, and the Federally-facilitated Exchange will, establish a standard policy for setting premium payment deadlines:

(1) In a Federally-facilitated Exchange, for first month (or binder payment) premiums:

(i) For coverage being effectuated under regular coverage effective dates, as provided for in §§ 155.410(f) and 155.420(b)(1), premium payment deadlines must be no earlier than the coverage effective date, but no later than 30 calendar days from the coverage effective date; and

(ii) For coverage being effectuated under special effective dates, as provided in § 155.420(b)(2), premium payment deadlines must be 30 calendar days from the date the issuer receives the enrollment transaction.

(2) [Reserved]

* * * * *

■ 25. Section 155.410 is amended by revising paragraphs (e) and (f) to read as follows:

§ 155.410 Initial and annual open enrollment periods.

* * * * *

(e) *Annual open enrollment period.*

(1) For the benefit year beginning on January 1, 2015, the annual open enrollment period begins on November 15, 2014, and extends through February 15, 2015.

(2) For the benefit year beginning on January 1, 2016, the annual open

enrollment period begins on November 1, 2015 and extends through January 31, 2016.

(f) *Effective date.* (1) For the benefit year beginning on January 1, 2015, the Exchange must ensure coverage is effective—

(i) January 1, 2015, for QHP selections received by the Exchange on or before December 15, 2014.

(ii) February 1, 2015, for QHP selections received by the Exchange from December 16, 2014 through January 15, 2015.

(iii) March 1, 2015, for QHP selections received by the Exchange from January 16, 2015 through February 15, 2015.

(2) For the benefit year beginning on January 1, 2016, the Exchange must ensure that coverage is effective—

(i) January 1, 2016, for QHP selections received by the Exchange on or before December 15, 2015.

(ii) February 1, 2016, for QHP selections received by the Exchange from December 16, 2015 through January 15, 2016.

(iii) March 1, 2016, for QHP selections received by the Exchange from January 16, 2016 through January 31, 2016.

* * * * *

■ 26. Section 155.420 is amended by—

■ a. Revising paragraphs (b)(2)(i), (b)(2)(iv), (c)(2), (c)(3), (d)(1)(ii), (d)(2), and (d)(4).

■ b. Adding paragraphs (b)(2)(v), (b)(2)(vi), and (d)(6)(iv).

■ c. Removing paragraph (d)(10).

The revisions and additions read as follows:

§ 155.420 Special enrollment periods.

* * * * *

(b) * * *

(2) * * *

(i) In the case of birth, adoption, placement for adoption, or placement in foster care as described in paragraph (d)(2)(i) of this section, the Exchange must ensure that coverage is effective for a qualified individual or enrollee on the date of birth, adoption, placement for adoption, or placement in foster care, or it may permit the qualified individual or enrollee to elect a coverage effective date of the first of the month following the date of birth, adoption, placement for adoption, or placement in foster care, or in accordance with paragraph (b)(1) of this section. If the Exchange permits the qualified individual or enrollee to elect a coverage effective date of either the first of the month following the date of birth, adoption, placement for adoption or placement in foster care or in accordance with paragraph (b)(1) of this section, the Exchange must ensure

coverage is effective on the date duly selected by the qualified individual or enrollee.

* * * * *

(iv) If a consumer loses coverage as described in paragraph (d)(1) or (d)(6)(iii), or gains access to a new QHP as described in paragraph (d)(7) of this section, if the plan selection is made on or before the day of the triggering event, the Exchange must ensure that the coverage effective date is on the first day of the month following the loss of coverage. If the plan selection is made after the day of the triggering event, the Exchange must ensure that coverage is effective in accordance with paragraph (b)(1) of this section or on the first day of the following month, at the option of the Exchange.

(v) In the case of a court order as described in paragraph (d)(2)(i) of this section, the Exchange must ensure that coverage is effective for a qualified individual or enrollee on the date the court order is effective, or it may permit the qualified individual or enrollee to elect a coverage effective date in accordance with paragraph (b)(1) of this section. If the Exchange permits the qualified individual or enrollee to elect a coverage effective date in accordance with paragraph (b)(1) of this section, the Exchange must ensure coverage is effective on the date duly selected by the qualified individual or enrollee.

(vi) If an enrollee or his or her dependent dies as described in paragraph (d)(2)(ii) of this section, the Exchange must ensure that coverage is effective on the first day of the month following the plan selection, or it may permit the enrollee or his or her dependent to elect a coverage effective date in accordance with paragraph (b)(1) of this section. If the Exchange permits the enrollee or his or her dependent to elect a coverage effective date in accordance with paragraph (b)(1) of this section, the Exchange must ensure coverage is effective on the date duly selected by the enrollee or his or her dependent.

* * * * *

(c) * * *

(2) *Advanced availability.* A qualified individual or his or her dependent who is described in paragraph (d)(1) or (d)(6)(iii) or, beginning on January 1, 2017 or earlier at the option of the Exchange, paragraph (d)(7) of this section, has 60 days before and after the triggering event to select a QHP. Prior to January 1, 2017, a qualified individual or his or her dependent who is described in paragraph (d)(7) of this section may select a QHP in accordance with paragraph (c)(1) of this section.

(3) *Special rule.* In the case of a qualified individual or enrollee who is eligible for a special enrollment period as described in paragraphs (d)(4), (5), or (9) of this section, the Exchange may define the length of the special enrollment period as appropriate based on the circumstances of the special enrollment period, but in no event may the length of the special enrollment period exceed 60 days.

(d) * * *

(1) * * *

(ii) Is enrolled in any non-calendar year group health plan or individual health insurance coverage, even if the qualified individual or his or her dependent has the option to renew such coverage. The date of the loss of coverage is the last day of the plan or policy year;

* * * * *

(2)(i) The qualified individual gains a dependent or becomes a dependent through marriage, birth, adoption, placement for adoption, or placement in foster care, or through a child support order or other court order.

(ii) At the option of the Exchange, the enrollee loses a dependent or is no longer considered a dependent through divorce or legal separation as defined by State law in the State in which the divorce or legal separation occurs, or if the enrollee, or his or her dependent, dies.

* * * * *

(4) The qualified individual's or his or her dependent's, enrollment or non-enrollment in a QHP is unintentional, inadvertent, or erroneous and is the result of the error, misrepresentation, misconduct, or inaction of an officer, employee, or agent of the Exchange or HHS, its instrumentalities, or a non-Exchange entity providing enrollment assistance or conducting enrollment activities. For purposes of this provision, misconduct includes the failure to comply with applicable standards under this part, part 156 of this subchapter, or other applicable Federal or State laws as determined by the Exchange.

* * * * *

(6) * * *

(iv) A qualified individual in a non-Medicaid expansion State who was previously ineligible for advance payments of the premium tax credit solely because of a household income below 100 percent of the FPL, who was ineligible for Medicaid during that same timeframe, and who has experienced a change in household income that makes the qualified individual newly eligible

for advance payments of the premium tax credit.

* * * * *

■ 27. Section 155.430 is amended by—

■ a. Revising the section heading.

■ b. Revising paragraphs (a), (b)(1), (b)(2) introductory text, (c), (d) paragraph heading, (d)(2) introductory text, (d)(2)(iv), (d)(3) through (7), and (e)(1) and (2).

■ c. Adding paragraphs (b)(2)(vi), (d)(2)(v), and (d)(8).

The revisions and additions read as follows:

§ 155.430 Termination of Exchange enrollment or coverage.

(a) *General requirements.* The Exchange must determine the form and manner in which enrollment in a QHP through the Exchange may be terminated.

(b) * * *

(1) *Enrollee-initiated terminations.* (i) The Exchange must permit an enrollee to terminate his or her coverage or enrollment in a QHP through the Exchange, including as a result of the enrollee obtaining other minimum essential coverage. To the extent the enrollee has the right to terminate the coverage under applicable State laws, including “free look” cancellation laws, the enrollee may do so, in accordance with such laws.

(ii) The Exchange must provide an opportunity at the time of plan selection for an enrollee to choose to remain enrolled in a QHP if he or she becomes eligible for other minimum essential coverage and the enrollee does not request termination in accordance with paragraph (b)(1)(i) of this section. If an enrollee does not choose to remain enrolled in a QHP in such a situation, the Exchange must initiate termination of his or her enrollment in the QHP upon completion of the redetermination process specified in § 155.330.

(iii) The Exchange must establish a process to permit individuals, including enrollees' authorized representatives, to report the death of an enrollee for purposes of initiating termination of the enrollee's Exchange enrollment. The Exchange may require the reporting party to submit documentation of the death. Any applicable premium refund, or premium due, must be processed by the deceased enrollee's QHP in accordance with State law.

(2) *Exchange-initiated terminations.* The Exchange may initiate termination of an enrollee's enrollment in a QHP through the Exchange, and must permit a QHP issuer to terminate such coverage or enrollment, in the following circumstances:

* * * * *

(vi) Any other reason for termination of coverage described in § 147.106 of this subchapter.

(c) *Termination of coverage or enrollment tracking and approval.* The Exchange must—

(1) Establish mandatory procedures for QHP issuers to maintain records of termination of enrollment in a QHP through the Exchange;

(2) Send termination information to the QHP issuer and HHS, promptly and without undue delay in accordance with § 155.400(b).

(3) Require QHP issuers to make reasonable accommodations for all individuals with disabilities (as defined by the Americans with Disabilities Act) before terminating enrollment of such individuals through the Exchange; and

(4) Retain records in order to facilitate audit functions.

(d) *Effective dates for termination of coverage or enrollment.*

(2) In the case of a termination in accordance with paragraph (b)(1) of this section, the last day of enrollment through the Exchange is—

(iv) If the enrollee is newly eligible for Medicaid, CHIP, or the BHP, if a BHP is operating in the service area of the Exchange, the last day of enrollment in a QHP through the Exchange is the day before the individual is determined eligible for Medicaid, CHIP, or the BHP.

(v) The retroactive termination date requested by the enrollee, if specified by applicable State laws.

(3) In the case of a termination in accordance with paragraph (b)(2)(i) of this section, the last day of enrollment in a QHP through the Exchange is the last day of eligibility, as described in § 155.330(f), unless the individual requests an earlier termination effective date per paragraph (b)(1) of this section.

(4) In the case of a termination in accordance with paragraph (b)(2)(ii)(A) of this section, the last day of enrollment in a QHP through the Exchange will be the last day of the first month of the 3-month grace period.

(5) In the case of a termination in accordance with paragraph (b)(2)(ii)(B) of this section, the last day of enrollment in a QHP through the Exchange should be consistent with existing State laws regarding grace periods.

(6) In the case of a termination in accordance with paragraph (b)(2)(v) of this section, the last day of coverage in an enrollee's prior QHP is the day before the effective date of coverage in his or her new QHP, including any retroactive enrollments effectuated under § 155.420(b)(2)(iii).

(7) In the case of a termination due to death, the last day of enrollment in a QHP through the Exchange is the date of death.

(8) In cases of retroactive termination dates, the Exchange will ensure that appropriate actions are taken to make necessary adjustments to advance payments of the premium tax credit, cost-sharing reductions, premiums, claims, and user fees.

(e) * * *

(1) *Termination.* A termination is an action taken after a coverage effective date that ends an enrollee's enrollment through the Exchange for a date after the original coverage effective date, resulting in a period during which the individual was enrolled in coverage through the Exchange.

(2) *Cancellation.* A cancellation is specific type of termination action that ends a qualified individual's enrollment through the Exchange on the date such enrollment became effective resulting in enrollment through the Exchange never having been effective.

* * * * *

■ 28. Section 155.605 is amended by revising paragraphs (g)(3) and (g)(6)(i) and adding paragraph (g)(6)(iii) to read as follows:

§ 155.605 Eligibility standards for exemptions.

* * * * *

(g) * * *

(3) *Filing threshold.* The IRS may allow an applicant to claim an exemption without obtaining an exemption certificate number from an Exchange for a taxable year if, for such year, the applicant could not be claimed as a dependent by another taxpayer and the applicant's gross income was less than the applicant's applicable return filing threshold described in section 5000A(e)(2) of the Code;

* * * * *

(6) * * *

(i) The Exchange must determine an applicant eligible for an exemption for any month if he or she is an Indian eligible for services through an Indian health care provider, as defined in 42 CFR 447.51 and not otherwise eligible for an exemption under paragraph (f) of this section, or an individual eligible for services through the Indian Health Service in accordance with 25 U.S.C. 1680c(a), (b), or (d)(3).

* * * * *

(iii) The IRS may allow an applicant to claim the exemption specified in paragraph (g)(6) of this section without obtaining an exemption certificate number from an Exchange.

■ 29. Section 155.700(b) is amended by removing the definition of "Group participation rule" and by adding the definition of "Group participation rate" in alphabetical order to read as follows:

§ 155.700 Standards for the establishment of a SHOP.

* * * * *

(b) * * *

Group participation rate means the minimum percentage of all eligible individuals or employees of an employer that must be enrolled.

* * * * *

■ 30. Section 155.705 is amended by—

■ a. Revising paragraph (b)(4)(i)(B).

■ b. Redesignating paragraphs (b)(4)(ii)(A) and (B) as paragraphs (b)(4)(ii)(B) and (C), respectively.

■ c. Adding new paragraph (b)(4)(ii)(A).

■ d. Revising paragraphs (b)(7) and (10).

The additions and revisions read as follows:

§ 155.705 Functions of a SHOP.

* * * * *

(b) * * *

(4) * * *

(i) * * *

(B) Collect from each employer the total amount due and make payments to QHP issuers in the SHOP for all enrollees except as provided for in paragraph (b)(4)(ii)(A) of this section; and

* * * * *

(ii) * * *

(A) The SHOP may, upon an election by a qualified employer, enter into an agreement with a qualified employer to facilitate the administration of continuation coverage by collecting premiums for continuation coverage enrolled in through the SHOP directly from a person enrolled in continuation coverage through the SHOP consistent with applicable law and the terms of the group health plan, and remitting premium payments for this coverage to QHP issuers. A Federally-facilitated SHOP may elect to limit this service to the collection of premiums related to continuation coverage required under 29 U.S.C. 1161, *et seq.*

* * * * *

(7) *QHP availability in merged markets.* If a State merges the individual market and the small group market risk pools in accordance with section 1312(c)(3) of the Affordable Care Act, the SHOP may permit a qualified employee to enroll in any QHP meeting level of coverage requirements described in section 1302(d) of the Affordable Care Act.

* * * * *

(10) *Participation rules.* Subject to § 147.104 of this subchapter, the SHOP

may authorize a uniform group participation rate for the offering of health insurance coverage in the SHOP, which must be a single, uniform rate that applies to all groups and issuers in the SHOP. If the SHOP authorizes a minimum participation rate, such rate must be based on the rate of employee participation in the SHOP, not on the rate of employee participation in any particular QHP or QHPs of any particular issuer.

(i) For plan years beginning before January 1, 2016, subject to § 147.104 of this subchapter, a Federally-facilitated SHOP must use a minimum participation rate of 70 percent, calculated as the number of qualified employees accepting coverage under the employer's group health plan, divided by the number of qualified employees offered coverage, excluding from the calculation any employee who, at the time the employer submits the SHOP application, is enrolled in coverage through another employer's group health plan or through a governmental plan such as Medicare, Medicaid, or TRICARE. For purposes of this calculation, qualified employees who are former employees will not be counted.

(ii) For plan years beginning on or after January 1, 2016, subject to § 147.104 of this subchapter, a Federally-facilitated SHOP must use a minimum participation rate of 70 percent, calculated as the number of full-time employees accepting coverage offered by a qualified employer plus the number of full-time employees who, at the time the employer submits the SHOP group enrollment, are enrolled in coverage through another group health plan, governmental coverage (such as Medicare, Medicaid, or TRICARE), coverage sold through the individual market, or in other minimum essential coverage, divided by the number of full-time employees offered coverage.

(iii) Notwithstanding paragraphs (b)(10)(i) and (ii) of this section, a Federally-facilitated SHOP may utilize a different minimum participation rate in a State if there is evidence that a State law sets a minimum participation rate or that a higher or lower minimum participation rate is customarily used by the majority of QHP issuers in that State for products in the State's small group market outside the SHOP.

* * * * *

■ 31. Section 155.710 is amended by revising paragraph (e) to read as follows:

§ 155.710 Eligibility standards for SHOP.

* * * * *

(e) *Employee eligibility requirements.* An employee is a qualified employee

eligible to enroll in coverage through a SHOP if such employee receives an offer of coverage from a qualified employer.

A qualified employee is eligible to enroll his or her dependents in coverage through a SHOP if the offer from the qualified employer includes an offer of dependent coverage.

■ 32. Section 155.720 is amended by:

■ a. Removing “;” from paragraph (b)(5) and adding “; and” in its place.

■ b. Removing “; and” from paragraph (b)(6) and adding a period in its place.

■ c. Removing paragraph (b)(7).

■ d. Revising paragraph (e).

The revisions read as follows:

§ 155.720 Enrollment of employees into QHPs under SHOP.

* * * * *

(e) *Notification of effective date.* (1) For plan years beginning before January 1, 2017, the SHOP must ensure that a QHP issuer notifies a qualified employee enrolled in a QHP through the SHOP of the effective date of his or her coverage.

(2) For plan years beginning on or after January 1, 2017, the SHOP must ensure that a QHP issuer notifies an enrollee enrolled in a QHP through the SHOP of the effective date of his or her coverage.

(3) When a primary subscriber and his or her dependents live at the same address, a separate notice of the effective date of coverage need not be sent to each dependent at that address, provided that the notice sent to each primary subscriber at that address contains all required information about the coverage effective date for the primary subscriber and his or her dependents at that address.

* * * * *

■ 33. Section 155.725 is amended by revising paragraphs (a), (b), (g), (h), (i), and (j)(5) and adding paragraph (k) to read as follows:

§ 155.725 Enrollment periods under SHOP.

(a) *General requirements.* The SHOP must ensure that enrollment transactions are sent to QHP issuers and that such issuers adhere to coverage effective dates in accordance with this section.

(b) *Rolling enrollment in the SHOP.* The SHOP must permit a qualified employer to purchase coverage for its small group at any point during the year. The employer's plan year must consist of the 12-month period beginning with the qualified employer's effective date of coverage, unless the plan is issued in a State that has elected to merge its individual and small group risk pools under section 1312(c)(3) of the Affordable Care Act, in which case

the plan year will end on December 31 of the calendar year in which coverage first became effective.

* * * * *

(g) *Newly qualified employees.* (1) The SHOP must provide an employee who becomes a qualified employee outside of the initial or annual open enrollment period an enrollment period beginning on the first day of becoming a qualified employee. A newly qualified employee must have at least 30 days from the beginning of his or her enrollment period to select a QHP. The enrollment period must end no sooner than 15 days prior to the date that any applicable employee waiting period longer than 45 days would end if the employee made a plan selection on the first day of becoming eligible.

(2) The effective date of coverage for a QHP selection received by the SHOP from a newly qualified employee must always be the first day of a month, and must generally be determined in accordance with § 155.725(h), unless the employee is subject to a waiting period consistent with § 147.116 of this subchapter, in which case the effective date may be on the first day of a later month, but in no case may the effective date fail to comply with § 147.116 of this subchapter.

(h) *Initial and annual open enrollment effective dates.* (1) The SHOP must establish effective dates of coverage for qualified employees enrolling in coverage for the first time, and for qualified employees enrolling during the annual open enrollment period described in paragraph (e) of this section.

(2) For a QHP selection received by the Federally-facilitated SHOP from a qualified employee in his or her initial or annual open enrollment period:

(i) Between the first and fifteenth day of any month, the Federally-facilitated SHOP must ensure a coverage effective date of the first day of the following month.

(ii) Between the 16th and last day of any month, the Federally-facilitated SHOP must ensure a coverage effective date of the first day of the second following month.

(i) *Renewal of coverage.* (1) If a qualified employee enrolled in a QHP through the SHOP remains eligible for coverage, such employee will remain in the QHP selected the previous year unless—

(i) The qualified employee terminates coverage from such QHP in accordance with standards identified in § 155.430;

(ii) The qualified employee enrolls in another QHP if such option exists; or

(iii) The QHP is no longer available to the qualified employee.

(2) The SHOP may treat a qualified employer offering coverage through the SHOP as offering the same coverage under § 155.705(b)(3) at the same level of contribution under § 155.705(b)(11) unless:

(i) The qualified employer is no longer eligible to offer such coverage through the SHOP;

(ii) The qualified employer elects to offer different coverage or a different contribution through the SHOP;

(iii) The qualified employer withdraws from the SHOP; or

(iv) In the case of a qualified employer offering a single QHP, the single QHP is no longer available through the SHOP.

(j) * * *

(5) The effective dates of coverage for special enrollment periods are determined using the provisions of § 155.420(b).

* * * * *

(k) *Limitation.* Qualified employees will not be able to enroll unless the employer group meets any applicable minimum participation rate implemented under § 155.705(b)(10).

■ 34. Section 155.735 is amended by—

■ a. Revising the section heading.

■ b. Revising paragraphs (a), (b),

(c)(2)(ii), (c)(2)(iii), (d)(1) introductory text, and (d)(1)(iii), and the headings of paragraphs (d) and (e).

■ c. Adding paragraphs (c)(2)(iv), (c)(3), and (g).

The revisions and additions read as follows:

§ 155.735 Termination of SHOP enrollment or coverage.

(a) *General requirements.* The SHOP must determine the timing, form, and manner in which coverage or enrollment in a QHP through the SHOP may be terminated.

(b) *Termination of employer group health coverage or enrollment at the request of the employer.* (1) The SHOP must establish policies for advance notice of termination required from the employer and effective dates of termination.

(2) In the Federally-facilitated SHOP, an employer may terminate coverage or enrollment for all enrollees covered by the employer group health plan effective on the last day of any month, provided that the employer has given notice to the Federally-facilitated SHOP on or before the 15th day of any month. If notice is given after the 15th of the month, the Federally-facilitated SHOP may terminate the coverage or enrollment on the last day of the following month.

(c) * * *

(2) * * *

(ii) If premium payment is not received 31 days from the first of the

coverage month, the Federally-facilitated SHOP may terminate the qualified employer for lack of payment. The termination would take effect on the last day of the month for which the Federally-facilitated SHOP received full payment.

(iii) If a qualified employer is terminated due to lack of premium payment, but within 30 days following its termination the qualified employer requests reinstatement, pays all premiums owed including any prior premiums owed for coverage during the grace period, and pays the premium for the next month's coverage, the Federally-facilitated SHOP must reinstate the qualified employer in its previous coverage. A qualified employer may be reinstated in the Federally-facilitated SHOP only once per calendar year.

(iv) Enrollees enrolled in continuation coverage required under 29 U.S.C. 1161, *et seq.* through the Federally-facilitated SHOP may not be terminated if timely payment is made to the Federally-facilitated SHOP in an amount that is not less than \$50 less than the amount the plan requires to be paid for a period of coverage unless the Federally-facilitated SHOP notifies the enrollee of the amount of the deficiency and the enrollee does not pay the deficiency within 30 days of such notice, pursuant to the notice requirements in § 155.230.

(3) *Payment for COBRA Continuation Coverage.* Nothing in this section modifies existing obligations related to the administration of coverage required under 29 U.S.C. 1161, *et seq.*, as described in 26 CFR part 54.

(d) *Termination of employee or dependent coverage or enrollment.* (1) The SHOP must establish consistent policies regarding the process for and effective dates of termination of employee or dependent coverage or enrollment in the following circumstances:

* * * * *

(iii) The QHP in which the enrollee is enrolled terminates, is decertified as described in § 155.1080, or its certification as a QHP is not renewed;

* * * * *

(e) *Termination of enrollment or coverage tracking and approval.* * * *

* * * * *

(g) *Notice of termination.* Beginning January 1, 2016:

(1) Except as provided in paragraph (g)(3) of this section, if any enrollee's coverage or enrollment through the SHOP is terminated due to non-payment of premiums or due to a loss of the enrollee's eligibility to participate in the SHOP, including where an enrollee

loses his or her eligibility because a qualified employer has lost its eligibility, the SHOP must notify the enrollee of the termination. Such notice must include the termination effective date and reason for termination, and must be sent within 3 business days if an electronic notice is sent, and within 5 business days if a mailed hard copy notice is sent.

(2) Except as provided in paragraph (g)(3) of this section, if an employer group's coverage or enrollment through the SHOP is terminated due to non-payment of premiums or, where applicable, due to a loss of the qualified employer's eligibility to offer coverage through the SHOP, the SHOP must notify the employer of the termination. Such notice must include the termination effective date and reason for termination, and must be sent within 3 business days if an electronic notice is sent, and within 5 business days if a mailed hard copy notice is sent.

(3) Where State law requires a QHP issuer to send the notices described in paragraphs (g)(1) and (2) of this section, a SHOP is not required to send such notices.

(4) When a primary subscriber and his or her dependents live at the same address, a separate termination notice need not be sent to each dependent at that address, provided that the notice sent to each primary subscriber at that address contains all required information about the termination for the primary subscriber and his or her dependents at that address.

■ 35. Section 155.1000 is amended by adding paragraph (d) to read as follows:

§ 155.1000 Certification standards for QHPs.

* * * * *

(d) *Special rule for SHOP.* Except when a QHP is decertified by the Exchange pursuant to § 155.1080, in a SHOP that certifies QHPs on a calendar-year basis, the certification shall remain in effect for the duration of any plan year beginning in the calendar year for which the QHP was certified, even if the plan year ends after the calendar year for which the QHP was certified.

■ 36. Section 155.1075 is amended by revising paragraph (b) to read as follows:

§ 155.1075 Recertification of QHPs.

* * * * *

(b) *Timing.* The Exchange must complete the QHP recertification process no later than 2 weeks prior to the beginning of the open enrollment date at § 155.410(e)(2) of the applicable calendar year.

**PART 156—HEALTH INSURANCE
ISSUER STANDARDS UNDER THE
AFFORDABLE CARE ACT, INCLUDING
STANDARDS RELATED TO
EXCHANGES**

■ 37. The authority citation for part 156 continues to read as follows:

Authority: Title I of the Affordable Care Act, sections 1301–1304, 1311–1313, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, Pub. L. 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

■ 38. Section 156.20 is amended by adding a definition of “Plan” in alphabetical order to read as follows:

§ 156.20 Definitions.

* * * * *

Plan has the meaning given the term in § 144.103 of this subchapter.

* * * * *

■ 39. Section 156.100 is amended by revising paragraph (c) to read as follows:

§ 156.100 State selection of benchmark.

* * * * *

(c) *Default base-benchmark plan.* If a State does not make a selection using the process described in this section, the default base-benchmark plan will be the largest plan by enrollment in the largest product by enrollment in the State’s small group market.

■ 40. Section 156.110 is amended by revising paragraphs (c)(4) and (5) and removing paragraph (c)(6) to read as follows:

§ 156.110 EHB-benchmark plan standards.

* * * * *

(c) * * *

(4) The plan described in paragraph (b)(2)(i) of this section for pediatric oral care benefits; and

(5) The plan described in paragraph (b)(3)(i) of this section for pediatric vision care benefits.

* * * * *

■ 41. Section 156.115 is amended by revising paragraphs (a)(5)(i) and (ii) and adding paragraphs (a)(5)(iii) and (a)(6) to read as follows:

§ 156.115 Provision of EHB.

(a) * * *

(5) With respect to rehabilitative services and devices—

(i) Cover health care services and devices that help a person keep, learn, or improve skills and functioning for daily living (habilitative services). Examples include therapy for a child who is not walking or talking at the expected age. These services may include physical and occupational therapy, speech-language pathology and

other services for people with disabilities in a variety of inpatient and/or outpatient settings;

(ii) Do not impose limits on coverage of rehabilitative services and devices that are less favorable than any such limits imposed on coverage of rehabilitative services and devices; and

(iii) For plan years beginning on or after January 1, 2017, do not impose combined limits on habilitative and rehabilitative services and devices.

(6) For plan years beginning on or after January 1, 2016, for pediatric services that are required under § 156.110(a)(10), provide coverage for enrollees until at least the end of the month in which the enrollee turns 19 years of age.

* * * * *

■ 42. Section 156.120 is added to read as follows:

§ 156.120 Collection of data to define essential health benefits.

(a) *Definitions.* The following definitions apply to this section, unless the context indicates otherwise:

Health benefits means benefits for medical care, as defined at § 144.103 of this subchapter, which may be delivered through the purchase of insurance or otherwise.

Health plan has the meaning given to the term “Portal Plan” in § 159.110 of this subchapter.

State has the meaning given to that term in § 155.20 of this subchapter.

Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of coverage, or other similar limits on the scope or duration of treatment. Treatment limitations include only quantitative treatment limitations. A permanent exclusion of all benefits for a particular condition or disorder is not a treatment limitation.

(b) *Reporting requirement.* A State that selects a base-benchmark plan or an issuer that offers a default base-benchmark plan in accordance with § 156.100 must submit to HHS the following information in a form and manner, and by a date, determined by HHS:

(1) Administrative data necessary to identify the health plan;

(2) Data and descriptive information for each plan on the following items:

(i) All health benefits in the plan;

(ii) Treatment limitations;

(iii) Drug coverage; and

(iv) Exclusions.

■ 43. Section 156.122 is amended by revising paragraphs (a)(1), (a)(2), and (c) and adding paragraphs (a)(3), (d), and (e) to read as follows:

§ 156.122 Prescription drug benefits.

(a) * * *

(1) Subject to the exception in paragraph (b) of this section, covers at least the greater of:

(i) One drug in every United States Pharmacopeia (USP) category and class; or

(ii) The same number of prescription drugs in each category and class as the EHB-benchmark plan;

(2) Submits its formulary drug list to the Exchange, the State or OPM; and

(3) For plans years beginning on or after January 1, 2017, uses a pharmacy and therapeutics (P&T) committee that meets the following standards.

(i) *Membership standards.* The P&T committee must:

(A) Have members that represent a sufficient number of clinical specialties to adequately meet the needs of enrollees.

(B) Consist of a majority of individuals who are practicing physicians, practicing pharmacists and other practicing health care professionals who are licensed to prescribe drugs.

(C) Prohibit any member with a conflict of interest with respect to the issuer or a pharmaceutical manufacturer from voting on any matters for which the conflict exists.

(D) Require at least 20 percent of its membership to have no conflict of interest with respect to the issuer and any pharmaceutical manufacturer.

(ii) *Meeting standards.* The P&T committee must:

(A) Meet at least quarterly.

(B) Maintain written documentation of the rationale for all decisions regarding formulary drug list development or revision.

(iii) *Formulary drug list establishment and management.* The P&T committee must:

(A) Develop and document procedures to ensure appropriate drug review and inclusion.

(B) Base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other such information as it determines appropriate.

(C) Consider the therapeutic advantages of drugs in terms of safety and efficacy when selecting formulary drugs.

(D) Review policies that guide exceptions and other utilization management processes, including drug utilization review, quantity limits, and therapeutic interchange.

(E) Evaluate and analyze treatment protocols and procedures related to the plan's formulary at least annually.

(F) Review and approve all clinical prior authorization criteria, step therapy protocols, and quantity limit restrictions applied to each covered drug.

(G) Review new FDA-approved drugs and new uses for existing drugs.

(H) Ensure the issuer's formulary drug list:

(1) Covers a range of drugs across a broad distribution of therapeutic categories and classes and recommended drug treatment regimens that treat all disease states, and does not discourage enrollment by any group of enrollees; and

(2) Provides appropriate access to drugs that are included in broadly accepted treatment guidelines and that are indicative of general best practices at the time.

* * * * *

(c) A health plan providing essential health benefits must have the following processes in place that allow an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber, as appropriate) to request and gain access to clinically appropriate drugs not otherwise covered by the health plan (a request for exception). In the event that an exception request is granted, the plan must treat the excepted drug(s) as an essential health benefit, including by counting any cost-sharing towards the plan's annual limitation on cost-sharing under § 156.130 and when calculating the plan's actuarial value under § 156.135.

(1) *Standard exception request.* For plans years beginning on or after January 1, 2016:

(i) A health plan must have a process for an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber) to request a standard review of a decision that a drug is not covered by the plan.

(ii) A health plan must make its determination on a standard exception and notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage determination no later than 72 hours following receipt of the request.

(iii) A health plan that grants a standard exception request must provide coverage of the non-formulary drug for the duration of the prescription, including refills.

(2) *Expedited exception request.* (i) A health plan must have a process for an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or

other prescriber) to request an expedited review based on exigent circumstances.

(ii) Exigent circumstances exist when an enrollee is suffering from a health condition that may seriously jeopardize the enrollee's life, health, or ability to regain maximum function or when an enrollee is undergoing a current course of treatment using a non-formulary drug.

(iii) A health plan must make its coverage determination on an expedited review request based on exigent circumstances and notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage determination no later than 24 hours following receipt of the request.

(iv) A health plan that grants an exception based on exigent circumstances must provide coverage of the non-formulary drug for the duration of the exigency.

(3) *External exception request review.* For plans years beginning on or after January 1, 2016:

(i) If the health plan denies a request for a standard exception under paragraph (c)(1) of this section or for an expedited exception under paragraph (c)(2) of this section, the health plan must have a process for the enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber) to request that the original exception request and subsequent denial of such request be reviewed by an independent review organization.

(ii) A health plan must make its determination on the external exception request and notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage determination no later than 72 hours following its receipt of the request, if the original request was a standard exception request under paragraph (c)(1) of this section, and no later than 24 hours following its receipt of the request, if the original request was an expedited exception request under paragraph (c)(2) of this section.

(iii) If a health plan grants an external exception review of a standard exception request, the health plan must provide coverage of the non-formulary drug for the duration of the prescription. If a health plan grants an external exception review of an expedited exception request, the health plan must provide coverage of the non-formulary drug for the duration of the exigency.

(d)(1) For plan years beginning on or after January 1, 2016, a health plan must publish an up-to-date, accurate, and complete list of all covered drugs on its formulary drug list, including any

tiering structure that it has adopted and any restrictions on the manner in which a drug can be obtained, in a manner that is easily accessible to plan enrollees, prospective enrollees, the State, the Exchange, HHS, the U.S. Office of Personnel Management, and the general public. A formulary drug list is easily accessible when:

(i) It can be viewed on the plan's public Web site through a clearly identifiable link or tab without requiring an individual to create or access an account or enter a policy number; and

(ii) If an issuer offers more than one plan, when an individual can easily discern which formulary drug list applies to which plan.

(2) A QHP in the Federally-facilitated Exchange must make available the information described in paragraph (d)(1) of this section on its Web site in an HHS-specified format and also submit this information to HHS, in a format and at times determined by HHS.

(e) For plan years beginning on or after January 1, 2017, a health plan providing essential health benefits must have the following access procedures:

(1) A health plan must allow enrollees to access prescription drug benefits at in-network retail pharmacies, unless:

(i) The drug is subject to restricted distribution by the U.S. Food and Drug Administration; or

(ii) The drug requires special handling, provider coordination, or patient education that cannot be provided by a retail pharmacy.

(2) A health plan may charge enrollees a different cost-sharing amount for obtaining a covered drug at a retail pharmacy, but all cost sharing will count towards the plan's annual limitation on cost sharing under § 156.130 and must be accounted for in the plan's actuarial value calculated under § 156.135.

■ 44. Section 156.130 is amended by revising paragraph (c) to read as follows:

§ 156.130 Cost-sharing requirements.

* * * * *

(c) *Special rule for network plans.* In the case of a plan using a network of providers, cost sharing paid by, or on behalf of, an enrollee for benefits provided outside of such network is not required to count toward the annual limitation on cost sharing (as defined in paragraph (a) of this section).

* * * * *

■ 45. Section 156.145 is amended by revising paragraph (a) introductory text to read as follows:

§ 156.145 Determination of minimum value.

(a) *Acceptable methods for determining MV.* An employer-sponsored plan provides minimum value (MV) only if the percentage of the total allowed costs of benefits provided under the plan is greater than or equal to 60 percent, and the benefits under the plan include substantial coverage of inpatient hospital services and physician services. An employer-sponsored plan may use one of the following methods to determine whether the percentage of the total allowed costs of benefits provided under the plan is not less than 60 percent.

* * * * *

■ 46. Section 156.200 is amended by revising paragraph (b)(7) to read as follows:

§ 156.200 QHP issuer participation standards.

* * * * *

(b) * * *
(7) Comply with the standards under 45 CFR part 153.

* * * * *

■ 47. Section 156.230 is amended by revising paragraph (a) introductory text and paragraph (b) and adding paragraph (c) to read as follows:

§ 156.230 Network adequacy standards.

(a) *General requirement.* Each QHP issuer that uses a provider network must ensure that the provider network consisting of in-network providers, as available to all enrollees, meets the following standards—

* * * * *

(b) *Access to provider directory.* (1) A QHP issuer must make its provider directory for a QHP available to the Exchange for publication online in accordance with guidance from HHS and to potential enrollees in hard copy upon request. In the provider directory, a QHP issuer must identify providers that are not accepting new patients.

(2) For plan years beginning on or after January 1, 2016, a QHP issuer must publish an up-to-date, accurate, and complete provider directory, including information on which providers are accepting new patients, the provider's location, contact information, specialty, medical group, and any institutional affiliations, in a manner that is easily accessible to plan enrollees, prospective enrollees, the State, the Exchange, HHS and OPM. A provider directory is easily accessible when—

(i) The general public is able to view all of the current providers for a plan in the provider directory on the issuer's

public Web site through a clearly identifiable link or tab and without creating or accessing an account or entering a policy number; and

(ii) If a health plan issuer maintains multiple provider networks, the general public is able to easily discern which providers participate in which plans and which provider networks.

(c) *Increasing consumer transparency.* A QHP issuer in a Federally-facilitated Exchange must make available the information described in paragraph (b) of this section on its Web site in an HHS specified format and also submit this information to HHS, in a format and manner and at times determined by HHS.

■ 48. Section 156.235 is revised to read as follows:

§ 156.235 Essential community providers.

(a) *General ECP standard.* (1) A QHP issuer that uses a provider network must include in its provider network a sufficient number and geographic distribution of essential community providers (ECPs), where available, to ensure reasonable and timely access to a broad range of such providers for low-income individuals or individuals residing in Health Professional Shortage Areas within the QHP's service area, in accordance with the Exchange's network adequacy standards.

(2) A plan applying for QHP certification to be offered through a Federally-facilitated Exchange has a sufficient number and geographic distribution of ECPs if it demonstrates in its QHP application that—

(i) The network includes as participating providers at least a minimum percentage, as specified by HHS, of available ECPs in each plan's service area with multiple providers at a single location counting as a single ECP toward both the available ECPs in the plan's service area and the issuer's satisfaction of the ECP participation standard; and

(ii) The issuer of the plan offers contracts to—

(A) All available Indian health care providers in the service area, applying the special terms and conditions required by Federal law and regulations as referenced in the recommended model QHP addendum for Indian health care providers developed by HHS; and

(B) At least one ECP in each of the ECP categories (Federally Qualified Health Centers, Ryan White Providers, Family Planning Providers, Indian Health Care Providers, Hospitals and other ECP providers) in each county in the service area, where an ECP in that category is available and provides

medical or dental services that are covered by the issuer plan type.

(3) If a plan applying for QHP certification to be offered through a Federally-facilitated Exchange does not satisfy the ECP standard described in paragraph (a)(2) of this section, the issuer must include as part of its QHP application a narrative justification describing how the plan's provider network provides an adequate level of service for low-income enrollees or individuals residing in Health Professional Shortage Areas within the plan's service area and how the plan's provider network will be strengthened toward satisfaction of the ECP standard prior to the start of the benefit year.

(4) Nothing in paragraphs (a)(1) through (3) of this section requires any QHP to provide coverage for any specific medical procedure.

(5) A plan that provides a majority of covered professional services through physicians employed by the issuer or through a single contracted medical group may instead comply with the alternate standard described in paragraph (b) of this section.

(b) *Alternate ECP standard.* (1) A plan described in paragraph (a)(5) of this section must have a sufficient number and geographic distribution of employed providers and hospital facilities, or providers of its contracted medical group and hospital facilities, to ensure reasonable and timely access for low-income individuals or individuals residing in Health Professional Shortage Areas within the plan's service area, in accordance with the Exchange's network adequacy standards.

(2) A plan described in paragraph (a)(5) of this section applying for QHP certification to be offered through a Federally-facilitated Exchange has a sufficient number and geographic distribution of employed or contracted providers if it demonstrates in its QHP application that—

(i) The number of its providers that are located in Health Professional Shortage Areas or five-digit zip codes in which 30 percent or more of the population falls below 200 percent of the Federal Poverty Line satisfies a minimum percentage, specified by HHS, of available ECPs in the plan's service area with multiple providers at a single location counting as a single ECP; and

(ii) The issuer's integrated delivery system provides all of the categories of services provided by entities in each of the ECP categories in each county in the plan's service area as outlined in the general ECP standard, or otherwise offers a contract to at least one ECP outside of the issuer's integrated delivery system per ECP category in

each county in the plan's service area that can provide those services to low-income, medically underserved individuals.

(3) If a plan does not satisfy the alternate ECP standard described in paragraph (b)(2) of this section, the issuer must include as part of its QHP application a narrative justification describing how the plan's provider networks provide an adequate level of service for low-income enrollees or individuals residing in Health Professional Shortage Areas within the plan's service area and how the plan's provider network will be strengthened toward satisfaction of the ECP standard prior to the start of the benefit year.

(c) *Definition.* An essential community provider is a provider that serves predominantly low-income, medically underserved individuals, including a health care provider defined in section 340B(a)(4) of the PHS Act; or described in section 1927(c)(1)(D)(i)(IV) of the Act as set forth by section 221 of Pub. L. 111-8; or a State-owned family planning service site, or governmental family planning service site, or not-for-profit family planning service site that does not receive Federal funding under special programs, including under Title X of the PHS Act, or an Indian health care provider, unless any of the above providers has lost its status under either of these sections, 340(B) of the PHS Act or 1927 of the Act as a result of violating Federal law.

(d) *Payment rates.* Nothing in paragraph (a) of this section may be construed to require a QHP issuer to contract with an ECP if such provider refuses to accept the same rates and contract provisions included in contracts accepted by similarly situated providers.

(e) *Payment of Federally qualified health centers.* If an item or service covered by a QHP is provided by a Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Act) to an enrollee of a QHP, the QHP issuer must pay the Federally qualified health center for the item or service an amount that is not less than the amount of payment that would have been paid to the center under section 1902(bb) of the Act for such item or service. Nothing in this paragraph (e) precludes a QHP issuer and Federally-qualified health center from agreeing upon payment rates other than those that would have been paid to the center under section 1902(bb) of the Act, as long as that rate is at least equal to the generally applicable payment rate of the issuer described in paragraph (d) of this section.

■ 49. Section 156.250 is revised to read as follows:

§ 156.250 Meaningful access to qualified health plan information.

A QHP issuer must provide all information that is critical for obtaining health insurance coverage or access to health care services through the QHP, including applications, forms, and notices, to qualified individuals, applicants, qualified employers, qualified employees, and enrollees in accordance with the standards described in § 155.205(c) of this subchapter. Information is deemed to be critical for obtaining health insurance coverage or access to health care services if the issuer is required by law or regulation to provide the document to a qualified individual, applicant, qualified employer, qualified employee, or enrollee.

■ 50. Section 156.265 is amended by revising paragraph (d) to read as follows:

§ 156.265 Enrollment process for qualified individuals.

(d) *Premium payment.* A QHP issuer must follow the premium payment process established by the Exchange in accordance with § 155.240 of this subchapter and the payment rules established in § 155.400(e) of this subchapter.

■ 51. Section 156.270 is amended by revising the section heading and paragraphs (a), (b), (c) introductory text, (g), and (i) to read as follows:

§ 156.270 Termination of coverage or enrollment for qualified individuals.

(a) *General requirement.* A QHP issuer may only terminate enrollment in a QHP through the Exchange as permitted by the Exchange in accordance with § 155.430(b) of this subchapter. (See also § 147.106 of this subchapter for termination of coverage.)

(b) *Termination of coverage or enrollment notice requirement.* If a QHP issuer terminates an enrollee's coverage or enrollment in a QHP through the Exchange in accordance with § 155.430(b)(2)(i), (ii), or (iii) of this subchapter, the QHP issuer must, promptly and without undue delay:

(1) Provide the enrollee with a notice of termination that includes the termination effective date and reason for termination.

(2) [Reserved]

(c) *Termination of coverage or enrollment due to non-payment of premium.* A QHP issuer must establish a standard policy for the termination of

enrollment of enrollees through the Exchange due to non-payment of premium as permitted by the Exchange in § 155.430(b)(2)(ii) of this subchapter. This policy for the termination of enrollment:

* * * * *

(g) *Exhaustion of grace period.* If an enrollee receiving advance payments of the premium tax credit exhausts the 3-month grace period in paragraph (d) of this section without paying all outstanding premiums, the QHP issuer must terminate the enrollee's enrollment through the Exchange on the effective date described in § 155.430(d)(4) of this subchapter, provided that the QHP issuer meets the notice requirement specified in paragraph (b) of this section.

* * * * *

(i) *Effective date of termination of coverage or enrollment.* QHP issuers must abide by the termination of coverage or enrollment effective dates described in § 155.430(d) of this subchapter.

* * * * *

■ 52. Section 156.285 is amended by—

■ a. Revising paragraphs (b)(1), (b)(4), (d) introductory text, (d)(1) introductory text, (d)(1)(i), and (d)(1)(iii);

■ b. Redesignating paragraphs (c)(3), (4), (5), (6), and (7) as paragraphs (c)(4), (5), (6), (7), and (8), respectively.

■ c. Adding new paragraph (c)(3).

■ d. Adding and reserving paragraph (d)(2).

The revisions and addition read as follows:

§ 156.285 Additional standards specific to SHOP.

* * * * *

(b) * * *

(1) Enroll a qualified employee in accordance with the qualified employer's initial and annual employee open enrollment periods described in § 155.725 of this subchapter;

* * * * *

(4) Adhere to effective dates of coverage established in accordance with § 155.725 of this subchapter.

(c) * * *

(3) Notify new enrollees of their effective date of coverage consistent with § 155.720(e) of this subchapter.

* * * * *

(d) *Termination of coverage or enrollment in the SHOP.* QHP issuers offering a QHP through the SHOP must:

(1) Comply with the following requirements with respect to termination of enrollees in the SHOP:

(i)(A) Effective in plan years beginning on or after January 1, 2015, requirements regarding termination of

coverage or enrollment established in § 155.735 of this subchapter, if applicable to the coverage or enrollment being terminated; otherwise

(B) General requirements regarding termination of coverage or enrollment established in § 156.270(a).

* * * * *

(iii)(A) Effective in plan years beginning on or after January 1, 2015, requirements regarding termination of coverage or enrollment effective dates as set forth in § 155.735 of this subchapter, if applicable to the coverage or enrollment being terminated; otherwise

(B) Requirements regarding termination of coverage or enrollment effective dates as set forth in § 156.270(i).

(2) [Reserved]

* * * * *

■ 53. Section 156.285 is further amended, effective January 1, 2016, by revising paragraph (d)(1)(ii) to read as follows:

§ 156.285 Additional standards specific to SHOP.

* * * * *

(d) * * *

(1) * * *

(ii) If a QHP issuer terminates an enrollee's coverage or enrollment through the SHOP in accordance with § 155.735(d)(1)(iii) or (v) of this subchapter, the QHP issuer must notify the qualified employer and the enrollee of the termination. Such notice must include the termination effective date and reason for termination, and must be sent within 3 business days if an electronic notice is sent, and within 5 business days if a mailed hard copy notice is sent. When a primary subscriber and his or her dependents live at the same address, a separate termination notice need not be sent to each dependent at that address, provided that the notice sent to each primary subscriber at that address contains all required information about the termination for the primary subscriber and his or her dependents at that address.

* * * * *

■ 54. Section 156.290 is amended by revising paragraphs (a)(1), (a)(2), (a)(5), and (c) introductory text to read as follows:

§ 156.290 Non-renewal and decertification of QHPs.

(a) * * *

(1) Notify the Exchange of its decision prior to the beginning of the recertification process and adhere to the procedures adopted by the Exchange in accordance with § 155.1075 of this subchapter;

(2) Fulfill its obligation to cover benefits for each enrollee through the end of the plan or benefit year through the Exchange;

* * * * *

(5) Terminate the coverage or enrollment through the Exchange of enrollees in the QHP in accordance with § 156.270, as applicable.

* * * * *

(c) *Decertification.* If a QHP is decertified by the Exchange, the QHP issuer must terminate the enrollment of enrollees through the Exchange only after:

* * * * *

■ 55. Section 156.410 is amended by removing the second paragraph designated as paragraph (d)(4)(ii) and adding paragraph (d)(4)(iii) to read as follows:

§ 156.410 Cost-sharing reductions for enrollees.

* * * * *

(d) * * *

(4) * * *

(iii) If the excess cost sharing was not paid by the provider, then, if the enrollee requests a refund, the refund must be provided to the enrollee within 45 calendar days of the date of the request.

■ 56. Section 156.420 is amended by adding paragraph (h) to read as follows:

§ 156.420 Plan variations.

* * * * *

(h) *Notice.* No later than November 1, 2015, for each plan variation that an issuer offers in accordance with the rules of this section, an issuer must provide a summary of benefits and coverage that accurately represents each plan variation consistent with the requirements set forth in § 147.200 of this subchapter.

■ 57. Section 156.425 is amended by adding paragraph (c) to read as follows:

§ 156.425 Changes in eligibility for cost-sharing reductions.

* * * * *

(c) *Notice upon assignment.* Beginning on January 1, 2016, if an individual's assignment to a standard plan or plan variation of the QHP changes in accordance with paragraph (a) of this section, the issuer must provide to that individual a summary of benefits and coverage that accurately reflects the new plan variation (or standard plan variation without cost-sharing reductions) in a manner consistent with § 147.200 of this subchapter as soon as practicable following receipt of notice from the Exchange, but not later than 7 business days following receipt of notice.

■ 58. Section 156.430 is amended by adding paragraph (c)(2)(i) and adding and reserving paragraph (c)(2)(ii) to read as follows:

§ 156.430 Payment for cost-sharing reductions.

* * * * *

(c) * * *

(2) * * *

(i) For reconciliation of cost-sharing reduction amounts advanced for the 2014 and 2015 benefit years, an issuer of a QHP using the standard or simplified methodology may calculate claims amounts attributable to EHB, including cost sharing amounts attributable to EHB, by reducing total claims amounts by the plan-specific percentage estimate of non-essential health benefit claims submitted on the Uniform Rate Review Template for the corresponding benefit year, if the following conditions are met:

(A) The non-essential health benefits percentage estimate is less than 2 percent; and

(B) Out-of-pocket expenses for non-EHB benefits are included in the calculation of amounts subject to a deductible or annual limitation on cost sharing, but copayments and coinsurance rates on non-EHB benefits are not reduced under the plan variation.

(ii) [Reserved]

* * * * *

■ 59. Section 156.602 is amended by revising paragraph (d) to read as follows:

§ 156.602 Other coverage that qualifies as minimum essential coverage.

* * * * *

(d) *State high risk pool coverage.* A qualified high risk pool as defined by section 2744(c)(2) of the Public Health Service Act established on or before November 26, 2014 in any State.

* * * * *

■ 60. Section 156.800 is amended by revising paragraph (c) to read as follows:

§ 156.800 Available remedies; Scope.

* * * * *

(c) *Compliance standard.* For calendar years 2014 and 2015, sanctions under this subpart will not be imposed if the QHP issuer has made good faith efforts to comply with applicable requirements.

* * * * *

■ 61. Section 156.815 is added to subpart I to read as follows:

§ 156.815 Plan suppression.

(a) *Suppression* means temporarily making a QHP certified to be offered through the Federally-facilitated

Exchange unavailable for enrollment through the Federally-facilitated Exchange.

(b) *Grounds for suppression.* A QHP may be suppressed as described in paragraph (a) of this section on one or more of the following grounds:

(1) The QHP issuer notifies HHS of its intent to withdraw the QHP from a Federally-facilitated Exchange when one of the exceptions to guaranteed renewability of coverage related to discontinuing a particular product or discontinuing all coverage under § 147.106(c) or (d) of this subchapter applies;

(2) Data submitted for the QHP is incomplete or inaccurate;

(3) The QHP is in the process of being decertified as described in § 156.810(c) or (d), or the QHP issuer is appealing a completed decertification as described in subpart J of this part;

(4) The QHP issuer offering the QHP is the subject of a pending, ongoing, or final State regulatory or enforcement action or determination that could affect the issuer's ability to enroll consumers or otherwise relates to the issuer offering QHPs in the Federally-facilitated Exchanges; or

(5) One of the exceptions to guaranteed availability of coverage related to special rules for network plans or financial capacity limits under § 147.104(c) or (d) of this subchapter applies.

(c) A multi-State plan as defined in § 155.1000(a) of this subchapter may be suppressed as described in paragraph (a) of this section if OPM notifies the Exchange that:

(1) OPM has found a compliance

(2) One of the grounds for suppression in paragraph (b) of this section exists for the multi-State plan.

■ 62. Section 156.1130 is added to subpart L to read as follows:

§ 156.1130 Quality improvement strategy.

(a) *General requirement.* A QHP issuer participating in an Exchange for 2 or more consecutive years must implement and report on a quality improvement strategy including a payment structure that provides increased reimbursement or other market-based incentives in accordance with the health care topic areas in section 1311(g)(1) of the Affordable Care Act, for each QHP offered in an Exchange, consistent with the guidelines developed by HHS under section 1311(g) of the Affordable Care Act.

(b) *Data requirement.* A QHP issuer must submit data that has been validated in a manner and timeframe specified by the Exchange to support the evaluation of quality improvement strategies in accordance with § 155.200(d) of this subchapter.

(c) *Timeline.* A QHP issuer must submit data annually to evaluate compliance with the standards for a quality improvement strategy in accordance with paragraph (a) of this section, in a manner and timeframe specified by the Exchange.

(d) *Multi-State plans.* Issuers of multi-State plans, as defined in § 155.1000(a) of this subchapter, must provide the data described in paragraph (b) of this section to the U.S. Office of Personnel Management, in the manner and timeframe specified by the U.S. Office of Personnel Management.

■ 63. Section 156.1220 is amended by revising paragraph (c) to read as follows:

§ 156.1220 Administrative appeals.

(c) *Review by the Administrator of CMS.* (1) Either the issuer or CMS may request review by the Administrator of CMS of the CMS hearing officer's decision. A request for review of the CMS hearing officer's decision must be submitted to the Administrator of CMS within 15 calendar days of the date of the CMS hearing officer's decision, and must specify the findings or issues that the issuer or CMS challenges. The issuer or CMS may submit for review by the Administrator of CMS a statement supporting the decision of the CMS hearing officer.

(2) After receiving a request for review, the Administrator of CMS has the discretion to elect to review the CMS hearing officer's decision or to decline to review the CMS hearing officer's decision. If the Administrator of CMS elects to review the CMS hearing officer's decision, the Administrator of CMS will also review the statements of the issuer and CMS, and any other information included in the record of the CMS hearing officer's decision, and will determine whether to uphold, reverse, or modify the CMS hearing officer's decision. The issuer or CMS must prove its case by clear and convincing evidence for issues of fact. The Administrator of CMS will send the decision and the reasons for the decision to the issuer.

(3) The Administrator of CMS's determination is final and binding.

PART 158—ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS

■ 64. The authority citation for part 158 continues to read as follows:

Authority: Section 2718 of the Public Health Service Act (42 U.S.C. 300gg–18), as amended.

■ 65. Section 158.140 is amended by adding paragraph (b)(1)(iii) to read as follows:

§ 158.140 Reimbursement for clinical services provided to enrollees.

* * * * *

(b) * * *

(1) * * *

(iii) Cost-sharing reduction payments received by the issuer to the extent not reimbursed to the provider furnishing the item or service.

* * * * *

■ 66. Section 158.162 is amended by revising paragraph (a)(2) and adding paragraph (b)(2)(iv) to read as follows:

§ 158.162 Reporting of Federal and State taxes.

(a) * * *

(2) Federal taxes not excluded from premium under subpart B of this part which include Federal income taxes on investment income and capital gains, as well as Federal employment taxes, as other non-claims costs.

(b) * * *

(2) * * *

(iv) State employment and similar taxes and assessments.

* * * * *

■ 67. Section 158.242 is amended by

■ a. Revising paragraph (b)(1)(iii);

■ b. Amending paragraph (b)(1)(iv) by removing the period and adding “; and” in its place; and

■ c. Adding paragraph (b)(1)(v).

The revision and addition read as follows:

§ 158.242 Recipients of rebates.

* * * * *

(b) * * *

(1) * * *

(iii) A cash refund to subscribers of the group health plan option for which the issuer is providing a rebate, who were enrolled in the group health plan option either during the MLR reporting year that resulted in the issuer providing the rebate or at the time the rebate is received by the policyholder;

* * * * *

(v) All rebate distributions made under paragraphs (b)(1)(i), (ii), or (iii) of this section must be made within 3 months of the policyholder's receipt of the rebate. Rebate distributions made after 3 months must include late payment interest at the current Federal Reserve Board lending rate or 10 percent

annually, whichever is higher, on the total amount of the rebate, accruing from the date payment was due under this section.

* * * * *

Dated: February 6, 2015.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Dated: February 17, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2015-03751 Filed 2-20-15; 4:15 pm]

BILLING CODE 4120-01-P

EXHIBIT 3

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Consumer Information & Insurance Oversight
200 Independence Avenue SW
Washington, DC 20201



Date: November 19, 2015

From: Center for Consumer Information & Insurance Oversight (CCIIO),
Centers for Medicare & Medicaid Services (CMS)

Subject: **Risk Corridors Payments for the 2014 Benefit Year**

On October 1, 2015, the Centers for Medicare & Medicaid Services (CMS) announced that for the first year of the three year risk corridors program, qualified health plan (QHP) issuers will pay charges of approximately \$362 million, and QHP issuers have requested \$2.87 billion of 2014 payments, based on current data for the 2014 benefit year.¹ Consistent with prior guidance, assuming full collections of risk corridors charges for the 2014 benefit year, insurers will be paid an amount that reflects a proration rate of 12.6% of their 2014 benefit year risk corridors payment requests.² The remaining 2014 risk corridors payments will be made from 2015 risk corridors collections, and if necessary, 2016 collections.

In the event of a shortfall for the 2016 program year, the Department of Health and Human Services (HHS) will explore other sources of funding for risk corridors payments, subject to the availability of appropriations. This includes working with Congress on the necessary funding for outstanding risk corridors payments.

HHS recognizes that the Affordable Care Act requires the Secretary to make full payments to issuers, and HHS is recording those amounts that remain unpaid following our 12.6% payment this winter as fiscal year 2015 obligation of the United States Government for which full payment is required.

¹ "Risk Corridors Payment Proration Rate for 2014." October 1, 2015. <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/RiskCorridorsPaymentProrationRatefor2014.pdf>

² "Risk Corridors and Budget Neutrality." April 11, 2014. <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/faq-risk-corridors-04-11-2014.pdf>. "Risk Corridors Payment Proration Rate." October 1, 2015. <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/RiskCorridorsPaymentProrationRatefor2014.pdf>

EXHIBIT 4

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Consumer Information and Insurance Oversight
200 Independence Avenue SW
Washington, DC 20201



Date: September 9, 2016

Subject: Risk Corridors Payments for 2015

Section 1342 of the Affordable Care Act directs the Secretary of the Department of Health and Human Services (HHS) to establish a temporary risk corridors program that provides issuers of qualified health plans (QHPs) in the individual and small group markets additional protection against uncertainty in claims costs during the first three years of the Marketplace. This program, which was modeled after a similar program used in the Medicare prescription drug benefit, encouraged issuers to keep their rates stable as they adjusted to the new health insurance reforms in the early years of the Marketplaces.

Under the risk corridors program, the federal government shares risk with QHP issuers – collecting charges from the issuer if the issuer’s QHP premiums exceed claims costs of QHP enrollees by a certain amount, and making payments to the issuer if the issuer’s premiums fall short by a certain amount, subject to certain adjustments for taxes, administrative expenses, and other costs and payments. On April 11, 2014, HHS issued a bulletin titled “Risk Corridors and Budget Neutrality,” which described how we intend to administer risk corridors over the three-year life of the program. We stated that if risk corridors collections for a particular year are insufficient to make full risk corridors payments for that year, risk corridors payments for the year will be reduced pro rata to the extent of any shortfall.

Today, HHS is announcing preliminary information about risk corridors for the 2015 benefit year. Risk corridors submissions are still undergoing review and complete information on payments and charges for the 2015 benefit year is not available at this time. However, based on our preliminary analysis, HHS anticipates that all 2015 benefit year collections will be used towards remaining 2014 benefit year risk corridors payments, and no funds will be available at this time for 2015 benefit year risk corridors payments. HHS expects to begin collection of risk corridors charges and remittance of risk corridors payments on the same schedule as last year. Collections from the 2016 benefit year will be used first for remaining 2014 benefit year risk corridors payments, then for 2015 benefit year risk corridors payments, then for 2016 benefit year risk corridors payments.

As we have said previously, in the event of a shortfall for the 2016 benefit year, HHS will explore other sources of funding for risk corridors payments, subject to the availability of appropriations. This includes working with Congress on the necessary funding for outstanding risk corridors payments. HHS recognizes that the Affordable Care Act requires the Secretary to make full payments to issuers. HHS will record risk corridors payments due as an obligation of the United States Government for which full payment is required.

We know that a number of issuers have sued in federal court seeking to obtain the risk corridors amounts that have not been paid to date. As in any lawsuit, the Department of Justice is vigorously defending those claims on behalf of the United States. However, as in all cases where there is litigation risk, we are open to discussing resolution of those claims. We are willing to begin such discussions at any time.

EXHIBIT 5

Department of Health & Human Services

Centers for Medicare & Medicaid Services
Center for Consumer Information & Insurance Oversight 200
Independence Avenue SW
Washington, DC 20201



Date: November 18, 2016

Subject: Risk Corridors Payment and Charge Amounts for the 2015 Benefit Year

Background:

Section 1342 of the Affordable Care Act directs the Secretary of the Department of Health and Human Services (HHS) to establish a temporary risk corridors program that provides issuers of qualified health plans (QHPs) in the individual and small group markets additional protection against uncertainty in claims costs during the first three years of the Marketplace.

HHS established a three-year payment framework for the risk corridors program and outlined the details of this payment framework in our April 11, 2014 guidance on *Risk Corridors and Budget Neutrality*.¹ As set forth in that guidance, if risk corridors collections for a particular year are insufficient to make full risk corridors payments for that year, risk corridors payments for the year will be reduced pro rata to the extent of any shortfall. Because risk corridors payments for the 2014 benefit year exceeded risk corridors collections for that benefit year, risk corridors collections for the 2015 benefit year will be used first towards remaining balances on 2014 benefit year risk corridors payments.

On September 9, 2016, HHS published guidance on *Risk Corridors Payments for 2015*, stating that we anticipated that all 2015 benefit year collections would be used toward remaining 2014 benefit year risk corridors payments, and that no funds would be available at this time for 2015 benefit year risk corridors payments.² Today, we are confirming that all 2015 benefit year risk corridors collections will be used to pay a portion of balances on 2014 benefit year risk corridors payments.

We are also announcing issuer-level risk corridors payments and charges for the 2015 benefit year. The tables below show risk corridors payments and charges calculated for the 2015 benefit year, by State and issuer, and the additional amount based on anticipated 2015 risk corridors collections that HHS expects to pay towards the calculated 2014 benefit year payments.³ Pursuant to 45 CFR

¹ *Risk Corridors and Budget Neutrality*, available at: <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/faq-risk-corridors-04-11-2014.pdf>

² *Risk Corridors Payments for 2015*, available at: <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/Risk-Corridors-for-2015-FINAL.PDF>

³ Risk corridor payment and charge amounts published in this bulletin do not reflect any payment or charge adjustments due to resubmissions after September 30, 2016 or any amount held back for appeals.

153.510(g), the 2015 benefit year risk corridors amounts listed in this report include the direct adjustment for issuers that reported certified estimates of the cost-sharing reduction portion of advance payments that were lower than the actual CSRs provided for the 2014 benefit year (as calculated under CSR reconciliation for the 2014 benefit year). On November 17, 2016, HHS notified issuers subject to the direct adjustment to 2015 benefit year risk corridors amounts of the calculated adjustment amount, consistent with guidance issued on September 15, 2016.⁴

Risk corridors payments are reduced pro rata based on risk corridors collections received. HHS intends to collect the full 2015 risk corridors charge amounts indicated in the tables below. HHS is collecting 2015 risk corridor charges in November 2016, and will begin remitting risk corridors payments to issuers in December 2016, as collections are received.

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS 2015 RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS 2015 RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	EXPECTED PAYMENT TOWARD 2014 AMOUNTS
AK	38344	Premiera Blue Cross Blue Shield of Alaska	\$7,479,997.83	\$716,228.92	\$274,005.10
AK	73836	Moda Health Plan, Inc.	\$28,630,662.11	\$2,900,481.02	\$56,006.61
AL	44580	Humana Insurance Company	\$2,935,440.73	\$0.00	\$31,461.63
AL	46944	Blue Cross and Blue Shield of Alabama	\$79,476,154.29	\$10,341,860.76	\$11,784.62
AL	59809	UnitedHealthcare Life Insurance Company	\$0.00	\$6,577.07	\$0.00
AL	68259	UnitedHealthcare of Alabama, Inc.	\$8,688,275.81	\$0.00	N/A
AR	62141	Celtic Insurance Company	\$1,812,823.37	\$0.00	\$0.00
AR	70525	QCA Health Plan, Inc.	\$476,592.83	\$0.00	\$138,891.20
AR	75293	USABLE Mutual Insurance Company	\$15,919,592.28	-\$7,883.38	\$0.00
AR	37903	QualChoice Life & Health Insurance Company, Inc.	\$4,524,487.98	\$0.00	N/A
AZ	23307	Humana Health Plan, Inc.	\$202,481.41	\$0.00	\$61,511.29
AZ	51485	Health Net Life Insurance Company	\$95,219,226.99	\$17,249,722.49	\$1,489,451.17
AZ	53901	Blue Cross and Blue Shield of Arizona, Inc.	\$51,990,665.22	\$0.00	\$388,258.91
AZ	60761	Meritus Health Partners	\$54,694,644.83	\$702,732.99	\$115,921.29
AZ	70239	Health Choice Insurance Co.	\$4,444,184.06	\$0.00	\$41,795.92
AZ	84251	Aetna Life Insurance Company	-\$389,753.48	\$0.00	\$1,995.46
AZ	86830	Cigna Health and Life Insurance Company	\$1,023,204.62	\$0.00	\$5,758.61
AZ	88925	University of Arizona Health Plans-University Healthcare, Inc.	\$1,213,077.74	\$0.00	\$21,429.04
AZ	91450	Health Net of Arizona, Inc.	\$38,681,654.46	\$5,438,853.29	\$1,523,528.06
AZ	92045	Meritus Mutual Health Partners	\$11,438,590.03	\$1,437,229.12	\$62,237.55

⁴ Reporting of Risk Corridors Amounts Reflecting Certified Estimates of 2014 Cost-Sharing Reduction Amounts in Part 3, Line 1.7 of the Medical Loss Ratio Annual Reporting Form for the 2015 Benefit Year, available at: https://www.regtap.info/uploads/library/RC_CSRandMLR_091516_v1_5CR_091516.pdf

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS 2015 RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS 2015 RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	EXPECTED PAYMENT TOWARD 2014 AMOUNTS
AZ	65441	Phoenix Health Plans, Inc.	\$34,931.14	\$0.00	N/A
AZ	80863	Time Insurance Company	\$7,624,448.10	\$0.00	N/A
AZ	98971	All Savers Insurance Company	\$7,002,813.66	\$0.00	N/A
CA	18126	MOLINA HEALTHCARE OF CALIFORNIA	\$1,784,227.07	\$0.00	\$0.00
CA	27603	Blue Cross of California(Anthem BC)	-\$808,605.43	\$0.00	\$0.00
CA	40513	Kaiser Foundation Health Plan, Inc.	\$39,758,493.83	\$47,233,593.74	\$1,226,858.64
CA	47579	Chinese Community Health Plan	-\$25,303.31	\$0.00	\$23,677.66
CA	67138	Health Net of California, Inc	\$24,828,036.37	\$0.00	\$0.00
CA	70285	CA Physician's Service dba Blue Shield of CA	\$29,839,109.20	-\$217,494.36	\$0.00
CA	84014	County of Santa Clara	\$151,037.85	\$0.00	\$0.00
CA	92499	Sharp Health Plan	\$0.00	\$31,033.86	\$258.29
CA	92815	Local Initiative Health Authority for Los Angeles County	\$8,255,198.64	\$0.00	\$450,495.26
CA	93689	Western Health Advantage	\$0.00	\$171,678.94	\$193.15
CA	99110	Health Net Life Insurance Company	\$130,379,454.51	\$10,868,970.44	\$168,047.08
CA	99483	CONTRA COSTA HEALTH PLAN	\$0.00	\$0.00	\$0.00
CO	11555	New Health Ventures Inc	\$88,645.17	\$0.00	\$3,538.44
CO	20472	Colorado Health Insurance Cooperative, Inc.	\$97,136,652.48	\$1,558,715.85	\$475,035.47
CO	21032	Kaiser Foundation Health Plan of Colo.	\$52,928,909.77	\$0.00	\$470,397.66
CO	49375	Cigna Health and Life Insurance Company	\$2,017,361.36	\$0.00	\$0.00
CO	63312	Colorado Choice Health Plans	\$1,597,077.24	\$60,789.09	\$199,569.45
CO	66699	Denver Health Medical Plan, Inc	\$141,372.24	\$0.00	\$9,551.66
CO	74320	Humana Health Plan	\$2,856,524.81	\$0.00	\$105,754.43
CO	76680	HMO Colorado, Inc., dba HMO Nevada	\$3,002,631.67	\$38,482.92	\$49,152.32
CO	80208	Rocky Mountain Health Care Options	\$0.00	\$0.00	\$14,634.44
CO	92137	All Savers Insurance Company	\$184,407.92	\$0.00	\$0.00
CO	97879	Rocky Mountain HMO	\$32,345,160.48	\$780,733.56	\$68,035.75
CT	49650	UnitedHealthcare Insurance Company	\$222,890.06	\$265,020.43	\$375.35
CT	76962	ConnectiCare Benefits, Inc.	\$0.00	\$0.00	\$0.00
CT	86545	Anthem Health Plans Inc(Anthem BCBS)	-\$691,198.86	\$0.00	\$0.00
CT	91069	HealthyCT, Inc.	\$12,859,364.54	\$1,723,783.09	\$60,918.61
DC	41842	UnitedHealthcare Insurance Company	\$0.00	\$0.00	\$0.00
DC	73987	Aetna Health Inc. (a PA corp.)	\$0.00	\$220,036.68	\$0.00
DC	75753	Optimum Choice, Inc.	\$0.00	-\$240,089.45	\$0.00
DC	77422	Aetna Life Insurance Company	\$42,898.21	\$112,048.45	\$0.00

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS 2015 RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS 2015 RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	EXPECTED PAYMENT TOWARD 2014 AMOUNTS
DC	78079	GHMSI	\$0.00	\$0.00	\$0.00
DC	86052	CareFirst BlueChoice, Inc.	-\$3,513.64	\$0.00	\$0.00
DC	94506	Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc.	\$1,054,566.82	\$1,802,662.82	\$41,761.59
DC	21066	UnitedHealthcare of the Mid-Atlantic Inc	\$0.00	\$14,598.52	N/A
DE	13537	Coventry Health and Life	-\$61,257.16	\$0.00	\$0.00
DE	76168	Highmark BCBSD Inc.	\$21,566,965.70	\$0.00	\$201,814.53
DE	81914	Coventry Health Care of Delaware, Inc.	-\$6,863.38	\$0.00	\$0.00
DE	29497	Aetna Life Insurance Company	\$965,123.20	\$0.00	N/A
DE	67190	Aetna Health Inc. (a PA corp.)	\$528,909.73	-\$12,042.12	N/A
FL	16842	Blue Cross and Blue Shield of Florida	\$0.00	\$0.00	\$479,525.97
FL	23841	Aetna Life Insurance Company	-\$7,303,625.54	\$0.00	\$0.00
FL	27357	Health First Health Plans, Inc.	\$0.00	\$0.00	\$3,421.47
FL	30252	Health Options, Inc.	\$0.00	\$0.00	\$378,082.04
FL	35783	Humana Medical Plan, Inc.	\$45,750,026.92	\$0.00	\$1,369,627.28
FL	48121	Cigna Health and Life Insurance Company	\$43,174,253.76	\$0.00	\$135,140.32
FL	51398	Preferred Medical Plan, Inc.	-\$5,243,952.57	\$0.00	\$1,155,250.77
FL	54172	Molina Healthcare of Florida, Inc	\$25,417,985.09	\$0.00	\$1,296.70
FL	56503	Florida Health Care Plan, Inc.	\$719,021.99	-\$114,905.82	\$0.00
FL	57451	Coventry Health Care of Florida, Inc.	-\$19,865,425.63	\$0.00	\$1,016,497.42
FL	77150	Health First Insurance, Inc.	-\$142,937.08	\$165,954.93	\$61,531.94
FL	86382	Sunshine State Health Plan	\$0.00	\$0.00	\$0.00
FL	18628	Aetna Health Inc. (a FL corp.)	\$11,484,155.02	\$0.00	N/A
FL	62662	Time Insurance Company	\$61,174,353.15	\$0.00	N/A
FL	68398	UnitedHealthcare of Florida, Inc.	\$42,781,167.93	\$39,290.23	N/A
GA	45495	Peach State Health Plan	\$0.00	\$0.00	\$0.00
GA	49046	Blue Cross Blue Shield Healthcare Plan of Georgia, Inc.	\$2,761,214.17	\$0.00	\$0.00
GA	83761	Alliant Health Plans	\$10,736,274.64	\$0.00	\$4.15
GA	89942	Kaiser Foundation Health Plan of Georgia	\$9,263,922.53	\$0.00	\$65,821.65
GA	93332	Humana Employers Health Plan of Georgia, Inc.	\$113,127,699.47	\$0.00	\$2,789,450.27
GA	20544	Time Insurance Company	\$7,352,482.72	\$0.00	N/A
GA	43802	UnitedHealthcare of Georgia, Inc.	\$12,145,393.47	\$0.00	N/A
GA	47783	Aetna Health Inc., a Georgia Corp	\$18,355,167.74	\$0.00	N/A
GA	50491	Cigna Health and Life Insurance Company	\$560,890.22	\$0.00	N/A
HI	18350	Hawaii Medical Service Association	\$17,759,344.35	\$0.00	\$0.00
HI	60612	Kaiser Foundation Health Plan, Inc.	\$18,747,151.44	\$83,687.07	\$618,200.26
IA	18973	Aetna Health of Iowa Inc.	\$705,180.40	\$0.00	\$89,945.49
IA	27651	Gundersen Health Plan, Inc.	\$110,467.33	\$189,148.64	\$3,781.59

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS 2015 RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS 2015 RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	EXPECTED PAYMENT TOWARD 2014 AMOUNTS
IA	71268	CoOpportunity Health	\$2,863,639.96	\$3,779,496.69	\$1,860,385.66
IA	74980	Avera Health Plans, Inc.	-\$345,059.90	\$829,146.07	\$3,352.13
IA	77638	Health Alliance Midwest, Inc.	\$0.00	\$0.00	\$0.00
IA	85930	Sanford Health Plan	\$0.00	\$0.00	\$4,289.68
ID	26002	SelectHealth	\$36,856,890.10	\$2,127,750.55	\$862,397.38
ID	44648	Regence Blue Shield of Idaho	\$0.00	\$0.00	\$0.00
ID	59765	BridgeSpan Health Company	\$939,702.69	\$0.00	\$927.39
ID	60597	PacificSource Health Plans	\$2,063,613.63	\$0.00	\$74,499.13
ID	61589	Blue Cross of Idaho Health Service, Inc.	\$43,056,603.68	\$0.00	\$1,329,989.79
ID	38128	Montana Health Cooperative	\$22,795,348.35	\$129,413.38	N/A
IL	20129	Health Alliance Medical Plans, Inc.	\$8,788,291.05	\$3,260.79	\$92,150.39
IL	35670	Coventry Health & Life Co.	-\$654,220.63	\$0.00	\$11,235.99
IL	36096	Blue Cross Blue Shield of Illinois	\$288,419,830.50	\$3,075,700.10	\$6,549,724.23
IL	58288	Humana Health Plan, Inc.	\$0.00	\$0.00	\$26,607.30
IL	68303	Humana Insurance Company	\$3,149,288.79	\$0.00	\$159,490.95
IL	72547	Aetna Life Insurance Company	-\$11,538.40	\$0.00	\$5,199.74
IL	79763	Land of Lincoln Mutual Health Insurance Company	\$59,546,957.17	\$12,286,293.83	\$149,224.78
IL	96601	Coventry Health Care of Illinois, Inc.	\$2,643,435.82	\$0.00	\$105,554.82
IL	16724	UnitedHealthcare of the Midwest, Inc.	\$115,915.27	\$0.00	N/A
IL	67807	Time Insurance Company	\$1,111,551.75	\$0.00	N/A
IL	68432	IlliniCare Health Plan, Inc.	-\$4,500.83	\$0.00	N/A
IN	17575	Anthem Ins Companies Inc(Anthem BCBS)	-\$691,308.47	-\$10,160.00	\$26,992.54
IN	35065	Coordinated Care Corporation Indiana	\$0.00	\$0.00	\$0.00
IN	50816	Physicians Health Plan of Northern Indiana, Inc.	\$3,583,336.00	\$35,701.79	\$109,794.99
IN	85320	MDwise, Inc.	\$0.00	\$0.00	\$0.00
IN	20855	Advantage Health Solutions, Inc.	\$0.00	\$0.00	N/A
IN	33380	Indiana University Health Plans, Inc.	\$66,286.64	\$88.16	N/A
IN	36373	All Savers Insurance Company	\$11,449,513.89	\$0.00	N/A
IN	54192	CareSource Indiana, Inc.	\$1,293,422.26	\$0.00	N/A
IN	62033	MDwise Marketplace, Inc.	\$0.00	\$0.00	N/A
IN	67920	Southeastern Indiana Health Organization	\$21,739.31	\$0.00	N/A
IN	76179	Celtic Insurance Company	-\$1,443,802.06	\$0.00	N/A
IN	91842	Time Insurance Company	\$4,618,815.85	\$0.00	N/A
KS	18558	Blue Cross and Blue Shield of Kansas, Inc.	\$25,619,644.74	\$910,894.46	\$466,357.32
KS	61430	Coventry Health and Life	\$22,585,325.23	\$0.00	\$760,367.12
KS	65598	Coventry Health Care Of Kansas Inc	\$2,312,993.98	\$0.00	\$315,492.21

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS 2015 RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS 2015 RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	EXPECTED PAYMENT TOWARD 2014 AMOUNTS
KS	94248	Blue Cross and Blue Shield of Kansas City	\$6,371,297.95	\$408,600.97	\$41,905.95
KS	27811	BlueCross BlueShield Kansas Solutions, Inc.	\$12,789,305.41	\$179,041.01	N/A
KY	15411	Humana Health Plan, Inc.	\$2,482,523.85	\$0.00	\$200,273.54
KY	23671	UnitedHealthcare of Kentucky, Ltd.	\$0.00	\$13,606.24	\$0.00
KY	36239	Anthem Health Plans of KY (Anthem BCBS)	\$730,766.76	\$0.00	\$0.00
KY	40586	Baptist Health Plan, Inc.	\$0.00	\$3,214,861.78	\$48,900.21
KY	47949	Golden Rule Insurance Company	\$0.00	\$0.00	\$0.00
KY	77894	Kentucky Health Cooperative	\$77,311,836.24	\$0.00	\$2,560,299.94
KY	45636	CareSource Kentucky Co.	\$3,577,396.03	\$0.00	N/A
KY	72001	WELLCARE HEALTH PLANS OF KENTUCKY, INC	\$50,484.02	\$0.00	N/A
LA	19636	HMO Louisiana, Inc.	\$13,994,336.60	\$1,372,994.63	\$105,575.27
LA	44965	Humana Health Benefit Plan of Louisiana, Inc.	\$3,073,966.60	\$0.00	\$13,774.52
LA	67202	Louisiana Health Cooperative, Inc.	\$52,680,919.15	\$693,646.35	\$397,264.65
LA	67243	Vantage Health Plan, Inc.	-\$2,699,673.78	-\$22,641.24	\$804.48
LA	97176	Louisiana Health Service & Indemnity Company	\$37,710,617.93	\$6,165,160.07	\$1,173,859.13
LA	38499	UnitedHealthcare of Louisiana, Inc.	\$4,251,825.74	\$0.00	N/A
MA	29125	Tufts Associated Health Maintenance Org	\$209,387.13	\$76,520.57	\$0.00
MA	31234	CeltiCare Health Plan of MA	-\$192,735.20	\$0.00	\$6,669.56
MA	34484	Health New England, Inc.	-\$7,531.80	\$0.00	\$0.00
MA	36046	Harvard Pilgrim Health Care Inc.	\$0.00	\$0.00	\$0.00
MA	41304	Neighborhood Health Plan	\$7,881,196.72	\$6,922,012.85	\$595,716.02
MA	42690	Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc.	\$1,943,171.80	\$1,332,625.82	\$0.00
MA	59763	Tufts Health Public Plans Inc.	\$0.00	\$0.00	\$0.00
MA	73331	Minuteman Health, Inc	\$1,903,857.27	\$142,595.46	\$37,823.79
MA	82569	Boston Medical Center Health Plan, Inc.	\$0.00	\$0.00	\$57,686.30
MA	88806	Fallon Community Health Plan, Inc.	\$295,987.67	\$456,174.22	\$18,616.80
MA	95878	HPHC Insurance Company Inc.	\$8,829,688.42	\$9,254,420.81	\$40,347.74
MA	31779	UnitedHealthcare Insurance Company	\$166,087.58	\$0.00	N/A
MD	14468	Coventry Health Care of Delaware, Inc.	\$0.00	\$245,541.73	\$0.00
MD	23620	UnitedHealthcare Insurance Company	\$0.00	\$0.00	\$0.00
MD	28137	CareFirst BlueChoice, Inc.	\$22,163,894.49	-\$118,405.17	\$595,517.37
MD	31112	UnitedHealthcare of the Mid-Atlantic Inc	\$128,553.76	\$0.00	\$0.00

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS 2015 RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS 2015 RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	EXPECTED PAYMENT TOWARD 2014 AMOUNTS
MD	36677	All Savers Insurance Company	\$179,551.18	\$0.00	\$4,602.89
MD	45532	CareFirst of Maryland, Inc.	\$7,565,373.57	-\$79,109.81	\$180,782.85
MD	65635	MAMSI Life and Health Insurance Company	\$0.00	\$0.00	\$0.00
MD	68541	Coventry Health and Life	\$0.00	\$83,456.08	\$0.00
MD	72375	Optimum Choice, Inc.	\$0.00	-\$839,733.33	\$0.00
MD	72564	Evergreen Health Cooperative, Inc.	\$6,952,208.46	\$14,571,500.47	\$137,379.39
MD	90296	Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc.	\$17,161,594.80	\$0.00	\$18,697.89
MD	94084	GHMSI	\$3,594,558.80	-\$62,678.93	\$33,934.03
MD	32812	Cigna Health and Life Insurance Company	\$256,315.80	\$0.00	N/A
MD	66516	Aetna Health Inc. (a PA corp.)	\$0.00	-\$538.75	N/A
MD	70767	Aetna Life Insurance Company	\$0.00	\$0.00	N/A
ME	33653	Maine Community Health Options	\$19,331,299.03	\$301,696.58	\$8,029.43
ME	48396	Anthem Health Plans of ME(Anthem BCBS)	-\$31,628.48	\$0.00	\$0.00
ME	96667	Harvard Pilgrim Health Care Inc.	\$0.00	\$0.00	N/A
MI	15560	Blue Cross Blue Shield of Michigan Mutual Insurance Company	\$22,247,616.11	\$0.00	\$0.00
MI	20393	McLaren Health Plan	\$2,272,716.02	\$3,253,857.07	\$17,699.16
MI	29241	Priority Health Insurance Company (PHIC)	\$4,777,255.18	\$0.00	\$35,939.76
MI	29698	Priority Health	\$14,345,881.64	\$0.00	\$13,671.67
MI	37651	Health Alliance Plan (HAP)	\$0.00	-\$127,798.78	\$0.00
MI	40047	Molina Healthcare of Michigan, Inc.	-\$239,138.47	\$0.00	\$0.00
MI	41895	Consumers Mutual Insurance of Michigan	\$12,524,722.48	\$11,795,165.19	\$60,797.86
MI	45002	UnitedHealthcare Life Insurance Company	\$0.00	-\$1,088.34	\$1.08
MI	46275	Humana Medical Plan of Michigan, Inc.	\$0.00	\$0.00	\$269,137.91
MI	58594	Meridian Health Plan of Michigan, Inc.	-\$59,167.75	\$0.00	\$0.00
MI	67183	Total Health Care USA, Inc.	-\$152,456.94	-\$1,165,705.95	\$0.00
MI	67577	Alliance Health and Life Insurance Company	\$316,075.05	-\$214,568.98	\$2,146.80
MI	98185	Blue Care Network of Michigan	\$4,131,999.44	-\$981,975.51	\$571,141.44
MI	34620	Harbor Health Plan, Inc.	-\$8,559.18	\$0.00	N/A
MI	60829	Physicians Health Plan	\$0.00	\$0.00	N/A
MI	71667	UnitedHealthcare Community Plan, Inc.	\$144,054.47	\$0.00	N/A
MI	89029	Time Insurance Company	\$431,897.82	\$0.00	N/A
MN	31616	Medica Insurance Company	\$0.00	\$0.00	\$10,529.09
MN	34102	Group Health Plan, Inc.	\$9,221,388.74	\$0.00	\$86,769.71
MN	49316	BCBSM, INC.	\$174,955,826.46	\$0.00	\$231,054.51

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS 2015 RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS 2015 RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	EXPECTED PAYMENT TOWARD 2014 AMOUNTS
MN	65847	Medica Health Plans of Wisconsin	\$5,655,753.07	\$0.00	\$0.00
MN	85736	UCare Minnesota	\$10,464,932.43	\$0.00	\$0.00
MN	88102	PreferredOne Insurance Company	\$0.00	\$1,550,363.48	\$1,762,670.15
MN	57129	HMO Minnesota	\$5,872,656.21	\$20,610.90	N/A
MO	32753	Healthy Alliance Life Co(Anthem BCBS)	-\$1,003,114.69	\$0.00	\$750.46
MO	34762	Blue Cross and Blue Shield of Kansas City	\$11,344,959.57	\$157,134.97	\$93,269.52
MO	44240	Coventry Health and Life	\$7,567,905.73	\$0.00	\$965,882.56
MO	16049	All Savers Insurance Company	\$6,697,668.39	\$0.00	N/A
MO	30613	Humana Insurance Company	\$2,475,780.80	\$0.00	N/A
MO	74483	Cigna Health and Life Insurance Company	\$0.00	\$0.00	N/A
MS	48963	Humana Insurance Company	\$0.00	\$0.00	\$0.00
MS	61794	UnitedHealthcare Life Insurance Company	\$0.00	-\$4,883.84	\$0.00
MS	94237	Magnolia Health Plan	\$0.00	\$0.00	\$0.00
MS	90714	Ambetter of Magnolia Inc.	-\$2,810,643.19	\$0.00	N/A
MS	97560	UnitedHealthcare of Mississippi, Inc.	\$809,174.17	\$0.00	N/A
MT	23603	PacificSource Health Plans	\$11,649,353.31	\$4,210,514.48	\$64,378.94
MT	30751	Blue Cross and Blue Shield of Montana	\$39,917,958.84	\$3,150,150.04	\$797,636.79
MT	32225	Montana Health Cooperative	\$14,345,841.40	\$410,809.41	\$206,975.90
MT	24867	Time Insurance Company	\$253,920.36	\$0.00	N/A
NC	11512	Blue Cross and Blue Shield of NC	\$214,485,108.80	\$827,984.90	\$4,898,870.47
NC	56346	Coventry Health Care of the Carolinas, Inc.	\$16,459,753.99	\$0.00	\$338,453.99
NC	54332	UnitedHealthcare of North Carolina, Inc	\$18,401,376.06	\$0.00	N/A
ND	37160	Blue Cross Blue Shield of North Dakota	\$0.00	\$0.00	\$15,226.54
ND	73751	Medica Health Plans	-\$293,487.97	-\$96,938.69	\$7,982.33
ND	89364	Sanford Health Plan	\$987,406.20	\$0.00	\$0.00
ND	39364	Medica Insurance Company	\$0.00	\$0.00	N/A
NE	15438	Coventry Health Care of Nebraska Inc.	\$18,035,629.21	\$0.00	\$0.00
NE	29678	Blue Cross and Blue Shield of Nebraska	\$24,733,023.87	\$0.00	\$469,807.48
NE	43198	CoOpportunity Health	\$12,853,762.71	\$7,498,009.00	\$2,456,521.33
NE	77931	Health Alliance Midwest Inc.	\$0.00	\$0.00	\$243.07
NE	19524	Time Insurance Company	\$4,045,974.64	\$0.00	N/A
NH	96751	Matthew Thornton Hlth Plan(Anthem BCBS)	-\$9,685,908.73	-\$19,762.95	\$0.00
NH	19304	Maine Community Health Options	\$432,666.71	\$2,673,543.16	N/A
NH	42260	Time Insurance Company	\$925,446.08	\$0.00	N/A
NH	59025	Harvard Pilgrim Health Care of NE	\$0.00	\$0.00	N/A
NH	61163	Minuteman Health, Inc	\$3,131,228.08	\$27,084.63	N/A

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NJ	10191	Freelancers CO-OP of New Jersey, Inc.	\$21,700,609.51	\$1,475,511.90	\$4,988.21
NJ	77606	AmeriHealth HMO, Inc.	\$5,486,703.07	\$1,333,811.00	\$116,232.27
NJ	91661	Horizon Healthcare Services, Inc.	-\$3,703,866.20	\$0.00	\$105,814.71
NJ	91762	AmeriHealth Ins Company of New Jersey	\$12,445,206.11	\$2,462,716.68	\$38,455.14
NJ	48834	Oxford Health Plans (NJ), Inc.	\$1,357,526.59	\$0.00	N/A
NJ	50221	Oscar Insurance Corporation of New Jersey	\$2,132,615.32	\$0.00	N/A
NM	19722	Molina Healthcare of New Mexico, Inc.	-\$107,005.94	\$0.00	\$0.00
NM	52744	Presbyterian Insurance Company, Inc.	\$0.00	\$0.00	\$0.00
NM	57173	Presbyterian Health Plan, Inc.	-\$499,336.69	-\$60,281.72	\$82,341.14
NM	75605	Blue Cross Blue Shield of New Mexico	\$18,627,474.95	\$0.00	\$218,141.39
NM	93091	New Mexico Health Connections	\$14,280,094.79	\$4,706,916.14	\$139,903.95
NM	72034	CHRISTUS Health Plan	\$134,369.02	\$0.00	N/A
NV	16698	Prominence HealthFirst	\$501,439.74	\$0.00	\$0.00
NV	34996	Nevada Health CO-OP	\$29,901,096.25	\$3,753,264.74	\$355,443.99
NV	60156	HMO Colorado, Inc., dba HMO Nevada	\$3,155,927.89	\$0.00	\$90.21
NV	95865	Health Plan of Nevada, Inc.	\$643,589.93	\$0.00	\$0.00
NV	29211	Time Insurance Company	\$7,321,151.53	\$0.00	N/A
NY	11177	MetroPlus Health Plan	\$8,797,440.70	\$338,440.65	\$290,817.51
NY	18029	Independent Health Benefits Corporation	\$0.00	\$868,523.25	\$0.00
NY	25303	New York State Catholic Health Plan, Inc.	\$0.00	\$0.00	\$0.00
NY	31808	American Progressive Life & Health Insurance Company of New York	\$0.00	\$0.00	\$0.00
NY	40064	HealthNow New York	\$1,448,976.32	\$8,170,408.69	\$0.00
NY	54235	UnitedHealthcare of New York, Inc.	\$909,112.89	\$0.00	\$0.00
NY	56184	MVP Health Plan, Inc.	-\$2,414,553.41	\$1,447,961.39	\$51,511.72
NY	57165	Affinity Health Plan, Inc.	\$0.00	\$0.00	\$39,176.64
NY	71644	Freelancers Health Service Corporation d/b/a Health Republic Insurance of New York	\$180,865,046.61	\$133,175,392.41	\$4,960,652.92
NY	74289	Oscar Insurance Corporation	\$50,645,914.29	\$0.00	\$310,349.58
NY	78124	Excellus Health Plan, Inc.	\$1,024,558.12	\$23,738,013.87	\$250,017.32
NY	80519	Empire HealthChoice HMO, Inc.	-\$297,726.69	\$0.00	\$0.00
NY	82483	North Shore-LIJ Insurance Company Inc	\$10,162,882.20	\$4,911,774.19	\$116,826.04
NY	85629	Oxford Health Insurance, Inc.	\$0.00	\$0.00	\$0.00
NY	88582	Health Insurance Plan of Greater New York	\$3,645,672.92	\$17,504,832.79	\$0.00
NY	91237	Healthfirst PHSP, Inc.	\$697,039.60	\$0.00	\$2,508.78

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NY	92551	CDPHP Universal Benefits Inc.	\$0.00	\$35,536,715.61	\$485,222.26
NY	94788	CDPHP	-\$1,282,843.60	\$0.00	\$0.00
NY	95456	Atlantis Health Plan	\$0.00	\$0.00	\$0.00
NY	39595	WellCare of New York	\$162,701.86	\$0.00	N/A
OH	20126	HealthSpan Integrated Care	\$7,797,117.69	\$4,745,409.18	\$372,126.62
OH	28162	AultCare Insurance Company	-\$9,718.54	\$139,327.35	\$21,712.60
OH	29276	Community Insurance Company(Anthem BCBS)	-\$4,249,438.31	\$0.00	\$532.71
OH	41047	Buckeye Community Health Plan	\$0.00	\$0.00	\$0.00
OH	52664	Summa Insurance Company, Inc.	-\$463,101.73	\$296,546.81	\$71,621.06
OH	64353	Molina Healthcare of Ohio, Inc.	-\$508,729.76	\$0.00	\$0.00
OH	66083	Humana Health Plan of Ohio, Inc.	\$225,079.88	\$0.00	\$307,880.64
OH	74313	Paramount Insurance Company	\$0.00	\$0.00	\$0.00
OH	77552	CareSource	\$0.00	\$0.00	\$0.00
OH	92036	HealthSpan	\$8,014,533.10	\$644,630.91	\$168,341.59
OH	98894	Coventry Health and Life	-\$623,281.14	\$0.00	\$19,021.68
OH	99969	Medical Health Insuring Corp. of Ohio	\$4,279,010.69	\$0.00	\$165,344.99
OH	14650	Time Insurance Company	\$494,806.51	\$0.00	N/A
OH	16204	Coordinated Health Mutual, Inc.	\$37,187,153.00	\$678,737.94	N/A
OH	26734	Premier Health Plan, Inc.	\$2,572,926.75	\$0.00	N/A
OH	33931	UnitedHealthcare of Ohio, Inc.	\$902,297.30	\$0.00	N/A
OH	67129	Aetna Life Insurance Company	\$0.00	\$0.00	N/A
OK	53524	Coventry Health and Life	-\$502,544.02	\$0.00	\$5,324.95
OK	66946	Aetna Life Insurance Company	-\$135,795.55	\$0.00	\$14,285.36
OK	76668	Coventry Health Care of Kansas, Inc.	\$0.00	\$0.00	\$41,955.52
OK	85408	GlobalHealth, Inc.	\$3,852,896.40	\$13,731.93	\$93,194.38
OK	87571	Blue Cross Blue Shield of Oklahoma	\$115,115,001.13	\$4,316,218.67	\$1,790,207.78
OK	87698	CommunityCare Life & Health Insurance Co	\$0.00	\$634,317.06	\$5,090.31
OK	98905	CommunityCare HMO Inc.	\$0.00	\$2,151,744.75	\$10,791.75
OK	29176	Time Insurance Company	\$568,168.32	\$0.00	N/A
OR	10091	PacificSource Health Plans	\$12,895,564.84	\$1,492,522.43	\$99,914.34
OR	10940	Health Net Health Plan of Oregon, Inc.	\$0.00	\$0.00	\$78,230.95
OR	32536	ATRIO Health Plans	\$491,055.00	-\$7,359.48	\$3,934.18
OR	39424	Moda Health Plan, Inc.	\$88,433,164.06	\$2,626,396.05	\$2,914,589.01
OR	56707	Providence Health Plan	\$5,718,501.21	\$0.00	\$63,203.86
OR	63474	BridgeSpan Health Company	\$88,117.39	\$0.00	\$0.00
OR	71287	Kaiser Foundation Healthplan of the NW	\$9,821,230.13	-\$523,898.26	\$0.00
OR	85804	LifeWise Health Plan of Oregon	\$28,911,006.31	\$0.00	\$160,308.99
OR	95417	Trillium Community Health Plan	\$0.00	-\$418.63	\$0.00
OR	96383	Health Republic Insurance Company	\$8,052,058.67	\$4,948,434.63	\$261,922.66
OR	99389	Oregon's Health CO-OP	\$12,246,711.70	\$883,407.48	\$50,781.41
PA	16481	UPMC Health Network, Inc.	-\$38,755.23	\$0.00	\$7,383.20

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PA	22444	Geisinger Health Plan	\$11,751,693.87	\$6,179,883.41	\$760,645.13
PA	31609	Independence Blue Cross (QCC Ins. Co.)	\$7,891,991.13	\$11,108,682.39	\$357,746.79
PA	33709	Highmark Inc.	\$168,580,028.14	\$5,879,605.39	\$5,308,855.59
PA	33871	Keystone Health Plan East, Inc	\$17,725,832.87	\$22,879,073.98	\$972,351.85
PA	33906	Aetna Life Insurance Company	\$1,872,197.90	\$0.00	\$10,141.68
PA	52899	UPMC Health Plan, Inc.	-\$623,294.78	\$679,452.52	\$452.03
PA	53789	Keystone Health Plan Central	\$431,670.61	\$0.00	\$3,870.32
PA	55957	First Priority Life Insurance Company, Inc.	\$40,107,921.26	\$263,953.76	\$363,201.89
PA	64844	Aetna Health Inc. (a PA corp.)	\$5,258,434.34	\$0.00	\$0.00
PA	70194	Highmark Health Insurance Company	\$38,670,122.39	\$406,775.20	\$1,052,688.76
PA	75729	Geisinger Quality Options	\$1,273,439.08	\$689,409.22	\$255,740.03
PA	82795	Capital Advantage Insurance Company CAIC	\$0.00	\$0.00	\$9,637.08
PA	91303	HealthAmerica Pennsylvania, Inc.	\$1,046,556.94	\$0.00	\$67,841.86
PA	16322	UPMC Health Options, Inc.	\$24,615,139.76	\$0.00	N/A
PA	19068	Time Insurance Company	\$1,450,728.94	\$0.00	N/A
PA	24872	UnitedHealthcare of Pennsylvania, Inc.	\$5,937,531.25	\$0.00	N/A
PA	45127	Capital Advantage Assurance Company	\$2,500,772.16	\$4,770.49	N/A
PA	62560	UPMC Health Coverage, Inc.	\$0.00	\$682,713.46	N/A
RI	15287	Blue Cross & Blue Shield of Rhode Island	\$381,639.63	\$0.00	\$0.00
RI	77514	Neighborhood Health Plan of Rhode Island	-\$5,233,486.30	-\$138,066.87	\$0.00
RI	79881	UnitedHealthcare of New England, Inc.	-\$94,105.37	\$0.00	\$25.33
RI	70760	Guardian Life Insurance Company of America	\$0.00	\$0.00	N/A
SC	26065	Blue Cross and Blue Shield of South Carolina	\$11,205,576.67	\$0.00	\$0.00
SC	41614	Coventry Health Care of the Carolinas, Inc.	\$2,975,127.19	\$0.00	\$169,278.09
SC	49532	BlueChoice HealthPlan of South Carolina, Inc.	\$6,375,309.45	\$1,462,098.16	\$0.00
SC	65122	Consumers' Choice Health Insurance Company	\$81,078,167.44	\$44,111.42	\$412,745.23
SC	39996	Time Insurance Company	\$1,451,025.54	\$0.00	N/A
SD	31195	Sanford Health Plan	\$3,972,231.55	\$909,904.23	\$117,478.56
SD	60536	Avera Health Plans, Inc.	\$17,177,873.59	\$2,309,953.60	\$264,640.41
SD	62210	South Dakota State Medical Holding Company, Inc.	\$12,926,212.21	\$277,466.87	\$2,628.17
TN	14002	BlueCross BlueShield of Tennessee	\$83,199,959.16	\$0.00	\$2,614,980.96
TN	66842	Community Health Alliance Mutual Insurance Company	\$29,930,892.43	\$252,120.24	\$12,208.18

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TN	82120	Humana Insurance Company	\$1,354,405.83	\$0.00	\$242,241.01
TN	99248	Cigna Health and Life Insurance Company	\$121,369.67	\$0.00	\$0.00
TN	60299	Time Insurance Company	\$234,775.92	\$0.00	N/A
TX	26539	SHA, LLC DBA FirstCare Health Plans	\$4,623,491.00	\$958,620.40	\$70,795.54
TX	27248	Community Health Choice, Inc.	\$2,042,945.29	\$0.00	\$0.00
TX	32673	Humana Health Plan of Texas, Inc.	\$20,835,819.27	\$0.00	\$2,033,942.87
TX	33602	Blue Cross Blue Shield of Texas	\$596,692,787.32	\$25,767,249.27	\$9,776,428.58
TX	40788	Scott and White Health Plan	\$22,204,375.02	\$0.00	\$25,591.70
TX	45786	Molina Healthcare of Texas, Inc.	-\$672,399.95	\$0.00	\$0.00
TX	46224	Community First Health Plans, Inc.	-\$17,727.14	\$0.00	\$324.66
TX	55409	Cigna Health and Life Insurance Company	\$25,063,932.77	\$0.00	\$427,894.45
TX	63141	Humana Insurance Company	\$7,347,250.49	\$0.00	\$168,549.65
TX	71837	Sendero Health Plans, inc.	\$2,200,617.89	\$0.00	\$22,751.14
TX	87226	Superior Health Plan	\$0.00	\$0.00	\$0.00
TX	91716	Aetna Life Insurance Company	\$8,680,426.35	\$0.00	\$36,588.55
TX	28020	Time Insurance Company	\$7,661,197.18	\$0.00	N/A
TX	63509	Allegian Insurance Company	\$0.00	\$0.00	N/A
TX	66252	CHRISTUS Health Plan	\$0.00	\$0.00	N/A
TX	85947	All Savers Insurance Company	\$62,422,090.52	-\$11,540.15	N/A
UT	18167	Molina Healthcare of Utah	\$3,557,849.34	\$0.00	\$0.00
UT	27619	Arches Mutual Insurance Company	\$43,467,274.22	\$2,943,893.04	\$399,177.92
UT	34541	BridgeSpan Health Company	\$7,713,827.87	\$0.00	\$67,003.07
UT	38927	Aetna Health of Utah Inc.	\$3,061,829.64	\$0.00	\$66,701.47
UT	56764	Humana Medical Plan of Utah, Inc.	\$489,707.31	\$0.00	\$321,228.20
UT	66413	UnitedHealthcare of Utah, Inc.	\$0.00	\$6,697.41	\$0.00
UT	68781	SelectHealth	\$85,912,175.23	\$25,143,079.57	\$2,774,954.11
UT	40335	Educators Health Plans Life, Accident, and Health, Inc	\$0.00	\$0.00	N/A
VA	10207	CareFirst BlueChoice, Inc.	\$1,952,573.46	\$0.00	\$24,275.00
VA	12028	Innovation Health Insurance Company	-\$5,300,607.23	\$0.00	\$14,179.48
VA	20507	Optima Health Plan	\$2,229,495.98	\$0.00	\$0.00
VA	38234	Aetna Life Insurance Company	-\$2,260,494.69	\$0.00	\$0.00
VA	40308	Group Hospitalization and Medical Services Inc.	\$155,508.63	\$0.00	\$0.00
VA	88380	HealthKeepers, Inc.	\$0.00	\$0.00	\$0.00
VA	95185	Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc.	\$33,418,222.77	\$1,037,808.40	\$5,672.26
VA	99663	Coventry Health Care of Virginia, Inc	-\$4,505,742.80	\$0.00	\$0.00
VA	15668	Piedmont Community HealthCare, Inc.	\$112,913.30	\$11,151.45	N/A

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VT	13627	Blue Cross Blue Shield of Vermont	\$2,096,136.84	\$2,661,673.15	\$0.00
VT	77566	MVP Health Plan, Inc.	\$0.00	\$0.00	\$51,920.11
WA	18581	Community Health Plan of Washington	\$1,187,131.21	\$0.00	\$0.00
WA	23371	Kaiser Foundation Healthplan of the NW	\$0.00	-\$152,819.47	\$0.00
WA	38498	LifeWise Health Plan of WA	\$11,748,045.56	\$0.00	\$0.00
WA	49831	Premiera Blue Cross	\$15,553,285.66	\$0.00	\$0.00
WA	53732	BridgeSpan Health Company	\$3,849,576.58	\$0.00	\$0.00
WA	61836	Coordinated Care Corporation	\$0.00	\$0.00	\$0.00
WA	80473	Group Health Cooperative	\$521,384.24	\$0.00	\$0.00
WA	84481	Molina Healthcare of Washington, Inc.	\$238,552.08	\$0.00	\$0.00
WA	65907	Moda Health Plan, Inc.	\$11,360,459.83	\$0.00	N/A
WI	35334	MercyCare Insurance Company	\$0.00	\$874,654.10	\$11,812.69
WI	37833	Unity Health Plans Insurance Corporation	\$11,131,237.20	\$0.00	\$0.00
WI	38166	Security Health Plan of Wisconsin, Inc.	\$34,959,297.51	\$1,198,009.90	\$29,087.82
WI	38345	Dean Health Plan	\$11,814,347.27	\$0.00	\$468,016.65
WI	47342	Health Tradition Health Plan	\$0.00	\$902,750.69	\$19,276.97
WI	52697	Molina Healthcare of Wisconsin, Inc.	\$21,340,461.88	\$0.00	\$0.00
WI	57637	Medica Insurance Company	\$0.00	\$1,140,492.00	\$15,987.24
WI	57845	Medica Health Plans of Wisconsin	-\$651,625.20	\$0.00	\$0.00
WI	58326	MercyCare HMO, Inc.	\$888,775.53	\$540,373.91	\$39,302.06
WI	58564	Physicians Plus Insurance Corporation	\$171,543.34	\$0.00	\$0.00
WI	79475	CompCare Health Serv Ins Co(Anthem BCBS)	-\$93,143.86	\$0.00	\$163,815.77
WI	84670	WPS Health Plan, Inc.	\$13,564,987.77	\$220,591.15	\$213,100.00
WI	87416	Common Ground Healthcare Cooperative	\$27,770,382.35	\$1,889,058.25	\$1,502,853.97
WI	91058	Gundersen Health Plan, Inc.	\$1,107,462.46	\$3,261,542.62	\$68,917.14
WI	94529	Group Health Cooperative of South Central Wisconsin	\$0.00	-\$758,698.27	\$0.00
WI	32754	Managed Health Services Insurance Corporation	-\$18,556.78	\$0.00	N/A
WI	39924	All Savers Insurance Company	\$7,972,985.11	-\$182,309.24	N/A
WV	31274	Highmark Blue Cross Blue Shield West Virginia	\$17,059,483.59	\$0.00	\$479,130.54
WY	11269	Blue Cross Blue Shield of Wyoming	\$3,314,544.94	\$0.00	\$20,177.33
WY	53189	WINhealth Partners	\$13,475,140.86	\$108,220.90	\$168,305.26

EXHIBIT 6

Department of Health & Human Services

Centers for Medicare & Medicaid Services
Center for Consumer Information & Insurance Oversight
200 Independence Avenue SW
Washington, DC 20201



Date: November 19, 2015

Subject: Risk Corridors Payment and Charge Amounts for Benefit Year 2014

Background:

Section 1342 of the Affordable Care Act directs the Secretary of the Department of Health and Human Services (HHS) to establish a temporary risk corridors program that provides issuers of qualified health plans (QHPs) in the individual and small group markets additional protection against uncertainty in claims costs during the first three years of the Marketplace. The program, which was modeled after a similar program implemented as part of the Medicare Part D prescription drug benefit program, encourages issuers to keep their rates stable as they adjust to the new health insurance reforms in the early years of the Marketplaces.

HHS has previously stated that if risk corridors collections for a particular year are insufficient to make full risk corridors payments for that year, risk corridors payments for the year will be reduced pro rata to the extent of any shortfall.¹ On October 1, 2015, HHS announced the payment proration rate for 2014 will be approximately 12.6 percent, reflecting risk corridors charges of \$362 million and payments of \$2.87 billion requested by issuers.² This proration rate was based on the most current risk corridors data submitted by issuers and assumes full collection of charges from issuers.

Today, HHS is releasing issuer-level risk corridors payments and charges based on the most current risk corridors data submitted by issuers and assuming full collection of charges from issuers, by market and state, for the 2014 benefit year. The tables below include the risk corridors payment or charge amounts for the individual and small group markets, respectively, and the prorated risk corridors payment, if applicable. **Risk corridors charges payable to HHS are not prorated, and the full risk corridors charge amounts are noted in the chart below. Only risk corridors payment amounts are prorated.** HHS will begin collection of risk corridors charges in November 2015 and will begin remitting risk corridors payments to issuers starting in December 2015.³

¹ "Risk Corridors and Budget Neutrality", published April 11, 2014 and posted at <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/faq-risk-corridors-04-11-2014.pdf>

² The exact proration rate for 2014 is 12.6178665287897%.

³ We note that the risk corridor payment and charge amounts published in this bulletin do not reflect any payment or charge adjustments due to resubmissions after September 15, 2015 or any amount held back for appeals.

Table 1 – Alabama

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
AL	44580	Humana Insurance Company	\$ 947,116.86	\$ -	\$ 119,505.94	\$ -
AL	46944	Blue Cross and Blue Shield of Alabama	\$ 354,762.84	\$ -	\$ 44,763.50	\$ -
AL	59809	UnitedHealthcare Life Insurance Company	\$ -	\$ (4,761.86)	\$ -	\$ (4,761.86)

Table 2 – Alaska

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
AK	38344	Premera Blue Cross Blue Shield of Alaska	\$ 8,126,435.92	\$ 122,178.45	\$ 1,025,382.84	\$ 15,416.31
AK	73836	Moda Health Plan, Inc.	\$ 1,237,418.79	\$ 448,597.16	\$ 156,135.85	\$ 56,603.39

Table 3 – Arizona

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
AZ	23307	Humana Health Plan, Inc.	\$ 1,851,728.19	\$ -	\$ 233,648.59	\$ -
AZ	51485	Health Net Life Insurance Company	\$ 38,309,878.15	\$ 6,528,368.90	\$ 4,833,889.29	\$ 823,740.87
AZ	53901	Blue Cross Blue Shield of Arizona, Inc.	\$ 11,688,096.55	\$ (216,623.22)	\$ 1,474,788.42	\$ (216,623.22)
AZ	60761	Meritus Health Partners	\$ 3,401,552.97	\$ 88,126.95	\$ 429,203.41	\$ 11,119.74

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
AZ	70239	Health Choice Insurance Company	\$ 1,258,219.04	\$ -	\$ 158,760.40	\$ -
AZ	84251	Aetna Life Insurance Company	\$ 60,071.04	\$ -	\$ 7,579.68	\$ -
AZ	86830	Cigna Health and Life Insurance Company	\$ 173,356.66	\$ -	\$ 21,873.91	\$ -
AZ	88925	University of Arizona Health Plans-University Healthcare, Inc.	\$ 645,097.22	\$ -	\$ 81,397.51	\$ -
AZ	91450	Health Net of Arizona, Inc.	\$ 44,674,893.78	\$ 1,189,199.69	\$ 5,637,018.47	\$ 150,051.63
AZ	92045	Meritus Mutual Health Partners	\$ 1,546,274.44	\$ 327,316.81	\$ 195,106.85	\$ 41,300.40

Table 4 – Arkansas

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
AR	62141	Celtic Insurance Company	\$ (15,850,813.36)	\$ -	\$ (15,850,813.36)	\$ -
AR	70525	QCA Health Plan, Inc.	\$ 4,181,163.09	\$ -	\$ 527,573.58	\$ -
AR	75293	USable Mutual Insurance Company	\$ -	\$ -	\$ -	\$ -

Table 5 – California

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
CA	18126	Molina Healthcare of California	\$ -	\$ -	\$ -	\$ -
CA	27603	Blue Cross of California	\$ (8,679,121.40)	\$ -	\$ (8,679,121.40)	\$ -
CA	40513	Kaiser Foundation Health Plan, Inc.	\$ (65,768,044.51)	\$ 36,933,195.21	\$ (65,768,044.51)	\$ 4,660,181.28
CA	47579	Chinese Community Health Plan	\$ -	\$ 712,789.33	\$ -	\$ 89,938.81
CA	67138	Health Net of California, Inc.	\$ -	\$ -	\$ -	\$ -
CA	70285	CA Physician's Service dba Blue Shield of CA	\$ (106,990,058.09)	\$ (136,577.80)	\$ (106,990,058.09)	\$ (136,577.80)
CA	84014	County of Santa Clara	\$ -	\$ -	\$ -	\$ -
CA	92499	Sharp Health Plan	\$ -	\$ 7,775.72	\$ -	\$ 981.13
CA	92815	Local Initiative Health Authority for Los Angeles County	\$ 13,561,651.72	\$ -	\$ 1,711,191.11	\$ -
CA	93689	Western Health Advantage	\$ (228,695.71)	\$ 138.73	\$ (228,695.71)	\$ 17.50
CA	99110	Health Net Life Insurance Company	\$ -	\$ 5,058,867.84	\$ -	\$ 638,321.19
CA	99483	Contra Costa Health Plan	\$ -	\$ -	\$ -	\$ -

Table 6 – Colorado

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
CO	11555	New Health Ventures, Inc.	\$ 106,520.81	\$ -	\$ 13,440.65	\$ -
CO	20472	Colorado Health Insurance Cooperative, Inc.	\$ 14,137,039.31	\$ 163,367.72	\$ 1,783,792.75	\$ 20,613.52

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
CO	21032	Kaiser Foundation Health Plan of Colorado	\$ 14,160,790.95	\$ -	\$ 1,786,789.70	\$ -
CO	49375	Cigna Health and Life Insurance Company	\$ (632,444.16)	\$ -	\$ (632,444.16)	\$ -
CO	63312	Colorado Choice Health Plans	\$ 5,893,514.24	\$ 114,299.01	\$ 743,635.76	\$ 14,422.10
CO	66699	Denver Health Medical Plan, Inc.	\$ 287,542.11	\$ -	\$ 36,281.68	\$ -
CO	74320	Humana Health Plan	\$ 3,183,617.97	\$ -	\$ 401,704.67	\$ -
CO	76680	HMO Colorado, Inc., dba HMO Nevada	\$ 1,479,675.14	\$ (21,811.05)	\$ 186,703.43	\$ (21,811.05)
CO	80208	Rocky Mountain Health Care Options	\$ -	\$ 440,553.54	\$ -	\$ 55,588.46
CO	92137	All Savers Insurance Company	\$ (107,467.82)	\$ -	\$ (107,467.82)	\$ -
CO	97879	Rocky Mountain HMO	\$ 1,470,136.36	\$ 578,003.29	\$ 185,499.84	\$ 72,931.68

Table 7 – Connecticut

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
CT	49650	UnitedHealthcare Insurance Company	\$ -	\$ 11,299.51	\$ -	\$ 1,425.76
CT	76962	ConnectiCare Benefits, Inc.	\$ (717,037.34)	\$ -	\$ (717,037.34)	\$ -
CT	86545	Anthem Health Plans, Inc. (Anthem BCBS)	\$ (863,733.24)	\$ (26,699.38)	\$ (863,733.24)	\$ (26,699.38)
CT	91069	HealthyCT, Inc.	\$ 1,561,247.18	\$ 272,638.90	\$ 196,996.09	\$ 34,401.21

Table 8 - DC

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
DC	41842	UnitedHealthcare Insurance Company	\$ -	\$ (991,539.08)	\$ -	\$ (991,539.08)
DC	73987	Aetna Health, Inc. (a PA corp.)	\$ -	\$ (64,837.39)	\$ -	\$ (64,837.39)
DC	75753	Optimum Choice, Inc.	\$ -	\$ (254,567.86)	\$ -	\$ (254,567.86)
DC	77422	Aetna Life Insurance Company	\$ (85,707.77)	\$ (599,078.47)	\$ (85,707.77)	\$ (599,078.47)
DC	78079	Group Hospitalization and Medical Services, Inc.	\$ -	\$ -	\$ -	\$ -
DC	86052	CareFirst BlueChoice, Inc.	\$ -	\$ -	\$ -	\$ -
DC	94506	Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc.	\$ 668,656.18	\$ 592,476.32	\$ 84,370.14	\$ 74,757.87

Table 9 – Delaware

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
DE	13537	Coventry Health and Life	\$ (98,081.56)	\$ -	\$ (98,081.56)	\$ -
DE	76168	Highmark BCBSD, Inc.	\$ 6,075,398.71	\$ (90,018.42)	\$ 766,585.70	\$ (90,018.42)
DE	81914	Coventry Health Care of Delaware, Inc.	\$ -	\$ (83,436.61)	\$ -	\$ (83,436.61)

Table 10 – Florida

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
FL	16842	Blue Cross and Blue Shield of Florida	\$ 14,407,419.27	\$ 28,169.07	\$ 1,817,908.93	\$ 3,554.34
FL	23841	Aetna Life Insurance Company	\$ -	\$ -	\$ -	\$ -
FL	27357	Health First Health Plans, Inc.	\$ -	\$ 102,999.55	\$ -	\$ 12,996.35
FL	30252	Health Options, Inc.	\$ 11,363,630.16	\$ 18,103.08	\$ 1,433,847.69	\$ 2,284.22
FL	35783	Humana Medical Plan, Inc.	\$ 41,231,083.98	\$ -	\$ 5,202,483.14	\$ -
FL	48121	Cigna Health and Life Insurance Company	\$ 4,068,246.94	\$ -	\$ 513,325.97	\$ -
FL	51398	Preferred Medical Plan, Inc.	\$ 34,777,521.17	\$ -	\$ 4,388,181.20	\$ -
FL	54172	Molina Healthcare of Florida, Inc.	\$ 39,035.74	\$ -	\$ 4,925.48	\$ -
FL	56503	Florida Health Care Plan, Inc.	\$ (1,687,550.49)	\$ (123,177.85)	\$ (1,687,550.49)	\$ (123,177.85)
FL	57451	Coventry Health Care of Florida, Inc.	\$ 30,600,508.00	\$ -	\$ 3,861,131.26	\$ -
FL	77150	Health First Insurance, Inc.	\$ 1,549,229.65	\$ 303,120.12	\$ 195,479.73	\$ 38,247.29
FL	86382	Sunshine State Health Plan	\$ (420,664.88)	\$ -	\$ (420,664.88)	\$ -

Table 11 - Georgia

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
GA	45495	Peach State Health Plan	\$ (675,263.76)	\$ -	\$ (675,263.76)	\$ -
GA	49046	Blue Cross Blue Shield Healthcare Plan of Georgia, Inc.	\$ (5,981,961.36)	\$ (3,041.08)	\$ (5,981,961.36)	\$ (3,041.08)
GA	83761	Alliant Health Plans	\$ -	\$ 125.18	\$ -	\$ 15.80
GA	89942	Kaiser Foundation Health Plan of Georgia	\$ -	\$ 2,003,716.30	\$ -	\$ 252,826.25
GA	93332	Humana Employers Health Plan of Georgia, Inc.	\$ 83,973,253.40	\$ -	\$ 10,595,633.03	\$ -

Table 12 – Hawaii

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
HI	18350	Hawaii Medical Service Association	\$ -	\$ -	\$ -	\$ -
HI	60612	Kaiser Foundation Health Plan, Inc.	\$ 12,727,673.62	\$ 6,060,129.80	\$ 1,605,960.87	\$ 764,659.09

Table 13 - Idaho

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
ID	26002	SelectHealth	\$ 24,386,583.14	\$ 1,574,917.17	\$ 3,077,066.51	\$ 198,720.95
ID	44648	Regence Blue Shield of Idaho	\$ -	\$ -	\$ -	\$ -
ID	59765	BridgeSpan Health Company	\$ 27,918.21	\$ -	\$ 3,522.68	\$ -
ID	60597	PacificSource Health Plans	\$ 2,242,712.26	\$ -	\$ 282,982.44	\$ -
ID	61589	Blue Cross of Idaho Health Service, Inc.	\$ 39,437,313.04	\$ 600,529.29	\$ 4,976,147.52	\$ 75,773.98

Table 14 – Illinois

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
IL	20129	Health Alliance Medical Plans, Inc.	\$ 2,759,245.94	\$ 14,837.77	\$ 348,157.97	\$ 1,872.21
IL	35670	Coventry Health & Life Company	\$ 338,246.81	\$ -	\$ 42,679.53	\$ -
IL	36096	Blue Cross Blue Shield of Illinois	\$ 193,846,813.95	\$ 3,325,244.33	\$ 24,459,332.25	\$ 419,574.89
IL	58288	Humana Health Plan, Inc.	\$ 800,982.85	\$ -	\$ 101,066.95	\$ -
IL	68303	Humana Insurance Company	\$ 4,801,295.28	\$ -	\$ 605,821.03	\$ -
IL	72547	Aetna Life Insurance Company	\$ 156,532.35	\$ -	\$ 19,751.04	\$ -
IL	79763	Land of Lincoln Mutual Health Insurance Company	\$ 4,165,273.75	\$ 326,970.05	\$ 525,568.68	\$ 41,256.64
IL	96601	Coventry Health Care of Illinois, Inc.	\$ 3,177,608.98	\$ -	\$ 400,946.46	\$ -

Table 15 – Indiana

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
IN	17575	Anthem Insurance Companies, Inc. (Anthem BCBS)	\$ 812,580.18	\$ (319.45)	\$ 102,530.28	\$ (319.45)
IN	35065	Coordinated Care Corporation Indiana	\$ (263,623.41)	\$ -	\$ (263,623.41)	\$ -
IN	50816	Physicians Health Plan of Northern Indiana, Inc.	\$ 2,918,313.81	\$ 386,940.55	\$ 368,228.94	\$ 48,823.64
IN	85320	MDwise, Inc.	\$ (14,303,011.22)	\$ -	\$ (14,303,011.22)	\$ -

Table 16 – Iowa

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
IA	18973	Aetna Health, Inc. (an IA corp.)	\$ 2,707,707.64	\$ -	\$ 341,654.94	\$ -
IA	27651	Gundersen Health Plan, Inc.	\$ 105,688.49	\$ 8,152.09	\$ 13,335.63	\$ 1,028.62
IA	71268	CoOpportunity Health	\$ 40,166,052.95	\$ 15,838,758.46	\$ 5,068,098.95	\$ 1,998,513.40
IA	74980	Avera Health Plans, Inc.	\$ 96,106.84	\$ 4,805.45	\$ 12,126.63	\$ 606.35
IA	77638	Health Alliance Midwest, Inc.	\$ -	\$ -	\$ -	\$ -
IA	85930	Sanford Health Plan	\$ -	\$ 129,136.07	\$ -	\$ 16,294.22

Table 17 – Kansas

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
KS	18558	Blue Cross and Blue Shield of Kansas, Inc.	\$ 13,740,981.12	\$ 298,179.85	\$ 1,733,818.66	\$ 37,623.94
KS	61430	Coventry Health and Life	\$ 22,889,994.47	\$ -	\$ 2,888,228.95	\$ -
KS	65598	Coventry Health Care Of Kansas, Inc.	\$ 9,497,537.20	\$ -	\$ 1,198,386.57	\$ -
KS	94248	Blue Cross and Blue Shield of Kansas City	\$ 1,261,531.48	\$ (265,838.16)	\$ 159,178.36	\$ (265,838.16)

Table 18 - Kentucky

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
KY	15411	Humana Health Plan, Inc.	\$ 6,029,009.18	\$ -	\$ 760,732.33	\$ -
KY	23671	UnitedHealthcare of Kentucky, Ltd.	\$ -	\$ (26,994.08)	\$ -	\$ (26,994.08)
KY	36239	Anthem Health Plans of KY(Anthem BCBS)	\$ (620,075.73)	\$ (12,523.99)	\$ (620,075.73)	\$ (12,523.99)
KY	40586	Bluegrass Family Health, Inc.	\$ -	\$ 1,472,085.68	\$ -	\$ 185,745.81
KY	77894	Kentucky Health Cooperative	\$ 77,074,941.10	\$ (69,347.11)	\$ 9,725,213.20	\$ (69,347.11)

Table 19 - Louisiana

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
LA	19636	HMO Louisiana, Inc.	\$ 2,638,100.44	\$ 540,123.96	\$ 332,871.99	\$ 68,152.12
LA	44965	Humana Health Benefit Plan of Louisiana, Inc.	\$ 414,666.60	\$ -	\$ 52,322.08	\$ -
LA	67202	Louisiana Health Cooperative, Inc.	\$ 11,945,268.95	\$ 13,935.30	\$ 1,507,238.09	\$ 1,758.34
LA	67243	Vantage Health Plan, Inc.	\$ -	\$ 24,218.07	\$ -	\$ 3,055.80
LA	97176	Louisiana Health Service & Indemnity Company	\$ 27,386,455.30	\$ 7,951,249.65	\$ 3,455,586.38	\$ 1,003,278.07

Table 20- Maine

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
ME	33653	Maine Community Health Options	\$ (2,045,819.48)	\$ 241,717.00	\$ (2,045,819.48)	\$ 30,499.53
ME	48396	Anthem Health Plans of ME (Anthem BCBS)	\$ -	\$ (4,426.93)	\$ -	\$ (4,426.93)

Table 21 – Maryland

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
MD	14468	Coventry Health Care of Delaware, Inc.	\$ -	\$ (3,504.62)	\$ -	\$ (3,504.62)
MD	23620	UnitedHealthcare Insurance Company	\$ -	\$ (2,371,783.62)	\$ -	\$ (2,371,783.62)

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
MD	28137	CareFirst BlueChoice, Inc.	\$ 17,927,378.59	\$ (200,100.92)	\$ 2,262,052.70	\$ (200,100.92)
MD	31112	UnitedHealthcare of the Mid-Atlantic, Inc.	\$ -	\$ (552,561.24)	\$ -	\$ (552,561.24)
MD	36677	All Savers Insurance Company	\$ 138,564.85	\$ -	\$ 17,483.93	\$ -
MD	45532	CareFirst of Maryland, Inc.	\$ 5,442,263.96	\$ (52,255.73)	\$ 686,697.60	\$ (52,255.73)
MD	65635	MAMSI Life and Health Insurance Company	\$ -	\$ (1,511,616.91)	\$ -	\$ (1,511,616.91)
MD	68541	Coventry Health and Life	\$ -	\$ (3,959.56)	\$ -	\$ (3,959.56)
MD	72375	Optimum Choice, Inc.	\$ -	\$ (1,635,883.00)	\$ -	\$ (1,635,883.00)
MD	72564	Evergreen Health Cooperative, Inc.	\$ 902,808.54	\$ 3,232,843.21	\$ 113,915.18	\$ 407,915.84
MD	90296	Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc.	\$ 220,063.25	\$ 347,036.82	\$ 27,767.29	\$ 43,788.64
MD	94084	Group Hospitalization and Medical Services, Inc.	\$ 1,021,545.92	\$ (133,466.80)	\$ 128,897.30	\$ (133,466.80)

Table 22 – Massachusetts

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
MA	29125	Tufts Associated HMO	\$ -	\$ -	\$ -	\$ -
MA	31234	CeltiCare Health Plan of MA	\$ 191,649.92	\$ -	\$ 24,182.13	\$ -
MA	34484	Health New England, Inc.	\$ -	\$ -	\$ -	\$ -
MA	36046	Harvard Pilgrim Health Care, Inc.	\$ -	\$ -	\$ -	\$ -
MA	41304	Neighborhood Health Plan	\$ 7,389,737.55	\$ 10,543,621.21	\$ 932,427.22	\$ 1,330,380.05

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
MA	42690	Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc.	\$ -	\$ -	\$ -	\$ -
MA	59763	Tufts Health Public Plans Inc.	\$ -	\$ -	\$ -	\$ -
MA	73331	Minuteman Health, Inc.	\$ 1,138,642.67	\$ -	\$ 143,672.41	\$ -
MA	82569	Boston Medical Center Health Plan, Inc.	\$ 1,736,581.18	\$ -	\$ 219,119.50	\$ -
MA	88806	Fallon Community Health Plan, Inc.	\$ 200,285.65	\$ 435,622.91	\$ 25,271.78	\$ 54,966.32
MA	95878	HPHC Insurance Company, Inc.	\$ 255,319.27	\$ 959,303.93	\$ 32,215.84	\$ 121,043.69

Table 23 – Michigan

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
MI	15560	Blue Cross Blue Shield of Michigan Mutual Insurance Company	\$ -	\$ (676,390.04)	\$ -	\$ (676,390.04)
MI	20393	McLaren Health Plan	\$ 532,813.30	\$ -	\$ 67,229.67	\$ -
MI	29241	Priority Health Insurance Company (PHIC)	\$ 1,049,112.59	\$ 50,769.62	\$ 132,375.63	\$ 6,406.04
MI	29698	Priority Health	\$ 452,162.74	\$ 12,391.43	\$ 57,053.29	\$ 1,563.53
MI	37651	Health Alliance Plan (HAP)	\$ (617,846.91)	\$ (461,796.54)	\$ (617,846.91)	\$ (461,796.54)
MI	40047	Molina Healthcare of Michigan, Inc.	\$ (33,005.69)	\$ -	\$ (33,005.69)	\$ -
MI	41895	Consumers Mutual	\$ 198,351.34	\$ 1,442,311.90	\$ 25,027.71	\$ 181,988.99

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
		Insurance of Michigan				
MI	45002	UnitedHealthcare Life Insurance Company	\$ -	\$ 32.68	\$ -	\$ 4.12
MI	46275	Humana Medical Plan of Michigan, Inc.	\$ 8,102,093.26	\$ -	\$ 1,022,311.31	\$ -
MI	58594	Meridian Health Plan of Michigan, Inc.	\$ (11,519.73)	\$ -	\$ (11,519.73)	\$ -
MI	67183	Total Health Care USA, Inc.	\$ -	\$ -	\$ -	\$ -
MI	67577	Alliance Health and Life Insurance Company	\$ 64,626.98	\$ (176,039.32)	\$ 8,154.55	\$ (176,039.32)
MI	98185	Blue Care Network of Michigan	\$ 17,193,568.72	\$ (47,526.91)	\$ 2,169,461.55	\$ (47,526.91)

Table 24 – Minnesota

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
MN	31616	Medica Insurance Company	\$ -	\$ 316,966.63	\$ -	\$ 39,994.43
MN	34102	Group Health Plan, Inc.	\$ 2,612,104.28	\$ -	\$ 329,591.83	\$ -
MN	49316	BCBSM, Inc.	\$ 6,955,635.49	\$ -	\$ 877,652.80	\$ -
MN	65847	Medica Health Plans of Wisconsin	\$ -	\$ -	\$ -	\$ -
MN	85736	UCare Minnesota	\$ -	\$ -	\$ -	\$ -
MN	88102	PreferredOne Insurance Company	\$ 53,344,373.74	\$ 176,995.83	\$ 6,730,921.88	\$ 22,333.10

Table 25 - Mississippi

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
MS	48963	Humana Insurance Company	\$ (900,401.14)	\$ -	\$ (900,401.14)	\$ -
MS	61794	UnitedHealthcare Life Insurance Company	\$ -	\$ (1,130.50)	\$ -	\$ (1,130.50)
MS	94237	Magnolia Health Plan	\$ (13,190,322.25)	\$ -	\$ (13,190,322.25)	\$ -

Table 26 - Missouri

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
MO	32753	Healthy Alliance Life Company (Anthem BCBS)	\$ -	\$ 22,591.92	\$ -	\$ 2,850.62
MO	34762	Blue Cross and Blue Shield of Kansas City	\$ 2,807,773.67	\$ (183,601.01)	\$ 354,281.13	\$ (183,601.01)
MO	44240	Coventry Health and Life	\$ 29,076,804.73	\$ -	\$ 3,668,872.41	\$ -

Table 27 – Montana

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
MT	23603	PacificSource Health Plans	\$ 1,938,055.47	\$ -	\$ 244,541.25	\$ -
MT	30751	Blue Cross and Blue Shield of Montana	\$ 23,457,847.95	\$ 554,107.74	\$ 2,959,879.94	\$ 69,916.58
MT	32225	Montana Health Cooperative	\$ 6,754,127.62	\$ 62,383.51	\$ 852,226.81	\$ 7,871.47

Table 28 – Nebraska

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
NE	15438	Coventry Health Care of Nebraska, Inc.	\$ -	\$ -	\$ -	\$ -
NE	29678	Blue Cross and Blue Shield of Nebraska	\$ 14,143,024.12	\$ (267,402.83)	\$ 1,784,547.91	\$ (267,402.83)
NE	43198	CoOpportunity Health	\$ 51,080,793.04	\$ 22,870,010.14	\$ 6,445,306.29	\$ 2,885,707.35
NE	77931	Health Alliance Midwest, Inc.	\$ (53,340.12)	\$ 7,317.35	\$ (53,340.12)	\$ 923.29

Table 29 – Nevada

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
NV	16698	Prominence HealthFirst	\$ (71,742.47)	\$ -	\$ (71,742.47)	\$ -
NV	34996	Nevada Health CO-OP	\$ 10,388,059.14	\$ 312,181.20	\$ 1,310,751.44	\$ 39,390.61
NV	60156	HMO Colorado, Inc., dba HMO Nevada	\$ (53,370.48)	\$ 2,715.74	\$ (53,370.48)	\$ 342.67
NV	95865	Health Plan of Nevada, Inc.	\$ -	\$ -	\$ -	\$ -

Table 30 – New Hampshire

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
NH	96751	Matthew Thornton Health Plan (Anthem BCBS)	\$ (2,966,744.60)	\$ -	\$ (2,966,744.60)	\$ -

Table 31 – New Jersey

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
NJ	10191	Freelancers CO-OP of New Jersey, Inc.	\$ (2,895,760.17)	\$ 150,164.60	\$ (2,895,760.17)	\$ 18,947.57
NJ	77606	AmeriHealth HMO, Inc.	\$ 3,360,296.37	\$ 138,744.96	\$ 423,997.71	\$ 17,506.65
NJ	91661	Horizon Healthcare Services, Inc.	\$ (27,523,171.51)	\$ 3,185,432.61	\$ (27,523,171.51)	\$ 401,933.64
NJ	91762	AmeriHealth Insurance Company of New Jersey	\$ (2,318,123.55)	\$ 1,157,648.85	\$ (2,318,123.55)	\$ 146,070.59

Table 32 – New Mexico

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
NM	19722	Molina Health Care of New Mexico, Inc.	\$ (628,432.85)	\$ -	\$ (628,432.85)	\$ -
NM	52744	Presbyterian Insurance Company, Inc.	\$ -	\$ -	\$ -	\$ -
NM	57173	Presbyterian Health Plan, Inc.	\$ 2,478,787.11	\$ (82,897.17)	\$ 312,770.05	\$ (82,897.17)
NM	75605	Blue Cross Blue Shield of New Mexico	\$ 6,563,110.63	\$ 3,789.97	\$ 828,124.54	\$ 478.21

NM	93091	New Mexico Health Connections	\$ 4,211,650.62	\$ -	\$ 531,420.45	\$ -

Table 33 – New York

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
NY	11177	MetroPlus Health Plan	\$ 8,754,733.06	\$ -	\$ 1,104,660.53	\$ -
NY	18029	Independent Health Benefits Corporation	\$ (2,870,470.22)	\$ (530,639.45)	\$ (2,870,470.22)	\$ (530,639.45)
NY	25303	New York State Catholic Health Plan, Inc.	\$ (3,499,761.14)	\$ -	\$ (3,499,761.14)	\$ -
NY	31808	American Progressive Life & Health Insurance Company of New York	\$ (344,586.33)	\$ -	\$ (344,586.33)	\$ -
NY	40064	HealthNow New York	\$ (4,020,217.24)	\$ (1,216,594.18)	\$ (4,020,217.24)	\$ (1,216,594.18)
NY	54235	UnitedHealthcare of New York, Inc.	\$ (626,658.79)	\$ -	\$ (626,658.79)	\$ -
NY	56184	MVP Health Plan, Inc.	\$ (3,547,343.87)	\$ 1,550,702.41	\$ (3,547,343.87)	\$ 195,665.56
NY	57165	Affinity Health Plan, Inc.	\$ 1,179,368.76	\$ -	\$ 148,811.18	\$ -
NY	71644	Freelancers Health Service Corporation d/b/a Health Republic Insurance of New York	\$ 89,568,960.58	\$ 59,765,898.72	\$ 11,301,691.90	\$ 7,541,181.33
NY	74289	Oscar Insurance Corporation	\$ 9,342,723.93	\$ -	\$ 1,178,852.44	\$ -
NY	78124	Excellus Health Plan, Inc.	\$ (5,505,909.10)	\$ 7,526,489.35	\$ (5,505,909.10)	\$ 949,682.38
NY	80519	Empire HealthChoice HMO, Inc.	\$ -	\$ -	\$ -	\$ -

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
NY	82483	North Shore-LIJ Insurance Company, Inc.	\$ 3,109,088.97	\$ 407,827.19	\$ 392,300.70	\$ 51,459.09
NY	85629	Oxford Health Insurance, Inc.	\$ -	\$ -	\$ -	\$ -
NY	88582	Health Insurance Plan of Greater New York	\$ -	\$ -	\$ -	\$ -
NY	91237	Healthfirst PHSP, Inc.	\$ 75,523.98	\$ -	\$ 9,529.51	\$ -
NY	92551	CDPHP Universal Benefits, Inc.	\$ -	\$ 14,607,068.85	\$ -	\$ 1,843,100.45
NY	94788	CDPHP	\$ (1,382,551.74)	\$ -	\$ (1,382,551.74)	\$ -
NY	95456	Atlantis Health Plan	\$ -	\$ -	\$ -	\$ -

Table 34 – North Carolina

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
NC	11512	Blue Cross and Blue Shield of NC	\$ 147,421,876.38	\$ 53,091.97	\$ 18,601,495.60	\$ 6,699.07
NC	56346	Coventry Health Care of the Carolinas, Inc.	\$ 10,188,775.76	\$ -	\$ 1,285,606.13	\$ -

Table 35 – North Dakota

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
ND	37160	Blue Cross Blue Shield of North Dakota	\$ 458,378.00	\$ -	\$ 57,837.52	\$ -
ND	73751	Medica Health Plans	\$ 135,903.29	\$ 104,395.86	\$ 17,148.10	\$ 13,172.53
ND	89364	Sanford Health Plan	\$ (36,822.51)	\$ (525,477.50)	\$ (36,822.51)	\$ (525,477.50)

Table 36 – Ohio

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
OH	20126	HealthSpan Integrated Care	\$ 11,010,446.61	\$ 192,005.52	\$ 1,389,283.46	\$ 24,227.00
OH	28162	AultCare Insurance Company	\$ (352,697.76)	\$ 653,633.59	\$ (352,697.76)	\$ 82,474.61
OH	29276	Community Insurance Company (Anthem BCBS)	\$ (1,827,325.84)	\$ 16,036.90	\$ (1,827,325.84)	\$ 2,023.51
OH	41047	Buckeye Community Health Plan	\$ (138,688.52)	\$ -	\$ (138,688.52)	\$ -
OH	52664	Summa Insurance Company, Inc.	\$ 1,029,971.11	\$ 1,126,100.28	\$ 129,960.38	\$ 142,089.83
OH	64353	Molina Healthcare of Ohio	\$ (59,275.67)	\$ -	\$ (59,275.67)	\$ -
OH	66083	Humana Health Plan of Ohio, Inc.	\$ 9,268,399.33	\$ -	\$ 1,169,474.26	\$ -
OH	74313	Paramount Insurance Company	\$ -	\$ -	\$ -	\$ -
OH	77552	CareSource	\$ (2,330,396.51)	\$ -	\$ (2,330,396.51)	\$ -
OH	92036	HealthSpan	\$ 4,984,820.40	\$ 82,913.27	\$ 628,977.98	\$ 10,461.89
OH	98894	Coventry Health and Life	\$ 572,626.39	\$ -	\$ 72,253.23	\$ -
OH	99969	Medical Health Insuring Corporation of Ohio	\$ 4,162,818.87	\$ 814,705.62	\$ 525,258.93	\$ 102,798.47

Table 37 – Oklahoma

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
OK	53524	Coventry Health and Life	\$ 160,301.63	\$ -	\$ 20,226.65	\$ -
OK	66946	Aetna Life Insurance Company	\$ 430,044.89	\$ -	\$ 54,262.49	\$ -
OK	76668	Coventry Health Care of Kansas, Inc.	\$ 1,263,023.77	\$ -	\$ 159,366.65	\$ -
OK	85408	GlobalHealth, Inc.	\$ 2,789,907.94	\$ 15,603.96	\$ 352,026.86	\$ 1,968.89
OK	87571	Blue Cross Blue Shield of Oklahoma	\$ 51,750,597.82	\$ 2,141,587.80	\$ 6,529,821.36	\$ 270,222.69
OK	87698	CommunityCare Life & Health Insurance Company	\$ -	\$ 153,238.12	\$ -	\$ 19,335.38
OK	98905	CommunityCare HMO, Inc.	\$ (89,579.39)	\$ 324,873.59	\$ (89,579.39)	\$ 40,992.12

Table 38 – Oregon

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
OR	10091	PacificSource Health Plans	\$ 3,007,808.62	\$ -	\$ 379,521.28	\$ -
OR	10940	Health Net Health Plan of Oregon, Inc.	\$ 2,355,054.51	\$ -	\$ 297,157.63	\$ -
OR	32536	ATRIO Health Plans	\$ 79,569.24	\$ 38,865.04	\$ 10,039.94	\$ 4,903.94
OR	39424	Moda Health Plan, Inc.	\$ 86,224,498.21	\$ 1,515,915.79	\$ 10,879,692.10	\$ 191,276.23
OR	56707	Providence Health Plan	\$ (884,714.62)	\$ (14,562.34)	\$ (884,714.62)	\$ (14,562.34)
OR	63474	BridgeSpan Health Company	\$ (10,125.33)	\$ -	\$ (10,125.33)	\$ -
OR	71287	Kaiser Foundation Healthplan of the NW	\$ -	\$ (103,672.86)	\$ -	\$ (103,672.86)

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
OR	85804	LifeWise Health Plan of Oregon	\$ 4,825,921.49	\$ -	\$ 608,928.33	\$ -
OR	95417	Trillium Community Health Plan	\$ (4,991.57)	\$ -	\$ (4,991.57)	\$ -
OR	96383	Health Republic Insurance Company	\$ 4,206,407.40	\$ 3,678,478.75	\$ 530,758.87	\$ 464,145.54
OR	99389	Community Care of Oregon, Inc.	\$ 1,528,717.06	\$ (53,520.17)	\$ 192,891.48	\$ (53,520.17)

Table 39 – Pennsylvania

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
PA	16481	UPMC Health Network, Inc.	\$ -	\$ 222,263.08	\$ -	\$ 28,044.86
PA	22444	Geisinger Health Plan	\$ 17,817,403.51	\$ 5,080,960.02	\$ 2,248,176.19	\$ 641,108.75
PA	31609	Independence Blue Cross (QCC Ins. Co.)	\$ (1,308,105.69)	\$ 10,769,563.46	\$ (1,308,105.69)	\$ 1,358,889.14
PA	33709	Highmark, Inc.	\$ 158,255,675.15	\$ 1,561,432.70	\$ 19,968,489.86	\$ 197,019.49
PA	33871	Keystone Health Plan East, Inc.	\$ 14,274,873.45	\$ 14,996,681.97	\$ 1,801,184.48	\$ 1,892,261.31
PA	33906	Aetna Life Insurance	\$ 305,303.92	\$ -	\$ 38,522.84	\$ -

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
		Company				
PA	52899	UPMC Health Plan, Inc.	\$ -	\$ 13,607.91	\$ -	\$ 1,717.03
PA	53789	Keystone Health Plan Central	\$ 116,511.72	\$ (10,554.40)	\$ 14,701.29	\$ (10,554.40)
PA	55957	First Priority Life Insurance Company, Inc.	\$ 10,933,783.20	\$ -	\$ 1,379,610.17	\$ -
PA	64844	Aetna Health Inc. (a PA corp.)	\$ (345,573.38)	\$ -	\$ (345,573.38)	\$ -
PA	70194	Highmark Health Insurance Company	\$ 31,690,007.63	\$ -	\$ 3,998,602.87	\$ -
PA	75729	Geisinger Quality Options	\$ 3,707,248.35	\$ 3,991,516.95	\$ 467,775.65	\$ 503,644.28
PA	82795	Capital Advantage Insurance Company CAIC	\$ 235,466.09	\$ 54,647.55	\$ 29,710.80	\$ 6,895.35
PA	91303	HealthAmerica Pennsylvania, Inc.	\$ 2,042,302.79	\$ -	\$ 257,695.04	\$ -

Table 40 – Rhode Island

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
RI	15287	Blue Cross & Blue Shield of Rhode Island	\$ -	\$ -	\$ -	\$ -
RI	77514	Neighborhood Health Plan of Rhode Island	\$ (211,788.19)	\$ (4,014.40)	\$ (211,788.19)	\$ (4,014.40)
RI	79881	UnitedHealthcare of New England, Inc.	\$ -	\$ 762.71	\$ -	\$ 96.24

Table 41 – South Carolina

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
SC	26065	Blue Cross and Blue Shield of South Carolina	\$ (5,288,866.75)	\$ (529,578.40)	\$ (5,288,866.75)	\$ (529,578.40)
SC	41614	Coventry Health Care of the Carolinas, Inc.	\$ 5,095,926.05	\$ -	\$ 642,997.15	\$ -
SC	49532	BlueChoice HealthPlan of South Carolina, Inc.	\$ (2,329,264.72)	\$ (21,230.33)	\$ (2,329,264.72)	\$ (21,230.33)
SC	65122	Consumers' Choice Health Insurance Company	\$ 12,425,229.72	\$ (1,019.57)	\$ 1,567,798.90	\$ (1,019.57)

Table 42 – South Dakota

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
SD	31195	Sanford Health Plan	\$ 2,970,388.46	\$ 566,171.13	\$ 374,799.65	\$ 71,438.72
SD	60536	Avera Health Plans, Inc.	\$ 7,572,477.64	\$ 394,223.31	\$ 955,485.12	\$ 49,742.57
SD	62210	South Dakota State Medical Holding Company, Inc.	\$ 66,565.39	\$ 12,552.90	\$ 8,399.13	\$ 1,583.91

Table 43 – Tennessee

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
TN	14002	BlueCross BlueShield of Tennessee	\$ 78,721,051.43	\$ -	\$ 9,932,917.20	\$ -
TN	66842	Community Health Alliance Mutual Insurance Company	\$ 212,418.39	\$ 155,095.17	\$ 26,802.67	\$ 19,569.70
TN	82120	Humana Insurance Company	\$ 7,292,392.28	\$ -	\$ 920,144.32	\$ -
TN	99248	Cigna Health and Life Insurance Company	\$ (31,703.92)	\$ -	\$ (31,703.92)	\$ -

Table 44 – Texas

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
TX	26539	SHA, LLC DBA FirstCare Health Plans	\$ 1,675,416.16	\$ 359,876.56	\$ 211,401.77	\$ 45,408.74
TX	27248	Community Health Choice, Inc.	\$ (4,628.30)	\$ -	\$ (4,628.30)	\$ -
TX	32673	Humana Health Plan of Texas, Inc.	\$ 61,229,555.45	\$ -	\$ 7,725,863.58	\$ -
TX	33602	Blue Cross Blue Shield of Texas	\$ 275,081,527.88	\$ 19,226,824.55	\$ 34,709,420.03	\$ 2,426,015.06
TX	40788	Scott and White Health Plan	\$ 770,409.24	\$ -	\$ 97,209.21	\$ -
TX	45786	Molina Healthcare of	\$ (421,460.88)	\$ -	\$ (421,460.88)	\$ -

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
		Texas				
TX	46224	Community First Health Plans, Inc.	\$ 10,771.93	\$ -	\$ 1,359.19	\$ -
TX	55409	Cigna Health and Life Insurance Company	\$ 12,881,279.86	\$ -	\$ 1,625,342.70	\$ -
TX	63141	Humana Insurance Company	\$ 5,073,997.06	\$ -	\$ 640,230.18	\$ -
TX	71837	Sendero Health Plans, Inc.	\$ -	\$ -	\$ -	\$ -
TX	87226	Superior Health Plan	\$ (141,809.67)	\$ -	\$ (141,809.67)	\$ -
TX	91716	Aetna Life Insurance Company	\$ 1,101,457.25	\$ -	\$ 138,980.41	\$ -

Table 45 – Utah

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
UT	18167	Molina Healthcare of Utah	\$ (34,983.73)	\$ -	\$ (34,983.73)	\$ -
UT	27619	Arches Mutual Insurance Company	\$ 11,541,794.74	\$ 475,006.15	\$ 1,456,328.26	\$ 59,935.64
UT	34541	BridgeSpan Health Company	\$ 2,017,051.99	\$ -	\$ 254,508.93	\$ -
UT	38927	Aetna Health of Utah, Inc.	\$ 2,007,972.57	\$ -	\$ 253,363.30	\$ -
UT	56764	Humana Medical Plan of Utah, Inc.	\$ 9,670,212.71	\$ -	\$ 1,220,174.53	\$ -
UT	66413	UnitedHealthcare of Utah, Inc.	\$ -	\$ (83,844.54)	\$ -	\$ (83,844.54)
UT	68781	SelectHealth	\$ 62,294,564.39	\$ 21,242,298.51	\$ 7,860,244.99	\$ 2,680,324.87

Table 46 – Vermont

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
VT	13627	Blue Cross Blue Shield of Vermont	\$ (30,650.56)	\$ (36,128.73)	\$ (30,650.56)	\$ (36,128.73)
VT	77566	MVP Health Plan, Inc.	\$ 918,153.01	\$ 644,843.45	\$ 115,851.32	\$ 81,365.49

Table 47 – Virginia

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
VA	10207	CareFirst BlueChoice, Inc.	\$ 730,771.62	\$ -	\$ 92,207.79	\$ -
VA	12028	Innovation Health Insurance Company	\$ 426,857.46	\$ -	\$ 53,860.30	\$ -
VA	20507	Optima Health Plan	\$ -	\$ -	\$ -	\$ -
VA	38234	Aetna Life Insurance Company	\$ (659,270.22)	\$ -	\$ (659,270.22)	\$ -
VA	40308	Group Hospitalization and Medical Services, Inc.	\$ (64,661.14)	\$ (1,025,296.29)	\$ (64,661.14)	\$ (1,025,296.29)
VA	88380	HealthKeepers, Inc.	\$ -	\$ (2,548.51)	\$ -	\$ (2,548.51)
VA	95185	Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc.	\$ -	\$ 178,089.11	\$ -	\$ 22,471.05
VA	99663	Coventry Health Care of Virginia, Inc.	\$ -	\$ -	\$ -	\$ -

Table 48 – Washington

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
WA	18581	Community Health Plan of Washington	\$ (753,546.87)	\$ -	\$ (753,546.87)	\$ -
WA	23371	Kaiser Foundation Healthplan of the NW	\$ (3,394,261.77)	\$ (369,811.39)	\$ (3,394,261.77)	\$ (369,811.39)
WA	38498	LifeWise Health Plan of WA	\$ (1,919,519.31)	\$ -	\$ (1,919,519.31)	\$ -
WA	49831	Premera Blue Cross	\$ (5,476,090.21)	\$ -	\$ (5,476,090.21)	\$ -
WA	53732	BridgeSpan Health Company	\$ (2,033,720.54)	\$ -	\$ (2,033,720.54)	\$ -
WA	61836	Coordinated Care Corporation	\$ -	\$ -	\$ -	\$ -
WA	80473	Group Health Cooperative	\$ (6,356,225.50)	\$ -	\$ (6,356,225.50)	\$ -
WA	84481	Molina Healthcare of Washington, Inc.	\$ (1,376,733.58)	\$ -	\$ (1,376,733.58)	\$ -

Table 49 – West Virginia

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
WV	31274	Highmark Blue Cross Blue Shield West Virginia	\$ 14,385,457.00	\$ 38,227.31	\$ 1,815,137.76	\$ 4,823.47

Table 50 – Wisconsin

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
WI	35334	MercyCare Insurance Company	\$ -	\$ 355,607.79	\$ -	\$ 44,870.12
WI	37833	Unity Health Plans Insurance Corporation	\$ -	\$ -	\$ -	\$ -
WI	38166	Security Health Plan of Wisconsin, Inc.	\$ -	\$ 875,656.06	\$ -	\$ 110,489.11
WI	38345	Dean Health Plan	\$ 15,750,038.55	\$ -	\$ 1,987,318.84	\$ -
WI	47342	Health Tradition Health Plan	\$ 297,680.24	\$ 282,631.37	\$ 37,560.90	\$ 35,662.05
WI	52697	Molina Healthcare of Wisconsin, Inc.	\$ (2,294,384.22)	\$ -	\$ (2,294,384.22)	\$ -
WI	57637	Medica Insurance Company	\$ -	\$ 481,277.84	\$ -	\$ 60,727.00
WI	57845	Medica Health Plans of Wisconsin	\$ (1,883,070.63)	\$ -	\$ (1,883,070.63)	\$ -
WI	58326	MercyCare HMO, Inc.	\$ 628,033.47	\$ 555,110.94	\$ 79,244.43	\$ 70,043.16
WI	58564	Physicians Plus Insurance Corporation	\$ (400,853.60)	\$ -	\$ (400,853.60)	\$ -
WI	79475	CompCare Health Services Insurance Company (Anthem BCBS)	\$ 4,931,489.14	\$ -	\$ 622,248.72	\$ -
WI	84670	WPS Health Plan, Inc.	\$ 6,415,135.24	\$ -	\$ 809,453.20	\$ -
WI	87416	Common Ground Healthcare Cooperative	\$ 44,457,568.86	\$ 784,154.58	\$ 5,609,596.70	\$ 98,943.58
WI	91058	Gundersen Health Plan, Inc.	\$ -	\$ 2,074,673.03	\$ -	\$ 261,779.47
WI	94529	Group Health Cooperative-SCW	\$ (214,772.33)	\$ (487,586.65)	\$ (214,772.33)	\$ (487,586.65)

Table 51 – Wyoming

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET)	HHS RISK CORRIDOR AMOUNT (SMALL GROUP MARKET)	PRORATED AMOUNT (INDIVIDUAL MARKET)	PRORATED AMOUNT (SMALL GROUP MARKET)
WY	11269	Blue Cross Blue Shield of Wyoming	\$ (3,909,210.30)	\$ 607,415.77	\$ (3,909,210.30)	\$ 76,642.91
WY	53189	WINhealth Partners	\$ 4,996,309.90	\$ 70,330.08	\$ 630,427.71	\$ 8,874.16

EXHIBIT 7



FEDERAL REGISTER

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Part III

Department of Health and Human Services

45 CFR Part 153

Patient Protection and Affordable Care Act; Standards Related to
Reinsurance, Risk Corridors and Risk Adjustment; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES**45 CFR Part 153****[CMS–9975–P]****RIN 0938–AR07****Patient Protection and Affordable Care Act; Standards Related to Reinsurance, Risk Corridors and Risk Adjustment****AGENCY:** Department of Health and Human Services.**ACTION:** Proposed rule.

SUMMARY: This proposed rule would implement standards for States related to reinsurance and risk adjustment, and for health insurance issuers related to reinsurance, risk corridors, and risk adjustment consistent with title I of the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act of 2010, referred to collectively as the Affordable Care Act. These programs will mitigate the impact of potential adverse selection and stabilize premiums in the individual and small group markets as insurance reforms and the Affordable Insurance Exchanges (“Exchanges”) are implemented, starting in 2014. The transitional State-based reinsurance program serves to reduce the uncertainty of insurance risk in the individual market by making payments for high-cost cases. The temporary Federally-administered risk corridor program serves to protect against uncertainty in the Exchange by limiting the extent of issuer losses (and gains). On an ongoing basis, the State-based risk adjustment program is intended to provide adequate payments to health insurance issuers that attract high-risk populations (such as individuals with chronic conditions).

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. Eastern Standard Time (E.S.T.) on September 28, 2011.

ADDRESSES: In commenting, please refer to file code CMS–9975–P. Because of staff and resource limitations, we cannot accept comments by facsimile (Fax) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions under the “More Search Options” tab.

2. *By regular mail.* You may mail written comments to the following

address *only*: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–9975–P, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address *only*: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–9975–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification; commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD: Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document’s paperwork requirements by following the instructions at the end of the “Collection of Information Requirements” section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Sharon Arnold at (301) 492–4415 for general information.

Wakina Scott at (301) 492–4393 for matters related to reinsurance and risk corridors.

Kelly O’Brien at (301) 492–4399 for matters related to risk adjustment.

Grace Arnold at (301) 492–4272 for matters related to the collection of information requirements.

Brigid Russell at (301) 492–4421 for matters related to the summary of preliminary regulatory impact analysis.

Abbreviations:

Affordable Care Act—The collective term for the Patient Protection and Affordable Care Act (Pub. L. 111–148) and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152)

CMS Centers for Medicare & Medicaid Services

HHS U.S. Department of Health and Human Services

HIPAA Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191)

MLR Medical Loss Ratio

PHS Act Public Health Service Act (42 U.S.C. 201 *et seq.*)

QHP Qualified Health Plan

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this proposed rule to assist us in fully considering issues and developing policies. Comments will be most useful if they are organized by the section of the proposed rule to which they apply. You can assist us by referencing the file code [CMS–9975–P] and the specific “issue identifier” that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all electronic comments received before the close of the comment period on the following public Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at Room 445–G, Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, call 1–800–743–3951.

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I. Background**A. Legislative Overview**

Starting in 2014, individuals and small businesses will be able to purchase private health insurance through State-based competitive marketplaces called Affordable Insurance Exchanges, or “Exchanges.” Exchanges will offer Americans competition, choice, and clout. Insurance companies will compete for business on a level playing field, driving down costs. Consumers will have a choice of health plans to fit their needs. And Exchanges will give individuals and small businesses the same purchasing clout as big businesses. The Departments of Health and Human Services, Labor, and the Treasury (the Departments) are working in close coordination to release guidance related to Exchanges in several phases. The first in this series was a Request for Comment relating to Exchanges, published in the **Federal Register** on August 3, 2010. Second, Initial Guidance to States on Exchanges was issued on November 18, 2010. Third, a proposed rule for the application, review, and reporting process for waivers for State innovation was published in the **Federal Register** on March 14, 2011. Fourth, two proposed regulations, including this one, are published in this issue of the **Federal Register** to implement components of the Exchange and health insurance premium stabilization policies in the Affordable Care Act.

Section 1341 of the Affordable Care Act provides that each State must

establish a transitional reinsurance program to help stabilize premiums for coverage in the individual market during the first three years of Exchange operation (2014–2016). Section 1342 provides that the Secretary must establish a transitional risk corridor program that will apply to the qualified health plans in the individual and small group markets for the first three years of Exchange operation (2014–2016). Section 1343 provides that each State may establish a program of risk adjustment for all non-grandfathered plans in the individual and small group market both inside and outside of the Exchange. These risk-spreading mechanisms, which will be implemented by the Secretary and the States, are designed to mitigate the potential impact of adverse selection and provide stability for health insurance issuers in the individual and small group markets.

Section 1321(a) also provides broad authority for the Secretary to establish standards and regulations to implement the statutory requirements related to Exchanges, reinsurance, risk adjustment, and other components of title I of the Affordable Care Act. Section 1321(a)(2) requires, in issuing such regulations, the Secretary to engage in stakeholder consultation in a way that ensures balanced representation among interested parties. We describe the consultation activities the Secretary has undertaken later in this introduction. Section 1321(c)(1) authorizes the Secretary to establish Exchanges and implement reinsurance, risk adjustment and other components of title I of the Affordable Care Act in States that have not done so.

B. Introduction

Underpinning the goals of high-quality, affordable health insurance coverage is the need to minimize the possible negative effects of adverse selection. Adverse selection occurs when each new health insurance purchaser understands his or her own potential health risk better than health insurance insurers do, and health insurance issuers are therefore less able to accurately price their products.

To avoid adverse selection, issuers may set premiums higher than necessary in order to offset the potential expense of high-cost enrollees. This uncertainty could also result in an issuer being more cautious about offering certain plan designs in the Exchange. This risk will be greatest in the first years of the Exchange, and become less as the new market matures and issuers learn more about new enrollees.

As experience in States has shown, offsetting the adverse selection from insurance reforms may be best accomplished by broadening the risk pool: making coverage affordable through lower premiums and targeted financial assistance and making coverage a responsibility so that people pay premiums in sickness and in health. In addition, to minimize the negative effects of adverse selection and foster a stable marketplace from year one, the Affordable Care Act establishes transitional reinsurance and temporary risk corridor programs, and a permanent risk adjustment program to provide payments to health insurance issuers that cover higher-risk populations and to more evenly spread the financial risk borne by issuers.

The transitional reinsurance program and temporary risk corridor program, which begin in 2014, are designed to provide issuers with greater payment stability as insurance market reforms are implemented. The reinsurance program, which is a State-based program, will reduce the uncertainty of insurance risk in the individual market by making payments for high-cost cases. This program will attenuate individual market rate increases that might otherwise occur because of the immediate enrollment of individuals with unknown health status, potentially including, at the State's discretion, those currently in State high risk pools. The risk corridor program, which is a Federally-administered program, will protect against uncertainty in setting rates in the Exchange by limiting the extent of issuer losses (and gains). Under the risk corridor program, an issuer of a qualified health plan (QHP) plan whose gains are greater than three percent of the issuer's projections must remit charges to HHS, while HHS must make payments to an issuer of a QHP plan that experiences losses greater than three percent of the issuer's projections. On an ongoing basis, the risk adjustment program is intended to provide adequate payments to health insurance issuers that attract high-risk populations (such as those with chronic conditions). Under this program, generally, funds are transferred from issuers with lower risk enrollees to issuers with higher risk enrollees. Section 1343 indicates that the Secretary may utilize criteria and methods similar to the criteria and methods utilized under part C or D of title XVIII of the Social Security Act. Proposed standards for these critical programs are addressed in this proposed rule. The chart below summarizes these programs:

Program	Reinsurance	Risk corridors	Risk adjustment
What	Provides funding to plans that enroll highest cost individuals.	Limit issuer loss (and gains)	Transfers funds from lowest risk plans to highest risk plans.
Program Oversight	State or State Option if no State-Run Exchange.	HHS	State Option in a State-Run Exchange.
Who Participates	All issuers and TPAs contribute funding; non-grandfathered individual market plans (inside and outside the Exchange) are eligible for payments.	Qualified Health Plans (QHPs)	Non-grandfathered individual and small group market plans, inside and outside the Exchange.
When	Throughout the year 2014–2016 ..	After reinsurance and risk adjustment 2014–2016.	After end of benefit year 2014 and subsequent years.
Why	Offsets high cost outliers	Protect against inaccurate rate-setting.	Protects against adverse selection.
Time Frame	3 years (2014–2016)	3 years (2014–2016)	Permanent.

On August 3, 2010, HHS published a Request for Comment (RFC) inviting the public to provide input regarding the rules that will govern the Exchanges and related functions such as reinsurance and risk adjustment. In particular, HHS asked States, tribal representatives, consumer advocates, employers, issuers, and other interested stakeholders to comment on the types of standards Exchanges and related functions should be required to meet. The comment period closed on October 4, 2010. In this proposed rule, we do not directly respond to comments from the RFC; however, we generally describe the comments received at the beginning of each subpart and refer to them, where applicable, when discussing specific regulatory proposals. We intend to respond to comments from the RFC, along with comments received on this proposed rule, as part of the final rule. We also plan to disseminate parameters that will rely on factors that may change each year, such as the national reinsurance contribution rate and the Federally-certified risk adjustment model, in an annually updated Federal notice of benefit and payment parameters. In addition to the RFC, we have consulted with stakeholders through weekly meetings with the National Association of Insurance Commissioners, regular contact with States that received Exchange planning grants, and meetings with tribal representatives, health insurance issuers, trade groups, consumer advocates, employers, and other interested parties.

II. Provisions of the Proposed Regulation

A. Subpart A—General Provisions

1. Basis and Scope (§ 153.10)

Section 153.10(a) of subpart A specifies that the general statutory authority for the standards proposed in part 153 are based on the following

sections of title I of the Affordable Care Act: sections 1321 and 1341–1343. Section 153.10(b) specifies that this part establishes standards for the establishment and operation of a transitional reinsurance program, temporary risk corridors, and a permanent risk adjustment program.

2. Definitions (§ 153.20)

Under § 153.20, we set forth definitions for terms that are used throughout part 153. Many of the definitions presented in § 153.20 are taken directly from the Affordable Care Act, from existing regulations, or from § 155.20 of the notice of proposed rulemaking entitled “Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans,” published in this issue of the **Federal Register**. New definitions were created for the purposes of carrying out regulations proposed in part 153. When a term is defined in part 153 other than in subpart A, the definition of the term is applicable only to the relevant subpart or section. The application of the terms defined in this section is limited to this proposed rule.

Specifically, several terms are defined by the Affordable Care Act, including “individual market” (section 1304(a)(2)), “qualified health plan” (section 1301(a)(1)), and “health plan” (section 1301(b)(1)). The definition for an “Exchange” is drawn from the statutory text in section 1311(d)(1) and 1311(d)(2)(A). The term “State” is also taken directly from section 1304(d) of the Affordable Care Act to mean the 50 States and the District of Columbia.

Some definitions were taken from other interim final regulations issued pursuant to the Affordable Care Act, including the term “grandfathered plan” from § 147.140. The definitions for the terms “group health plan,” “health insurance issuer,” and “health insurance coverage” are cross-referenced to the definitions established in § 144.103. The definitions for the

terms “enrollee,” “benefit year,” and “small group market” are cross-referenced to the definitions in the notice of proposed rulemaking entitled “Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans,” published in this issue of the **Federal Register**. Other definitions used throughout this proposed rule are established for specific purposes. For example, the terms “applicable reinsurance entity,” “contributing entity,” and “reinsurance-eligible plan” relate to reinsurance programs, while the term “risk adjustment covered plan” relates to the risk adjustment program.

B. Subpart B—State Notice of Insurance Benefits and Payment Parameters

In this subpart, we propose a process by which the States that are operating an Exchange or establishing a reinsurance program issue an annual notice to disseminate information to issuers and other stakeholders about specific requirements to support payment-related functions. This notice may also be a mechanism to address updates to other Exchange-related provisions proposed elsewhere that impact payment and benefit design. This provides a practical way to update certain payment and benefit factors that may change annually, such as reinsurance contribution rates that are based on annually changing thresholds.

1. Establishment of State insurance benefits and payment parameters (§ 153.100)

In § 153.100(a), we propose that a State operating an Exchange, as well as a State establishing a reinsurance program, issue an annual notice to describe the specific parameters that the State will employ if that State intends to utilize any reinsurance or risk adjustment parameters that differ from those specified in the forthcoming annual Federal notice of benefit and payment parameters. We believe the

information contained in the State notice should be provided one year in advance of the benefit year so that issuers may account for any updates in their design and review of plan benefits and in establishing and reviewing rates. As such, in paragraph (b), we propose specific deadlines for the State notice, if it intends on modifying Federally-proposed parameters, which will be tied to a forthcoming annual Federal notice of benefit and payment parameters, upon which the public will have an opportunity to comment. Below are charts detailing the schedules for the forthcoming annual Federal notice of benefit and payment parameters for 2014 and subsequent years, with the first two dates occurring in the calendar year two years before the effective date.

ANNUAL FEDERAL NOTICE OF BENEFIT AND PAYMENT PARAMETERS

HHS publishes advance notice.	Mid-October.
Comment period ends	Mid-November.
HHS publishes final notice	Mid-January.

We propose that States that plan to modify Federal parameters issue their notice by early March in the calendar year before the effective date. We understand that States may have their own timelines for public notice; this proposed requirement sets an outer bound for the final notice to be issued by a State that intends to utilize any reinsurance or risk adjustment parameters that differ from those specified in the forthcoming annual Federal notice of benefit and payment parameters. We seek comment on whether the proposed timing allows issuers sufficient time to reflect these State requirements in setting rates. In particular, we seek comment as to whether the schedule should be adjusted in the initial year to provide issuers additional time for setting rates for 2014.

We also propose in paragraph (c) that if a State operating an Exchange or establishing a reinsurance program does not provide public notice of its intent to have State-specific parameters for any provision within the period specified in paragraph (b) of this section, the parameters set forth in the forthcoming annual Federal notice of benefits and payment parameters will serve as the State parameters.

2. Standards for the State Notice (§ 153.110)

In paragraph (a)(1), we propose that content related to the reinsurance program include the data requirements and data collection frequency for health

insurance issuers to receive reinsurance payment. In paragraph (a)(2), we propose that the State specify the attachment point, reinsurance cap, and coinsurance rate if the State plans to use different values than those set forth in the forthcoming annual Federal notice of benefit and payment parameters. In paragraph (a)(3), we propose that if a State plans to use more than one reinsurance entity, the State must include in the notice information related to the geographic boundaries of each applicable reinsurance entity and estimates related to the number of enrollees, payments, and premiums available for contributions in each region. We note that the forthcoming annual Federal notice of benefit and payment parameters will provide States with estimates for these values at the State level.

In paragraph (b), we propose content related to the risk adjustment program if the State intends to modify the risk adjustment parameters set forth in the forthcoming annual Federal notice of benefits and payment parameters, including a detailed description of and rationale for any modification. Specifically, the State description of modifications should include: the methodology for determining average actuarial risk, including the establishment of risk pools and the Federally-certified risk adjustment model; and the risk adjustment data validation methodology.

C. Subpart C—State Standards for the Transitional Reinsurance Program for the Individual Market

Section 1341 of the Affordable Care Act provides that a transitional reinsurance program is established in each State to help stabilize premiums for coverage in the individual market during the years 2014 through 2016. Under this provision, all health insurance issuers, and third-party administrators on behalf of self-insured group health plans, must make contributions to a not-for-profit reinsurance entity to support reinsurance payments to individual market issuers that cover high-cost individuals, except for high-cost individuals in grandfathered individual market health plans. As a basis for reinsurance payments, the law directs the Secretary to develop a list of 50 to 100 medical conditions to identify high-cost individuals or to identify alternative methods for payment in consultation with the American Academy of Actuaries (AAA). In this subpart, we codify section 1341 of the Affordable Care Act as it relates to establishing a reinsurance program.

Related standards on health insurance issuers with respect to reinsurance are proposed in subpart E.

We identified three critical policy goals of the transitional reinsurance program. First, the transitional reinsurance program should offer protection to health insurance issuers against medical cost overruns for high-cost enrollees in the individual market, particularly those that are newly insured or those with previously excluded conditions, thereby allowing issuers to set lower premiums.

Second, a transitional reinsurance program should permit early and prompt payment of reinsurance funds during the benefit year to help offset the potential high costs of health insurance issuers early in the benefit year. This objective is particularly important since the two other risk sharing protections against adverse selection—risk adjustment and risk corridors—are likely to be calculated after the end of the benefit year.

Third, the transitional reinsurance program should require minimal administrative burden since it is a temporary program. Given the short-term nature of the program, the costs of setting up and administering this program must be commensurate with its benefits over the three-year window.

We received a number of comments on the transitional reinsurance program in response to the RFC. Multiple respondents emphasized that, although underlying conditions are referenced in the Affordable Care Act with respect to the reinsurance provisions, reinsurance programs typically do not consider the health status of the individual. Health insurance issuers seek traditional reinsurance to protect against unusually high medical cost of enrollees during a coverage year. Generally, reinsurance is not tied to underlying conditions that lead to high enrollee medical costs but to high claims costs beyond a specific dollar threshold within a coverage period, regardless of health condition.

Several commenters asserted that coverage of specific conditions under a reinsurance program could lead to discriminatory practices toward certain individuals, with one commenter noting that identifying medical conditions as a basis for reinsurance payments requires a level of verification beyond that of traditional reinsurance. Another commenter contended that traditional reinsurance that makes payments based solely on incurred costs does not encourage efficient and effective care.

We considered all of these comments in the development of this subpart, along with commenter suggestions on entities that could serve as the

applicable reinsurance entity for a State. As explained more fully below, we believe that States should have discretion to make a number of decisions within the proposed standards, including the appropriateness of any specific entity as an administrator of the reinsurance program.

1. Definitions (§ 153.200)

In § 153.200, we propose several definitions that are critical to the establishment of a properly functioning transitional reinsurance program. We define an “attachment point” as the threshold dollar amount of costs incurred by a health insurance issuer for payment of essential health benefits provided for an enrolled individual, after which threshold, the costs for covered essential health benefits are eligible for reinsurance payments. The definition of “essential health benefits” will be proposed in future rulemaking. We define “coinsurance rate” as the rate at which the applicable reinsurance entity will reimburse the health insurance issuer for costs incurred to cover essential health benefits after the attachment point and before the reinsurance cap. We define the “reinsurance cap” as the threshold dollar amount for costs incurred by a health insurance issuer for payment of essential health benefits provided for an enrolled individual, after which threshold, the costs for covered essential health benefits are no longer eligible for reinsurance payments. In order to ensure reinsurance payments are made on a comparable set of benefits, we propose that payments be calculated for costs to cover the essential health benefits package. We solicit comments on alternatives to the use of the essential health benefits package.

We define “contribution rate” as the rate, based on a percent of premium, used to determine the dollar amounts each health insurance issuer and third party administrator, on behalf of a self-insured group health plan, must contribute to a State reinsurance program. We define the “percent of premium” as the percent of total revenue, based on earned premiums as described in § 158.130(a), in all fully-insured markets (inside and outside of the Exchange) or the percent of total medical expenses in a self-insured market. Part 158 describes standards for health insurance issuers implementing the medical loss ratio requirements under section 2718 of the PHS Act. Finally, we define “third party administrator” as the claims processing entity for a self-insured group health plan. As such, if a self-insured group

health plan processes its own claims, the self-insured plan will be considered a third-party administrator for the purpose of the reinsurance program.

2. State Establishment of a Reinsurance Program (§ 153.210)

In § 153.210, we describe standards for States regarding the establishment of a reinsurance program. We propose in paragraph (a) that each State that elects to operate an Exchange must also establish a reinsurance program as required by the law. In paragraph (a)(1), we codify section 1341(a) of the Affordable Care Act, which requires that such States must either enter into a contract with an existing applicable reinsurance entity or establish an applicable reinsurance entity to carry out the provisions for the reinsurance program discussed in this subpart. We believe the statute allows State flexibility in selecting an applicable reinsurance entity and do not propose more specific guidelines.

The Affordable Care Act also allows States to set up more than one reinsurance entity, although this option may increase administrative costs. We propose in paragraph (a)(2) that, for any State that chooses to have more than one reinsurance entity, the State must publish in a State notice, described in § 153.110, information regarding the geographic divisions between the applicable entities. We further interpret the statute to imply that the geographic divisions of the applicable reinsurance entities must be distinct and, together, cover the entire individual market in the State and not just certain areas or populations. In paragraph (a)(3), we propose to allow the State to permit a reinsurance entity to subcontract administrative functions, provided that the State reviews and approves these subcontracted arrangements as described in paragraph (a)(4). We interpret the statute to allow flexibility in the performance of administrative functions, with the understanding that the responsible party must be the applicable reinsurance entity.

We propose in paragraph (a)(5) that the establishment of, or contract with, the applicable reinsurance entity must extend for a sufficient period to ensure that the entity can fulfill all reinsurance requirements for all benefit years through 2016 and any activities required to be undertaken in subsequent periods. Any State in which contributions remain to be disbursed for benefit years beyond 2016 must ensure that an applicable reinsurance entity is available for required payment activities for additional benefit years. When establishing or contracting with an

applicable reinsurance entity, States must establish sufficient time to pay reinsurance claims after 2016. This time cannot extend past December 31, 2018 as described in section 1341(b)(4) of the Affordable Care Act.

We clarify in paragraph (b) that there may be situations in which an applicable reinsurance entity operates a reinsurance program for more than one State. In other words, several States may contract with one reinsurance entity, but that entity must maintain separate risk pools for each State’s reinsurance programs. In such cases, we consider each contract to be an individual reinsurance arrangement between a specific State and the applicable reinsurance entity.

We propose in paragraph (c) to allow a State that does not elect to establish an Exchange to operate its own reinsurance program. Under this circumstance, the State will be required to carry out the provisions of this subpart. In paragraph (d), we propose that, if a State does not elect to establish an Exchange and does not determine to operate its own reinsurance program, HHS will establish the reinsurance program to perform all the reinsurance functions for that State. These functions would include the collection of all contributions described in § 153.220, including funds required to operate and administer the applicable reinsurance functions. In paragraph (e), we propose that each State that establishes an Exchange or operates a reinsurance program must ensure that each applicable reinsurance entity complies with all provisions of this subpart and with subpart E.

3. Collection of Reinsurance Contribution Funds (§ 153.220)

In § 153.220, we describe standards for how States must ensure that the reinsurance entity collects reinsurance contribution funds. Section 1341 provides for the collection of contribution funds to cover all reinsurance payments and also permits the collection of funds to cover administrative costs incurred by the applicable reinsurance entity. These contribution funds must be collected by the reinsurance entity from all health insurance issuers and third party administrators on behalf of self-insured plans. The aggregate contribution funds for purposes of making reinsurance payments are specified as \$10 billion in 2014, \$6 billion in 2015, and \$4 billion in 2016 as described in section 1341(b)(3)(B)(iii). None of these funds can be used for any purpose other than paying reinsurance or administering the reinsurance programs. The aggregate

contribution funds would be returned to those issuers that qualify for the transitional reinsurance program. In paragraph (a)(1), we codify the aggregate contribution amounts.

The statute also requires that the reinsurance entity collect specified additional contribution funds for deposit into the general fund of the U.S. Treasury. The additional contribution funds to the general fund are set at \$2 billion in calendar years 2014 and 2015, and \$1 billion in 2016 as described in section 1341(b)(3)(B)(iv). The Congressional Budget Office considered the additional contributions to score as an offset for the costs of administering the Early Retiree Reinsurance Program within the 10 year budget window, however, these funds will not be used to directly pay for ERRP costs. In paragraph (a)(2), we codify these additional contribution amounts.

Although the transitional reinsurance program is State-based, section 1341(b)(3) sets contribution levels for the program on a national basis. We considered two approaches by which to collect contribution funds: (1) Use of a national uniform contribution rate, and (2) use of a State-level allocation, both set by HHS to ensure that the sum of all contribution funds equals the national amounts set forth in statute. In paragraph (b) we propose the first approach to collect contribution funds for amounts listed in paragraph (a)(1) and (a)(2). Use of a national contribution rate is a simpler approach. Further, since there is significant uncertainty about Exchange enrollment, the overall health of the enrolled population, and the cost of care for new enrollees, we believe that a national contribution rate would be the less ambiguous approach of the two. All contribution funds collected by a State establishing a reinsurance program, using the national contribution rate, will stay in that State and be used to make reinsurance payments on valid claims submitted by reinsurance-eligible plans in that State. A State-level allocation would be more complex to administer. We solicit comments regarding whether to use a State-level allocation or a national rate.

There are two methods we considered for determining contributions using a national rate: (1) A percent of premium amount applied to all contributing entities, and (2) a flat per capita amount applied to all covered enrollees of contributing entities. In paragraph (b)(1), we propose the percent of premium method as the fairest method by which to collect these contributions, as it allows States that tend to have higher premium and health care costs, and thus reinsurance claims, to collect

additional funds towards reinsurance. A flat, per capita amount could represent an excessively high percent of premium for products that are designed and intended to have low premiums targeted toward a population such as young adults and children. HHS will establish the percentage through a forthcoming annual Federal notice of benefit and payment parameters, based on its estimate of total premiums in the fully insured market and medical expenses in the self-insured market. We invite comments regarding the preferred method for calculating health insurance issuer contribution funds using a national rate.

In paragraph (b)(2), we also propose that all contribution funds collected for reinsurance payments must be used for reinsurance, and all contribution funds collected for the U.S. Treasury must be paid to the U.S. Treasury. In paragraph (b)(3)(i), we propose that a State may collect more than its amount collected in the national rate, if the State believes that these amounts are not sufficient to cover the payments it will make under the payment formula. Nothing in the Affordable Care Act precludes a State from supplementing this program. In paragraph (b)(3)(ii), we also propose that a State may collect more than its amount collected at the national rate to cover the administrative costs of the applicable reinsurance entity.

We have also considered the frequency by which applicable reinsurance entities should collect contribution funds from contributing entities. For example, applicable reinsurance entities could collect contribution funds intended for reinsurance payments and payments to the U.S. Treasury on a monthly basis beginning in January 2014 so that reinsurance payments could begin in February 2014. We invite comments on the most appropriate method and frequency to collect reinsurance contribution funds.

4. Calculation of Reinsurance Payments (§ 153.230)

As required, in § 153.230 we set the payment policy for the reinsurance program based upon consultation with the AAA. The reinsurance payment policy addresses two basic issues: (1) How to determine the individuals who are covered by reinsurance, and (2) how to determine appropriate payment amounts. Given the short-term nature of the program, our primary objective is to select an implementation approach that is administratively and operationally simple, but satisfies the goals of the program. Therefore, we would use reliable and readily accessible data

sources that would allow health insurance issuers to receive prompt payment. We propose in paragraph (a) of this section that coverage be based on items and services within the essential health benefits for an individual enrollee that exceeds an attachment point. We invite comments regarding this proposed provision or if we should allow reinsurance payment for more generous coverage beyond that provided by essential health benefits.

In paragraph (b), we propose to announce the reinsurance payment formula and State-specific values for the attachment point, reinsurance cap, and coinsurance rate in the forthcoming annual Federal notice of benefits and payment parameters. We believe that publishing this information in a Federal notice is the best approach for announcing the attachment point and reinsurance cap as these values may change in years 2015 and 2016. The Affordable Care Act does not suggest that the three-year reinsurance program should replace commercial reinsurance or internal risk mitigation strategies. There will be a continued need for ongoing commercial reinsurance. Therefore, we propose establishing a reinsurance cap set at the attachment point of traditional reinsurance. We seek comment on this approach.

In paragraph (b)(1), we propose that the reinsurance payment amount be a percentage of those costs above an attachment point and below a reinsurance cap. However, we believe States may have unique situations and recommend allowing a State that runs the reinsurance program to establish its own payment formula by varying the attachment point, coinsurance rate, and reinsurance cap. The reasoning for the policy proposed in paragraph (b)(1) follows below, along with a discussion of some operational issues related to the timing of reinsurance payments.

In our consultation, AAA laid out a number of different ways to implement the reinsurance payment provisions. A letter outlining this issue can be found on their Web site at <https://www.actuary.org/pdf/health/Reinsurance%20Options%209%2022%202010.pdf>. With respect to the determination of who will be covered, AAA identified four possible approaches:

- (1) Identification of individuals with specific conditions based on claims data.
- (2) Identification of individuals with specific conditions based on survey data.
- (3) Identification of high-risk individuals using risk adjustment data

and a condition-based risk adjustment model.

(4) Identification of reinsurance-eligible individuals based on medical cost to the health insurance issuer for covered benefits.

The last option, which we propose to adopt, focuses on all high-cost enrollees without respect to the conditions that caused the increased cost. This approach would be most familiar to health insurance issuers and administratively less burdensome than the first and second options. Data will be immediately available and dependent only on health insurance issuers filing proof of payment for claims. While the third option might mitigate some of the burden and cost concerns, it would not eliminate the timing issues that are critical to effective reinsurance implementation. In 2014, we will be able to collect reliable condition information only for those conditions that are diagnosed during that benefit year. In other words, condition-based reinsurance will not be a predictive model until at least 2015 due to lack of sufficient and timely data. As a result, we found all of the condition-based approaches to eligibility identification to be considerably more burdensome in comparison to the medical cost approach without significant improvement in outcomes from a determination standpoint. We solicit comments for a suitable method for ensuring that issuer costs are appropriate and accurate.

With respect to the decision on how to calculate payments, AAA discussed the following two principal approaches:

(1) Payments for costs incurred above an attachment point.

(2) Fixed payment schedule for specific conditions.

The first option, payment for costs incurred above an attachment point, aligns compensation with cost by reimbursing health insurance issuers that have enrollees in the individual market who actually experience higher health costs. We propose this approach, which represents a more traditional view of reinsurance. It is also consistent with the Early Retiree Reinsurance Program. Health insurance issuers are eligible for reinsurance payments only when costs are in excess of a certain level. The proposed approach is simpler from an operational perspective; the only data required to implement it will be cost and claims data for individuals. This approach also works in tandem with the medical-cost method of determining eligibility.

The fixed payment schedule option, which we are not proposing to adopt, has the effect of paying the same

amount for all individuals who present with a specific condition regardless of actual enrollee cost. This method assumes that high-cost individuals incurring highest costs across plans are of equal care mix and does not make distinctions. This method also penalizes issuers that attract more individuals with higher disease burden within disease categories, and thus may be less effective in mitigating the actual financial impact of adverse selection.

In sum, we propose using medical cost experience only to identify eligible enrollees for which health insurance issuers would receive reinsurance. Accordingly, we also propose to use the attachment point approach for determining payment. As described by AAA, an attachment method for calculating reinsurance payments considers costs only for high-risk individuals and may reduce incentives for health insurance issuers to control costs. However, use of a reinsurance cap, as well as the requirement for health insurance issuer coinsurance rate above the attachment point and below the cap, may incentivize health insurance issuers to control costs. We invite comment regarding the best method of determining payments for the reinsurance program, which can relate to either our criteria for selecting eligible enrollees for payment or the method for calculating the payment amounts.

We propose in § 153.230(b)(2) that all payments to the general fund of the U.S. Treasury be made in a manner specified in the forthcoming annual Federal notice of benefits and payment parameters. We have also considered the frequency for which payments should be made to the U.S. Treasury. For example, the applicable reinsurance entities could remit payment on a monthly or quarterly basis commencing February 28, 2014, continuing through January 31, 2017 or until States have remitted the full amount of all payments. We invite comment as to the most appropriate frequency and method for applicable reinsurance entities to remit payment to the U.S. Treasury.

We propose in § 153.230(c) to allow some degree of State variation from the reinsurance parameters proposed by HHS. The Affordable Care Act contemplates the potential of modifications to the payment parameters through a statutory reference to “model regulation” as opposed to strict Federal regulation. Therefore, we propose in paragraph (c)(1) that the State may alter the attachment point, reinsurance cap, including elimination of the cap, and coinsurance rate. We propose in paragraph (c)(2) that States

must publish any modification to the reinsurance payment formula and parameters in a State notice as described in § 153.110 of this part. We propose in paragraph (c)(3) that the State must ensure that all proposed alterations to the reinsurance formulas proposed by HHS, including payments and contributions, result in the applicable reinsurance entity having sufficient contributions to meet all of its obligations for payments. Such alterations to reinsurance parameters do not require HHS approval.

We believe that a State may have many reasons to make adjustments to the HHS reinsurance payment formula. First, the State may determine to increase the reinsurance benefit above the level established by HHS. Second, the State may have additional unexpended funds from a prior contribution period and may seek to adjust the reinsurance formulas to disburse the unexpended funds. Third, the State may elect to pay the same amounts recommended by HHS, but may wish to make those payments either earlier or later in the medical cost experience. Finally, the State may decide to vary the annual amounts without varying the total across all three years.

5. Disbursement of Reinsurance Payments (§ 153.240)

In § 153.240, we propose parameters for the timing of reinsurance payments. In paragraph (a) of this section, we propose that States must ensure that the applicable reinsurance entity collects from health insurance issuers of reinsurance-eligible plans data required to calculate payments described in § 153.230, according to the data requirements and data collection frequency specified by the State in the notice described in § 153.110 or in the forthcoming annual Federal notice of benefit and payment parameters.

Since we are proposing that reinsurance eligibility and payments be based on the health insurance issuer medical costs, we believe that a standard method of collecting the required information should be a reasonable goal and easily achievable. Further, a standard method will enable multi-State health insurance issuers to submit data promptly without causing disruption for any single-State health insurance issuer.

In paragraph (b), we propose that the State must ensure that each applicable reinsurance entity makes payments that do not exceed contributions and makes payments to health insurance issuers of reinsurance-eligible plans according to § 153.230. We also propose in paragraph

(b)(2) to allow States to reduce payments on a pro rata basis to match the amount of contributions received by the State in a given reinsurance year. Any pro rata reductions made by the State must be made in a fair and equitable manner for all health insurance issuers in the individual market.

In paragraph (b)(3), we propose that the State must ensure that an applicable reinsurance entity makes payments as specified in § 153.410(b) to the issuer of a reinsurance-eligible plan after receiving a valid claim for payment. We invite comments as to the most appropriate timeframe that an applicable reinsurance entity should make payments for reinsurance claims submitted, particularly, since reinsurance claims may exceed contributions for a given month, but not total projected contributions for the entire year.

We have also considered deadlines by which a health insurance issuer could submit a claim for a given reinsurance benefit year. For example, Medicare Part D has a requirement for data submission within 6 months after the end of the coverage year, and we believe this is an appropriate standard. We seek comment as to whether the deadline for health insurance issuers for submitting reinsurance claims should be the same or different.

A standard deadline would allow for an orderly completion of the payment processes that depend upon reinsurance, specifically the risk corridors program and the medical loss ratio (MLR) reporting to support the rebate calculations in section 2718 of the PHS Act. Health insurance issuers must know the value of their reinsurance payments and must report that value to HHS under the risk corridor and MLR reporting provisions. Failure to establish a standard deadline could result in excessive delays in the completion of the rebate calculations under section 2718 of the PHS Act. Such delays would in turn delay receipt of rebate payments by the affected enrollees. We invite comment on the use of a standard deadline and the most appropriate deadline considering the interaction of the reinsurance program with risk corridor and the MLR process.

Finally, in paragraph (c), we propose that for each benefit year, the State maintains all records related to the reinsurance program for 10 years, consistent with requirements for record retention under the False Claims Act. We solicit comments on this record retention requirement.

5. Coordination With High-Risk Pools (§ 153.250)

In § 153.250, we codify the requirement under section 1341(d) of the Affordable Care Act that States shall eliminate or modify high risk pools to the extent necessary to carry out the reinsurance program. As stated in the introduction to this subpart, the reinsurance program required under the Affordable Care Act is designed to help mitigate adverse selection risks in the first three years of Exchange operation. In paragraph (a), we codify the above-referenced section. In paragraph (b), we propose to allow a State that continues its high risk pool to coordinate its high risk pool with its reinsurance program to the extent it conforms to the provisions of this subpart. We seek comment regarding whether a high risk pool that continues operation after January 1, 2014 should be considered an individual market plan eligible for reinsurance under this provision.

D. Subpart D—State Standards Related to the Risk Adjustment Program

In subpart D, we propose standards for States with respect to the risk adjustment program required under section 1343 of the Affordable Care Act. Parallel provisions on health plans are proposed in subpart G of this subpart. Section 1343 provides for a program of risk adjustment for all non-grandfathered plans in the individual and small group market both inside and outside of the Exchange. Under this provision, the Secretary, in consultation with the States, must establish criteria and methods to be used by States in determining the actuarial risk of plans within a State. States electing to operate an Exchange, or HHS on behalf of States not electing to operate an Exchange, will assess charges to plans that experience lower than average actuarial risk and use them to make payments to plans that have higher than average actuarial risk. Thus, the risk adjustment program is intended to reduce or eliminate premium differences between plans based solely on expectations of favorable or unfavorable risk selection or choices by higher risk enrollees in the individual and small group market. The risk adjustment program also serves to level the playing field inside and outside of the Exchange, reducing the potential for excessive premium growth or instability within the Exchange.

We received a variety of comments on the risk adjustment process in response to the RFC. Many commenters expressed strong opinions about the extent of Federal oversight in risk adjustment and the level of flexibility

afforded States for developing a risk adjustment model and how much to rely on current prospective models being used, for example, in Medicare Advantage or concurrent risk adjustment models being used.

We also received comments related to data standards and the role of the Federal government. Commenters noted difficulties in obtaining certain types of data accurately and expressed concerns about audit requirements. Commenters discussed upcoding problems, as well as issues of credibility of the underlying systems to support risk adjustment. Commenters also raised issues related to the transition both to the Exchanges and the risk adjustment program, with the primary issue being the timing of claims data availability in the early years of the program. Some States indicated that they are developing “all payer claims databases,” although not all of these databases are expected to be complete by 2014. However, even existing “all payer” databases will not contain any data from the currently uninsured individuals, who are expected to comprise a segment of new individual market enrollees.

Overall, we believe that States have discretion to make a number of decisions within the standards we propose herein.

1. Definitions (§ 153.300)

We propose several definitions that are specifically applicable to this subpart in § 153.300. First, we distinguish between risk adjustment models and risk adjustment methodologies. We define “risk adjustment model” as an actuarial tool used to predict health plan costs based on the relative actuarial risk of enrollees in risk adjustment covered plans, which we had previously defined as non-grandfathered plans in the individual and small group market. We define “risk adjustment methodology” as the specific set of procedures used to determine average actuarial risk.

A “Federally-certified risk adjustment methodology” is a risk adjustment methodology that has been developed and promulgated by HHS or has been certified by HHS. As explained further in § 153.330, States may use a modified methodology if it has been certified by HHS and deemed a Federally-certified risk adjustment methodology. An “alternate risk adjustment methodology” is a risk adjustment methodology proposed by one or more States for use in place of the Federally-certified risk adjustment methodology, not yet certified by HHS. Additionally, we define “risk pool” as the population

across which risk is distributed in risk adjustment.

2. Risk Adjustment Administration (§ 153.310)

Section 1343(a) of the Affordable Care Act establishes that States must assess risk adjustment charges and provide risk adjustment payments based on plan actuarial risk as compared to a State average. We interpret this provision to mean that risk pools must be aggregated at the State level, even if a State decides to utilize regional Exchanges. Furthermore, section 1343(c) indicates that risk adjustment applies to individual and small group market health insurance issuers of non-grandfathered plans within a State, both inside and outside of the Exchange. Accordingly, similar to our approach in reinsurance, if multiple States contract with a single entity to administer risk adjustment, risk may not be combined across State lines, but must be pooled at the individual State-level.

In this section, in paragraph (a)(1), we specify that any State electing to establish an Exchange is eligible to establish a risk adjustment program. Pursuant to section 1321(a)(1)(D) of the Affordable Care Act, we propose in paragraph (a)(2) that for States that do not operate an Exchange, HHS will establish a risk adjustment program. We also clarify in (a)(3) that HHS will administer all of the risk adjustment functions for any State that elects to establish an Exchange but does not elect to administer risk adjustment. In paragraph (b), we clarify that the State may elect to have an entity other than the Exchange perform the risk adjustment functions of this subpart provided that the selected entity meets the requirements for eligibility to serve as the Exchange proposed in § 155.110 of the notice of proposed rulemaking entitled, “Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans.”

In paragraph (c), we propose timeframes for completion of the risk adjustment process. We propose that all payment calculations must commence with the 2014 benefit year. The Affordable Care Act does not explicitly set forth a timeframe by which risk adjustment programs must start. However, we believe risk adjustment must be coordinated with reinsurance and risk corridors to help stabilize the individual and small group markets and ensure the viability of the Exchanges, which begin in 2014. Timely completion of the risk adjustment process is important because risk adjustments affect calculations of both risk corridors and the rebates specified

under section 2718 of the PHS Act. By law, HHS will be performing the risk corridors calculations for all qualified health plans (QHP) in all States. Therefore, we seek comment on the appropriate deadline by which risk adjustment must be completed. For example, HHS may require that States complete risk adjustment activities by June 30 of the year following the benefit year. This timing assumes at least a three-month lag from items and services furnished in a benefit year and the end of the data collection period. This approach is similar to the Medicare Advantage (Part C) risk adjustment data submission, in which the annual deadline for risk adjustment data submission is 2-months after the end of the 12-month benefit period, but may, at CMS’s discretion, include a 6-month lag time.

Since risk adjustment is designed as a budget neutral activity, States would likely need to receive remittances from issuers of low actuarial risk plans before making payments to issuers of high actuarial risk plans. We seek comment on an appropriate timeframe for State commencement of payments.

To ensure the each State’s risk adjustment program is functioning properly, we believe that States should provide HHS with a summary report of risk adjustment activities for each benefit year in the year following the calendar year covered in the report. The summary report should include the average actuarial risk score for each plan, corresponding charges or payments, and any additional information HHS deems necessary to support risk adjustment methodology determinations. We seek comment on the requirements for such reports, including data elements and timing.

3. Federally-Certified Risk Adjustment Methodology (§ 153.320)

Section 1343(b) of the Affordable Care Act requires HHS to establish criteria and methods for risk adjustment in coordination with the States. We interpret this provision to mean that HHS will establish a baseline methodology to be used by a State, or HHS on behalf of the State, in determining average actuarial risk. To fulfill the terms of that basic requirement, we propose in paragraph (a)(1) a Federally-certified risk adjustment methodology that will be developed and authorized by HHS. Section 1343 indicates that the Secretary may utilize criteria and methods similar to the criteria and methods utilized under part C or D of title XVIII of the Social Security Act. We seek to minimize issuer burden and will

leverage existing processes of part C and D wherever appropriate while recognizing the differences in market demographics in determining methodologies.

We considered proposing a requirement that all States utilize a Federally-certified risk adjustment methodology that was developed and promulgated by HHS. However, we recognize that States may have alternative methods that can achieve similar results. We also know that some States have already implemented risk adjustment models for programs such as Medicaid. We believe that the terms “methods and criteria” in the Affordable Care Act can be interpreted to allow certain levels of State variation provided that States meet basic Federal standards. Therefore, we propose in paragraph (a)(2) that a State-submitted alternative risk adjustment methodology may become a Federally-certified risk adjustment methodology through HHS certification. States that would like to use other methodologies should view the Federally-certified risk adjustment methodology as a comparative standard for their alternate risk adjustment methodologies. A State’s alternate risk adjustment methodology should offer similar or better performance in that State than the Federally-certified risk adjustment methodology as determined based on the criteria set forth in § 153.330(a)(2). After HHS approves a State alternative risk adjustment methodology, that methodology is considered a Federally-certified risk adjustment methodology.

We propose in paragraph (b) of this section that a State that is operating a risk adjustment program must use one of the Federally-certified risk adjustment methodologies that HHS will publish in a forthcoming annual Federal notice of benefit and payment parameters or that has been published by the State in that State’s annual notice, as described in § 153.110(b). These notices will include a full description of the risk adjustment model, including but not limited to: demographic factors, diagnostic factors, and utilization factors if any; the qualifying criteria for establishing that an individual is eligible for a specific factor; the weights assigned to each factor; the data required to support the model; and information regarding the deadlines for data submission and the schedule for risk adjustment factor determination. We seek comments on other information that should be included in this notice.

In paragraph (b)(2), we propose that the risk adjustment methodology will also describe any adjustments made to

the risk adjustment model weights when calculating average actuarial risk, including premium rating variation. Under section 2701 of the PHS Act as amended by the Affordable Care Act, issuers may vary rates within defined maximum ranges based on age and tobacco use. Plans may also vary rates by geographic rating area and family size. An approach is needed to account for this allowed variation in rating so that risk adjustment does not adjust for the actuarial risk that issuers have been allowed to incorporate into their premium rates.

We invite comments on possible approaches to achieving the stated policy goals. In particular, we request comments on the implications of approaches for market efficiency, potential incentives created in how issuers set rates, and how approaches address allowed rating variation for age, family size, and tobacco use. We request comments on other approaches to determining average actuarial risk and whether links exist between potential actuarial risk methodology and potential payments and charges methodology as described in § 153.345. We also request comments on the extent of State flexibility that should be allowed in adopting an approach to determine average actuarial risk.

In paragraph (c), we propose that HHS will specify in a forthcoming annual Federal notice of benefit and payment parameters the Federally-certified risk adjustment methodology that will apply when the Federal government operates the risk adjustment program in States that do not elect to operate an Exchange, or that elect to operate an Exchange but not a risk adjustment program.

To assist States in assessing a potential alternate risk adjustment methodology, HHS will publish the basic standards any alternate risk adjustment methodology must meet in the forthcoming annual Federal notice of benefit and payment parameters that contains the details of one or more Federally-certified risk adjustment methodologies. These standards will likely include the minimum number or types of factors that must be included and the statistical metrics the models will be expected to achieve. Prior to that formal publication of standards, and as part of the development of the Federally-certified methodologies and associated standards for alternate risk adjustment methodologies, HHS will consult with States regarding its development and the minimum standards for alternate risk adjustment methodologies. States may use information from the consultation process to either develop their own

methodologies or decide to utilize the Federally-certified risk adjustment methodology.

The statute is not specific with respect to the method by which States are expected to determine the precise value of payments and charges. We believe the payments and charges methodology should mitigate the financial impact of adverse selection on risk adjustment covered plans, while limiting overall issuer uncertainty. We have identified two methods that may achieve those goals—multiplying plan average actuarial risk by the State average normalized premiums and multiplying plan average actuarial risk by the specific premiums collected for each plan. To determine the precise value of payments and charges using State average normalized premiums, plan average premiums are first normalized to the actuarial value of their benefits by dividing each plan's premiums by the plan's actuarial value. This step is necessary because plan premiums reflect differences in the benefits and administration, including actuarial value.

Next, States would use these normalized average premiums as the basis for the State normalized average premiums, weighted by enrollee months, for all plans in a specific risk pool. The State normalized average premium represents the premium that will be used in the charges and payments calculation. Next, the amount by which a plan's average actuarial risk deviates from the state average actuarial risk is calculated. This deviation in actuarial risk is multiplied by the State normalized average premium, the plan's enrollee months, and the plan's actuarial value.

The alternative methodology uses plan-specific premiums as the basis for calculating the gross plan charges and gross plan payments, assuming that health plan premiums reflect State average actuarial risk and the expectation that risk adjustment accounts for favorable or adverse selection. Under this methodology, the deviation in actuarial risk is multiplied by the aggregated plan premiums to determine the gross plan charges and total plan payments that should be collected from or disbursed to health plans through risk adjustment. We request comment on the validity of these assumptions, including the two methods described, and any alternative methods that could be used to calculate payments and charges that would reduce uncertainty for plans. Finally, we request comment on any intentional and unintentional consequences from the use of either methodology.

Due to premium variance, we expect inequalities between payments and charges, which could result in aggregate surpluses or deficits if a simple collection of gross plan charges and disbursement of gross plan payments is implemented. We have identified at least three methods for adjusting gross calculations when gross plan payments are greater than gross plan charges: decrease plan payments on a prorated basis to equal plan charges; increase plan charges on a prorated basis to equal plan payments; or split the shortfall between high-risk and low-risk plans and pro-rating in both directions. We also identified two methods for when gross plan charges are greater than the sum of gross plan payments: reducing gross plan charges on a prorated basis such that the net plan charges are sufficient to cover total plan payments; and putting excess plan charges in a reserve account that would provide a margin of error to ensure that all necessary payments can be covered by charges.

We request comment on these methodologies and whether there are alternative methodologies that might be used, including their strengths, limitations, intentional or unintentional consequences and any links that exist between the payments and charges methodology and the actuarial risk methodology.

4. State Alternate Risk Adjustment Methodologies (§ 153.330)

We interpret the statutory provision regarding the Secretary's establishment of criteria and methods for risk adjustment under section 1343(b) to require substantive Federal oversight of the risk adjustment process. Accordingly, while we propose to allow States to utilize alternate risk adjustment methodologies, we also propose in paragraph (a) of § 153.330 that States taking advantage of this flexibility must submit their proposed alternate risk adjustment methodologies for HHS review and certification.

As outlined in paragraph (a)(1), the State request must include certain information about the State's proposed risk adjustment methodology. As noted in paragraph (a)(1)(i), any request must identify the risk pools to which the methodology will apply. Paragraph (a)(1)(ii) also indicates that the proposed risk adjustment methodology must include a full description of the risk adjustment model, consisting of: factors employed in the model; weights associated with each factor; the data collection method; the schedule for data collection and risk adjustment factor calculation; and the calibration

methodology. HHS will also review the relevant statistical performance metrics of the model, such as R-squared or predictive ratios, which indicates the predictive power of the model. If the State wants to use a Federally-certified risk adjustment model but with State-specific weights, retaining all other characteristics of that model, the State would only need to provide the State-specific weights and a description of the calibration methodology, as well as an attestation that all other model attributes will be implemented consistently with the Federally-certified methodology.

As with the Federally-certified risk adjustment methodology, the schedule for collection and submission of data and calculation of factors are critical success elements for any State-proposed alternate risk adjustment methodology. If a State proposes to deviate from the Federally-certified methodology with respect to these elements, HHS expects to evaluate a State proposed alternate risk adjustment methodology to ensure that the proposed approach will meet HHS goals for the risk adjustment program.

We propose in paragraph (a)(1)(iii) that States must describe any adjustments they propose to make to the risk adjustment model weights when determining average actuarial risk. We expect that States will also incorporate a rating factor into the proposed risk adjustment methodology.

In paragraph (a)(2), we propose that all requests be evaluated against criteria that HHS establishes for risk adjustment methodologies. Alternate risk adjustment methodologies should be evaluated based on the extent to which the methodology: accurately explains cost variation within a given population; chooses risk factors that are clinically meaningful to providers; encourages favorable behavior and discourages unfavorable behavior; uses data that is complete, high in quality and available in a timely fashion; provides stable risk scores over time and across plans; and minimizes administrative burden. This criteria is based on the principles that guided the creation of the hierarchical condition categories (HCC) model used in Medicare's risk adjustment program, as well as criteria described by AcademyHealth in its 2004 risk assessment paper (see <http://www.hcfo.org/pdf/riskadjustment.pdf>) and criteria described by the American Academy of Actuaries in its 2010 risk adjustment paper (see http://www.actuary.org/pdf/health/Risk_Adjustment_Issue_Brief_Final_5-26-10.pdf).

To ensure the stability and predictability of payments, we contemplated proposing that requests must be submitted to HHS no later than early November in the calendar year two years before the effective date. HHS recognizes that health insurance issuers must have detailed information about risk adjustment prior to setting rates for any benefit year because the risk adjustment methodology will affect both the total value of premiums received after accounting for payments and charges, as well as health plan administrative costs. Therefore, under this scenario, HHS would evaluate the proposed alternate risk adjustment methodologies submitted within the required timeframes and notify States within 60 days, at the time of the publication of the forthcoming annual Federal notice of benefits and payment parameters whether such methodologies have been certified. In this scenario, if HHS approves an alternate risk adjustment methodology, such a methodology would be considered a Federally-certified risk adjustment methodology and could be implemented in the State that proposed the methodology as well as any other State that elects to implement an Exchange.

We recognize that the above contemplated timeframe requires States to submit requests for alternate methodology certification only 30 days after the advance annual Federal notice of benefit and payment parameters and prior to publication of the final annual Federal notice of benefit and payment parameters. However, we believe any advantage in allowing States additional time would be offset by a lesser ability to leverage State alternative models and inadequate time for issuers to reflect methodology decisions in setting rates. We seek comments regarding our contemplated timeline and potential alternatives for States to request submissions for alternate risk adjustment methodology.

In paragraph (b), we propose that States that operate a risk adjustment program must renew HHS certification of alternate risk adjustment methodologies whenever changes occur, including at the time of recalibration, which the State must identify when initially requesting certification for the alternate risk adjustment model. The proposed requirements for describing an update to a certified risk adjustment model are the same as those for the initial model. The State must describe any change to the model between the last certified version and the recalibrated version. For example, if the only change was to the schedule for data submission, then the State would need

to provide that update when seeking certification. Additionally, we propose that States send a notification if they intend to use the certified alternate risk adjustment model with no changes to any of the basic parameters. We expect to use this certification process to ensure that States make updates to their alternate risk adjustment methodologies at reasonable intervals.

5. Data Collection Under Risk Adjustment (§ 153.340)

As described above, a robust risk adjustment process requires data to support the determination of an individual's risk score and the corresponding plan and State averages. In paragraph (a) we propose that a State, or HHS on behalf of the State, is responsible for collecting the data for use in determining individual risk scores.

HHS considered three possibilities for data collection: (1) A centralized approach in which issuers submit raw claims data sets to HHS; (2) an intermediate State-level approach in which issuers submit raw claims data sets to the State government, or the entity responsible for administering the risk adjustment process at the State level; and (3) a distributed approach in which each issuer must reformat its own data to map correctly to the risk assessment database and then pass on self-determined individual risk scores and plan averages to the entity responsible for assessing risk adjustment charges and payments.

A fully distributed approach would leverage existing infrastructures established to support Exchanges. A distributed approach also keeps individual-level data with the issuers, eliminating privacy risks related to transmission. However, there is reason to be concerned that some issuers would make errors in calculating individual risk scores and plan averages. Furthermore, we believe that the complicated nature of a distributed risk adjustment model may prove challenging for some issuers, especially smaller issuers and would thus require significant involvement by the State, or HHS on behalf of the State. In addition, this approach would require issuers to be able to respond to multiple queries to support other functions, such as data to recalibrate the Federally-certified risk adjustment model, reconciling cost-sharing reductions payments, verifying risk corridor submissions, or auditing cost-sharing reductions or reinsurance payments. We seek comment on use of this data for auditing purposes. We believe the proposed intermediate approach would result in the most

complete, actuarially sound risk adjustment methodology and provides support for other functions that also require encounter level data, while maintaining State flexibility. We recognize this approach may raise concerns related to consumer privacy and standard submission formats. Accordingly, we propose national standards to address each of these issues. We seek comment on the proposed approach, as well as comments on the potential advantages and disadvantages of the alternative approaches.

We propose in paragraph (b) that States, or HHS on behalf of the State, use standard HIPAA transaction standards for data collection. We note that HIPAA provides measures to achieve cost savings through administrative simplification. As described in Health Insurance Reform: Standards for Electronic Transactions, “The purpose of this part is to improve the efficiency and effectiveness of the health care system, by encouraging the development of a health information system through the establishment of standards and requirements to enable the electronic exchange of certain health information.” (65 FR 50312) “We estimated that the impact of the proposed rules would result in net savings to health plans and health care providers of \$1.5 billion during the first 5 years; use of the standards would continue to save the industry money.” (65 FR 50345)

Although the transaction standards promulgated under the HIPAA administrative simplification provisions do not specifically apply to data collections under section 1343 of the Affordable Care Act, we propose in paragraph (b)(1) and (b)(2) to require States to utilize two specific HIPAA transaction standards for risk adjustment data collection: the ASC X12N 837 Health Care Claim transaction standard for any claims-related data including encounters; and the ASC X12N 834 Enrollment and Maintenance transaction standard for any enrollment or demographic data. In this paragraph, we also allow the use of the NCPDP claims transaction standard for prescription drug, claims and encounter data. We solicit comment on whether we should rely on the existing HIPAA and NCPDP standards or engage stakeholders to develop a new set of national standards for use in risk adjustment, for example, leveraging the claims standards developed with stakeholder input by the Agency for Healthcare Research and Quality. In paragraph (b)(3), to address consumer privacy concerns, we propose that

States must utilize specific privacy standards in its data collection risk adjustment procedures. We solicit comments on whether submission of issuers’ rate setting rules should be required.

We believe that standardizing data collection will allow State flexibility in modeling while not unreasonably increasing issuer burden for multi-State issuers. Under the proposed approach, States may limit the minimum information required to specific data elements, provided that the information submitted represents standard code sets and values on the HIPAA transactions. We also propose that States must accept any valid transaction submitted by an issuer provided that the transaction contains the minimum data required by the State. In other words, the State may not reject a HIPAA compliant transaction strictly on the basis that it contains more data than the State requires.

In paragraph (c), we propose that States with existing all payer claims databases may request an exception from the minimum standards for data collection. We are contemplating syncing the timing of the request submission with requirements for alternate risk adjustment models. Similarly, we are contemplating that HHS will notify States as to exception status concurrently with the publication of the forthcoming annual Federal notice of benefit and payment parameters. We seek comment on these contemplated timelines. We propose that requests for exception from minimum data collection standards must include technical specifications, as well as proposed modifications to support risk adjustment and other claims-related activities.

Seeking data submission efficiencies, in paragraph (d), we propose that the State must make certain claims and encounter data collected under risk adjustment available to support other activities including: recalibrating Federally-certified risk adjustment models; verifying of risk corridor submissions; and verifying and auditing reinsurance claims. We also anticipate encounter and claims data collected for risk adjustment may be required to support other Exchange-related functions such as cost-sharing requirements and quality reporting. We solicit comment on these alternative uses of risk adjustment data.

6. Risk Adjustment Data Validation Standards (§ 153.350)

In § 153.350, we propose that States have a reliable data validation process, which is essential to the establishment

of a credible risk adjustment program. The credibility of risk adjustment is important to establishing the issuer confidence required for risk adjustment to have a positive impact on premium reduction. We propose that States, and HHS, when HHS performs the risk adjustment function on behalf of States, will perform some form of validation regarding the data submitted. We also believe that issuers will want such data validations to be performed since the effect of risk adjustment will be a transfer of premiums between issuers. One of the critical aspects of risk adjustment under the Affordable Care Act is that it represents a relative actuarial risk calculation. Therefore, for any data validation to have the capacity to extrapolate to adjust specific charges and payments, the validation must cover a sufficient number of plans to allow an equitable adjustment to all health plan risk adjustment factors.

In paragraph (a) of § 153.350, we propose that the State, or HHS on behalf of the State, validate a statistically valid sample of all issuers that submit data for risk adjustment every year. We also propose an appropriate use of the information derived from the data validation. For a validation to work under this form of risk adjustment, States must be able to adjust the average actuarial risk of each plan to account for the inaccuracies noted during the data validation process. As such, we propose in paragraph (b) that the State, or HHS on behalf of the State, may adjust the average actuarial risk for each plan based on the error rate found in the validation. In paragraph (c), we further propose that the State, or HHS on behalf of the State, adjust payments and charges based on the changes to average actuarial risk. We seek comment on appropriate timeframes for completion of the data validation process. For example, we may propose a three-year deadline for completing data validation, so as to ensure some finality in the risk adjustment process. Finally, in paragraph (d), we propose that States, or HHS on behalf of the State, must provide an appeals process for issuers. We believe that there may be alternative methods that allow sufficient coverage to estimate the validation impact on all plans. We solicit comments on this data validation provision and any alternatives that may be able to satisfy the need to provide assurance that the charges and payments truly represent relative plan risk.

E. Subpart E—Health Insurance Issuer Standards Related to the Transitional Reinsurance Program

In this subpart, we propose requirements for health insurance issuers that complement the requirements for the transitional reinsurance program fully described in the preamble for subpart C. Since the reinsurance program is operated at the State level, many elements related to the purpose, methods, and operation of this program will vary across States and are discussed in greater detail in the preamble for subpart C. In this subpart, we discuss the elements of the program that relate specifically to the requirements for health insurance issuers and third party administrators on behalf of self-insured group health plans.

1. Reinsurance Contribution Funds (§ 153.400)

In § 153.400, we codify section 1341 of the Affordable Care Act, which requires that the reinsurance program be funded by contribution funds from contributing entities. In paragraph (a), we propose that all contributing entities make contributions, in a frequency and manner to be determined by the State or HHS, to the applicable reinsurance entity in the State. For example, contributing entities may be required to submit contributions on a monthly or quarterly basis starting in January 2014. We invite comments on the appropriate frequency and manner in which payments should be made by contributing entities.

In paragraph (b), we propose that if any State establishes multiple applicable reinsurance entities, the contributing entities must contribute an appropriate payment to each applicable reinsurance entity according to the formula established by the State. We propose in paragraph (c) that contributing entities will be required to provide the data necessary for the applicable reinsurance entity to calculate the amounts due from each contributing entity. The type of data required will depend on the contributing entity. For contributing entities in the individual and fully insured market, we propose that data on enrollment and premiums be required. For contributing entities in the self-insured market, data on covered lives and total medical expenses would be required. This data, for example, could be collected on a monthly or quarterly basis beginning January 2014. We invite comments on the appropriate timing to collect data submissions from contributing entities. We also seek

comment on whether there are existing sources of this data that can be drawn upon.

2. Requests for Reinsurance Payment (§ 153.410)

The reinsurance program as proposed in subpart C will make payments to reinsurance-eligible plan issuers. In paragraph (a), we propose that reinsurance-eligible plan issuers must submit a request for reinsurance payment to the applicable reinsurance entity. We propose in paragraph (b) that this request is made according to the method that will be specified in the forthcoming annual Federal notice of benefit and payment parameters. We invite comments regarding methods for requesting payments, and the frequency and deadline for such requests. We also invite comments on how to manage late claims from reinsurance eligible plan issuers.

F. Subpart F—Health Insurance Issuer Standards Related to the Temporary Risk Corridors Program

In this subpart, we propose requirements on health insurance issuers related to the temporary risk corridor program. Section 1342 of the Affordable Care Act establishes a program of risk corridors for the first three years of Exchange operation. In addition to risk adjustment and reinsurance, the risk corridor program limits adverse selection and stabilizes markets as changes are implemented starting in 2014. Risk corridors create a mechanism for sharing risk for allowable costs between the Federal government and QHP issuers. QHP issuers of QHPs with costs that are less than 97 percent of the QHP's costs projections will remit charges for a percentage of those savings to HHS, while QHP issuers of QHP's with costs greater than 103 percent of cost projections will receive payments from HHS to offset a percentage of those losses. The Affordable Care Act directs HHS to administer the risk corridors program.

1. Definitions (§ 153.500)

In § 153.500, we propose a number of definitions for the purpose of administering risk corridors. First, we define “allowable costs” as an amount equal to the total medical costs, which include clinical costs, excluding allowable administrative costs, paid by the QHP issuer in providing benefits covered by the QHP. We define “allowable administrative costs” as total non-medical costs defined in § 158.160(b), including costs for the administration and operation of the

health insurance issuer. We invite comment on whether we should consider costs for activities that improve health care quality as described in § 158.150 and § 158.151 for allowable costs to be consistent with the medical loss ratio (MLR) policy in the Affordable Care Act. We also invite comment on whether we should limit administrative costs to 20 percent consistent with MLR. If the allowable administrative costs differ from calculations for the MLR rebate, issuers may be incentivized to use risk corridors payments to pay for their MLR rebates.

We define “charge” as the flow of funds from QHP issuers to HHS. We define “direct and indirect remuneration” in the same way it was defined in the risk corridor provision implemented as a result of Medicare Prescription Drug, Improvement, and Modernization Act of 2003. It means prescription drug price concessions or similar benefits from manufacturers, pharmacies or similar entities obtained by a QHP issuer or an intermediary contracting organization with which a QHP issuer has contracted. Such concessions include but are not limited to: discounts, charge backs, rebates, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, and grants. We further specify that the term applies regardless of whether the intermediary contracting organization retains all or a portion of the direct and indirect remuneration or passes the entire direct and indirect remuneration to the QHP issuer and regardless of the terms of the contract between the issuer and the intermediary contracting organization.

We define “payment” as the flow of funds from HHS to QHP issuers. We define “qualified health plan” consistent with the term proposed in the general definitions section of the Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans, published in this issue of the **Federal Register**. We define “risk corridor” as any payment adjustment system based on the ratio of allowable costs of a plan to the plan's target amount. Finally, we define “target amount” to be the amount equal to the total premiums incurred by the QHP, including any premium tax credits or financial assistance from any governmental program, reduced by the allowable administrative costs of the health insurance issuer.

2. Risk Corridor Establishment and Payment Methodology (§ 153.510)

The risk corridor provision in 1342 of the Affordable Care Act directs HHS to

establish and administer a program of risk corridors. In § 153.510, HHS proposes to establish risk corridors by specifying risk percentages above and below the target amount. In paragraph (a), we propose to require a QHP issuer to adhere to the requirements set by HHS for the establishment and administration of a risk corridor program for calendar years 2014 through 2016. We will issue guidance in the forthcoming annual Federal notice of benefits and payment parameters for QHPs regarding reporting and the administration of payments and charges similar to part 158. Risk corridors guidance will be plan specific and not issuer specific as indicated in part 158. We interpret the risk corridor provision to apply to all QHPs offered in the Exchange.

In § 153.510, we also establish the payment methodology for the risk corridor program, using the thresholds and risks-sharing levels specified in statute. The risk corridor thresholds are applied when a QHP's allowable costs reach plus or minus three percent of the target amount. Accordingly, HHS will pay a QHP issuer whose QHP incurred allowable costs for a benefit year that are greater than 103 percent of its target amount. Conversely, a QHP issuer must pay HHS if its QHP's allowable costs for a benefit year are less than 97 percent of its target amount. A QHP issuer whose QHP's allowable costs for a benefit year are greater than 97 percent but less than 103 percent of the target amount will neither make nor receive payments for risk corridors. For example, a QHP issuer with a QHP that has a target amount of \$10 million will not receive or pay a risk corridor payment if its allowable charges range between \$9.7 million and \$10.3 million.

Paragraph (b) of this section describes the method for determining payment amounts to QHP issuers as well as the timing of those payments. For a QHP with allowable costs in excess of 103 percent but not more than 108 percent of the target amount, HHS will pay the QHP issuer 50 percent of the amount in excess of 103 percent of the target amount. For example, a QHP has a target amount of \$10 million, and the QHP has allowable costs of \$10.5 million, or 105 percent of the target amount. Since 103 percent of the target amount would equal \$10.3 million, the amount of allowable costs that exceed 103 percent of the target amount is \$200,000. Therefore, HHS would pay 50 percent of that amount, or \$100,000 to the QHP issuer.

For QHPs that have allowable costs that exceed 108 percent of the target amount, the Affordable Care Act directs

HHS to pay the QHP issuer an amount equal to 2.5 percent of the target amount plus 80 percent of the amount in excess of 108 percent of the target amount. For example, a QHP has a target amount of \$10 million. The QHP has allowable costs of \$11.5 million, or 115 percent of the target amount. Since 108 percent of the target amount would be \$10.8 million, the amount of allowable costs that exceed 108 percent of the target amount is \$700,000. Therefore, HHS pays 2.5 percent of the target amount, or \$250,000, plus 80 percent of \$700,000, or \$560,000, for a total of \$810,000.

Paragraph (c) describes the circumstances under which QHP issuers will remit charges to HHS, as well as the means by which HHS will determine those charge amounts. We propose that QHP issuers will begin to remit charges to HHS for the first dollar of allowable charges less than 97 percent of the target amount. For a QHP that has allowable costs that are less than 97 percent of the target amount but greater than 92 percent of the target amount, HHS will charge the QHP issuer an amount equal to 50 percent of the difference between 97 percent of the target amount and the actual value of allowable costs. For example, a QHP has a target amount of \$10 million. The amount of allowable costs for this QHP is \$9.3 million, or 93 percent of the target amount. The difference between 97 percent of the target amount, or \$9.7 million, and the actual allowable charges is \$400,000. The QHP issuer must pay HHS 50 percent of that amount, or \$200,000.

For QHPs with allowable costs below 92 percent of the target amount, the QHP issuer will remit charges to HHS an amount equal to 2.5 percent of the target amount plus 80 percent of the difference between 92 percent of the target amount and the actual value of allowable costs. For that same QHP with a \$10 million target amount, assume the allowable charges are now \$8.8 million, or 88 percent of the target amount. Ninety-two percent of the target amount would be \$9.2 million, and the difference between 92 percent of the target amount and the actual value of allowed costs is \$400,000. The QHP issuer will remit charges to HHS an amount equal to 2.5 percent of the target amount, or \$250,000, plus 80 percent of \$400,000, or \$320,000, for a total of \$570,000.

While we are not proposing deadlines at this time, HHS has considered timeframes for QHP issuers to remit charges to HHS. For example, a QHP issuer required to make a risk corridor payment may be required to remit charges within 30 days of receiving notice from HHS. Similarly, HHS would

make payments to QHP issuers that are owed risk corridor amounts from HHS within a 30-day period after HHS determines that a payment should be made to the QHP issuer. We believe that QHP issuers who are owed these amounts will want prompt payment, and also believe that the payment deadlines should be the same for HHS and QHP issuers. We invite comments as to the appropriate frequency QHP issuers should remit charges to HHS.

3. Risk Corridor Standards for QHP Issuers (§ 153.520)

To support the risk corridor program calculations, we propose in § 153.520 that all QHP issuers submit data needed to determine actual performance relative to their target amounts. The data would be collected in standard formats specified by HHS. We propose in paragraph § 153.520(a) that QHP issuers must submit data related to actual premium amounts collected by QHP issuers, including premium amounts paid by parties other than the enrollee in a QHP and specifically advance premium tax credits paid by the government. We also regard risk adjustment and reinsurance as an after-the-fact adjustment to premiums for purposes of determining risk corridor amounts. Medicare Advantage, Medicare Prescription Drug Benefit Program and Medicaid managed care risk adjustment programs similarly result in adjustments to total payments to plans. However, in these programs, the adjustment occurs concurrently with payments because they are made by the government (excluding monthly premium payments made by beneficiaries). For reinsurance, we anticipate health insurance issuers will reduce their premiums by an amount that would approximate the average reinsurance that they expect to receive, filling in the gap between the premium charged and the health insurance issuer's revenue needs.

Therefore, in paragraph (a)(1), we propose that the reported premium amounts must be increased by the amounts paid to the QHP issuer for risk adjustment and reinsurance. Similarly, we propose in paragraph (a)(2) that the reported premium amounts be reduced for any risk adjustment charges the QHP issuer pays on behalf of the plan, reinsurance contributions that the QHP issuer makes on behalf of the plan, and Exchange user fees that the QHP issuer pays on behalf of the plan. We invite comment on the treatment of reinsurance and risk adjustment as after-the-fact adjustments to premium for purposes of determining risk corridor amounts.

In paragraph (a)(3), we propose rules for accounting for reinsurance claims submitted on a date to be determined by HHS for a given reinsurance benefit year. Specifically, we propose that QHP issuers attribute reinsurance payments to risk corridors based on the date on which the valid reinsurance claim was submitted. For example, if the QHP issuer submits a claim on or before the deadline for a benefit year, that QHP issuer would attribute the claim payment to risk corridor calculation for the benefit year in which the costs were accrued. Conversely, if the QHP issuer submits a claim after the deadline for a benefit year, that health QHP would attribute the claim payment to risk corridor calculation for the following benefit year. We invite comments on how the risk corridor calculations would interact with the MLR process.

We propose in paragraph (b) that QHP issuers must submit allowable cost data to calculate the risk corridors in a format specified by HHS. We propose that allowable costs must be reduced for any direct or indirect remuneration received in paragraph (b)(1). In paragraph (b)(2), we also propose that the allowable costs must be reduced by the amount of any cost-sharing reductions received from HHS. We invite comment on an appropriate deadline for QHP issuers to complete submission of all risk corridor data especially since this would interact with the MLR process. We also invite comment as to how HHS could determine allowable costs for QHP issuers in calculating risk corridors, if a QHP issuer fails to comply with the reporting provisions in paragraph (b).

HHS seeks to limit the reporting requirements on issuers in submitting this information and would like to prevent duplicative data collection requirements on issuers for the temporary risk corridors program. As such, we seek comment on how we can utilize data from 2718 to meet the data submission requirements for risk corridors.

G. Subpart G—Health Insurance Issuer Standards Related to the Risk Adjustment Program

Section 1343 of the Affordable Care Act provides for a program of risk adjustment for all non-grandfathered plans in the individual and small group market both inside and outside of the Exchange. We noted in the introduction to subpart D of this part that the risk adjustment program described in section 1343 employs a model to determine comparative actuarial risk of plans within a State. That overview can serve as a reference for this subpart as

well. We note that subpart D of this part describes some of the comments to the RFC related to risk adjustment and our approach to the process, methodology, and model for implementing the risk adjustment program under section 1343 of the Affordable Care Act. This subpart proposes the health issuer standards that are necessary to carry out risk adjustment as described in subpart D.

1. Definitions (§ 153.600)

In § 153.600, we define “risk adjustment data” to mean any data that is used in a risk adjustment model.

2. Risk Adjustment Issuer Requirements (§ 153.610)

We propose in paragraph (a) of § 153.610 that all issuers of risk adjustment covered plans submit risk adjustment data according to the timetable and format prescribed by the State, or HHS on behalf of the State. Since there will be some variety in approaches to risk adjustment, both across States as well as over time, we expect that these data will include demographic data; encounter data for items and services provided in conjunction with a risk adjustment covered plan; and prescription drug utilization data. We seek comment on whether other categories of data such as methods for setting rates should be required in support of risk adjustment.

We considered proposing the following timelines for risk adjustment data submission: claims and encounter data must be submitted every 30 days and no later than the end of 180 days following the date of service; enrollment and demographic information must be submitted by the end of the month following enrollment; issuer rate-setting rules must be submitted by the end of the month in which they become effective; prescription drug utilization data must be submitted every 30 days, and no later than the end of 90 days following date of service. We recognize that these timeframes may limit the ability of States to collect a full calendar year of data on risk adjustment. However, given the traditional lag of claims submissions, we did not think a shortened timeframe was feasible. Additionally, monthly data submission would address anticipated issuer difficulty in transmitting large volumes of data at the end of the data collection period. We solicit comments on these and alternative data submission timeframes.

We interpret the Affordable Care Act to require participation in the risk adjustment program for all risk adjustment covered plans. We believe that any voluntary participation

provisions would result in non-participation by the lowest actuarial risk plans, which in turn would defeat the purpose of the provision. Additionally, in paragraph (b), we propose to permit contractual arrangements between issuers and providers, suppliers, physicians, and other practitioners to ensure that issuers receive the necessary risk adjustment data.

We discuss the calculation of payments and charges extensively describing the methods by which we propose States could perform that function. After the State, or HHS on behalf of the State, has calculated all payments and charges for all risk adjustment covered plans, the State, or HHS on behalf of the State, will determine a net value of payments and charges for each risk adjustment covered plan issuer. In paragraph (c), we propose that risk adjustment covered plan issuers who owe a net balance of risk adjustment charges will be assessed those net charges upon completion of the risk adjustment process. We interpret the Affordable Care Act to mean that the payment of charges is mandatory for issuers who have a net charges payable balance based on the difference between the charges calculated for their low actuarial risk plans and the payments calculated for their high actuarial risk plans.

Additionally, we considered proposing that issuers be given a 30 day timeframe in which to pay all these net charges to the State that assessed those charges, or to HHS on behalf of the State. We solicit comment on this and alternative timelines. Since risk adjustment pools individual and small group market risk on a State level, payments and charges will be netted out at the State level, and issuers in multiple States must settle with each State individually.

3. Compliance With Risk Adjustment Standards (§ 153.620)

The credibility of risk adjustment is important to making health insurance premiums in Exchanges stable. Issuers should have confidence that, if they experience adverse selection, their actuarial risk as calculated under this risk adjustment program will reflect the degree to which they have experienced adverse selection and that, if competing plans have low actuarial risk, that those plans cannot inflate their risk score. Therefore, a data validation program is necessary. Consistent with proposed § 153.350, we propose in § 153.620 that risk adjustment covered plan issuers provide the required documentation in response to any HHS or State validation to substantiate the risk adjustment data that they have submitted. We believe

that all risk adjustment covered plans should support such an audit to ensure the integrity of charges they may be required to pay, as well as to ensure that any payments they receive are sufficient to cover additional medical costs incurred due to adverse selection. In paragraph (b), we propose that risk adjustment covered plan issuers must retain the required documentation to substantiate the risk adjustment data that they have submitted for a period of ten years.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Below is a summary of the proposed information collection requirements outlined in this regulation. Throughout this section we employ assumptions regarding the frequency of data collection as this level of detail is not proposed in regulation text, but is discussed in preamble. A number of assumptions are made regarding the wages of personnel needed to accomplish the proposed collection of information. Wage rates are based on the Employer Costs for Employee Compensation report by U.S. Bureau of Labor Statistics and represent a national average. Some states or employers may face higher or lower wage burdens. Wage rates estimates include a 35% fringe benefit estimate for state employees and a 30% fringe benefit estimate for private sector employees. For purposes of presenting an estimate of paperwork burden for States, we reflect full participation of all States and the District of Columbia in operating an Exchange and assume all States operate the reinsurance and risk adjustment programs. However, we recognize that not all States will elect to operate their

own Exchanges, so these estimates should be considered an upper bound of burden estimates. These estimates may be adjusted proportionally in the final rule based upon additional information as States progress in their Exchange development processes.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICRs Regarding the State Notice of Insurance Benefits and Payment Parameters (§ 153.100)

As discussed in § 153.100, States would issue an annual notice of benefits and payment parameters specific to that State. We estimate a minimum burden for the development of the State notice as States have the option to adopt the parameters in the forthcoming annual Federal notice of benefits and payments parameters, and would only have to indicate their intention of using these parameters in their annual notice.

We assume that all 50 States and the District of Columbia would be subject to these reporting requirements. Again, this estimate should be considered an upper bound, and we may revise these estimates in the final rule based upon additional information as States progress in their Exchange development processes. We estimate that it will take each State approximately 160 hours to meet the requirements of this subpart with a total estimated burden of 8,160 hours. We estimate that it will take a financial analyst 120 hours (at an average wage rate of \$62 an hour) and a senior manager 40 hours (at \$77 an hour) to meet these requirements. The cost estimate for each State is \$10,520 for a total estimated cost burden of \$536,520.

B. ICRs Regarding State Standards for the Transitional Reinsurance Program in the Individual Market (§ 153.240)

Within Part 153, subpart C we describe reporting requirements and maintenance of records for States for reinsurance. States would ensure that the applicable reinsurance entity collects the data required from issuers to make reinsurance payments. The type of data required is currently not described in this proposed rule to allow for State flexibility in determining the data type and collection method. However, the type of data that might be used to make reinsurance payments may include claims data or encounter data. We estimate that it will take about 12 hours on an annual basis for the applicable reinsurance entity to collect this information in an electronic format from

issuers on an annual basis. This estimate is similar to estimates provided in Medicare Part D rule for data submission. For example, Medicare Part D estimated that it would take plan sponsors approximately 10 hours annually for plan sponsors to submit data on aggregated negotiated drug pricing from pharmaceutical companies described in § 423.104. We provide a slightly higher estimate for the collection of data from issuers for reinsurance payments due to the complexity of the program.

States that operate an Exchange would also maintain any records associated with the reinsurance program. For this requirement, we estimate that it will take approximately 52 hours annually for States to maintain records. This is a broad estimate that includes not only the maintenance of data for the reinsurance program, but all books, records, documents, and other evidence of accounting procedures and practices related to the reinsurance program. This estimate is similar to Medicare Part D, where it was estimated that it will take 52 hours on an annual basis for plan sponsors to maintain books, records, and documents on accounting procedures and practices as described in § 423.505.

We assume that 50 States and the District of Columbia will be subject to the reporting requirements in this subpart. This estimate is an upper bound of burden as a result of the reporting requirements in this subpart; we will revise these estimates in the final rule as States progress in their Exchange development. We estimate that it will take each State approximately 64 hours to meet the provisions of this subpart for a total burden estimate of 3,264 hours. We presume that it will take a financial analyst 54 hours (at \$55 an hour) and a senior manager 10 hours (at \$77 an hour) to meet the reporting requirements. The burden cost estimate for each State is \$3,740 for a total burden cost estimate of \$190,740.

C. ICRs Regarding State Standards for the Risk Adjustment Program (§ 153.310–§ 153.340)

Part 153, subpart D describes reporting requirements for States related to the risk adjustment program. We provide minimum burden estimates in this section for the collection and submission of risk-related data, particularly encounter data, as States would be required to collect this information for Medicaid beginning in 2012.

States would be required to implement privacy standards for all data

to be collected for the risk adjustment program. We estimate it will take States approximately 40 hours to create and implement privacy standards for this data collection. This estimate presumes it will take a policy analyst 10 hours (at \$55 per hour), an operations analyst 25 hours (at \$55 per hour) and a senior manager 5 hours (at \$77 per hour). We expect it will cost each state \$2,310 to create and implement privacy standards. The total burden of this requirement is \$117,810.

States may file for an exception from minimum data collection standards, as described in § 153.430(c). We estimate that filing for an exception would take 17 hours and that 5 states will elect to file for exception. This includes 15 hours for an operations analyst (at \$55 per hour) and 2 hours for a senior manager (at \$77 per hour). The total burden of a minimum data reporting exception is \$979 and a total of \$4,895.

States would also collect risk-related data from health insurance issuers. This risk-related data includes claims, encounter, demographic, and enrollment data as described in § 153.340. While we do not specify the data collection timeframe for risk adjustment data, we provide an assumption on the timing of submission of this data. We estimate that it will take an issuer approximately 12 hours to collect this data electronically on an annual basis. We estimate that it will take an operations analyst 12 hours (at \$55 per hour) to collect this data annually.

States would submit to HHS de-identified claims and encounter data for use in recalibrating Federally-certified risk adjustment models. We estimate that it will take 3 hours for States to submit this information to HHS. This estimate is slightly lower than Medicare Part D estimates for data submission as discussed previously and is a minimum burden estimate for this requirement since States will have already collected this data in the format requested for the risk adjustment program. States would submit summarized claims cost for use in verifying risk corridor submissions. Again we provide a minimum burden estimate of 2 hours since States would have already collected this information for risk adjustment.

States would submit summarized and individual-level claims and encounter data from reinsurance-eligible plans for audit purposes. We estimate a minimum burden of 2 hours for States to submit this information to HHS. Finally, States would also provide claims and encounter data for Exchange-related activities such as cost-sharing requirements and quality reporting. We

estimate a minimum burden of 3 hours for States to submit this information for this purpose.

We assume that all 50 States and the District of Columbia will be subject to these reporting requirements. This estimate is an upper bound of burden as a result of the reporting requirements in this subpart; we will revise these estimates in the final rule as States progress in their Exchange development. We estimate that it will take each State approximately 30 hours to meet these requirements with a total estimated burden of 1,530 hours. We presume that it will take an operations analyst 22 hours (at \$55 an hour) and a senior manager 8 hours (at \$77 an hour) to meet these requirements for a cost estimate of \$1,826. The total estimated cost burden is \$93,126.

As discussed in § 153.330, States must submit a request to HHS for review and approval of an alternate risk adjustment methodology. We estimate that 5 States will request an approval for an alternate risk adjustment methodology. We presume all states requesting approval of an alternative risk adjustment methodology will update their methodology once. We presume that it will take an operations analyst 22 hours (at \$55 an hour) and a senior manager 6 hours (at \$77 an hour). Updating the methodology is expected to take an operations analyst 8 hours and a senior manager 2 hours. In total, we estimate that it will take approximately 38 hours for a State electing to establish an alternate risk adjustment methodology to meet the reporting requirements with a total estimated burden of 190 hours. We expect it will cost each state \$2,266 to meet these requirements. The total estimated cost burden for five States is \$11,330.

States choosing to run a risk adjustment program must validate their risk adjustment data annually. We estimate data collection and validation will take an operations analyst 25 hours (at \$55 per hour) and a senior manager 5 hours (at \$77 per hour). The cost estimate for validating the risk adjustment data annually is \$1,760 per state and a total burden of \$89,760.

D. ICRs Regarding Health Insurance Issuer Standards Related to the Transitional Reinsurance Program (§ 153.400 and § 153.410)

Within part 153, subpart E we discuss reporting requirements for health insurance issuers related to the transitional reinsurance program. We would require all health insurance issuers both inside and outside of the exchange to provide enrollment and premium data (covered lives and total

expenses for the self-insured market) to the applicable reinsurance entity for the estimation and collection of contributions. We also would require that health insurance issuers of reinsurance-eligible plans submit data necessary in order to receive reinsurance payment.

For the purpose of this estimate and whenever we refer to burden requirements for issuers, we utilize estimates of the number of issuers provided by the *Healthcare.gov* Web site as this site provides the best estimate of possible issuers at this time. Based on preliminary findings there are approximately 1827 issuers in the individual and small group markets. While we recognize that not all issuers will offer QHPs, we use the estimate of 1827 issuers as the upper bound of participation and burden.

We further estimate that it will take each issuer approximately 12 hours to submit enrollment and premium data electronically on an annual basis and 12 hours to submit data for reinsurance payment on an annual basis. This estimate is similar to Medicare Part D estimates as discussed previously.

As such, we estimate that it will take each issuer approximately 24 hours to comply with these requirements for a total estimated annual burden of 43,848 hours. We presume that it will take a financial analyst 16 hours (at \$57 an hour) and a senior manager 8 hours (at \$72 an hour) to meet these requirements. The cost estimate for meeting these requirements for each issuer is of \$1,488. The total burden cost estimate for all issuers is \$2,718,576.

E. ICRs Regarding Health Insurance Issuer Standards Related to the Temporary Risk Corridors Program (§ 153.520)

Within part 153, subpart F we discuss reporting requirements for qualified health plan issuers related to the risk corridors program. We would require all qualified health plan issuers to submit data on premiums collected and allowable costs. While we recognize that not all issuers will offer QHPs, we use the estimate of 1827 issuers as the upper bound of participation and burden. We further estimate that it will take each issuer approximately 12 hours to comply with this requirement on an annual basis. This estimate is similar to estimates for data submission in Medicare Part D as discussed previously with a slight increase due to the complexity of the risk corridor program. The total estimated annual burden is 21,924 hours. We presume that it will take a financial analyst 8 hours (at \$57 an hour) and a senior manager 4 hours (at

\$72 an hour) for a cost estimate of \$744. The total burden cost estimate for all issuers is \$1,359,288.

F. ICRs Regarding Health Insurance Issuer Standards for the Risk Adjustment Program (§ 153.610–§ 153.630)

Within part 153, subpart G, we described reporting requirements for health insurance issuers related to the risk adjustment program. Health insurance issuers would be required to submit data required for risk adjustment. This data may include claims and encounter data for items and services rendered; enrollment and demographic information; issuer rate-setting rules; and prescription drug utilization data. While we do not

specify the data collection timeframe for risk adjustment data, we provide an assumption on the timing of submission of this data. We estimate that it will take an issuer approximately 20 hours to submit this data electronically on an annual basis. This estimate is a slight increase from the Medicare Advantage requirements for submitting data for drug claims as described for § 423.329 for Medicare Part D and reflects the complexity of risk adjustment for the Exchange program.

Health insurance issuers would also submit data for validation and verification activities to HHS and States. Again, we estimate that it will take an issuer approximately 12 hours to submit this data electronically on an annual basis as this should be data they already

collect for risk adjustment. Finally, health insurance issuers would maintain risk adjustment data for a period of ten years. We estimate that it will take approximately 2 hours annually for issuers to maintain this data.

We estimate that 1827 issuers must comply with these requirements. We further estimate that it will take each issuer approximately 34 hours to meet the reporting provisions in this subpart for a total of 62,118 hours. We presume that it will take a financial analyst 30 hours (at \$57 an hour) and a senior manager 4 hours (at \$72 an hour) for a cost estimate of \$2,002 for each issuer. The total estimated annual burden cost for all issuers is \$3,657,654.

Regulation section(s)	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Labor cost of reporting per response (\$)	Total labor cost of reporting (\$)
153.100	51	1	160	8,160	10,520	536,520
153.240	51	1	64	3,264	3,740	190,740
153.310 & 153.340	51	1	62	3,162	3,674	187,374
153.340(c)	5	1	17	85	979	4,895
153.330	5	1	38	190	2,266	11,330
153.350	51	1	30	1,530	1,760	89,760
153.400 & 153.410	1827	1	24	43,848	1,488	2,717,576
153.520	1827	1	12	21,924	744	1,359,288
153.610 & 153.630	1827	1	34	62,118	2,002	3,657,654

Note: Salaries and fringe benefit estimates were taken from the Bureau of Labor Statistics Web site (http://www.bls.gov/oco/ohm_index.htm).

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, *Attention: CMS Desk Officer*, CMS-9975-P; *Fax: (202) 395-5806*; or *E-mail: OIRA_submission@omb.eop.gov*

IV. Summary of Preliminary Regulatory Impact Analysis

The summary analysis of benefits and costs included in this proposed rule is drawn from the detailed Preliminary Regulatory Impact Analysis, available at <http://cciio.cms.gov> under “Regulations and Guidance.” That preliminary impact analysis evaluates the impacts of this proposed rule and a second proposed rule “Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans.” The second proposed rule is published in this issue of the **Federal Register**. The following summary focuses on the benefits and costs of this proposed rule.

A. Introduction

HHS has examined the impacts of the proposed rule under Executive Orders 12866 and 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits (both quantitative and qualitative) of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated an “economically” significant rule, under section 3(f)(1) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Few if any insurance issuers offering comprehensive health

insurance policies fell below the size thresholds for “small” business established by the SBA. CMS tentatively concludes that this NPRM would not have a significant impact on a substantial number of small entities. We request comment on whether the small entities affected by this rule have been fully identified.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is approximately \$136 million, using the most current (2011) Implicit Price Deflator for the Gross Domestic Product. Because States are not required to set up an Exchange or operate reinsurance and risk adjustment, the NPRM does not impose a mandate to incur costs above that \$136 million UMRA threshold on State, local, or tribal governments.

B. Need for This Regulation

This proposed rule would implement standards for States related to reinsurance and risk adjustment, and for health insurance issuers related to reinsurance, risk corridors, and risk adjustment consistent with title I of the Patient Protection and Affordable Care Act (Pub. L. 111–148) as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), referred to collectively as the Affordable Care Act. These programs will mitigate the impacts of potential adverse selection and stabilize the individual and small group markets as insurance reforms and the Affordable Insurance Exchanges (“Exchanges”) are implemented, starting in 2014. The transitional State-based reinsurance program serves to reduce the uncertainty of insurance risk in the individual market by making payments for high-cost cases. The temporary Federally-administered risk corridor program serves to protect against rate-setting uncertainty in the Exchange by limiting the extent of issuer losses (and gains). On an ongoing basis, the State-based risk adjustment program is intended to protect health insurance issuers that attract high-risk populations (such as individuals with chronic conditions).

C. Summary of Costs and Benefits of the Proposed Requirements

Two proposed regulations are being published simultaneously to implement components of the Exchange and health insurance premium stabilization policies in the Affordable Care Act. The detailed PRIA evaluates the impacts of both proposed rules, while this summary focuses on the benefits and costs of the proposed requirements in this NPRM.

Methods of Analysis

This preliminary impact analysis references the estimates of the CMS Office of the Actuary (OACT) (CMS, April 22, 2010), but primarily uses the underlying assumptions and analysis done by the Congressional Budget Office (CBO) and the staff of the Joint Committee on Taxation. Their modeling effort accounts for all of the interactions among the interlocking pieces of the Affordable Care Act including its tax policies, and estimates premium effects that are important to assessing the benefits of the NPRM. A description of CBO’s methods used to estimate budget and enrollment impacts is available.¹ The CBO estimates are not significantly different than the comparable components produced by OACT; the Administration is working on developing an integrated modeling

capacity that will estimate Federal spending, revenue, and private premium impacts comparable to those of CBO. Based on our review, we expect that the requirements in these NPRMs will not substantially alter the estimates of the budget impact of Exchanges or enrollment. The proposed requirements are well within the parameters used in the CBO modeling of the Affordable Care Act and do not diverge from assumptions embedded in the model. Our review and analysis of the proposed requirements indicate that the impacts are within the model’s margin of error.

Summary of Costs and Benefits

CBO estimated program payments and receipts for reinsurance and risk adjustment. As Exchanges do not begin operation until 2014, there are no outlays for reinsurance and risk adjustment in 2012 and 2013. CBO estimates that risk adjustment payments and collections are equal in the aggregate, but that risk adjustment payments lag revenues by one quarter. CBO did not score the impact of risk corridors, but assumed collections would equal payments to plans in the aggregate. The payments and receipts in risk adjustment, reinsurance, and risk corridors are financial transfers between issuers.

TABLE 1—ESTIMATED OUTLAYS AND RECEIPTS FOR REINSURANCE AND RISK ADJUSTMENT PROGRAMS FY 2012–FY2016
(In billions of dollars)

Year	2012	2013	2014	2015	2016
Reinsurance and Risk Adjustment Program Payments ^a			11	18	18
Reinsurance and Risk Adjustment Program Receipts ^a			12	16	18

^a Risk-adjustment payments lag receipts by one quarter.

Source: CBO. 2011. Letter to Hon. Nancy Pelosi. March 20, 2010. Available at <http://www.cbo.gov/ftpdocs/113xx/doc11379/AmendReconProp.pdf>.

Benefits. Payments through reinsurance, risk adjustment, and risk corridors reduce the increased risk of financial loss that health insurance issuers might otherwise expect to incur in 2014 due to market reforms such as guaranteed issue and the elimination of medical underwriting. Insurers charge premiums for expected costs plus a risk premium, in order to build up reserve funds in case medical costs are higher than expected. Reinsurance, risk adjustment and risk corridors payments reduce the risk to the issuer and the issuer can pass on a reduced risk premium to beneficiaries.

Costs. There are administrative costs to States and Exchanges to set up and

administer these risk mitigation programs. It is important to note that per section 1311 of the Affordable Care Act, States may use Exchange Planning and Establishment Grant funding to help with the development of these programs. For issuers not receiving payments, any contribution is an additional cost, which is typically passed on to beneficiaries through premium increases. There are also reporting costs for issuers to submit data and financial information.

Regulatory Options Considered

Options considered for reinsurance, risk adjustment and risk corridor programs parallel the options

considered for Exchanges. These programs aim to mitigate the impacts of potential adverse selection and stabilize the individual and small group markets as insurance reforms and the Affordable Insurance Exchanges are implemented, starting in 2014. The Affordable Care Act structures reinsurance and risk adjustment as State-run programs with Federal guidelines on methodology, while it establishes risk corridors as a Federally-run program.

In addition to the proposed baseline, HHS has identified two regulatory options for this proposed rule as required by Executive Order 12866.

¹ CBO. “CBO’s Health Insurance Simulation Model: A Technical Description.” (2007, October).

Uniform Standard for Operations of Exchange and Exchange-Related Programs

Under this option HHS would require a single standard for State operations of Exchanges, reinsurance, risk adjustment and risk corridors. This alternative model would restrict State flexibility, requiring a more uniform standard that States must enact in order to achieve certification.

State Flexibility for Operation of Exchange and Exchange-Related Programs

Under this option, States would have a great deal of flexibility around

whether and how to implement Exchanges, reinsurance and risk adjustment. This alternative would allow States to develop these programs to fit their State-specific characteristics. The programs would be subject to few Federal standards.

Summary of Estimate Costs for Each Option

HHS notes that a single standard for State operations of Exchanges, reinsurance, risk adjustment and risk corridors could produce a benefit of reduced Federal oversight cost. However this option may reduce innovation and therefore limit diffusion

of successful policies. HHS also notes that while State flexibility could allow for innovation for States, it would increase administrative burden on the Federal government and national issuers, as policies and procedures would vary between States. HHS proposes a middle approach that aims to limit administrative costs for temporary programs while also ensuring that the policy aims of these risk mitigation programs are met. These costs and benefits are discussed more fully in the detailed impact analysis.

D. Accounting Statement

Category	Primary estimate	Year dollar	Unit discount rate (percent)	Period covered
Benefits				
Annualized	Not estimated	2011	7	2012–2016
Monetized (\$millions/year)	Not estimated	2011	3	2012–2016
Costs				
Annualized	Not estimated	2011	7	2012–2016
Monetized (\$millions/year)	Not estimated	2011	3	2012–2016
Transfers				
Federal Annualized	9925	2011	7	2012–2016
Monetized (\$millions/year)	9633	2011	3	2012–2016
Qualitative	Risk Adjustment transfers funds among individual and small group market health plan issuers. Reinsurance collects funds from all issuers and distributes it to individual market issuers.			

Note: For full documentation and discussion of these estimated costs and benefits see the detailed PRIA, available at <http://cciio.cms.gov> under “Regulations and Guidance.”

V. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of the proposed rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The Act generally defines a “small entity” as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of “small entity.” HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent.

As discussed above, this proposed rule is necessary to implement standards for States related to

reinsurance and risk adjustment, and for health insurance issuers related to reinsurance, risk corridors, and risk adjustment consistent with title I of the Patient Protection and Affordable Care Act (Pub. L. 111–148) as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), referred to collectively as the Affordable Care Act. For purpose of the Regulatory Flexibility Analysis, we expect entities offering health insurance plans including fully insured health plan issuers, self-insured health plan issuers, TPAs and other organizations to be affected by this proposed rule. We believe that health insurers would be classified under the North American Industry Classification System (NAICS) Codes 524114 (Direct Health and Medical Insurance Carriers) According to SBA size standards, entities with average annual receipts of \$7 million or less would be considered small entities for both of these NAICS codes. Health issuers could possibly be classified in 621491 (HMO Medical Centers) and, if

this is the case, the SBA size standard would be \$10 million or less.

As discussed in the Web Portal interim final rule (75 FR 24481), HHS examined the health insurance industry in depth in the Regulatory Impact Analysis we prepared for the proposed rule on establishment of the Medicare Advantage program (69 FR 46866, August 3, 2004). In that analysis, we determined that there were few, if any, insurance firms underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) that fell below the size thresholds for “small” business established by the SBA (currently \$7 million in annual receipts for health insurers, based on North American Industry Classification System Code 524114).²

Additionally, as discussed in the Medical Loss Ratio interim final rule (75 FR 74918), the Department used a data set created from 2009 National Association of Insurance Commissioners (NAIC) Health and Life Blank annual

financial statement data to develop an updated estimate of the number of small entities that offer comprehensive major medical coverage in the individual and group markets. For purposes of that analysis, the Department used total Accident and Health (A&H) earned premiums as a proxy for annual receipts. The Department estimated that there were 28 small entities with less than \$7 million in A&H earned premiums offering individual or group comprehensive major medical coverage; however, this estimate may overstate the actual number of small health insurance issuers offering such coverage, since it does not include receipts from these companies' other lines of business.

As discussed earlier in this summary of the preliminary RIA, the Department is seeking comments on the potential impacts of the requirements in this proposed regulation on issuers' administrative costs. The Department is also seeking comments relating to potential impacts on small issuers.

This rule proposes standards for premium stabilization programs required of health plan issuers including the risk adjustment program as well as the transitional reinsurance and risk corridors programs. Because health plan issuers are the only entities impacted by this rule and as evidenced above, few if any insurance firms offering comprehensive health insurance policies fell below the size thresholds for "small" business established by the SBA. We request comment on whether the small entities affected by this rule have been fully identified. We also request comment and information on potential costs for these entities and on any alternatives that we should consider.

VI. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing proposed rule (and subsequent final rule) that includes any Federal mandate that may result in expenditures in any one year by a State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately \$136 million. Because States are not required to set up an Exchange or operate reinsurance and risk adjustment, the NPRM does not impose a mandate to incur costs above the \$136 million UMRA threshold on State, local, or tribal governments.

VII. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct costs on State and local governments, pre-empts State law, or otherwise has Federalism implications. Because States have flexibility in designing their Exchange and Exchange-related programs, State decisions will ultimately influence both administrative expenses and overall premiums. States are not required to operate an Exchange, risk adjustment, or reinsurance. For States electing to operate an Exchange, risk adjustment and reinsurance, much of the initial costs to the creation of Exchanges and Exchange-related programs will be funded by Exchange Planning and Establishment Grants. After this time, Exchanges will be financially self-sustaining with revenue sources at the discretion of the State. Current State Exchanges charge user fees to issuers.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have Federalism implications or limit the policy making discretion of the States, the Department has engaged in efforts to consult with and work cooperatively with affected States, including participating in conference calls with and attending conferences of the National Association of Insurance Commissioners, and consulting with State insurance officials on an individual basis.

Throughout the process of developing this NPRM, the Department has attempted to balance the States' interests in regulating health insurance issuers, and Congress' intent to provide access to Affordable Insurance Exchanges for consumers in every State. By doing so, it is the Department's view that we have complied with the requirements of Executive Order 13132.

Pursuant to the requirements set forth in section 8(a) of Executive Order 13132, and by the signatures affixed to this regulation, the Department certifies that CMS has complied with the requirements of Executive Order 13132 for the attached proposed regulation in a meaningful and timely manner.

VIII. Regulations Text

List of Subjects in 45 CFR Part 153

Administrative practice and procedure, Adverse selection, Consumer protection, Health care, Health insurance, Health records, Hospitals, Indians, Individuals with disabilities, Organization and functions

(Government agencies), Reporting and recordkeeping requirements, Reinsurance, Risk adjustment, Risk corridors, Risk mitigation, State and local governments.

For the reasons set forth in the preamble, the Department of Health and Human Services proposes to amend 45 CFR subtitle A, subchapter B, as set forth below:

SUBTITLE A—DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCHAPTER B—REQUIREMENTS RELATING TO HEALTH CARE ACCESS

Part 153 is added as follows:

PART 153—STANDARDS RELATED TO REINSURANCE, RISK CORRIDORS, AND RISK ADJUSTMENT UNDER THE AFFORDABLE CARE ACT

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Sec.

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Subpart B—State Notice of Insurance Benefits and Payment Parameters

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Subpart G—Health Insurance Issuer Standards Related to the Risk Adjustment Program

153.600 Definitions.

153.610 Risk adjustment issuer requirements.

153.620 Compliance with risk adjustment standards.

Authority: Title I of the Affordable Care Act, Sections 1321, 1341–1343.

Subpart A—General Provisions

§ 153.10 Basis and scope.

(a) *Basis.* This part is based on the following sections of title I of the Affordable Care Act:

1321. State flexibility in operation and enforcement of Exchanges and related requirements.

1341. Transitional reinsurance program for individual market in each State.

1342. Establishment of risk corridors for plans in individual and small group markets.

1343. Risk adjustment.

(b) *Scope.* This part establishes standards for the establishment and operation of a transitional reinsurance program, temporary risk corridors, and a permanent risk adjustment program.

§ 153.20 Definitions.

The following definitions apply to this part, unless the context indicates otherwise:

Applicable reinsurance entity means a not-for-profit organization that carries out the reinsurance program established under this part.

Benefit year has the meaning given to the term in § 155.20.

Contributing entity means any health insurance issuer and, in the case of a self-insured group health plan, the third party administrator of the group health plan.

Enrollee has the meaning given to the term in § 155.20.

Exchange has the meaning given to the term in § 155.20.

Grandfathered health plan means coverage provided by a group health plan, or a health insurance issuer as provided in accordance with requirements under § 147.140.

Group health plan has the meaning given to the term in § 144.103.

Health insurance issuer or *issuer* has the meaning given to the term in § 144.103.

Health plan has the meaning given to the term in § 155.20.

Individual market means the market for health insurance coverage offered to individuals other than in connection with a group health plan.

Reinsurance-eligible plan means, for the purpose of the reinsurance program,

any health plan offered in the individual market with the exception of grandfathered plans.

Risk adjustment covered plan means, for the purpose of the risk adjustment program, any plan offered in the individual or small group market with the exception of grandfathered plans.

Small group market has the meaning given to the term in § 155.20.

State has the meaning given to the term in § 155.20.

Subpart B—State Notice of Insurance Benefits and Payment Parameters

§ 153.100 Establishment of State insurance benefits and payment parameters.

(a) *General requirement.* A State operating an Exchange, as well as a State establishing a reinsurance program, must issue an annual notice of benefits and payment parameters specific to that State if that State intends to modify any reinsurance or risk adjustment parameters from those specified in the forthcoming annual Federal notice of benefit and payment parameters.

(b) *State notice deadlines.* If a State elects to publish an annual notice of benefits and payment parameters, the State must issue the notice by early March of the year prior to the benefit year.

(c) *State failure to publish notice.* Any State operating an Exchange or establishing a reinsurance program that fails to publish a notice within the period specified in paragraph (b) of this section must adhere to the parameters, as specified in the forthcoming annual Federal notice of benefit and payment parameters.

§ 153.110 Standards for the State Notice.

(a) *Reinsurance content.* If a State operating an Exchange or establishing a reinsurance program intends to modify a Federal reinsurance payment parameter, the State notice must specify at least the following information:

(1) The data requirements and data collection frequency for health insurance issuers to receive reinsurance payment.

(2) The reinsurance attachment point, reinsurance cap, and coinsurance rate, as specified in § 153.230, if different from the corresponding parameters specified in the forthcoming annual Federal notice of benefit and payment parameters;

(3) If a State plans to use more than one applicable reinsurance entity, for each applicable reinsurance entity, the geographic boundaries for that entity and estimates of:

(i) The number of enrollees in group health plans, including the fully insured and self insured market;

(ii) The number of enrollees in the individual market;

(iii) The amount of reinsurance payments that will be made to issuers; and

(iv) The amount of all premiums in the geographic region that will be available for contributions for each reinsurance entity.

(b) *Risk adjustment content.* If a State operating an Exchange intends to modify a Federal risk adjustment parameter, the State notice must provide a detailed description of and rationale for any modifications, including:

(1) The methodology for determining average actuarial risk, including the establishment of risk pools and the Federally-certified risk adjustment model as specified in § 153.320; and

(2) The risk adjustment data validation methodology set forth in § 153.350.

Subpart C—State Standards for the Transitional Reinsurance Program for the Individual Market

§ 153.200 Definitions.

The following definitions apply to this subpart.

Attachment point means the threshold dollar amount of costs incurred by a health insurance issuer for payment of essential health benefits, as defined in section 1302(b) of the Affordable Care Act, provided for an enrolled individual, after which threshold, the costs for covered essential health benefits, as defined in section 1302(b) of the Affordable Care Act, are eligible for reinsurance payments.

Coinsurance rate means the rate at which the applicable reinsurance entity will reimburse the health insurance issuer for costs incurred to cover essential health benefits, as defined in section 1302(b) of the Affordable Care Act, after the attachment point and before the reinsurance cap.

Contribution rate means the rate, based on a percent of premium, used to determine the dollar amounts each health insurance issuer and third party administrator, on behalf of a self-insured group health plan, must contribute to a State reinsurance program.

Percent of premium means the percent of total revenue, based on earned premiums as described in § 158.130(a), in a fully insured market or the percent of total medical expenses in a self-insured market.

Reinsurance cap means the threshold dollar amount for costs incurred by a

health insurance issuer for payment of essential health benefits, as defined in section 1302(b) of the Affordable Care Act, provided for an enrolled individual, after which threshold, the costs for covered essential health benefits, as defined in section 1302(b) of the Affordable Care Act, are no longer eligible for reinsurance payments.

Third party administrator means the claims processing entity for a self-insured group health plan.

§ 153.210 State establishment of a reinsurance program.

(a) *General requirement.* Each State that elects to operate an Exchange must establish a reinsurance program for the years 2014 through 2016.

(1) The State must enter into a contract with an existing applicable reinsurance entity or establish an applicable reinsurance entity to carry out the provisions of this subpart.

(2) If a State establishes or contracts with more than one applicable reinsurance entity, the State must:

(i) Ensure that each applicable reinsurance entity operates in a distinct geographic area with no overlap of jurisdiction with any other applicable reinsurance entity; and

(ii) Publish the geographic boundaries for each applicable reinsurance entity in a State notice described in § 153.110.

(3) Under authority granted by the State, an applicable reinsurance entity may subcontract specific administrative functions required under this subpart and part 156 subpart G.

(4) States must review and approve subcontracting arrangements to ensure efficient and appropriate expenditures of administrative funds collected under this subpart.

(5) States must ensure that the contract or establishment of the applicable reinsurance entity is of sufficient duration to cover completion of all reinsurance-related activities for benefit years commencing in 2014 through 2016 and any activities required to be undertaken in subsequent periods.

(b) *Multi-State reinsurance arrangements.* Multiple States may contract with a single not-for-profit entity to serve as the applicable reinsurance entity for each State. In such cases, each contractual arrangement between the not-for-profit entity and the individual State will be treated as an individual State applicable reinsurance entity separate and distinct from all other applicable reinsurance entities operated by the not-for-profit entity.

(c) *Special State circumstances for establishing a reinsurance program.* For each State that does not elect to

establish an Exchange, the State may determine to operate its own reinsurance program and must carry out all of the provisions in this subpart.

(d) *Non-electing States.* For each State that does not elect to establish an Exchange and does not determine to operate its own reinsurance program, HHS will carry out all of the provisions of this subpart on behalf of the State and establish the reinsurance program to perform all the reinsurance functions for that State.

(e) *Oversight.* Each State that establishes an Exchange or operates a reinsurance program must ensure that each applicable reinsurance entity complies with all provisions of this subpart and subpart E throughout the duration of its contract or establishment.

§ 153.220 Collection of reinsurance contribution funds.

(a) *General requirement.* The State must ensure that the applicable reinsurance entity collects contributions to fund the following:

(1) Reinsurance contributions that will total, on a national basis, \$10 billion in 2014, \$6 billion in 2015, and \$4 billion in 2016.

(2) U.S. Treasury contributions that will total, on a national basis, \$2 billion in 2014, \$2 billion in 2015, and \$1 billion in 2016.

(b) *Contribution rate.* The State must adhere to a national contribution rate set by HHS for the amounts listed in paragraph (a)(1) and (a)(2) of this section.

(1) HHS will set the contribution rate as a percent of premium through a forthcoming annual Federal notice of benefit and payment parameters.

(2) At a minimum, the State must ensure that all applicable reinsurance entities operating in a State collect from all contributing entities the amount set forth by the national rate. The contributions allocated for—

(i) Reinsurance payments must be used for reinsurance payments.

(ii) Payments to the U.S. Treasury must be paid to the U.S. Treasury.

(3) An applicable reinsurance entity may collect more than the amounts collected from the set national rate to provide—

(i) Additional funding for reinsurance payments if the State believes the amount is not sufficient to fund required reinsurance payments; and

(ii) Funding for administrative expenses of the applicable reinsurance entity.

§ 153.230 Calculation of reinsurance payments.

(a) *General requirement.* A health insurance issuer of a non-grandfathered

individual market plan becomes eligible for reinsurance payments when its expenses for items and services within the essential health benefits, as defined in section 1302(b) of the Affordable Care Act, of an individual enrollee exceed an attachment point.

(b) *Reinsurance payment.* States may use the payment formula and values for the attachment point, reinsurance cap, and coinsurance rate for each year commencing in 2014 and ending in 2016, established in the forthcoming annual Federal notice of benefit and payment parameters.

(1) States must ensure that the reinsurance payment represents the product of the coinsurance rate times all health insurance issuer costs for an individual's essential health benefits, as defined in section 1302(b) of the Affordable Care Act, which the health insurance issuer incurs between the attachment point and the reinsurance cap.

(2) The State, or the applicable reinsurance entity on behalf of the State, must remit the amounts in paragraph § 153.220(a)(2) of this section to the general fund of the U.S. Treasury at a frequency to be determined by HHS.

(c) *State modification of reinsurance payment formula.* States may modify the reinsurance payment formula to values determined appropriate by the State.

(1) States may use one or all of the following methods:

(i) Increasing or decreasing the attachment point;

(ii) Increasing, decreasing, or eliminating the reinsurance cap; and

(iii) Increasing or decreasing the coinsurance rate.

(2) States must publish any modification to the reinsurance payment formula and parameters in a State notice as described in § 153.110.

(3) States that develop a State formula for reinsurance payments must ensure that contributions toward reinsurance are sufficient to cover:

(i) All payments that the applicable reinsurance entity is obligated to make under that State formula for the given calendar year for the reinsurance program;

(ii) All contributions to the U.S. Treasury described in § 153.220(a)(2).

§ 153.240 Disbursement of reinsurance payments.

(a) *Data collection.* The State must ensure that the applicable reinsurance entity collects from health insurance issuers of reinsurance-eligible plans data required to calculate payments described in § 153.230, according to the data requirements and data collection

frequency specified by the State in the notice described in § 153.110 or in the forthcoming annual Federal notice of benefit and payment parameters.

(b) *Reinsurance entity payments.* The State must ensure that each applicable reinsurance entity make payments to health insurance issuers that do not exceed contributions.

(1) Payments must be made to health insurance issuers of reinsurance-eligible plans based on the applicable payment notice identified in § 153.230(b) or the payment parameters set pursuant to § 153.230(c).

(2) Payments may be reduced on a pro rata basis to match the amount of contributions received by the State in a given reinsurance year. Any pro rata reductions that the State determines are necessary must be fair and equitable for all health insurance issuers in the individual market.

(3) The State must ensure that an applicable reinsurance entity makes payment as specified in § 153.410(b) to the health insurance issuer of a reinsurance-eligible plan after receiving a valid claim for payment from that health insurance issuer.

(c) *Maintenance of Records.* The State must maintain books, records, documents, and other evidence of accounting procedures and practices of the reinsurance program for each benefit year for at least 10 years.

§ 153.250 Coordination with high-risk pools.

(a) *General requirement.* The State shall eliminate or modify any State high risk pool to the extent necessary to carry out the reinsurance program established under this subpart.

(b) *Coordination with high-risk pools.* The State may coordinate the State high risk pool with the reinsurance program to the extent it conforms to the provisions of this subpart.

Subpart D—State Standards for the Risk Adjustment Program

§ 153.300 Definitions.

The following definitions apply to this subpart:

Alternate risk adjustment methodology means a risk adjustment methodology proposed by a State for use instead of existing Federally-certified risk adjustment models, but not yet certified by HHS.

Federally-certified risk adjustment methodology means a risk-adjustment methodology that has been either developed and promulgated by HHS or has been certified by HHS.

Risk adjustment methodology means the specific procedures used to determine average actuarial risk.

Risk adjustment model means an actuarial tool used to predict health plan costs based on the relative actuarial risk of enrollees in risk adjustment covered plans.

Risk pool means the population across which risk is distributed in risk adjustment.

§ 153.310 Risk adjustment administration.

(a) *State eligibility to establish a risk adjustment program.* (1) A State that elects to operate an Exchange is eligible to establish a risk adjustment program.

(2) Any State that does not elect an Exchange, or that HHS has not approved to operate an Exchange, will forgo implementation of all State functions in this subpart and HHS will carry out all of the provisions of this subpart on behalf of the State.

(3) Any State that elects to establish an Exchange but does not elect to administer risk adjustment will forgo implementation of all State functions in this subpart and HHS will carry out all of the provisions of this subpart on behalf of the State.

(b) *Entities eligible to carry out risk adjustment activities.* A State may elect to have an entity other than the Exchange perform the risk adjustment functions of this subpart provided that the entity selected meets the requirements proposed in § 155.110 of the notice of proposed rulemaking entitled, “Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans,” published in this issue of the **Federal Register**.

(c) *Timeframes.* A State, or HHS on behalf of the State, must commence calculating payment and charges with the 2014 benefit year.

§ 153.320 Federally-certified risk adjustment methodology.

(a) *General requirement.* Any risk adjustment methodology used by a State, or HHS on behalf of the State, must be established as a Federally-certified risk adjustment methodology. A risk adjustment methodology may become Federally-certified by one of the following processes:

(1) A risk adjustment methodology developed by HHS, with its use authorized and published in a forthcoming annual Federal notice of benefits and payment parameters; or

(2) An alternative risk adjustment methodology submitted by a State in accordance with § 153.330, and reviewed and certified by HHS. After HHS approves a State alternative risk adjustment methodology, that methodology is considered a Federally-certified risk adjustment methodology.

(b) *Publication of methodology in notices.* A State must use one of the Federally-certified risk adjustment methodologies that will be published by HHS in a forthcoming annual Federal notice of benefits and payment parameters or that has been published by the State in the annual State notice described in § 153.110(b). Each methodology will include:

(1) A complete description of the risk adjustment model, including—

(i) Factors to be employed in the model, including but not limited to demographic factors, diagnostic factors, and utilization factors, if any;

(ii) The qualifying criteria for establishing that an individual is eligible for a specific factor;

(iii) Weights assigned to each factor; and

(iv) The schedule for collection of risk adjustment data and determination of factors; and

(2) Any adjustments made to the risk adjustment model weights to determine average actuarial risk.

(c) *Use of methodology for States that do not elect an Exchange.* HHS will specify in the forthcoming annual Federal notice of benefits and payment parameters the Federally-certified risk adjustment methodology that will apply in States that do not elect to operate an Exchange.

§ 153.330 State alternate risk adjustment methodology.

(a) *State request for alternate methodology certification.*

(1) The State request to HHS for the certification of an alternative risk adjustment model must include:

(i) A description of specific risk pools to which the methodology will be applied;

(ii) A complete description of the risk adjustment model, including—

(A) Factors to be employed in the methodology, including but not limited to demographic factors, diagnostic factors, and utilization factors, if any;

(B) The qualifying criteria for establishing that an individual is eligible for a specific factor;

(C) Weights assigned to each factor;

(D) The schedule for collection of risk adjustment data and the method of data collection;

(E) Calibration methodology and frequency of calibration; and

(F) Statistical performance metrics, as specified by HHS; and

(iii) Any adjustments made to the base risk adjustment model weights to determine average actuarial risk.

(2) The request must include the extent to which the methodology:

(i) Accurately explains the variation in the expenses of a given population;

(ii) Links risk factors to daily clinical practice and are clinically meaningful to providers;

(iii) Encourages favorable behavior among providers and health plans and discourages unfavorable behavior;

(iv) Uses data that is complete, high in quality and available in a timely fashion;

(v) Is easy for stakeholders to understand and implement;

(vi) Provides stable risk scores over time and across plans; and

(vii) Minimizes administrative costs.

(b) *State renewal of alternate methodology.* The State may not implement a recalibrated risk adjustment model or otherwise altered methodology without first obtaining HHS certification.

(1) Recalibration of the risk adjustment model must be performed at least as frequently as described in paragraph (a)(1)(ii)(E);

(2) Request must include any changes to the parameters described in paragraph (a)(1).

§ 153.340 Data collection under risk adjustment.

(a) *Data collection requirements.* The State, or HHS on behalf of the State, must collect risk-related data to determine individual risk scores that form the basis for risk adjustment.

(b) *Minimum standards.* The State, or HHS on behalf of the State, may vary the amount and type of data collected provided that the State, or HHS on behalf of the State, uses the following standards for risk adjustment data collection:

(1) The NCPDP claims transaction or the HIPAA standard ASC X12N 837 Health Care Claim transaction for all claims and encounter data;

(2) The HIPAA standard ASC X12N 834 Benefit Enrollment and Maintenance transaction for all demographic and enrollment data; and

(3) To ensure adequate data privacy standards, the State, or any official, employee, agent or representative of the State must use individually identifiable information only as specifically required or permitted by this part and must not disclose individually identifiable information except as provided in paragraph (d) of this section.

(i) The State should interpret this provision as separate from the authority of other applicable laws for disclosing individual identifiable information under paragraph (d) of this section.

(ii) The State must implement security standards that provide administrative, physical, and technical safeguards for the individually

identifiable information consistent with the security standards described at 45 CFR 164.308, 164.310, and 164.312.

(iii) The State must establish privacy standards that set forth approved uses and disclosures of individually identifiable information.

(c) *Exception for States with all payer claims databases.* Any State with an all payer claims database that is operational on or before January 1, 2013 may request an exception from the data collection minimum standards described in paragraph (b) of this section by submitting:

(1) Technical specifications for the all payer claims database including data formats;

(2) Proposed system modifications to support risk adjustment activities;

(3) Proposed system modifications to meet requirements set forth in paragraph (d) of this section and other Exchange-related activities.

(d) *Uses of risk adjustment data.* The State, or HHS on behalf of the State, must make relevant claims and encounter data collected under risk adjustment available to support claims-related activities as follows:

(1) Provide HHS with de-identified claims and encounter data for use in recalibrating Federally-certified risk adjustment models;

(2) Provide HHS with summarized claims cost for use in verifying risk corridor submissions; and

(3) Provide the reinsurance entity with summarized claims and encounter data from reinsurance-eligible plans for payment verification purposes and individual-level from reinsurance-eligible plans for audit purposes.

§ 153.350 Risk adjustment data validation standards.

(a) *General requirement.* The State, or HHS on behalf of the State, must validate a statistically valid sample of risk adjustment data from each issuer that offers at least one risk adjustment covered plan in that State.

(b) *Use of data validation to adjust risk.* The State, or HHS on behalf of the State, may adjust the average actuarial risk calculated in § 153.310 for all risk adjustment covered plans offered by an issuer based on the risk score error determined in the data validation conducted pursuant to paragraph (a) of this section.

(c) *Adjustment to charges and payments.* The State may adjust charges and payments to all risk adjustment covered plan issuers based on the adjustments calculated in paragraph (b) of this section.

(d) *Appeals.* The State must provide an administrative process to appeal data validation findings.

Subpart E—Health Insurance Issuer Standards Related to the Transitional Reinsurance Program

§ 153.400 Reinsurance contribution funds.

(a) *General requirement.* Each contributing entity must make payments of contributions, in a frequency and manner determined by the State or HHS, to the applicable reinsurance entity for each State in which the contributing entity issues health insurance for the contributions specified pursuant to § 153.220(b).

(b) *Multiple reinsurance entities.* If the State establishes or contracts with more than one reinsurance entity, the contributing entity must make payments to each applicable reinsurance entity that covers each geographic area in which the contributing entity issues health insurance.

(c) *Data requirements.* Each contributing entity must submit to each applicable reinsurance entity data required to substantiate the contribution amounts for the contributing entity.

(1) Each contributing entity in the individual and fully insured market must submit enrollment and premium data.

(2) Each contributing entity in the self-insured market must submit data on covered lives and total expenses.

§ 153.410 Requests for reinsurance payment.

(a) *General requirement.* A reinsurance-eligible plan issuer may make a request for payment when an enrollee of that reinsurance-eligible plan has met the criteria for reinsurance payment.

(b) *Manner of request.* Reinsurance-eligible plan issuers must make requests for payment in a manner that will be specified by the State as described in § 153.110 or in the forthcoming annual Federal notice of benefit and payment parameters.

Subpart F—Health Insurance Issuer Standards Related to the Temporary Risk Corridors Program

§ 153.500 Definitions.

Allowable administrative costs means the total non-medical costs as defined in § 158.160(b), including costs for the administration and operation incurred by the plan as set forth in § 158.160(b)(2).

Allowable costs means an amount equal to the total medical costs, which include clinical costs, excluding allowable administrative costs, paid by the QHP issuer in providing benefits covered by the QHP.

Charge means the flow of funds from QHP issuers to HHS.

Direct and indirect remuneration means prescription drug price concessions or similar benefits from manufacturers, pharmacies or similar entities obtained by a QHP issuer or an intermediary contracting organization with which a QHP issuer has contracted. Such concessions include but are not limited to: Discounts, charge backs, rebates, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, and grants. We further specify that the term applies regardless of whether the intermediary contracting organization retains all or a portion of the direct and indirect remuneration or passes the entire direct and indirect remuneration to the QHP issuer and regardless of the terms of the contract between the issuer and the intermediary contracting organization.

Payment means the flow of funds from HHS to QHP issuers.

Qualified Health Plan, or QHP, has the meaning given to the term proposed in the general definitions section of the Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans, published in this issue of the **Federal Register**.

Risk corridor means any payment adjustment system based on the ratio of allowable costs of a plan to the plan's target amount.

Target amount means an amount equal to the total premiums incurred by a QHP, including any premium tax credit under any governmental program, reduced by the allowable administrative costs of the plan.

§ 153.510 Risk corridor establishment and payment methodology.

(a) *General requirement.* A QHP issuer must adhere to the requirements set by HHS in this subpart and in the forthcoming annual Federal notice of benefits and payment parameters for the establishment and administration of a program of risk corridors for calendar years 2014, 2015, and 2016.

(b) *HHS payments to health insurance issuers.* QHP issuers will receive payment from HHS in the following amounts under the following circumstances:

(1) When a QHP's allowable costs for any benefit year are more than 103 percent but not more than 108 percent of the target amount, HHS pays the QHP issuer an amount equal to 50 percent of the target amount in excess of 103 percent of the target amount; and

(2) When a QHP's allowable costs for any benefit year are more than 108 percent of the target amount, HHS pays to the QHP issuer an amount equal to the sum of 2.5 percent of the target

amount plus 80 percent of allowable costs in excess of 108 percent of the target amount.

(c) *Health insurance issuers' remittance of charges.* QHP issuers must remit charges to HHS in the following amounts under the following circumstances:

(1) If a QHP's allowable costs for any benefit year are less than 97 percent but not less than 92 percent of the target amount, the QHP issuer must remit charges to HHS an amount equal to 50 percent of the difference between 97 percent of the target amount and the allowable costs; and

(2) When a QHP's allowable costs for any benefit year are less than 92 percent of the target amount, the QHP issuer must remit charges to HHS an amount equal to the sum of 2.5 percent of the target amount plus 80 percent of the difference between 92 percent of the target amount and the allowable costs.

§ 153.520 Risk corridor standards for QHP issuers.

(a) *Adjusted premium data.* QHP issuers must submit to HHS data on the premiums collected for each QHP that the issuer offers in a format specified by HHS. These premium amounts must be adjusted in the following manner:

(1) Increased by the amount of any payments received for—

(i) Risk adjustment, and

(ii) Reinsurance as described in

§ 153.230; and

(2) Reduced for any—

(i) Risk adjustment charges assessed,

(ii) Reinsurance contributions made as described in § 153.220, and

(iii) User fees paid.

(3) *Accounting for reinsurance*

payments. QHP issuers must attribute reinsurance payments to risk corridors based on the date, to be determined by HHS, on which the valid reinsurance claim was submitted.

(b) *Allowable costs.* All QHP issuers offering QHP's must submit to HHS the allowable costs incurred for each QHP that the QHP issuer offers in a format to be specified in the forthcoming annual Federal notice of benefits and payment parameters.

(1) Allowable costs must be net of direct and indirect remuneration.

(2) Allowable costs must be reduced for any cost-sharing reductions payments received from HHS.

Subpart G—Health Insurance Issuer Standards Related to the Risk Adjustment Program

§ 153.600 Definitions.

Risk adjustment data means all data that are used in the application of a risk adjustment payment model.

§ 153.610 Risk adjustment issuer requirements.

(a) *Data submission.* All issuers that offer risk adjustment covered plans must submit all required risk adjustment data for those risk adjustment covered plans in the manner and timeframes established by the State, or by HHS on behalf of the State. This data may include but is not limited to:

(1) Claims and encounter data for items and services rendered;

(2) Enrollment and demographic information; and

(3) Prescription drug utilization data.

(b) *Issuer contracts.* Issuers that offer risk adjustment covered plans may include in their contracts with providers, suppliers, physicians, and other practitioners, provisions that require such contractor's submission of complete and accurate risk adjustment data in the manner and timeframes established by the State, or HHS on behalf of the State. These provisions may include financial penalties for failure to submit complete, timely, or accurate data.

(c) *Assessment of charges.* After charges and payments for all risk adjustment covered plans have been calculated, issuers that offer risk adjustment covered plans with a net balance of risk adjustment charges payable will be notified by the State, or by HHS on behalf of the State, for those net charges and must remit those risk adjustment charges to the State, or to HHS on behalf of the State.

§ 153.620 Compliance with risk adjustment standards.

(a) *Issuer support of data validation.* All issuers that offer risk adjustment covered plans must make available to HHS and the State any data requested to support validation of risk adjustment data reported under this subpart of this part.

(b) *Issuer records maintenance requirements.* All issuers that offer risk adjustment covered plans must retain any risk adjustment data reported under this subpart of this part for a period of at least ten years after the date of the report.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

41956

Federal Register / Vol. 76, No. 136 / Friday, July 15, 2011 / Proposed Rules

Dated: June 29, 2011.

Donald M. Berwick,

*Administrator, Centers for Medicare &
Medicaid Services.*

Dated: July 7, 2011.

Kathleen Sebelius,

Secretary.

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EXHIBIT 8



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Part IV

Department of Health and Human Services

45 CFR Part 153

Patient Protection and Affordable Care Act; Standards Related to
Reinsurance, Risk Corridors and Risk Adjustment; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES**45 CFR Part 153****[CMS-9975-F]****RIN 0938-AR07****Patient Protection and Affordable Care Act; Standards Related to Reinsurance, Risk Corridors and Risk Adjustment****AGENCY:** Department of Health and Human Services.**ACTION:** Final rule.

SUMMARY: This final rule implements standards for States related to reinsurance and risk adjustment, and for health insurance issuers related to reinsurance, risk corridors, and risk adjustment consistent with title I of the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act of 2010, referred to collectively as the Affordable Care Act. These programs will mitigate the impact of potential adverse selection and stabilize premiums in the individual and small group markets as insurance reforms and the Affordable Insurance Exchanges (“Exchanges”) are implemented, starting in 2014. The transitional State-based reinsurance program serves to reduce uncertainty by sharing risk in the individual market through making payments for high claims costs for enrollees. The temporary Federally administered risk corridors program serves to protect against uncertainty in rate setting by qualified health plans sharing risk in losses and gains with the Federal government. The permanent State-based risk adjustment program provides payments to health insurance issuers that disproportionately attract high-risk populations (such as individuals with chronic conditions).

DATES: *Effective Date:* These regulations are effective on May 22, 2012.

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SUPPLEMENTARY INFORMATION:**Abbreviations**

CMS Centers for Medicare & Medicaid Services

HHS U.S. Department of Health and Human Services

HIPAA Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-191)

MLR Medical Loss Ratio

PCIP Pre-existing Condition Insurance Plan

PHS Act Public Health Service Act (42 U.S.C. 201 *et seq.*)

QHP Qualified Health Plan

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I. Background**A. Legislative Overview**

Starting in 2014, individuals and small businesses will be able to purchase private health insurance through State-based competitive marketplaces called Affordable Insurance Exchanges, or “Exchanges.” Exchanges will offer Americans competition, choice, and clout. Insurance companies will compete for business on a level playing field, driving down costs. Consumers will have a choice of health plans to fit their needs. In addition, Exchanges will give individuals and small businesses the same purchasing power as big businesses. The Departments of Health and Human Services, Labor, and the Treasury are working in close coordination to release guidance related to Exchanges in several phases. A Request for Comment relating to Exchanges was published in the **Federal Register** on August 3, 2010. An Initial Guidance to States on Exchanges was issued on November 18, 2010. A proposed rule for the application, review, and reporting process for waivers for State innovation was published in the **Federal Register** on March 14, 2011. Two proposed rules, including the proposed form of this rule, were published in the **Federal Register** on July 15, 2011 to implement

components of Exchanges and health insurance premium stabilization programs (that is, reinsurance, risk corridors, and risk adjustment) from the Affordable Care Act. A proposed rule regarding eligibility for Exchanges was published in the **Federal Register** on August 17, 2011. A proposed rule on the Health Insurance Premium Tax Credit was published in the **Federal Register** on August 17, 2011. A proposed rule making changes to eligibility for the Medicaid program was published in the **Federal Register** on August 17, 2011. The final versions of the Exchange Establishment and Eligibility rules were made available for public inspection at the Office of the Federal Register on March 12, 2012. A final version of the Medicaid rule is being made available for public inspection at the Office of the Federal Register on the same date as this rule.

Section 1341 of the Affordable Care Act provides that each State must establish a transitional reinsurance program to help stabilize premiums for coverage in the individual market during the first three years of Exchange operation (2014 through 2016). Section 1342 provides that HHS must establish a temporary risk corridors program that will apply to QHPs in the individual and small group markets for the first three years of Exchange operation (2014 through 2016). Section 1343 provides that each State must establish a permanent program of risk adjustment for all non-grandfathered plans in the individual and small group markets both inside and outside of the Exchanges. These risk-spreading mechanisms, which will be implemented by HHS and the States, are designed to mitigate the potential impact of adverse selection and provide stability for health insurance issuers in the individual and small group markets. If a State chooses not to establish a transitional reinsurance program or a risk adjustment program, this final rule provides that HHS will do so on its behalf.

Section 1321(a) also provides broad authority for HHS to establish standards and regulations to implement the statutory requirements related to reinsurance, risk adjustment, and the other components of title I of the Affordable Care Act. Section 1321(a)(2) requires, in issuing such regulations, HHS to engage in stakeholder consultation in a way that ensures balanced representation among interested parties. We describe the consultation activities HHS has undertaken later in this introduction. Section 1321(c)(1) authorizes HHS to establish and implement reinsurance,

risk adjustment, and the other components of title I of the Affordable Care Act in States that have not done so.

B. Introduction

Underpinning the goals of high-quality, affordable health insurance coverage is the need to minimize the possible negative effects of adverse selection. Adverse selection results when a health insurance purchaser understands his or her own potential health risk better than the health insurance issuer does, resulting in a health plan having higher costs than anticipated.

To protect themselves from adverse selection, issuers may include a margin in their pricing (that is, set premiums higher than necessary) in order to offset the potential expense of high-cost enrollees. The uncertainty resulting from adverse selection could also lead an issuer to be more cautious about offering certain plan designs in the Exchange. This risk will likely be greatest in the first years of the Exchange; however, the risk should decrease as the new market matures and issuers gain actual claims experience with this new population.

As experience in States has shown, offsetting the adverse selection from insurance reforms may be best accomplished by broadening the risk pool: Making coverage affordable through lower premiums and targeted financial assistance and making coverage a responsibility so that people pay premiums regardless of their current need for health care. In addition, to further minimize the negative effects of adverse selection and foster a stable marketplace from year one of implementation, the Affordable Care Act establishes transitional reinsurance and temporary risk corridors programs, and a permanent risk adjustment program to provide payments to health insurance issuers that cover higher-risk populations and to more evenly spread the financial risk borne by issuers.

The transitional reinsurance program and the temporary risk corridors program, which begin in 2014, are designed to provide issuers with greater payment stability as insurance market reforms are implemented. The reinsurance program, which is a State-based program, will reduce the uncertainty of insurance risk in the individual market by partially offsetting

risk for high-cost enrollees. By limiting issuers' exposure to high-cost enrollees, this program will attenuate individual market rate increases that might otherwise occur because of the immediate enrollment of individuals with unknown health status. The risk corridors program, which is a Federally administered program, will protect against uncertainty in rates for QHPs by limiting the extent of issuer losses (and gains). On an ongoing basis, the risk adjustment program is intended to provide increased payments to health insurance issuers that attract higher-risk populations (such as those with chronic conditions) and reduce the incentives for issuers to avoid higher-risk enrollees. Under this program, funds are transferred from issuers with lower-risk enrollees to issuers with higher-risk enrollees. Section 1343 of the Affordable Care Act authorizes HHS to utilize criteria and methods similar to those utilized under Parts C or D of title XVIII of the Social Security Act to implement risk adjustment. Standards for the reinsurance, risk corridors, and risk adjustment programs are addressed in this final rule. The following chart summarizes these programs:

Program	Reinsurance	Risk corridors	Risk adjustment
What	Provides funding to issuers that incur high claims costs for enrollees.	Limits issuer losses (and gains)	Transfers funds from lower risk plans to higher risk plans.
Program Operation	State option to operate, regardless of whether the State establishes an Exchange.	HHS	State option to operate if the State establishes an Exchange.
Who Participates	All issuers and third party administrators on behalf of group health plans contribute funding; non-grandfathered individual market plans (inside and outside the Exchange) are eligible for payments.	Qualified health plans	Non-grandfathered individual and small group market plans, inside and outside the Exchange.
Why	Offsets high cost outliers	Protects against inaccurate rate-setting.	Protects against adverse selection.
When	Throughout the year	After reinsurance and risk adjustment.	Before June 30 of the calendar year following the benefit year.
Time Frame	3 years (2014–2016)	3 years (2014–2016)	Permanent.

II. Provisions of the Proposed Regulations and Analysis of and Responses to Public Comments

As indicated in our proposed rule, HHS published a Request for Comment (RFC) on August 3, 2010, inviting the public to provide input regarding the rules that will govern the Exchanges. The comment period closed on October 4, 2010. Comments were submitted by consumer advocacy organizations, medical and health care professional trade associations and societies, medical and health care professional entities, health insurance issuers, insurance trade associations, members of the general public, and employer

organizations. The RFC comments were considered in the development of the proposed rule.

Leading up to the issuance of the Premium Stabilization proposed rule, HHS consulted with stakeholders through weekly meetings with the National Association of Insurance Commissioners (NAIC), regular contact with States through the Exchange grant process, and meetings with tribal representatives, health insurance issuers, trade groups, consumer advocates, employers, and other interested parties. We continue to consult with these stakeholders on the development of guidance related to the reinsurance, risk adjustment, and risk

corridors programs. In this final rule, we have responded to comments submitted in response to the Premium Stabilization proposed rule and the RFC, where relevant.

On July 15, 2011, we published in the **Federal Register** (76 FR 41950–41956) the proposed Standards related to Reinsurance, Risk Corridors, and Risk Adjustment. We received approximately 700 comments on the proposed rule. Of the comments received, approximately 200 were submitted as part of letter campaigns related to women's and mental health services, or were general comments on the Affordable Care Act and the government's role in health

care, but were not specific to the proposed rule.

Comments that were specific to the proposed rule represented a wide variety of stakeholders, including States and tribal organizations, health insurance issuers, consumer groups, healthcare providers, industry experts, and members of the public. Many commenters emphasized the importance of the premium stabilization programs as Exchanges and insurance reforms are implemented and addressed the balance between flexibility for States and standardization and predictability for consumers nationwide.

A. Subpart A—General Provisions

1. Basis and Scope (§ 153.10)

Section 153.10(a) of subpart A specified that the general statutory authority for the standards proposed in part 153 are based on the following sections of title I of the Affordable Care Act: sections 1321 and 1341–1343. Section 153.10(b) specified that this part establishes standards for the establishment and operation of a transitional reinsurance program, a temporary risk corridors program, and a permanent risk adjustment program. We received a number of supportive comments on these provisions and we are finalizing them without modification.

2. Definitions (§ 153.20)

In § 153.20, § 153.200, § 153.300, and § 153.600 of the proposed rule, we set forth definitions for terms that are critical to the reinsurance, risk adjustment, and risk corridors programs. Many of the definitions presented in § 153.20 were taken directly from the Affordable Care Act or from existing regulations. New definitions were created to carry out the regulations in part 153. When a term is defined in part 153 other than in subpart A, the definition of the term is applicable only to the relevant subpart or section. The application of the terms defined in § 153.20 is limited to part 153.

Considering the comments received, we are finalizing this section as proposed, with the following modifications:

We are moving a number of definitions that previously appeared in subparts C, D, and G of the proposed rule to subpart A of this final rule. We are revising the definition of “attachment point” to clarify that reinsurance payments will apply to claims costs accumulated on an incurred basis in a benefit year, and to specify that reinsurance payments are payable on all covered benefits. We are

making conforming revisions to the definitions of “coinsurance rate” and “reinsurance cap.” We are revising the definition of “contribution rate” to be a per capita amount payable with respect to reinsurance contribution enrollees who reside in a State. We are adding a new defined term, “reinsurance contribution enrollee,” which means an individual covered by a plan for which reinsurance contributions must be made pursuant to § 153.400(b). We are removing the definition of “percent of premium” because this definition is no longer used.

We are modifying the definition of “risk adjustment methodology” to mean all parts of the risk adjustment process—the risk adjustment model, the calculation of plan average actuarial risk, the calculation of payments and charges, the risk adjustment data collection approach, and the schedule for the risk adjustment program. We are doing so to clarify the distinct parts of the risk adjustment process. The risk adjustment model calculates individual risk scores. The calculation of plan average actuarial risk adjusts those individual risk scores for rating variation, and calculates average actuarial risk at the plan level. The plan average actuarial risk is used for the calculation of payments and charges for risk adjustment covered plans. The risk adjustment data collection approach specifies how risk adjustment data will be stored, collected, accessed, transmitted, and validated, and the timeframes, data format, and privacy and security standards associated with each. The schedule for the risk adjustment program is the schedule for calculating payments and charges, invoicing issuers for charges, and disbursing payments. We are modifying the definition of “risk adjustment data” to mean all data that are used in a risk adjustment model, the calculation of plan average actuarial risk, or the calculation of payments and charges, or that are used for validation or audit of such data. We have added several new definitions—“individual risk score,” “calculation of plan average actuarial risk,” “calculation of payments and charges,” and “risk adjustment data collection approach.”

Finally, we are making a number of clarifying modifications throughout this section.

Comment: We received one comment suggesting that HHS define the benefit year as a calendar year and that the reinsurance program would be best operated on a calendar year basis.

Response: The benefit year was defined as the calendar year in the Exchange Establishment rule. We have

cross-referenced this definition in this final rule.

Comment: Although a few commenters supported the proposal that reinsurance be payable only on essential health benefits, the majority of commenters urged that reinsurance be payable on all covered benefits, with several citing the administrative complexity of distinguishing between claims for essential health benefits and claims for other covered benefits.

Response: Because it would be administratively burdensome for issuers to distinguish claims for covered essential health benefits from other claims, we are revising the definitions so that reinsurance is payable on all covered benefits.

Comment: We received several comments disagreeing with the inconsistency in the proposed definition of percent of premium, which would include administrative costs for the fully insured market, but not the self-insured market.

Response: We believe that the statute intended for self-insured plans also to pay administrative costs. However, since we have modified the policy for the collection of contributions as discussed in the preamble to § 153.220, we are no longer proposing a definition for percent of premium.

Comment: We received a number of comments requesting clarification of the definition of a contributing entity for the reinsurance program. Several commenters suggested that HHS clarify that third-party administrators are not financially liable for contributions to be made by group health plans for which they administer benefits.

Response: The Affordable Care Act requires that health insurance issuers and third party administrators on behalf of group health plans make contributions. We are including text in § 153.400 that clarifies which issuers must make reinsurance contributions and which are exempt.

Comment: A few commenters expressed support for the differentiation between the defined terms “risk adjustment model” and “risk adjustment methodology.” Another commenter suggested an expanded set of definitions to capture more of the steps in the risk adjustment process, including a term to define the methodology for transferring money between plans, and a term to describe an individual enrollee’s relative cost compared to that of an average enrollee.

Response: We are adding a definition of “individual risk score” to describe a relative measure of predicted health care costs for a particular enrollee. We are adding a definition of “calculation

of plan average actuarial risk” to describe the specific calculations used to determine plan average actuarial risk from individual risk scores for a risk adjustment covered plan, including the specification of the risk pool from which average actuarial risk will be calculated. We are adding a definition of “calculation of payments and charges” to describe the specific procedures used to determine plan average actuarial risk from individual risk scores for a risk adjustment covered plan, including adjustment for variable rating factors and the specification of the risk pool from which average actuarial risk is to be calculated. We are adding a definition of “risk adjustment data collection approach” to describe the specific procedures by which risk adjustment data is to be stored, collected, accessed, and transmitted, and the timeframes, data format, and privacy and security standards with respect thereto.

Comment: We received two comments about the definition of “risk adjustment data.” One commenter suggested that the definition be expanded to encompass all aspects of the risk adjustment process. Another commenter requested that HHS not adopt language that would curtail the use of a prospective risk adjustment model.

Response: We are aligning the definition with a number of the other new definitions encompassed in “risk adjustment methodology.” We do not intend to curtail the use of a prospective risk adjustment model.

Comment: We received a few comments requesting clarification as to the types of plans that are subject to risk adjustment. Commenters asked specifically about Medicaid managed care plans and multi-State plans.

Response: Section 1343 of the Affordable Care Act requires that health plans (except grandfathered plans) in the individual or small group markets participate in the risk adjustment program. We are modifying the definition of “risk adjustment covered plan” in response to comments. This modification clarifies that all health insurance coverage, including multi-State plans and Consumer Operated and Oriented Plans, are risk adjustment covered plans. The risk adjustment program does not apply to Medicare Advantage plans or Medicare Prescription Drug Plans, under which private health plans contract with Medicare to provide Medicare-covered benefits, or to contracts with State Medicaid agencies to provide Medicaid benefits, as payments for such coverage are regulated under provisions of the Social Security Act.

Insurance coverage solely for excepted benefits under title XXVII of the PHS Act will be excluded from risk adjustment. Excepted benefit plans cover a specific set of services, such as vision benefits, while “major medical” plans cover a broader set of benefits such as physician and hospital visits. These differences make fair enrollee risk comparison between excepted benefit plans and major medical plans difficult. We are modifying the definition of risk adjustment covered plan to exclude plans determined not to be risk adjustment covered plans in the annual HHS notice of benefit and payment parameters.

B. Subpart B—State Notice of Benefit and Payment Parameters

In this subpart, we proposed a process by which the States that are operating a risk adjustment program or establishing

a reinsurance program issue an annual notice of benefit and payment parameters to disseminate information to issuers and other stakeholders about specific requirements to support payment-related functions. This provides a practical way to update certain payment and benefit parameters that may change annually, such as reinsurance contribution rates that are based on annually changing thresholds. This notice will also serve as a mechanism to address other Exchange-related provisions.

1. State Notice of Benefit and Payment Parameters (§ 153.100)

In § 153.100(a), we proposed that a State operating an Exchange, as well as a State establishing a reinsurance program, be required to issue a notice to describe the specific parameters that the State will employ if that State intends to utilize any reinsurance or risk adjustment parameters that differ from those specified in the annual HHS notice of benefit and payment parameters. In paragraph (b) (now paragraph (c)), we proposed specific deadlines for the State notice of benefit and payment parameters. We proposed that those deadlines be tied to the publication of the annual HHS notice of benefit and payment parameters, upon which the public will have an opportunity to comment. Below is a chart detailing the schedules for the annual HHS notice of benefit and payment parameters for benefit year 2014 and subsequent years, with the first two milestones occurring in the calendar year two years before the effective date.

ANNUAL HHS NOTICE OF BENEFIT AND PAYMENT PARAMETERS

HHS publishes advance notice	Mid-October two calendar years before the benefit year.
Comment period ends	Mid-November two calendar years before the benefit year.
HHS publishes final notice	Mid-January of the calendar year before the benefit year.

We proposed that a State that plans to modify Federal parameters issue its notice by early March in the calendar year before the benefit year. We proposed that this requirement set an outer bound for the date by which the final notice is to be issued by a State that intends to utilize any reinsurance or risk adjustment parameters that differ from those specified in the annual HHS notice of benefit and payment parameters.

We also proposed in paragraph (c) (now paragraph (d)), that if a State operating an Exchange or establishing a

reinsurance program does not provide public notice of its intent to have State-specific parameters within the period specified, the parameters set forth in the annual HHS notice of benefit and payment parameters will serve as the State parameters.

For the reasons described in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 153.100 of the proposed rule, with the following modifications: We are clarifying that a State must publish a notice of benefit and payment parameters if it intends to

modify the data requirements for reinsurance payments, collect reinsurance contributions, use more than one applicable reinsurance entity, or modify any reinsurance parameters. We are directing a State that operates a risk adjustment program to publish a notice of benefit and payment parameters setting forth the risk adjustment methodology and data validation standards it will use. We are specifying that State notices be issued by March 1 of the calendar year prior to the first benefit year for which the notice applies. We are clarifying that a

State that does not publish a notice of benefit and payment parameters forgoes its right to modify the data requirements for reinsurance payments, collect reinsurance contributions, use more than one applicable reinsurance entity, or use any risk adjustment methodology or data validation standards other than those published in the annual HHS notice of benefit and payment parameters for use by HHS when operating risk adjustment on behalf of a State. We are also making a number of clarifying modifications throughout this section.

Comment: We received a number of comments in support of a requirement that States publish a State notice of benefit and payment parameters. One commenter suggested that we include a requirement that all notices be made public with a period for comment. Another commenter proposed that States be required to justify deviation from any methodologies or parameters set forth in the annual HHS notice of benefit and payment parameters.

Response: While we recognize the value of requiring a public comment period for State notices, we believe that such a requirement should be left to State law and practice. HHS will provide an opportunity for public comment when HHS administers risk adjustment or reinsurance. State law will govern what administrative process is necessary when a State adopts a risk adjustment methodology, or modifies reinsurance parameters, subject to the limits of this final rule and the HHS notice of benefit and payment parameters. We are clarifying the content of the justification to be published by a State that seeks to use a risk adjustment methodology other than the methodology used by HHS when operating risk adjustment on behalf of a State. However, we are not requiring that a State must provide justification for changes to reinsurance payment parameters. As discussed in the preamble in subpart C, we believe a State may have many reasons to make adjustments to the HHS reinsurance payment parameters. As such, we believe that each State should have the flexibility to determine the parameters that best suit the administration of its reinsurance program.

Comment: A number of commenters expressed support for the timing of notice releases as proposed. However, we received a number of comments stating that the proposed timeframe did not allow sufficient time for issuers to prepare their applications for certification for participation in the Exchange in time for the October 2013 open enrollment period. Commenters

proposed alternative timeframes for the release of the HHS notice that ranged from January 2012 to June 30, 2012. A number of commenters also stated that, particularly in the initial years, more advanced notice of Federal and State program parameters will be necessary in order for issuers to prepare premiums for the 2014 benefit year.

Response: The timeframe for implementation of the Affordable Care Act makes it difficult for the Federal and State governments to provide more notice than was proposed in the proposed rule. To accommodate States' and issuers' desire for further information with respect to risk adjustment, HHS is planning a number of working sessions with issuers and States. We believe these sessions will provide sufficient information to issuers and States, while providing HHS the time necessary to more fully develop the Federal parameters for the reinsurance and risk adjustment programs. For these reasons, we are clarifying and finalizing the proposed requirement that State notices of benefit and payment parameters be published by March 1 of the calendar year prior to the benefit year.

Comment: We received a comment supporting the requirement that, if a State establishing a reinsurance program does not provide public notice of its intent to have State-specific parameters, the parameters set forth in the annual HHS notice of benefit and payment parameters will serve as the State parameters.

Response: We are finalizing our policy that a State that elects to establish a reinsurance program that does not publish a State notice of benefit and payment parameters by March 1 must adhere to the parameters set forth in the HHS notice of benefit and payment parameters.

2. Standards for the State Notice of Benefit and Payment Parameters (§ 153.110)

We proposed in paragraph (a)(1) (now paragraph (a)), that content related to the reinsurance program include the data requirements and data collection frequency for health insurance issuers to receive reinsurance payments. In paragraph (a)(2) (now paragraph (e)), we proposed that a State that establishes a reinsurance program must specify the attachment point, reinsurance cap, and coinsurance rate if the State plans to use values different from those set forth in the annual HHS notice of benefit and payment parameters. In paragraph (a)(3) (now paragraph (d)), we proposed that if a State plans to use more than one applicable reinsurance entity, the State

must include in its State notice of benefit and payment parameters information related to the geographic boundaries of each applicable reinsurance entity and estimates related to the number of enrollees, payments, and premiums available for contributions in each region.

In paragraph (b) (now paragraph (f)), we proposed content related to the risk adjustment program if the State intends to modify the risk adjustment parameters set forth in the annual HHS notice of benefit and payment parameters, including a detailed description of and rationale for any modification.

For the reasons described in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 153.110 with the following modifications: We are specifying that a State establishing a reinsurance program that elects to collect reinsurance contributions from the fully insured market must announce its intention to do so, and must set forth the data requirements for reinsurance payments in the State notice of benefit and payment parameters. We are clarifying that a State must apply any modified reinsurance parameters uniformly throughout the State. However, as discussed in Subpart C, a State must inform HHS by December 1, 2012, of its intent to collect reinsurance contributions for the 2014 benefit year, and by September 1 of the calendar year that is two years prior to the applicable benefit year if the State elects to collect reinsurance contributions for any benefit year after 2014. A State that elects to collect additional reinsurance contributions must describe the purpose of the additional collection and the additional contribution rate. We are making a number of clarifying modifications throughout this section.

Comment: One commenter supported affording States the flexibility to provide higher reinsurance payments to plans.

Response: We believe that States should have the flexibility to vary reinsurance payments, so long as the reinsurance parameters are uniform throughout the State. However, a State electing to change reinsurance parameters must publish those changed parameters in the State notice of benefit and payment parameters. A State electing to make higher reinsurance payments will be required to collect any additional reinsurance contributions required to fund those higher payments through a State applicable reinsurance entity.

Comment: We received a comment asking that States be provided the

flexibility to use multiple coinsurance rates.

Response: We believe that States generally should have flexibility in setting payment parameters, but we do not believe that the Affordable Care Act intended for a State to allow an applicable reinsurance entity to set multiple payment parameters in the State, or for multiple applicable reinsurance entities in a State to set different payment parameters. We believe that payment parameters set by the State or HHS on behalf of the State should be uniform throughout the State.

Comment: Several commenters supported the requirement that if there are multiple applicable reinsurance entities in a State, these entities must be required to operate in distinct geographic areas.

Response: We are finalizing that requirement in § 153.210(a)(2).

Comment: Several commenters asked for clarification or changes in the content that a State must provide in its notice of benefit and payment parameters. In particular, commenters stated that the proposed rule did not define the term “risk adjustment data validation methodology.”

Response: We believe our proposed rule struck a balance between providing minimal baselines for States and providing States with flexibility for their State notices. We are clarifying the provisions related to risk adjustment data validation by requiring that § 153.110(f) align with § 153.330(a) and § 153.350.

C. Subpart C—State Standards Related to the Reinsurance Program

Section 1341 of the Affordable Care Act directs that a transitional reinsurance program be established in each State to help stabilize premiums for coverage in the individual market during the benefit years 2014 through 2016. Under this provision, all health insurance issuers, and third-party administrators on behalf of self-insured group health plans, must make contributions to support reinsurance payments to non-grandfathered plans of individual market issuers that cover high-cost individuals. As a basis for reinsurance payments, the law directs HHS to develop a list of 50 to 100 medical conditions to identify high-cost individuals, or to identify alternative methods for payment in consultation with the American Academy of Actuaries.

In subpart C of the proposed rule, we proposed to codify in regulation section 1341 of the Affordable Care Act as it relates to establishing a reinsurance program. Related standards on health

insurance issuers with respect to reinsurance were proposed in subpart E of the proposed rule.

1. Reserved (§ 153.200)

Section 153.200 of the proposed rule defined a number of terms used in this subpart. Those definitions have been moved to subpart A. We are reserving this section for future use.

2. State Establishment of a Reinsurance Program (§ 153.210)

In § 153.210 of the proposed rule, we described standards for States regarding the establishment of a reinsurance program. We proposed in paragraph (a) that each State that elects to operate an Exchange must also establish a reinsurance program as required by the law. In paragraph (a)(1), we proposed to codify in regulation section 1341(a) of the Affordable Care Act, which requires that States must either enter into a contract with an existing applicable reinsurance entity or establish an applicable reinsurance entity to carry out the provisions for the reinsurance program. We believe the statute allows State flexibility in selecting an applicable reinsurance entity and did not propose more specific guidelines.

The Affordable Care Act also allows States to set up more than one reinsurance entity, although this option may increase administrative costs. We proposed in paragraph (a)(2) that, for any State that chooses to have more than one reinsurance entity, the State must publish in a State notice of benefit and payment parameters, described in subpart B, information regarding the geographic divisions between the applicable entities. We further interpret the statute to imply that the geographic divisions of the applicable reinsurance entities must be distinct and together cover the entire individual market in the State and not just certain areas or populations. In paragraph (a)(3), we proposed to allow the State to permit a reinsurance entity to subcontract for administrative functions, provided that the State reviews and approves these subcontracted arrangements as described in paragraph (a)(4). We interpreted the statute to allow flexibility in the performance of administrative functions, with the understanding that the responsible party must be the applicable reinsurance entity.

We proposed in paragraph (a)(5) that the establishment of, or contract with, an applicable reinsurance entity must extend for a sufficient period to ensure that the entity can fulfill all reinsurance requirements for the benefit years 2014 through 2016, and any activities

required to be undertaken in subsequent periods. Any State in which contributions remain to be disbursed for benefit years beyond 2016 must ensure that an applicable reinsurance entity is available for required payment activities for such additional periods. Section 1341(b)(4) of the Affordable Care Act requires that these payments be completed by December 31, 2018.

We clarified in paragraph (b) that there may be situations in which an applicable reinsurance entity operates a reinsurance program for more than one State. In such cases, we consider each contract to be an individual reinsurance arrangement between a specific State and the applicable reinsurance entity.

We proposed in paragraph (c) to allow a State that does not elect to establish an Exchange to operate its own reinsurance program. Under this circumstance, the State will be required to carry out the provisions of this subpart. In paragraph (d), we proposed that if a State does not elect to establish an Exchange and does not elect to establish its own reinsurance program, HHS will establish the reinsurance program and will perform all the reinsurance functions for that State. These functions would include the collection of all contributions described in § 153.220, including funds required to operate and administer the applicable reinsurance functions. In paragraph (e), we proposed that each State that establishes a reinsurance program must ensure that each applicable reinsurance entity within the State complies with all provisions of this subpart and with subpart E.

For the reasons described in the proposed rule and considering the comments received, we are finalizing these provisions with the following modifications:

In paragraph (a), we are clarifying that because reinsurance is no longer a required Exchange function, each State is eligible to establish a reinsurance program regardless of whether the State establishes an Exchange; we are removing proposed paragraph (c) to conform to this change. We are clarifying in paragraph (a)(2) that each State is required to notify HHS in the manner and timeframe specified by HHS of the percentage of reinsurance contributions received by HHS for the State to be allocated to each applicable reinsurance entity, if applicable. We are moving the requirement that a State publish the geographic boundaries for each applicable reinsurance entity, if it elects to have more than one, to subpart B. Finally, we are making a number of clarifying modifications to this section.

Comment: We received a comment suggesting a number of entities that could serve as a not-for-profit reinsurance entity for a State. We received a few comments urging that we provide more guidance on entities eligible to be State applicable reinsurance entities. One commenter suggested that the State reinsurance entity be subject to both Federal and State oversight.

Response: We believe that a State should have the discretion to select the entity that will administer its reinsurance program, and do not establish specific standards for that selection. We understand the commenter's concern about oversight, and note that § 153.210(d) requires States to ensure compliance with subpart C when the State is operating the reinsurance program. When HHS is operating a reinsurance program on behalf of the State, HHS will also ensure such compliance. Because we believe that States should have flexibility in selection and oversight over the applicable reinsurance entity, we are not proposing further guidance on those matters.

Comment: We received a comment suggesting that HHS provide options for States to terminate an entity for cause.

Response: We believe that nothing in this final rule precludes States from terminating a contract with an applicable reinsurance entity in a manner consistent with State law (including regulations governing contracting). In such an event, the State should ensure a seamless transition of reinsurance functions to another applicable reinsurance entity to prevent any disruption in the program.

Comment: We received many comments suggesting that a State establishing an Exchange not be required to operate a reinsurance program. Commenters stated that it would be difficult for a State to identify a not-for-profit entity to operate the transitional reinsurance program. One commenter suggested that HHS execute a master contract with a single reinsurance entity that satisfies all of the requirements in this final rule and permit States to use that entity. Another commenter stated that a State's options for establishing a reinsurance program should be similar to those it has with respect to establishing a risk adjustment program.

Response: We are no longer requiring that States that establish an Exchange also establish a reinsurance program. We believe that this flexibility is appropriate because some States have previously established reinsurance programs, and may feel they are

prepared to operate a reinsurance program for their State. If a State chooses not to establish a reinsurance program, HHS will establish a reinsurance program for that State.

Comment: We received one comment asking HHS to publish a white paper on draft methodologies for reinsurance.

Response: We are describing the general methodology for collecting reinsurance contributions and making reinsurance payments in subpart C of this final rule. We plan to provide further details on this methodology, including the national rate for contributions and State-based reinsurance payment parameters, in the HHS notice of benefit and payment parameters.

Comment: We received a comment seeking clarification on the use of unexpended contribution funds collected in calendar years 2014 through 2016, and funds that may remain after 2016.

Response: We believe that unused reinsurance funds should be used by the State until expended or by December 31, 2018, whichever date comes first, to make reinsurance payments. States are not prohibited from continuing a reinsurance program, but may not use reinsurance contribution funds collected under the reinsurance program in calendar years 2014 through 2016 to fund the program in years after 2018. If contribution funds collected for a calendar year between 2014 and 2016 remain unspent by December 31 of the year, those funds may be carried into the next year to make payments for the next year or to make retroactive payments for prior years.

Comment: We received a comment asking that existing State reinsurance programs be permitted to serve as a combined reinsurance program. The commenter further suggested permitting the use of reinsurance contributions collected under the transitional reinsurance program for an existing State reinsurance program.

Response: We believe that a State with an existing reinsurance program in place can modify that program to comply with the standards for the transitional reinsurance program. The State would be required to contract with a not-for-profit reinsurance entity to administer the program, and the applicable reinsurance entity must comply with the standards.

Contributions collected for the transitional reinsurance program must be used to make reinsurance payments pursuant to the transitional reinsurance program based on the payment parameters established by the State or HHS on behalf of the State, and may not

be used to fund a separate State reinsurance program.

3. Collection of Reinsurance Contribution Funds (§ 153.220)

In § 153.220 of the proposed rule, we described standards for the collection of reinsurance contribution funds. In paragraph (a)(1) (now paragraph (c)), we proposed to codify in regulation the aggregate contribution amounts required under the Affordable Care Act for reinsurance. The Affordable Care Act requires that the reinsurance entity collect specified additional contribution funds for deposit into the general fund of the U.S. Treasury. In paragraph (a)(2), we proposed to codify in regulation these additional contribution amounts.

Although the transitional reinsurance program is State-based, section 1341(b)(3) sets contribution amounts for the program on a national basis. We considered two approaches to collecting contribution funds: (1) Use of a national uniform contribution rate, and (2) use of a State-level allocation, both set by HHS to ensure that the sum of all contribution funds equals the national amounts set forth in the Affordable Care Act. In paragraph (b), we proposed using a national contribution rate. Use of a national contribution rate is a simpler approach. Further, since there is significant uncertainty about individual market enrollment, the overall health of the enrolled population, and the cost of care for new enrollees, we believed that a national contribution rate would be the less ambiguous approach of the two. All contribution funds collected by a State establishing a reinsurance program under the national contribution rate would stay in that State and be used to make reinsurance payments on valid claims submitted by reinsurance-eligible plans in that State. There are two methods we considered for determining contributions using a national rate: (1) A percent of premium amount applied to all contributing entities, and (2) a flat per capita amount applied to all covered enrollees of contributing entities. In paragraph (b)(1) (now paragraph (e)), we proposed the percent of premium method as the fairest method by which to collect these contributions.

In paragraph (b)(2) (now paragraph (e)), we also proposed requiring that all contribution funds collected for reinsurance payments be used for reinsurance, and all contribution funds collected for the U.S. Treasury be paid to the U.S. Treasury. In paragraph (b)(3)(i), we proposed that a State may collect more than would be collected under the national rate, if the State believes that these amounts are not sufficient to cover the payments it will

make under the payment formula. In paragraph (b)(3)(ii) (now paragraph (g)), we proposed permitting a State to collect more than the amount collected at the national rate to cover the administrative costs of the applicable reinsurance entity.

We also considered the frequency with which applicable reinsurance entities should collect contribution funds from contributing entities. For example, applicable reinsurance entities could collect contribution funds intended for reinsurance payments and payments to the U.S. Treasury on a monthly basis beginning in January 2014 so that reinsurance payments could begin in February 2014.

Considering the comments received, we are finalizing these provisions with the following modifications:

In paragraph (a), we are revising the proposed provisions so that HHS would collect contribution funds from self-insured plans and third-party administrators on their behalf, whether or not a state elects to establish a reinsurance program. This policy is consistent with traditional Federal oversight of self-insured plans. States that establish a reinsurance program would have the option, but not the obligation, to collect contributions from issuers in the fully insured market. If a State does not elect to collect from the fully insured market, HHS would collect contributions from both fully insured and self-insured plans.

In paragraph (b), we are clarifying that a State that elects to establish a reinsurance program must generally notify HHS by September 1 of the calendar year that is two years prior to the applicable benefit year if the State plans to collect reinsurance contributions from fully insured plans. However, due to States' anticipated workload in establishing Exchanges in the fall of 2012, we are postponing the deadline for notifying HHS of a State's intent to collect reinsurance contributions from fully insured plans to December 1, 2012, for the 2014 benefit year (with the notification being required by September 1 of the calendar year two years prior to the applicable benefit year for any benefit year after 2014). The State's notification will be effective for the applicable benefit year and each subsequent benefit year during which reinsurance-related activities continue.

Paragraph (d) describes how contribution funds collected by HHS will be distributed: HHS will distribute the reinsurance contributions collected to the applicable reinsurance entity for a State, net of the State's share of the U.S. Treasury contribution and

administrative expenses incurred when performing reinsurance functions under this subpart.

In paragraph (e), we are clarifying that HHS will set the national contribution rate in the annual HHS notice of benefit and payment parameters along with the proportion of the national contribution rate that will be allocated to reinsurance payments, payments to the U.S. Treasury, and administrative expenses of the applicable reinsurance entity for the State or HHS when performing reinsurance functions under this subpart.

In paragraph (g), we are clarifying that a State may elect to collect more than the amounts that would be collected based on the contribution rate to provide funding for administrative expenses or additional reinsurance payments. This policy was proposed in paragraph (b)(3) of the proposed rule. In paragraph (h), we describe the administration of additional State collections. If a State establishes a reinsurance program and elects to collect more than the amounts that would be collected based on the national contribution rate for administrative expenses, then the State must notify HHS within 30 days after publication of the proposed annual HHS notice of benefit and payment parameters of the additional contribution rate that it elects to collect for administrative expenses. Further, the State must ensure that the State's applicable reinsurance entity collects any additional amount for administrative expenses, or accepts additional amounts from HHS in accordance with the State's election under paragraph (a)(1). For reinsurance payments, notwithstanding paragraphs (a)(1) and (a)(2), the State must ensure that the State applicable reinsurance entity collects all additional reinsurance contributions from contributing entities for the purpose of reinsurance payments. In sum, HHS will only collect additional amounts for administrative expenses for a State, and will not collect additional amounts for reinsurance payments for a State. The collection of additional amounts for reinsurance payments must be carried out by the State's applicable reinsurance entity. We are also making a number of clarifying modifications throughout this section.

Comment: We received many comments expressing concern that States may lack the ability to collect contributions from self-insured plans, due to the States' lack of authority and oversight of self-insured plans.

Response: We are revising the proposed collection process so that HHS

collects from the self-insured market in all States. We believe that this change in collection process will create a more efficient, centralized collection from self-insured plans that is beneficial to both States and third party administrators on behalf of group health plans. This collection is authorized under HHS' authority under section 1321(c)(1) of the Affordable Care Act to "take such actions as are necessary to implement" the requirements of title I of the Affordable Care Act.

Comment: We received overwhelming support for the proposed use of a national uniform contribution rate. However, one commenter expressed concern with this approach, and suggested a State-level allocation to make the redistribution of contribution funds proportional to the size of the State's individual market.

Response: Consistent with the majority of comments, we believe that a national uniform contribution rate is the better approach because it is simpler and more easily implemented for a transitional program. The statute does not specify the approach for collection of contributions, but requires HHS to consult with the NAIC in determining provisions for the reinsurance program. NAIC supported the use of a national contribution rate because it minimizes the burden on States and issuers and is more equitable. NAIC also stated in its official response to the proposed rule that a State-level allocation would be more administratively burdensome for issuers and States and would not guarantee fairness in the collection of contributions. While one commenter expressed concern that use of a national contribution rate would result in underfunding of reinsurance, we believe that a State's right to increase the contribution rate addresses this concern.

Comment: Many commenters supported the proposed percent of premium method, arguing that a percent of premium method better allocates contributions to States with higher premium and healthcare costs. A few commenters opposed use of a percent of premium method due to its complexity and a concern that it could adversely impact the market.

Response: HHS has considered the advantages and disadvantages of both methods, along with the overarching goals for the transitional reinsurance program, which are to (1) Stabilize premiums by offering protection to health insurance issuers against medical cost overruns for high-cost enrollees in the individual market; (2) provide early and prompt payment of reinsurance funds during the benefit year; (3) minimize administrative burden; and (4)

allow contributions collected by or on behalf of a State to remain in that State. Given these goals and the time-limited nature of the program, we believe that the per capita approach will be less complex to administer, particularly with regard to the self-insured market. Further, the per capita approach will better enable us to maintain the goals of the reinsurance program by providing issuers with a more straightforward approach in making contributions to the reinsurance program with minimal administrative burden. A State would still be allowed to collect additional contributions towards reinsurance payment.

While several commenters expressed support for our original proposal of a percent of premium method, these same stakeholders also support timely collection and payment in the reinsurance program, which is an important component of the premium stabilization provided by the reinsurance program. We believe that the per capita approach will best achieve this goal.

4. Calculation of Reinsurance Payments (§ 153.230)

In § 153.230 of the proposed rule, we set the payment policy for the reinsurance program based upon consultation with the American Academy of Actuaries. The reinsurance payment policy must address two basic issues: (1) How to determine the individuals who are covered by reinsurance, and (2) how to determine appropriate payment amounts. Given the short-term nature of the program, our primary objective is to select an implementation approach that is administratively and operationally simple, but satisfies the goals of the program. Therefore, we prefer to use reliable and readily accessible data sources that will allow health insurance issuers to receive prompt payment. We proposed in paragraph (a) that coverage be based on items and services within the essential health benefits for an individual enrollee that exceeds an attachment point.

In paragraph (b), we proposed to announce the reinsurance payment formula and State-specific values for the attachment point, reinsurance cap, and coinsurance rate in the annual HHS notice of benefit and payment parameters. We believe that publishing this information in a Federal notice is the best approach for announcing the attachment point and reinsurance cap, as these values may change in calendar years 2015 and 2016. The Affordable Care Act does not suggest that the three-year reinsurance program should

replace commercial reinsurance or internal risk mitigation strategies. There will be a continued need for ongoing commercial reinsurance. Therefore, we proposed establishing a reinsurance cap set at a level approximately equal to the attachment point for traditional commercial reinsurance.

In paragraph (b)(1) (now paragraph (c)), we proposed that the reinsurance payment amount be a percentage of those costs above an attachment point and below a reinsurance cap. However, we believe States may have unique situations, and will permit a State that establishes a reinsurance program to establish its own payment formula by varying the attachment point, coinsurance rate, and reinsurance cap. The preamble to the proposed rule contains a further discussion of the reasoning and background behind the policy proposed in paragraph (b)(1).

We proposed using medical cost experience to identify eligible enrollees for which health insurance issuers would receive reinsurance. This approach for calculating reinsurance payments considers costs only for high-risk individuals. However, use of a reinsurance cap, as well as the fact that a health insurance issuer pays only a portion of costs above the attachment point and below the cap, may incentivize health insurance issuers to control costs.

We proposed in paragraph (b)(2) (now moved to § 153.220(f)(2)(ii)), that all payments to the general fund of the U.S. Treasury be made on a frequency to be determined by HHS. We have also considered the frequency with which payments should be made to the U.S. Treasury. For example, the applicable reinsurance entities could remit payment on a monthly or quarterly basis commencing February 28, 2014 and continuing through January 31, 2017 or until States have remitted the full amount of all payments. We proposed in paragraph (c) (now paragraph (d)), to allow some degree of State variation from the reinsurance parameters proposed by HHS. We proposed in paragraph (c)(1) (now paragraph (d)(1)), that the State may alter the attachment point, reinsurance cap, including elimination of the cap, and coinsurance rate. We proposed in paragraph (c)(2) (now paragraph (d)(2)), that States must publish any modification to the reinsurance payment formula and parameters in a State notice of benefit and payment parameters as described in subpart B of this part. We proposed in paragraph (c)(3) (now paragraph (d)(3)), that the State must ensure that all proposed alterations to the reinsurance formulas proposed by HHS, including

payments and contributions, result in the applicable reinsurance entity having sufficient contributions to meet all of its obligations for payments. These alterations to reinsurance parameters do not require HHS approval.

We believe that a State may have many reasons to make adjustments to the HHS reinsurance payment formula. First, the State may decide to increase reinsurance payments above the levels established by HHS. Second, the State may have additional unexpended funds from a prior contribution period and may seek to adjust the reinsurance formulas to disburse the unexpended funds. Finally, the State may elect to pay the same amounts recommended by HHS, but may wish to modify the frequency of those payments.

For the reasons described in the proposed rule and considering the comments received, we are finalizing these provisions, with the following modifications:

In paragraph (a), we are no longer requiring that payment be linked to the coverage of essential health benefits. In paragraph (b), we are clarifying that the States must use, subject to any modifications made pursuant to paragraph (d), the payment formula and values for the attachment point, reinsurance cap, and coinsurance rate for each year commencing in 2014 and ending in 2016, established in the annual HHS notice of benefit and payment parameters for the applicable benefit year. We are removing paragraph (b)(2) due to the new policy on collections and payments to the U.S. Treasury set forth in § 153.220. We are revising paragraph (c)(3) (now paragraph (d)(3)), to clarify that any State modification to the reinsurance payment formula pursuant to paragraph (d)(1) must be reasonably calculated to ensure that contributions received toward reinsurance are sufficient to cover payments that the applicable reinsurance entity is obligated to make under that State formula for the given benefit year for the reinsurance program. We are making a number of clarifying modifications throughout this section.

Comment: We received a number of comments that emphasized that reinsurance programs typically are tied not to underlying conditions that lead to high enrollee medical costs, but to claims costs beyond a specific dollar threshold within a coverage period, regardless of enrollees' health condition. Several commenters stated that coverage of specific conditions under a reinsurance program could lead to discriminatory practices toward certain individuals, with one commenter noting

that identifying medical conditions as a basis for reinsurance payments would require more extensive verification than usually required by traditional reinsurance. Another commenter stated that reinsurance that makes payments based solely on incurred costs does not encourage efficient and effective care.

Response: We are finalizing the provisions that base reinsurance payments on total claims costs, rather than specific diagnoses. We believe that because reinsurance payments are likely to only reimburse a portion of claims costs above the attachment point and will pay no costs above the reinsurance cap, there will still be incentives for an issuer to encourage efficient and effective care.

Comment: We received a few comments suggesting that States be permitted to use one of the other approaches proposed by the American Academy of Actuaries for determining eligible individuals for reinsurance.

Response: In consultation with HHS, the American Academy of Actuaries proposed four approaches for determining eligible individuals for the reinsurance program, described in the preamble to the proposed rule. From those proposals, we selected the approach based on total claims costs. We believe that permitting States the flexibility to select one of the other American Academy of Actuaries approaches would unnecessarily burden issuers operating in multiple States. Because reinsurance is a transitional program, we wish to avoid that additional burden on issuers, and are finalizing the proposed policy that uses total claims cost.

Comment: We received many comments supporting our proposed approach for calculating reinsurance payments based on the use of an attachment point, coinsurance rate, and reinsurance cap. One commenter expressed concern that the proposed approach may reduce the incentive to control costs.

Response: We understand the concerns regarding cost control. However, since issuers are likely to not be fully reimbursed under the reinsurance program for claims costs above the attachment point, we believe that they will continue to have an incentive to control costs.

Comment: We received a comment asking for clarification on whether reinsurance payments are made on an incurred basis.

Response: As indicated in the proposed definitions for “attachment point,” “coinsurance rate,” and “reinsurance cap,” we intend for claims costs to be measured on an incurred

basis for purposes of calculating reinsurance payments.

5. Disbursement of Reinsurance Payments (§ 153.240)

In § 153.240, we proposed parameters for the timing of reinsurance payments. In paragraph (a) of this section, we proposed that States must ensure that the applicable reinsurance entity collects from health insurance issuers of reinsurance-eligible plans data required to calculate payments described in § 153.230, according to the data requirements and data collection frequency specified by the State in the State notice of benefit and payment parameters described in subpart B, or in the annual HHS notice of benefit and payment parameters.

In paragraph (b), we proposed that a State must ensure that each applicable reinsurance entity makes payments that do not exceed contributions and makes payments to health insurance issuers of reinsurance-eligible plans according to § 153.230. We also proposed in paragraph (b)(2) (now paragraph (b)(1)), to allow a State to reduce payments on a pro rata basis to match the amount of contributions received by the State in a given reinsurance year, and to require that pro rata reductions made by the State be made in a fair and equitable manner for all health insurance issuers in the individual market.

In paragraph (b)(3) (now paragraph (b)(2)), we proposed that a State be required to ensure that an applicable reinsurance entity make payments as specified in § 153.410(b) to the issuer of a reinsurance-eligible plan after receiving a valid claim for payment. Finally, in paragraph (c), we proposed that for each benefit year, the State be required to maintain all records related to the reinsurance program for 10 years, consistent with requirements for record retention under the False Claims Act.

For the reasons described in the proposed rule and considering the comments received, we are finalizing these provisions with the following modifications:

We are clarifying in paragraph (b) that the State must ensure that each applicable reinsurance entity does not make reinsurance payments that exceed contributions received to date. We are removing paragraph (b)(1) because those requirements are covered in § 153.230 and paragraph (b)(2) (formerly paragraph (b)(3)). We are clarifying in paragraph (b)(1) (formerly paragraph (b)(2)), that if a State, or HHS on behalf of the State, determines that reinsurance payments requested for a calendar year will likely exceed the reinsurance contributions that will be received for

the year, the State, or HHS on behalf of the State, may reduce reinsurance payments, so long as the manner in which payments are reduced is fair and equitable for all health insurance issuers in the individual market. We are making a number of clarifying modifications throughout this section.

Comment: We received many comments related to the timing of reinsurance payments. Some commenters asked that States be provided flexibility in determining payment timeframes. A few commenters suggested that contributions be collected monthly, but that payments be made quarterly. One commenter suggested providing early funds to small carriers to cover potential cash flow shortfalls.

Response: We recognize the importance of providing issuers with reinsurance payments in a timely manner, but we believe it is prudent to maintain flexibility in payment timing to ensure that sufficient contributions are available to fund those payments. We are finalizing the proposal permitting States to establish the payment timeframe in the State notice of benefit and payment parameters described in subpart B. For reinsurance programs established by HHS on behalf of the State, HHS will publish the payment timeframe in the HHS notice of benefit and payment parameters. We anticipate that States will take into account the cash flow needs of small issuers in setting the reinsurance payment timeframes.

Comment: We received several comments suggesting that HHS prohibit health insurance issuers from passing reinsurance payment shortfalls on to providers.

Response: We understand the concern raised by the commenters, and we encourage providers to work with plan issuers concerning this matter.

Comment: We received several comments on the duration of the record maintenance requirement. Commenters suggested retention requirements ranging from two to fifteen years, with many commenters suggesting a five-year period.

Response: We believe that the record retention requirements for reinsurance should be consistent with other Federal record retention requirements, and are finalizing the proposed provision that requires records to be retained for ten years, as explained above.

6. Coordination With High-Risk Pools (§ 153.250)

In § 153.250(a) of the proposed rule, we proposed to codify in regulation section 1341(d) of the Affordable Care

Act, which requires that States eliminate or modify high-risk pools to the extent necessary to carry out the reinsurance program. In paragraph (a), we proposed to codify in regulation the above-referenced section. In paragraph (b), we proposed to permit a State that continues its high-risk pool to coordinate its high-risk pool with its reinsurance program to the extent it conforms with the provisions of this subpart.

For the reasons described in the proposed rule and considering the comments received, we are finalizing these provisions with no modifications.

Comment: We received several comments recommending that high-risk pools be permitted to be offered as individual market plans eligible for reinsurance. One commenter requested that reinsurance contributions be used to fund the costs of operating State high-risk pools during the three-year period. Several commenters suggested not combining reinsurance funds with funds for high-risk pools, and opposed permitting high-risk pools to receive reinsurance payments.

Response: We clarify in § 153.400 that State high-risk pools are excluded from contributions and payments. We clarify, as we did in the proposed rule, that none of the funds collected for reinsurance can be used for any purpose other than for making payments under the reinsurance program or for administering that program. We understand the concerns of some commenters regarding the transition of high-risk pool participants and point out that the Exchanges will work with State high-risk pools to ensure a smooth transition and continuity of care for these enrollees. We believe that the reinsurance program, along with the risk adjustment and risk corridors programs, were designed in anticipation of new high-cost enrollees, some of whom may currently be receiving coverage through State high-risk pools.

Comment: We received a comment suggesting coordination between PCIP and the transitional reinsurance program.

Response: Section 1101 of the Affordable Care Act requires coordination between PCIP and the Exchanges. To the extent that individuals previously enrolled in PCIP enroll in reinsurance-eligible plans, issuers will have access to the reinsurance program for these enrollees.

D. Subpart D—State Standards Related to the Risk Adjustment Program

In subpart D, we proposed standards for States with respect to the risk adjustment program required under

section 1343 of the Affordable Care Act. Parallel provisions for health insurance issuers were proposed in subpart G of this part. Section 1343 provides for a program of risk adjustment for all non-grandfathered plans in the individual and small group market both inside and outside of the Exchange. The risk adjustment program is intended to reduce or eliminate premium differences between plans based solely on expectations of favorable or unfavorable risk selection or choices by higher risk enrollees in the individual and small group market. The risk adjustment program also serves to level the playing field inside and outside of the Exchange, reducing the potential for excessive premium growth or instability within the Exchange. We interpret section 1343 to mean that risk pools must be aggregated at the State level, even if a State decides to utilize regional Exchanges. Furthermore, section 1343(c) indicates that risk adjustment applies to individual and small group market health insurance issuers of non-grandfathered plans within a State, both inside and outside of the Exchange. Accordingly, similar to our approach in reinsurance, if multiple States contract with a single entity to administer risk adjustment, risk may not be combined across State lines, but must be pooled within each State.

1. Reserved (§ 153.300)

Section 153.300 of the proposed rule defined a number of terms used in this subpart. Those definitions have been moved to subpart A. We are reserving this section for future use.

2. Risk Adjustment Administration (§ 153.310)

In this section, in paragraph (a)(1), we specified that any State electing to establish an Exchange is eligible to establish a risk adjustment program. Pursuant to section 1321(c)(1) of the Affordable Care Act, we proposed in paragraph (a)(2) that for States that do not operate an Exchange, HHS will establish a risk adjustment program. We also clarified in paragraph (a)(3) that HHS will administer all of the risk adjustment functions for any State that elects to establish an Exchange but does not elect to administer risk adjustment. We are finalizing this provision, with a number of clarifying modifications.

Comment: Many commenters supported permitting States to defer operation of a risk adjustment program to HHS. One commenter recommended that any State should be eligible to operate a risk adjustment program, whether or not the State is establishing an Exchange.

Response: An effective risk adjustment program is critical to prevent adverse selection and stabilize premiums inside and outside the Exchanges. Developing a risk adjustment program is methodologically and operationally complex. We believe that, particularly in the initial years, States may wish to defer risk adjustment operation to HHS in order to focus resources on establishing Exchanges. We are therefore finalizing these provisions to provide States the option to operate risk adjustment if they establish Exchanges. Because we believe that the Federally Facilitated Exchange should be operated in coordination with a risk adjustment program that is closely tied to its implementation, States not operating Exchanges and States entering into a partnership with or relying entirely on the Federally Facilitated Exchange will not be permitted to operate a risk adjustment program. We will clarify in future guidance the process through which a State will notify HHS of its choice to operate risk adjustment if it establishes an Exchange beginning in 2014 or any subsequent year.

In paragraph (b), we clarified that a State may elect to have an entity other than the Exchange perform the risk adjustment functions of this subpart, provided that the selected entity meets the requirements for eligibility to serve as an Exchange set forth in § 155.110 of the proposed Exchange Establishment rule. Considering the comments received, we are finalizing this provision, noting that the definition of an entity eligible to serve as an Exchange has been modified from the proposed definition.

Comments: Commenters offered varying opinions regarding the requirements for entities to be eligible to administer risk adjustment. Several commenters urged HHS to include stronger provisions prohibiting conflicts of interest. Those commenters stated that all members of the board of a risk adjustment entity should be free of financial ties to issuers, and that consumer representation on the board should be required. One commenter believed that an entity's eligibility to be a risk adjustment entity should be based on the entity's experience, and not on the requirements governing entities carrying out Exchange functions. Other commenters stated that the requirements on entities eligible to administer risk adjustment and carry out Exchange functions were overly restrictive, noting that the requirements would exclude State regulators, such as a State Department of Insurance. This commenter asked that the regulator in

each State be eligible to administer risk adjustment. Two commenters suggested that entities be eligible to administer both risk adjustment and reinsurance.

Response: We believe that a State may have a single entity administer reinsurance and risk adjustment, provided that the entity meets the separate requirements to administer both programs. We note that to be eligible to administer reinsurance, an entity must meet the definition outlined in § 153.20. We also appreciate concerns that risk adjustment entities may have board members with conflicts of interest and, further, that because risk adjustment involves the transfer of money between plans, these concerns may be especially relevant for this program. We encourage States to weigh these concerns when establishing a risk adjustment entity. However, we seek, to the extent possible, consistency between the requirements to serve as a risk adjustment entity and the requirements to serve as an entity performing other Exchange functions.

In paragraph (c), we proposed timeframes for the risk adjustment process. We proposed that all payment calculations commence with the 2014 benefit year. We sought comment on the appropriate deadline by which risk adjustment must be completed each year. In response to comments, we are finalizing the standard that risk adjustment be implemented beginning with the 2014 benefit year, and are including a requirement that each issuer be notified of risk adjustment payments owed to, or charges owed by, the issuer by June 30 of the year following the benefit year. We believe that this deadline best balances the need to coordinate risk adjustment payments and charges with other programs, and the need to ensure that high quality risk adjustment data is available to support the program.

Comments: We received a number of comments recommending that risk adjustment be performed before completion of the MLR calculation process. Two commenters specified that risk adjustment should be completed by late May of the year following the benefit year in order to accommodate the Federal MLR reporting deadline of June 1. Other commenters stated that it would be difficult to coordinate risk adjustment payments with MLR reporting. Two commenters suggested extending the MLR deadline for 2014 through 2016. One commenter suggested delaying the implementation of risk adjustment until 2016.

Response: The risk adjustment process relies in part on high quality claims data. Allowing for claims run-out

after the benefit year increases the amount and quality of claims data because issuers will have more time to receive, review and pay claims made during the benefit year. Better quality data will lead to more accurate risk scores, which ultimately feed into the calculation of plan average actuarial risk and the calculation of payments and charges.

In the preamble to the proposed rule, we discussed requiring that States complete the risk adjustment process by June 30 of the year following the benefit year, or June 30, 2015 for the benefit year 2014. States would be free to set a payment schedule (including interim payments throughout the benefit year), but would be required to comply with the June 30 deadline. Many commenters agreed that June 30 was a reasonable deadline for completion of the risk adjustment process. We have included in the final rule a June 30 deadline for the completion of the risk adjustment process. We believe that 6 months following the benefit year is a reasonable timeframe to complete the risk adjustment process.

The deadline to submit MLR reports to the Federal government is June 1 of the year following the calendar year experience being reported. MLR calculations must take into account risk adjustment payments and charges. We recognize that our proposed deadline is inconsistent with the current Federal MLR reporting deadline, but believe that allowing sufficient time to collect quality data to support risk adjustment is extremely important and would be extremely difficult to complete within current MLR timeframes. We will work to resolve this issue prior to 2014.

Comments: A few commenters suggested that risk adjustment payments be made quarterly, with the final payment to be made after the first quarter of the year following the benefit year.

Response: We believe that States should have the flexibility to set a payment schedule that best suits their program administration. Therefore, we did not include a requirement that States adhere to a specific payment schedule.

In the preamble to the proposed rule, we discussed our belief that States should provide HHS with a summary report of risk adjustment activities for each benefit year in the year following the calendar year covered in the report. The final rule directs States to submit an annual summary report of their program. We believe that this report will permit States to learn from other States' experience and will help HHS evaluate the implementation of the risk

adjustment program. We will specify the contents of the report in future guidance, but expect the report would include information such as plan average actuarial risk score and the risk adjustment payment or charge for each risk adjustment covered plan in the State, trends in risk scores over time, evidence of upcoding, and other risk adjustment-related elements. We expect that States will make summary reports publicly available. We believe this report will facilitate periodic evaluation, oversight, and continuous improvement of the risk adjustment program.

Comment: Several commenters supported the concept of providing summary reports. However, one commenter was unwilling to fully support the requirement until knowing the content that would be required in the report. Two commenters suggested that the report include the average actuarial risk for each plan, the risk adjustment charge or payment for each plan, and information on risk scores and cost trends, including evidence of upcoding and error rates determined under the most recently completed risk adjustment data validation audits. We also received comments requesting that HHS require that State risk adjustment entities report information about their States' risk adjustment program to issuers. Finally, we received one comment suggesting that all funds collected by the risk adjustment entity be required to be used only in connection with the risk adjustment program.

Response: Annual summary reports can serve as a tool for States and HHS to monitor and evaluate State programs across the country. HHS will also be able to use the reports to provide technical assistance to States administering risk adjustment programs when needed. The technical assistance will serve not only to improve a State's risk adjustment program, but will reduce the burden on each State to evaluate and improve its risk adjustment program. The information in the annual reports will also be useful in evaluating the implementation of the Federally developed risk adjustment methodology and other Federally certified risk adjustment methodologies. For these reasons, we have added paragraph (d) to this final rule to ensure that States submit annual risk adjustment program reports to HHS.

3. Federally Certified Risk Adjustment Methodology (§ 153.320)

Section 1343(b) of the Affordable Care Act requires HHS to establish criteria and methods for risk adjustment in coordination with the States. We

interpret this provision to mean that HHS will establish a baseline methodology to be used by a State, or HHS on behalf of the State, in determining plan average actuarial risk. In § 153.300 of the proposed rule, we defined the risk adjustment methodology as encompassing the risk adjustment model, the calculation of plan average actuarial risk, and the calculation of payments and charges.

We proposed in paragraph (a)(1) that a Federally certified risk adjustment methodology be developed by HHS. We proposed in paragraph (a)(2) that a State-submitted alternate risk adjustment methodology may become a Federally certified risk adjustment methodology through HHS certification. For the reasons described in the proposed rule and considering the comments received, we are finalizing these provisions, with certain clarifying modifications.

Comments: One commenter requested clarification on when State alternate methodologies would be required to be submitted and would be evaluated. Multiple commenters expressed a preference that State and Federal methodologies be announced early enough to give sufficient time for issuers to incorporate anticipated risk adjustment payments or charges into their rates.

Response: While the proposed timing necessitates a short window for submission and evaluation of the alternate risk adjustment methodologies, the timeframe permits a State to evaluate the methodology proposed by HHS in the proposed annual HHS notice of benefit and payment parameters. This timeframe also permits HHS to publish all certified methodologies at one time in the final annual HHS notice of benefit and payment parameters. In future years, HHS will evaluate whether it should accept and evaluate applications for alternate risk adjustment methodologies on an earlier timeframe. However, in the initial year, the HHS methodology will likely not have been fully developed in time to benchmark alternate risk adjustment methodologies on an earlier timeframe.

We proposed in paragraph (b)(1) of this section that a State that is operating a risk adjustment program must use one of the Federally certified risk adjustment methodologies that HHS will publish in an annual HHS notice of benefit and payment parameters. We proposed that State notices of benefit and payment parameters include a full description of the risk adjustment model, including, but not limited to: (1) Demographic factors, diagnostic factors, and utilization factors (if any); (2) the

qualifying criteria for establishing that an individual is eligible for a specific factor; (3) the weights assigned to each factor; and (4) the schedule for the calculation of individual risk scores. We sought comments on other information that should be included in this notice. In paragraph (b)(2), we proposed that the risk adjustment methodology will also describe any adjustments made to the risk adjustment model weights when calculating average actuarial risk, including premium rating variation.

Considering the comments received, we are finalizing this provision, with the following modifications: We are clarifying that notices must also include a description of the calculation of plan average actuarial risk, a description of the calculation of payments and charges, and a description the risk adjustment data collection approach. We are also including a number of other clarifying modifications.

Comments: We received several comments supporting a structure in which HHS will develop a risk adjustment methodology but States have the option to submit alternate methodologies for approval by HHS. Several commenters preferred that HHS establish one national methodology. Other commenters suggested that States be required to justify deviation from the methodology developed by HHS. Two commenters believed that HHS approval of State methodologies was unnecessary, and that any State alternate methodology should be deemed certified and available to all States. Some commenters suggested that all methodologies be subject to notice and comment.

Response: We recognize that States may wish to employ alternate risk adjustment methodologies, and believe that alternate approaches could achieve results similar to those that will be achieved by the methodology developed by HHS. We agree that States should submit a rationale for their proposed alternate methodology for certification. We are therefore finalizing the proposed rule, which required publication of a rationale, with a number of clarifying modifications. HHS will develop a Federal risk adjustment methodology, and States that wish to deviate from that methodology may submit an alternate methodology to HHS for approval. States must specify in their State notice of benefit and payment parameters which of the Federally certified methodologies published in the annual HHS notice of benefit and payment parameters they will use. We believe that the publication of the Federal methodology in a notice of benefit and payment parameters addresses certain

commenters' desire that interested parties be given opportunity to comment on the methodology proposed by HHS. HHS will provide an opportunity for public comment when it administers risk adjustment on behalf of a State. State law will govern what administrative process is necessary when a State adopts a risk adjustment methodology, subject to the limits of this final rule and the annual HHS notice of benefit and payment parameters.

In paragraph (c), we proposed that HHS will specify in the annual HHS notice of benefit and payment parameters the Federally certified risk adjustment methodology that will apply when HHS operates the risk adjustment program. We are finalizing this provision, with a number of clarifying modifications.

The statute is not specific with respect to the method by which States are expected to determine the precise value of payments and charges, so we requested comment on two payments and charges methodologies and whether there are alternate methodologies that might be used. We received a number of comments requesting consistency in methodology from State to State. Therefore, we plan to establish a national method for the calculation of payments and charges that States may not vary. A national method for the calculation of payments and charges ensures a degree of consistency in the risk adjustment program from State to State while allowing States to vary certain elements of the program.

Comments: Many commenters recommended that HHS establish one national methodology or limit States' ability to deviate from the methodology developed by HHS. Other commenters supported giving States the flexibility to propose alternate methodologies so long as those methodologies are as robust as the one proposed by HHS.

Response: The calculation of payments and charges requires selection of a baseline premium, for example, a plan average or State average premium. That premium basis is multiplied by the plan average actuarial risk to calculate risk adjustment payments or charges, and requires balancing if payments do not equal charges. Thus, the calculation of payments and charges affects the amount of funds transferred from low-risk to high-risk plans, and can affect premiums in low-risk and high-risk plans.

Although a national standard methodology for calculating payments and charges provides a degree of consistency from State to State, we recognize it may also limit States' ability

to implement novel methodologies. We believe that there may be potential to introduce State variation in the calculation of payments and charges in the future. We also believe that requiring a national methodology for calculating payments and charges initially, and leaving open the possibility of permitting State variation in later years, relieves States from the burden of developing such a methodology in the first year, and provides a starting point for States seeking to create alternate methodologies in later years.

4. State Alternate Risk Adjustment Methodologies (§ 153.330)

We proposed allowing States to utilize alternate risk adjustment methodologies, provided that States taking advantage of this flexibility submit their proposed alternate risk adjustment methodologies for HHS review and certification. We proposed in paragraph (a)(1) the information about the State's proposed risk adjustment methodology that the State must include in its request for certification. In paragraph (a)(2), we proposed that all requests include information relating to certain criteria to be used in the evaluation of the request.

For the reasons described in the proposed rule, and considering the comments received, we are finalizing these provisions with the following modifications: We are including new language requiring States to provide a description of the risk adjustment methodology. This change aligns this provision with changes made to § 153.320 discussed above. We are also making a number of clarifying modifications throughout this section.

Comments: Several commenters requested greater specificity about the validation requirements for the proposed alternate risk adjustment methodologies. One commenter requested that HHS permit States to vary payments based on whether a plan participates in the Exchange or the Small Business Health Options Program. Another commenter suggested that States be permitted to vary payments based on whether the issuer implements programs to improve population health. Other commenters suggested other requirements for certification of alternate risk adjustment methodologies. For example, one commenter recommended requiring that an alternate methodology include either a separate model for pediatrics or demonstrate the model's effectiveness in pediatric populations. Another commenter recommended requiring States to specify how they will move

from a retrospective to a prospective risk adjustment approach. A number of commenters supported use of a prospective approach, while others favored a retrospective approach. Some commenters supported a diagnosis-based risk adjustment model, while others favored a demographic approach. One commenter suggested that a survey-based approach be utilized.

Response: We anticipate that a number of different approaches could receive Federal certification. HHS will provide further details on the process for receiving Federal certification for alternate risk adjustment methodologies in the draft annual HHS notice of benefit and payment parameters. State alternate methodology requests will be accepted up to 30 days after publication of the draft annual HHS notice of benefit and payment parameters, and alternate methodologies that are certified by HHS will be published in the final HHS notice of benefit and payment parameters.

In paragraph (b), we proposed that a State that operates a risk adjustment program must renew HHS certification of alternate risk adjustment methodologies whenever changes occur, including at the time of recalibration, which the State must identify when initially requesting certification for the alternate risk adjustment model. Considering the comments received, we are finalizing this provision with the following modifications: We are including language clarifying that the need to obtain recertification of a recalibrated risk adjustment model applies to any alteration to the Federally certified risk adjustment methodology.

Comment: We received two comments supporting a requirement that States wishing to recalibrate or otherwise change their methodology submit that change to HHS for approval.

Response: We are finalizing this policy.

5. Data Collection Under Risk Adjustment (§ 153.340)

As described above, a robust risk adjustment process requires data to support the determination of an individual's risk score and the plan and State average actuarial risk. In paragraph (a), we proposed that a State, or HHS on behalf of the State, be responsible for collecting data for use in the risk adjustment program. HHS considered three possibilities for data collection: (1) A centralized approach in which issuers submit raw claims data sets to HHS; (2) an intermediate State-level approach in which issuers submit raw claims data sets to the State government or the entity responsible for administering the

risk adjustment process at the State level; and (3) a distributed approach in which each issuer must reformat its own data to map correctly to the risk assessment database, and then pass on individual risk scores to the entity responsible for assessing risk adjustment charges and payments.

Considering the comments received, we are modifying this paragraph as follows: Rather than specify an intermediate risk adjustment data collection approach, we are permitting States that elect to operate a risk adjustment program to choose the risk adjustment data collection approach that best suits their program. HHS will use a distributed approach when operating risk adjustment on behalf of a State. Because a distributed approach to data collection has not been implemented on this scale, we plan to evaluate the implementation and may make changes to the approach based on that evaluation. We are including a requirement that States operating risk adjustment collect or calculate, at a minimum, individual risk scores. This requirement minimizes the collection of sensitive data while allowing States to calculate rating variation adjustments and payments and charges. We are modifying the privacy and security standards applicable when a State is operating risk adjustment. Protecting the privacy and confidentiality of an individual's personal health information continues to be among HHS' highest priorities. Under a distributed approach, issuers will need to format risk adjustment data, maintain that data in a manner that complies with State or HHS specifications, and in some cases run risk adjustment software. In addition, a State, or HHS on behalf of the State, will not be required to collect claims data; however, the data validation and audit process will be more involved.

Comments: We received a large number of comments on the collection of risk adjustment data, including many comments supporting HHS' proposed collection of risk adjustment data at the State level. A number of other commenters expressed concern for patient privacy under the proposed method of data collection. Some of those concerned about patient privacy did not explicitly oppose the proposed risk adjustment data collection approach, but encouraged HHS to collect de-identified data or carefully consider privacy and security standards, such as techniques to mask or encrypt data. We received many comments in favor of a distributed approach to risk adjustment data collection. These comments focused on the administrative complexity of transmitting claims data

to HHS and the risk of exposing private information and competitively sensitive data, such as unit prices for medical services. Another commenter suggested that States be given flexibility to choose which risk adjustment data collection approach to use when operating risk adjustment.

Response: The transmission by issuers to HHS and the storage by HHS of large amounts of sensitive data pose potential risks to consumer privacy. A distributed approach would leverage the existing data infrastructure of issuers, potentially saving Federal and issuer resources. For these reasons, HHS will utilize a distributed approach to collecting risk adjustment data when operating risk adjustment on behalf of a State.

We considered requiring that all States utilize a distributed approach to risk adjustment data collection, as HHS will do. However, we believe that requiring a particular approach runs counter to the flexibility generally afforded States by the Affordable Care Act and HHS.

We proposed in paragraph (b) that the State, or HHS on behalf of the State, use standard HIPAA transaction standards when collecting data. We proposed in paragraphs (b)(1) and (b)(2) to require States to utilize two specific HIPAA transaction standards for risk adjustment data collection. In paragraph (b)(3), to address consumer privacy concerns, we proposed that States must utilize specific privacy standards in their data collection risk adjustment procedures.

Considering the comments received, we are modifying this paragraph as follows: We are including a requirement that States require issuers to comply with the data privacy and security standards set forth in the State's notice of benefit and payment parameters.

Because we maintain the flexibility for States that operate risk adjustment programs to choose their data collection approaches, we are including a requirement that States limit their collection to the information reasonably necessary to operate the risk adjustment program. For example, a State could not collect an enrollee's name, because that information would not be reasonably necessary to operate the risk adjustment program. We are prohibiting a State from collecting or storing any personally identifiable information for use as a unique identifier for an enrollee's data, unless that information is masked or encrypted by the issuer, with the key to that masking or encryption withheld from the State. The term "personally identifiable information" is a broadly used term across Federal agencies, and has been defined in the Office of

Management and Budget Memorandum M-07-16. In order to reduce duplicative guidance or potentially conflicting regulatory language, we are not defining personally identifiable information in this final rule, and incorporate the aforementioned definition into this final rule.

The privacy and security standards outlined above reflect the changes in the risk adjustment data collection approach in paragraph (a) of this section. We note that these standards should be read to represent a minimum standard to be used in the risk adjustment program. We expect that States will build on these minimum privacy and security standards when establishing a risk adjustment data collection program.

Comment: We received a number of comments about privacy concerns associated with the proposed collection of risk adjustment data. Some commenters believed that HHS should finalize a requirement that any risk adjustment data collected be de-identified. Others preferred that data not be collected.

Response: We are committed to applying strong privacy and security standards to risk adjustment data collected by States or HHS on behalf of a State. We are amending the proposed privacy and security standards so that States that limit their collection of personally identifiable information to that which is reasonably necessary to carry out their risk adjustment methodology. In paragraph (b)(4), we require States to implement security standards that provide administrative, technical, and physical safeguards consistent with the standards described in the HIPAA Security Rule at 45 CFR 164.308, 164.310, and 164.312. We recognize that the specific requirements for data collection may vary depending on the amount and type of data States choose to collect, and thus we decided to permit States to design security requirements to accommodate these requirements. This final rule does not preclude States from implementing stricter security standards, particularly if they choose to collect additional risk adjustment data. HHS will not be collecting the claims data from issuers needed to run the risk adjustment methodology when HHS runs risk adjustment on behalf of a State. HHS will issue further guidance regarding the privacy and security standards applicable when HHS is operating risk adjustment on behalf of a State.

In paragraph (c), we proposed that States with existing all-payer claims databases may request an exception from the minimum standards for data

collection. In paragraph (d), we proposed that the State must make certain risk adjustment data available to support other activities, including: recalibrating Federally certified risk adjustment models; verifying risk corridor submissions; and verifying and auditing reinsurance claims. We have removed paragraphs (c) and (d) because these requirements are not compatible with flexibility with regard to risk adjustment data collection. In the proposed rule and preamble, we discussed a number of ways risk adjustment data could be used to support other programs such as verifying risk corridor submissions, reinsurance payments, cost-sharing reductions, and quality improvement efforts. We are continuing to explore how to obtain the data needed to support these programs. We anticipate working closely with States and issuers to efficiently gather or access the data needed to support these programs.

Comments: We received a few comments requesting that existing data collection initiatives such as all-payer claims databases be utilized to the fullest extent possible to support risk adjustment.

Response: A State operating a risk adjustment program may choose to utilize all-payer claims databases, provided that the State complies with the requirements set forth in this paragraph.

Comments: We received several comments supporting the use of risk adjustment data for other Affordable Care Act purposes. Two commenters were wary of permitting access to data for uses beyond risk adjustment because they view the data as sensitive and wish to limit Federal access to it.

Response: We believe that HHS' use of a distributed approach for risk adjustment addresses many concerns regarding centralized data collection of risk adjustment data. We are currently exploring options to collect the information needed for other purposes. We believe that States administering a risk adjustment program should, to the extent possible, seek efficiencies in data collection across programs.

6. Risk Adjustment Data Validation Standards (§ 153.350)

In § 153.350, we proposed that States have a reliable data validation process, which is essential to the establishment of a credible risk adjustment program. In paragraph (a), we proposed that the State, or HHS on behalf of the State, validate a statistically valid sample of all issuers that submit data for risk adjustment every year. In paragraph (b), we proposed that the State, or HHS on

behalf of the State, be permitted to adjust the average actuarial risk for each plan based on the error rate found in the validation. In paragraph (c), we proposed that the State, or HHS on behalf of the State, be permitted to adjust payments and charges based on the changes to average actuarial risk. Finally, in paragraph (d), we proposed that the State, or HHS on behalf of the State, be required to provide an appeals process for issuers.

Considering the comments received, we are finalizing this provision, with the following modifications: We are expanding the data validation requirements to include requirements applicable to a distributed risk adjustment data collection approach, and are making a number of clarifying modifications throughout this section.

Comments: We received several comments on data validation. We received a number of comments supporting the proposed data validation requirements. For the most part, commenters supported data validation requirements for every issuer offering risk adjustment covered plans in a State. A few commenters suggested that HHS add requirements on States, establish a national validation methodology, or perform the validation itself.

One commenter suggested that States be allowed to establish minimum values, under which annual data validation would not be required. For example, issuers with fewer than 5,000 members and less than 1 percent of the overall market would not be required to validate data annually; instead, these issuers would be required to validate data every 2 or 3 years.

Response: We believe that the data validation standards we are finalizing represent appropriate minimum standards. We believe that annual data validation for all issuers is necessary to ensure a robust risk adjustment program, and so do not believe that minimum values for annual data validation or data validation that occurs less frequently are appropriate.

Comment: We also received a number of comments about the specific data validation methodology or process. Several commenters suggested that data validation be completed throughout the year and certified at the end of the year. One commenter suggested including a requirement that data validation be maintained for the duration of risk adjustment operation. One commenter suggested that diagnoses identified by health care providers apply even if, upon subsequent audit, HHS determines that the patient's medical records did not support the provider's diagnosis. One commenter urged that States be

required to design risk adjustment data validation standards using a methodology similar to that used under the CMS-Hierarchical Condition Category system.

Response: We believe that a State should have the discretion to design its risk adjustment program, including the method for data validation. Given that risk adjustment occurs at the State level, the possibility of differences from State to State do not present a significant problem. For this reason, we are finalizing the data validation requirements with the modifications described above.

Comment: We received one comment suggesting that we insert the phrase "or HHS on behalf of the State" in paragraph (c).

Response: In the preamble to the proposed rule, we proposed "that the State, or HHS on behalf of the State, adjust payments and charges based on the changes to average actuarial risk." However, the phrase "or HHS on behalf of the State" was omitted from the proposed regulation text in paragraph (c). We are amending the final rule text to be consistent with § 153.350(a) and (b) of, and the preamble to, the proposed rule.

E. Subpart E—Health Insurance Issuer and Group Health Plan Standards Related to the Reinsurance Program

In subpart E of the proposed rule, we proposed standards for health insurance issuers that complemented the standards for the transitional reinsurance program more fully described in the preamble to subpart C of the proposed rule. Subpart C discussed standards of the program applicable to States. In subpart E, we discussed the standards applicable to health insurance issuers and self-insured group health plans.

1. Reinsurance Contribution Funds (§ 153.400)

In § 153.400, we proposed to codify in regulation section 1341 of the Affordable Care Act, which requires that the reinsurance program be funded by contribution funds from contributing entities. In paragraph (a), we proposed that all contributing entities make contributions, in a frequency and manner to be determined by the State or HHS, to the applicable reinsurance entity in the State. In paragraph (b), we proposed that if the State establishes multiple applicable reinsurance entities, the contributing entity must contribute an appropriate payment to each applicable reinsurance entity. We proposed in paragraph (c) (now paragraph (d)), that contributing entities

be required to provide the data necessary for the applicable reinsurance entity to calculate the amounts due from each contributing entity.

For the reasons described in the proposed rule and considering the comments received, we are finalizing these provisions, with the following modifications:

We are clarifying in paragraph (a) that a contributing entity must make contributions for all reinsurance contribution enrollees who reside in a State at the national rate and any additional contribution rate if a State elects to collect additional contributions. We are adding paragraph (a)(1), which clarifies that all contributing entities must make reinsurance contributions on behalf of all group health plans and health insurance coverage they represent except those set forth in paragraph (a)(2). For example, contributing entities are required to make reinsurance contributions on behalf of plans in the Federal Employee Health Benefit Program, State and local government employee plans, and grandfathered health plans. The Affordable Care Act requires these issuers and third-party administrators on behalf of self-insured plans to make reinsurance contributions.

In paragraph (a)(2), we are clarifying that contributing entities are not required to make contributions on behalf of plans or health insurance coverage that consists solely of excepted benefits within the meaning of section 2791(c) of the PHS Act. Section 1341(b)(3)(B)(i) of the Affordable Care Act requires the contribution amount for an issuer to be based on the issuer's fully insured commercial book of business for all major medical products. Issuers of certain plans are excluded from making reinsurance contributions because those plans are not "commercial books of business" or "major medical" products. Thus, private Medicare and Medicaid plans and Federal and certain State high-risk pools are exempt from making reinsurance contributions because they are not a "commercial book of business." Further, stand-alone vision and dental plans and other plans defined as excepted benefits within the meaning of section 2791(c) of the PHS Act are exempt because they are not "major medical" products.

In a new paragraph (c), we are requiring that each contributing entity submit contributions due to the Federal applicable reinsurance entity on a quarterly basis beginning January 15, 2014. We believe this timeframe is consistent with industry practice and will allow for timely transfer of

contribution funds to States and the U.S. Treasury. We believe that States should have the flexibility to set the frequency of collections by the applicable reinsurance entity.

In a new paragraph (d), we are clarifying that each contributing entity must submit to HHS and each applicable reinsurance entity, if the State elects to collect reinsurance contributions, data required to substantiate contribution amounts, in the format and with the timing specified by the State or HHS. For example, HHS may request this data in the form of a report that specifies the number of reinsurance contribution enrollees covered by a plan in each State in a month.

Comment: We received a number of comments requesting clarification as to whether certain types of plans, such as multi-State plans and CO-OP plans, are contributing entities.

Response: We believe that section 1341(b)(1)(A) of the Affordable Care Act directs a broad cross-section of issuers and self-insured plans to make reinsurance contributions, given the uncertainty of the size and characteristics of the population that will participate in the Exchanges. We discuss whether certain plans are required to make reinsurance contributions in the preamble above.

Comment: One commenter suggested that HHS clarify whether the Basic Health Plans described in Section 1331 of the Affordable Care Act will be subject to reinsurance contributions or eligible for reinsurance payments.

Response: Since guidance and regulations regarding the Basic Health Plans have not yet been issued by HHS, we are unable to provide direction at present on whether these plans are subject to the reinsurance program.

Comment: We received several comments recommending that reinsurance contributions be collected on a quarterly basis. One commenter recommended an annual collection.

Response: We have included a provision that requires that contributions to HHS be submitted quarterly in paragraph (c). A State that elects to collect contributions may set its own timeframe for collection. However, we encourage States to adopt a timeframe similar to the one adopted by HHS to minimize the burden on issuers in multiple States.

2. Requests for Reinsurance Payment (§ 153.410)

The reinsurance program as proposed in subpart C will make payments to reinsurance-eligible plan issuers. In paragraph (a) of the proposed rule, we

proposed that reinsurance-eligible plan issuers be required to submit a request for reinsurance payment to the applicable reinsurance entity. We proposed in paragraph (b) that this request be made according to the method specified in the annual HHS notice of benefit and payment parameters.

For the reasons described in the proposed rule and considering the comments received, we are finalizing these provisions, with certain clarifying changes.

Comment: We received a comment requesting that HHS provide standards for issuers to request payment.

Response: Issuers of reinsurance-eligible plans will make requests for payment in accordance with the procedures set forth in the annual HHS notice of benefit and payment parameters. If a State establishes a reinsurance program, then it will publish guidance regarding data requirements for reinsurance payment in its State notice of benefit and payment parameters.

Comment: We received a few comments regarding the frequency of reinsurance payments. One commenter suggested a monthly reinsurance payment cycle. The commenter suggested that the reinsurance entity pay claims at 75 percent of the eligible amounts, with the remaining 25 percent of eligible claims becoming payable at the end of the year to the extent funds are available. One commenter suggested a payment process at the end of the benefit year. Another commenter suggested that reinsurance payment requests be permitted to be submitted whenever an individual claim causes a beneficiary's accumulated claims costs for the plan year to exceed the attachment point, and that adjustments be permitted to be submitted as the claim fully develops.

Response: Further guidance on the reinsurance claim and payment process will be provided in the HHS notice of benefit and payment parameters.

Comment: We received comments regarding the deadline for reinsurance payment requests and late claims. One commenter suggested that reinsurance-eligible claims be required to be submitted no more than six months after the plan year, and that claims not filed within that timeframe become ineligible for reinsurance payment. Another commenter suggested that the ability to submit late claims be restricted to ensure that late claims do not delay MLR rebates to consumers or risk corridors payments to insurers.

Response: We will provide further guidance on the deadline for requests

and on late claims in the annual HHS notice of benefit and payment parameters.

F. Subpart F—Health Insurance Issuer Standards Related to the Temporary Risk Corridors Program (§ 153.500–§ 153.530)

In this subpart, we proposed requirements on health insurance issuers related to the temporary risk corridors program which section 1342 of the Affordable Care Act established for the first three years of Exchange operation (2014–2016). Risk corridors create a mechanism for sharing risk for allowable costs between the Federal government and QHP issuers. QHP issuers with allowable costs that are less than 97 percent of the QHP's target amount will remit charges for a percentage of those savings to HHS, while QHP issuers with allowable costs greater than 103 percent of the QHP's target amount will receive payments from HHS to offset a percentage of those losses.

1. Definitions (§ 153.500)

In § 153.500, we proposed a number of definitions for purposes of administering risk corridors. We proposed to define “allowable administrative costs” as the total non-medical costs as defined in § 158.160(b), including costs for the administration and operation incurred by the plan as set forth in § 158.160(b)(2). We proposed to define “allowable costs” as an amount equal to the total medical costs, which include clinical costs, excluding allowable administrative costs, paid by the QHP issuer in providing benefits covered by the QHP. “Charge” was defined as the flow of funds from QHP issuers to HHS. “Direct and indirect remuneration” was defined by reference to the definition used for Medicare Part D purposes. “Payment” was defined as the flow of funds from HHS to QHP issuers. “Qualified health plan” was defined by reference to the definition for the term included in the proposed Exchange Establishment rule. “Risk corridors” was defined as any payment adjustment system based on the ratio of allowable costs of a plan to the plan's target amount. “Target amount” was defined as an amount equal to the total premiums incurred by a QHP, including any premium tax credit under any governmental program, reduced by the allowable administrative costs of the plan.

Considering the comments received and other considerations discussed below, we are finalizing this section with the following modifications:

We are adding the defined term, “administrative costs,” meaning total non-claims costs for a QHP as defined in § 158.160(b). We are revising the defined term, “allowable administrative costs,” to mean administrative costs, capped at 20 percent of premiums earned. We are revising the definition of “allowable costs” to reference the MLR term “incurred claims” and to include quality improvement and health information technology expenditures, as defined in the MLR rule. We are also referencing the after-the-fact adjustments described in § 153.530(b) for reinsurance and risk adjustment amounts paid or received by a QHP issuer.

We are revising the definition of “direct and indirect remuneration” to mean prescription drug rebates received by the issuer within the meaning of § 158.140(b)(1)(i). This definition matches the concept from the MLR rule, which takes into account rebates, but not other forms of remuneration, such as price concessions and discounts.

We are adding the defined term, “premiums earned,” meaning monies paid by or for enrollees with respect to a QHP as a condition of receiving coverage under that plan, including any fees or other contributions paid by or for enrollees. This defined term references the equivalent definition in the MLR rule, and is intended to clarify that premiums are to be determined in a manner consistent with the MLR rule, a consistency we seek with respect to the risk corridors program when practicable. We are revising the defined term, “target amount,” to reference the new defined term “premiums earned.”

We are moving the definition of “qualified health plan” to subpart A. We are not modifying the definitions of “charge,” “payment,” or “risk corridors.” Finally, we are making a number of clarifying modifications throughout this section. Many of the revisions we are making to defined terms in this subpart are intended to parallel terms used in the MLR rule, to the extent feasible. These revised definitions are used in the risk corridors calculation in a manner that is mathematically identical to the statutory formulation in section 1342 of the Affordable Care Act.

Comment: In the preamble of the proposed rule, we discussed the possibility of imposing a 20 percent limitation on allowable administrative costs. A number of commenters supported this limitation. Some commenters supported the 20 percent limitation because it would prevent an issuer with high administrative costs from receiving risk corridors payments,

and then using those payments to pay the required MLR rebates. Other commenters stated that imposing a limitation would be consistent with the MLR rule—a consistency that could reduce the need for issuers to maintain data for two different formulas.

Response: We are revising the definition of allowable administrative costs accordingly.

Comment: We received a number of comments that supported including quality improvement expenditures in allowable costs. Some commenters also suggested including health information technology expenses, which the MLR rule also takes into account. The commenters stated that including quality improvement expenses and health information technology expenditures in allowable costs would ensure consistency with MLR requirements, and would incentivize issuers to make these investments, which could inure to the benefit of enrollees. Some commenters requested that we adopt certain modifications to those MLR definitions. For example, two commenters suggested that HHS adopt a standard-based “functional approach” for determining whether an activity or function is a quality improvement activity similar to that employed by MLR. Under this approach, the function of the activity would dictate whether it was a quality improvement activity that issuers could include in allowable costs. Another commenter recommended that quality improvement activity expenditures be based on projections.

Response: We viewed the proposed rule as including these costs in allowable costs, because they are not among the administrative costs in § 158.160(b). We are revising the definition of allowable costs to make clear that it includes both expenditures to improve health care quality and expenditures related to health information technology and meaningful use requirements. However, we are not modifying those MLR definitions for purposes of risk corridors, in order to retain consistency with the MLR calculation.

Comment: A few commenters requested that the risk corridors program not utilize the Medicare Part D formulation of direct and indirect remuneration. They stated that the Part D formulation is too broad for the risk corridors program, and that a narrower construct is appropriate here. Commenters contrasted the formulation applicable to Medicare, a governmental program, with the formulation that in their view should be applicable to commercial plans. Commenters

recommended including a number of different definitions of rebates, discounts, and price concessions. One commenter recommended using the formulation used in the retiree drug subsidy program under subpart R of the Medicare Modernization Act regulations at 42 CFR 423.880 *et seq.*

Response: We acknowledge the breadth of the proposed definition of direct and indirect remuneration, and are revising the definition to be consistent with the approach adopted by the MLR rule. The MLR rule requires deduction of prescription drug rebates received by an issuer for both reporting and calculation purposes. We intend that MLR rules for defining and determining when prescription drug rebates are received by an issuer apply for risk corridors purposes.

Comment: One commenter recommended that allowable costs be defined as the sum of claims incurred during the risk corridors reporting year and paid through March 31 of the following year plus unpaid claims liabilities associated with claims incurred during the risk corridors reporting year.

Response: We agree that the calculation of allowable costs should include a run-out period and unpaid claims liabilities, and are clarifying that allowable costs should be calculated in accordance with the MLR rule.

Comment: We received four comments about the definition of “QHP.” Three commenters stated that a plan offered by an issuer outside of the Exchange that is identical to a QHP should be subject to the risk corridors program. Those commenters cited administrative simplicity, and stated that “the pricing of QHPs is supposed to be the same whether offered on or off an Exchange.” A fourth commenter requested guidance on the issue.

Response: The Affordable Care Act provides that the risk corridors program applies to QHPs. For risk corridors purposes, the QHP definition set forth in the Exchange Establishment rule applies. A QHP issuer is not precluded from offering a QHP outside an Exchange. If a QHP issuer does so, the QHP offered outside an Exchange is subject to the risk corridors program. We believe that, in keeping with the discussion of the same premium provision in the preamble of the Exchange Establishment rule, this generally means that health plans that are substantially the same as a QHP will be subject to the risk corridors program. HHS may clarify this standard in future rulemaking or guidance.

Comment: A number of commenters requested that the risk corridors

calculation take into account profits in a manner similar to the MLR rule. Some commenters requested that allowable administrative costs include profits, margin, or underwriting gain. This inclusion would be consistent with the MLR rule, which permits an issuer in certain circumstances to have administrative expenses and profits up to 20 percent of after-tax premium revenues before a rebate is due. Commenters also noted that section 1342(a) of the Affordable Care Act states that risk corridors calculations are to be based on a similar program under Medicare Part D, which includes return on investment, an analog to profits, in the definition of target amount.

Response: The proposed rule did not address profits in the risk corridors calculation. In the HHS notice of benefit and payment parameters, we intend to propose that profits be included within administrative costs for purposes of the risk corridors calculation, consistent with MLR.

Comment: A number of commenters requested that the risk corridors calculation take into account taxes in a manner similar to the MLR rule. The MLR rule requires reporting of a broad range of taxes, and deduction of certain taxes from premiums in the MLR denominator. One commenter noted that taxes may either be subtracted from premiums or added to allowable administrative costs.

Response: The proposed rule did not address taxes in the risk corridors calculation. In the HHS notice of benefit and payment parameters, we intend to propose that taxes and other expenses be included within administrative costs for purposes of the risk corridors calculation, with those Federal and State taxes and licensing and regulatory fees described in § 158.161(a), § 158.162(a)(1), and § 158.162(b)(1) exempt from the 20 percent cap on allowable administrative expenses.

Comments: Several commenters sought clarification as to whether any of the risk corridors elements were projections. Various commenters suggested that premiums or administrative costs should reflect projections. One commenter requested a clarification to confirm the intent to use projected costs as the targeted amount.

Response: Section 1342 of the Affordable Care Act does not allow the use of projections. Furthermore, because the temporary risk corridors program is designed to limit the extent of actual issuer losses (and gains) with respect to QHPs, the program will use actual data, not projected data.

2. Risk Corridors Establishment and Payment Methodology (§ 153.510)

In § 153.510 of the proposed rule, we proposed to establish risk corridors by specifying risk percentages above and below the target amount. In § 153.510(a), we proposed to require a QHP issuer to adhere to the requirements set by HHS for the establishment and administration of a risk corridors program for calendar years 2014 through 2016. The preamble to the proposed rule stated that we would issue guidance in the annual HHS notice of benefit and payment parameters for QHPs regarding reporting and the administration of payments and charges. The preamble also stated that risk corridors guidance will be plan-specific, and not issuer-specific, as is the case with respect to the MLR rule, and that we interpreted the risk corridors provisions to apply to all QHPs offered in the Exchange.

In § 153.510, we also established the payment methodology for the risk corridors program, using the thresholds and risk-sharing levels specified in statute. In § 153.510(b), we described the method for determining payment amounts to QHP issuers. For a QHP with allowable costs in excess of 103 percent but not more than 108 percent of the target amount, HHS will pay the QHP issuer 50 percent of the amount in excess of 103 percent of the target amount. For a QHP with allowable costs that exceed 108 percent of the target amount, the Affordable Care Act directs HHS to pay the QHP issuer an amount equal to 2.5 percent of the target amount plus 80 percent of the amount in excess of 108 percent of the target amount.

In § 153.510(c), we described the circumstances under which QHP issuers will remit charges to HHS, as well as the means by which HHS will determine those charge amounts. We proposed that QHP issuers will begin to remit charges to HHS for the first dollar of allowable charges less than 97 percent of the target amount. For a QHP with allowable costs that are less than 97 percent of the target amount but greater than 92 percent of the target amount, HHS will charge the QHP issuer an amount equal to 50 percent of the difference between 97 percent of the target amount and the actual value of allowable costs. For a QHP with allowable costs below 92 percent of the target amount, the QHP issuer will remit charges to HHS in an amount equal to 2.5 percent of the target amount plus 80 percent of the difference between 92 percent of the target amount and the actual value of allowable costs.

While we did not propose deadlines in the proposed rule, we discussed in the preamble timeframes for QHP

issuers to remit charges to HHS. We suggested, for example, that a QHP issuer required to make a risk corridors payment may be required to remit charges within 30 days of receiving notice from HHS, and that HHS would make payments to QHP issuers that are owed risk corridors amounts within a 30-day period after HHS determines that a payment should be made to the QHP issuer. QHP issuers who are owed these amounts will want prompt payment, and payment deadlines should be the same for HHS and QHP issuers. We sought comment on these proposed payment deadlines in the preamble to the proposed rule.

Considering the comments received, we are finalizing this section as proposed, with a few clarifying modifications.

Comments: We received a number of comments suggesting that the risk corridors calculation should be performed at a less granular level than the plan level. The most common suggestion was aggregation at the issuer level, although other alternatives were suggested. One commenter suggested aggregation at the carrier, State and business line level, while another recommended applying the risk corridors calculation separately to an issuer's aggregate non-group QHP business and aggregate small group QHP business. One reason advanced for these alternatives was consistency with the MLR rules, which apply at the issuer level. Commenters also noted that issuers do not currently accumulate data at the plan level. Some commenters stated that issuer-level data would be more credible and reliable.

Response: We have carefully considered the commenters' suggestions, but are not making the requested change. The statutory language governing risk corridors does not afford the necessary flexibility. The statutory provision that governs risk corridors at section 1342(a) of the Affordable Care Act describes the risk corridors program as one in which "a qualified health plan offered in the individual or small group market shall participate * * *". By contrast, section 2718 of the PHS Act, which governs the MLR program, requires the calculation of a ratio with respect to an issuer.

Comment: One commenter requested that the risk corridors program may be based on targeted medical costs (net premiums) in addition to the premium rates.

Response: We are not making the changes proposed by the commenter because section 1342 of the Affordable Care Act does not provide the flexibility necessary to do so. That section requires

that the risk corridors program be based upon the ratio of a plan's total costs, other than administrative costs, to its total premiums, reduced by the administrative costs. In codifying that section in regulation, we have sought to define the relevant terms in a manner consistent with those used in the MLR calculation.

Comments: A number of commenters addressed the risk corridors payment deadline. Three commenters agreed that 30 days was a reasonable timeframe for both payments and charges, and one commenter recommended that payments and charges be paid once per year. One commenter suggested requiring issuers of QHPs to submit risk corridors data within 30 days after submission of a request for payment to HHS or receipt of demand for payment from HHS.

Response: We plan to address the risk corridors payment deadline in the HHS notice of benefit and payment parameters.

3. Attribution and Allocation of Revenue and Expense Items (§ 153.520)

In § 153.520(a)(3) of the proposed rule (now § 153.530(d)), we proposed rules for accounting for reinsurance claims submitted on a date to be determined by HHS for a given reinsurance benefit year. Specifically, we proposed that a QHP issuer be required to attribute reinsurance payments to risk corridors based on the date on which the valid reinsurance claim was submitted. For example, if the QHP issuer were to submit a reinsurance claim on or before the deadline for a benefit year, that QHP issuer would attribute the claim payment to the risk corridors calculation for the benefit year in which the costs were accrued. Conversely, if the QHP issuer were to submit a claim after the deadline for a benefit year, that QHP issuer would attribute the claim payment to the risk corridors calculation for the following benefit year.

We are finalizing this provision as proposed, with the following modifications:

We are revising § 153.520(d) to clarify that an issuer must attribute not only reinsurance payments, but also reinsurance contributions and risk adjustment payments and charges to the benefit year for which the contributions, charges, or payments apply, not the year in which the claim was submitted.

In addition, we are including the new paragraphs § 153.520(a), § 153.520(b), § 153.520(c), and § 153.520(e) to clarify the attribution of items, such as quality improvement and health information technology expenditures, that are

typically not plan-specific. Paragraph 153.520(a) requires that each item of revenue and expense in allowable costs and target amount for a QHP must be reasonably attributable to that QHP's operations. Paragraph 153.520(b) states that each item must be reasonably allocated across the issuer's plans (that is, QHPs and non-QHPs). Thus, § 153.520(a) and § 153.520(b) require an issuer to allocate shared revenue and expense items between its health plans and its other business lines, and then to attribute its shared items within its health plans to each plan. To the extent that the issuer is utilizing a method for allocating expenses for MLR purposes, the method used for risk corridors purposes under § 153.520 must be consistent. Paragraph 153.520(c) requires an issuer to disclose to HHS a detailed description of the methods and bases for the attribution and allocation. We plan to specify the timing and method of disclosure in future guidance. Finally, § 153.520(e) requires an issuer to maintain the supporting records for the attribution and allocation for 10 years, and to make the records available to HHS upon request.

Comments: We received a few comments to the proposed provision attributing reinsurance payments to the applicable benefit year. One commenter stated that the rule was inconsistent with issuers' pricing practices, the MLR calculation, and financial reporting practices. The commenter stated that issuers could manipulate risk corridors payments by delaying claims submissions, and that claims not submitted in time for the 2016 calculation would not be eligible for risk corridors, since the program would have terminated. Another commenter recommended that reinsurance amounts be on a "basis other than a paid basis" in order to be consistent with the MLR calculation. Another commenter recommended attribution of reinsurance claims to the year of submission, even if the claims were incurred in a prior benefit year.

Response: We are clarifying in the rule that reinsurance and risk adjustment payments, contributions, and charges are attributed to the benefit year with respect to which the reinsurance or risk adjustment amounts apply. For example, reinsurance payments received in 2015 for claims costs incurred in 2014 (even if the reinsurance claim was properly submitted in 2015) would be attributed to 2014 for purposes of risk corridors calculations.

4. Risk Corridors Data Requirements (§ 153.530)

To support the risk corridors program calculations, we proposed in § 153.520 of the proposed rule that all QHP issuers submit data needed to determine actual performance relative to their target amounts, to be collected in standard formats specified by HHS. We proposed in § 153.520(a) to require that QHP issuers submit data related to actual premium amounts collected, including premium amounts paid by parties other than the enrollee in a QHP, and specifically, advance premium tax credits paid by the government. We also proposed that risk adjustment and reinsurance be regarded as after-the-fact adjustments to premiums for purposes of determining risk corridors amounts. Therefore, § 153.520(a)(1) of the proposed rule required that the reported premium amounts be increased by the amounts paid to the QHP issuer for risk adjustment and reinsurance, and § 153.520(a)(2) required that reported premium amounts be reduced for any risk adjustment charges the QHP issuer pays on behalf of the plan, reinsurance contributions that the QHP issuer makes on behalf of the plan, and Exchange user fees that the QHP issuer pays on behalf of the plan. We sought comment on this issue in the preamble.

We proposed in § 153.520(b) that QHP issuers be required to submit allowable cost data to calculate the risk corridors in a format to be specified by HHS, and that allowable costs be reduced for any direct and indirect remuneration received. Finally, we proposed that allowable costs be reduced by the amount of any cost-sharing reductions received from HHS.

Considering the comments received, we are finalizing this provision, with the following modifications:

In order to more clearly reflect section 1342(c)(1)(B) of the Affordable Care Act, we are revising this section so that the adjustments for reinsurance and risk adjustment are made to allowable costs. We are also making a number of clarifying modifications throughout this section.

Comments: Commenters generally agreed that reinsurance and risk adjustment payments and charges should be treated as after-the-fact adjustments to risk corridors. One commenter noted the inconsistency between the proposed rule's treatment of reinsurance and risk adjustment payments and charges as adjustments to premium revenue, and section 1342 of the Affordable Care Act, which requires that those adjustments be made to allowable costs. Another commenter

noted that under the MLR rule, these adjustments are made to premium revenue, and urged that the risk corridors program handle these adjustments in the same manner. One commenter requested clarification that the attribution of reinsurance payments “received” be determined on an accrual rather than cash basis. Another commenter, who requested that the risk adjustment program be delayed until at least 2016 because of the complexity of implementing the risk adjustment, reinsurance, and risk corridors programs simultaneously, requested that, for consistency, HHS only take into account reinsurance for purposes of the temporary risk corridors program during those initial years.

Response: In order to more clearly reflect the requirements of the Affordable Care Act, we are revising the section so that those payments and charges are adjustments to allowable costs, rather than premium revenue. We agree with the commenter that reinsurance and risk adjustment payments and charges should be reflected in risk corridors on an accrual basis, and are reflecting that requirement in § 153.520(d) of this final rule. Since all three programs will play important and different roles in stabilizing premiums beginning in 2014, we believe that both the risk adjustment and reinsurance programs should be taken into account as after-the-fact adjustments for purposes of the risk corridors calculation, as required by the statute.

Comments: Commenters expressed concern about the interaction of risk corridors, reinsurance, and risk adjustment with the MLR calculation. Commenters discussed the need for the MLR timeline to take into account those other calculations, payments, and charges. One commenter discussed the challenges faced by publicly held issuers who must also comply with Federal securities laws’ disclosure requirements. Two commenters included detailed timelines encompassing proposed due dates for reinsurance, risk adjustment, risk corridors and MLR.

Commenters also supported our efforts to use, where practicable, MLR definitions and concepts in the risk corridors rules, but noted difficulties in using data collected for MLR purposes for premium stabilization purposes because MLR data is compiled at the issuer level, while risk corridors data will be required to be collected at the plan level.

Response: We will provide additional details on timeline-related issues in future guidance. We anticipate that the

accounting profession will take appropriate measures to guide issuers, as it has in past analogous circumstances, such as with the retiree drug subsidy program under the Medicare Modernization Act, which was first effective in 2006. We will continue efforts to minimize reporting burden by seeking to utilize data already collected for MLR.

Comments: We received a comment on the issue of how to determine the allowable costs for a QHP if the issuer fails to comply with the reporting requirements in § 153.530. The commenter recommended that HHS use quarterly reports to determine a final payment liability using the lowest HHS payment liability minus a certain percentage of withhold (penalty) of either the premium payments or risk corridors payment.

Response: We interpret the comment as suggesting that HHS determine a baseline amount of allowable costs or payment liability reflecting experience of other issuers. The approach is one of several reasonable methods. We will consider it along with other approaches. We are evaluating measures we could take to address non-compliance.

G. Subpart G—Health Insurance Issuer Standards Related to the Risk Adjustment Program

Section 1343 of the Affordable Care Act provides for a program of risk adjustment for all non-grandfathered plans in the individual and small group markets both inside and outside of the Exchanges. We noted in the introduction to subpart D of this part that the risk adjustment program described in section 1343 is intended to reduce or eliminate premium differences between plans based solely on expectations of favorable or unfavorable risk selection or choices by higher risk enrollees in the individual and small group markets. The foregoing is relevant for this subpart as well, which finalizes the health insurance issuer standards that are necessary to carry out risk adjustment as described in subpart D.

1. Reserved (§ 153.600)

Section 153.600 of the proposed rule defined a number of terms used in this subpart. Those definitions have been moved to subpart A. We are reserving this section for future use.

2. Risk Adjustment Issuer Requirements (§ 153.610)

We proposed in paragraph (a) that all issuers of risk adjustment covered plans be required to submit risk adjustment data according to the timetable and

format prescribed by the State, or HHS on behalf of the State. Considering the comments received, we are finalizing this definition, with the following modifications: We are modifying the requirement that issuers submit risk adjustment data to the State, or HHS on behalf of the State, to align with the changes to § 153.340(a) and (b) discussed above. We are adding a requirement that issuers that offer risk adjustment covered plans store required risk adjustment data in accordance with the risk adjustment data collection approach established by HHS or the State. We note that use of a distributed model may require issuers to format risk adjustment data and maintain that data in a manner that complies with specifications promulgated by the State, or HHS on behalf of the State, and to run risk adjustment software.

Comment: We received many comments supporting the requirement that issuers submit risk adjustment data to the State, or HHS on behalf of the State. A number of commenters requested that HHS expand the definition of risk adjustment data to include rate setting data that may not be available from State Departments of Insurance. Other commenters stated that the amount and type of data envisioned in the proposed rule was appropriate.

Response: We are making only minor changes to this provision, to align with changes made to § 153.340(a).

Comment: One commenter suggested that participation in risk adjustment should be voluntary. Two other commenters urged HHS to delay risk adjustment until sufficient data is available. We received several comments suggesting that the timeframe for data submission be left to States.

Response: The Affordable Care Act requires that issuers of risk adjustment covered plans participate in the risk adjustment program. We believe that there will be sufficient data to administer the risk adjustment program, even in the initial years. Therefore, we are finalizing the policy that all issuers offering risk adjustment covered plans must participate in the program by providing the specified information to the State, or HHS on behalf of the State, on a timeframe determined by that State.

In paragraph (b) of the proposed rule, we proposed to permit contractual arrangements between issuers and providers, suppliers, physicians, and other practitioners to ensure that issuers receive the necessary risk adjustment data. Considering the comments received, we are finalizing this paragraph as paragraph (c).

Comments: We received a number of comments in response to this provision. Two commenters supported a requirement permitting issuers to require providers, suppliers, physicians, and other practitioners to submit risk adjustment data to those issuers. We received two comments expressing reservations about the requirement on the grounds that it would place additional burdens on practitioners.

Response: We believe that the risk adjustment program is highly dependent on high quality risk adjustment data. Issuers depend on providers, suppliers, physicians, and other practitioners to submit this data to them. Because issuers will receive or be required to make risk adjustment payments based in part on the amount and quality of this risk adjustment data, we believe it is fair to permit issuers to require suppliers, physicians, and other practitioners to submit that data to them in their contracts. We are therefore finalizing this paragraph.

In paragraph (c) of the proposed rule, we proposed that risk adjustment covered plan issuers who owe a net balance of risk adjustment charges will be assessed those net charges upon completion of the risk adjustment process. Additionally, we requested comment as to whether issuers should have a 30-day timeframe in which to pay net charges to the State that assessed those charges, or to HHS on behalf of the State. Considering the comments received, we are finalizing this paragraph, clarifying that charges include any adjustments made pursuant to data validation described in § 153.350.

Comment: We received a few comments supporting the requirement that issuers remit charges to the State, or HHS on behalf of the State.

Response: In response to comments, we are finalizing the requirement that issuers pay risk adjustment charges to the State, or HHS on behalf of the State. We are clarifying that charges include any adjustments made pursuant to data validation described in § 153.350.

Comment: We received one comment supporting a requirement that issuers be required to pay net charges within 30 days of the assessment of those charges by a State, or HHS on behalf of a State.

Response: In response to the comment, we are adding a provision that issuers must pay net charges to the State, or HHS on behalf of the State, within 30 days of the assessment of those charges.

3. Compliance With Risk Adjustment Standards (§ 153.620)

The credibility of risk adjustment is important to stabilizing health insurance premiums in the Exchanges. Consistent with § 153.350 of the proposed rule, we proposed in § 153.620 that risk adjustment covered plan issuers must make available data to HHS or the State to support validation of the risk adjustment data that they have submitted. In paragraph (b), we proposed that risk adjustment covered plan issuers retain the risk adjustment data that they have reported for a period of ten years. For the reasons described in the proposed rule and considering the comments received, we are finalizing these provisions as proposed with a few modifying clarifications.

Comment: We received several comments supporting the requirement that issuers make data required for validation of risk adjustment data available to States or HHS on behalf of the State. Two commenters suggested that HHS establish sanctions for issuers that do not comply with the data validation and records maintenance requirements. One commenter opposed this requirement, suggesting that the requirement would force issuers to disclose sensitive data.

Response: We believe that the data validation and records maintenance standards are necessary to support the credibility of the risk adjustment program. After consideration of the comments received, we are finalizing the proposed provision with a minor drafting change to § 153.610(b) to clarify that the provision applies when the State, or HHS on behalf of the State, requests the data.

Comment: We received several comments suggesting that a ten-year record retention requirement was too long and would impose a significant burden on issuers.

Response: We believe that the record retention requirements should be consistent with other Federal record retention requirements, and are finalizing the proposed provision.

III. Provisions of the Final Regulations

For the most part, this final rule incorporates the provisions of the proposed rule. Those provisions of the final rule that differ from the proposed rule are as follows:

Subpart A—General Provisions (§ 153.10 and § 153.20)

- We have moved a number of reinsurance-related definitions to subpart A. We have made technical changes to the definition of “attachment

point,” “coinsurance rate,” “contribution rate,” and “reinsurance cap” to reflect comments received.

- We have moved a number of risk adjustment-related definitions to subpart A. We have added several new definitions—“individual risk score,” “calculation of plan average actuarial risk,” “calculation of payments and charges,” “risk adjustment data collection approach,” and “risk adjustment data.” We also modified the definition of “risk adjustment methodology” to mean all parts of risk adjustment—the risk adjustment model, the calculation of plan average actuarial risk, the calculation of payments and charges, the risk adjustment data collection approach, and the schedule for the risk adjustment program. We have modified the definition of “risk adjustment data” to mean all data that are used in a risk adjustment model, or the calculation of plan average actuarial risk, or the calculation of payments and charges, or that are used for validation or audit of such data.

Subpart B—State Notice of Benefit and Payment Parameters (§ 153.100 and § 153.110)

- We have clarified that a State that establishes a reinsurance program must publish a notice of benefit and payment parameters if it intends to modify the data requirements for reinsurance payments, collect reinsurance contributions, use more than one applicable reinsurance entity, or modify any reinsurance parameters. We have clarified that States have the flexibility to establish a reinsurance entity regardless of whether or not they establish a State Exchange.

- We have clarified that a State operating a risk adjustment program must publish a notice of benefit and payment parameters setting forth the risk adjustment methodology and data validation that it will use.

- We have specified that State notices of benefit and payment parameters be issued by March 1 of the calendar year prior to the first benefit year for which the notice applies.

- We have clarified that a State that does not publish a notice of benefit and payment parameters forgoes its right to modify the data requirements for reinsurance payments, collect reinsurance contributions, use more than one applicable reinsurance entity, modify any reinsurance parameters, or use any risk adjustment methodology or data validation standards other than those published in the HHS notice of benefit and payment parameters for use by HHS when operating risk adjustment on behalf of the State.

- We have specified that a State that elects to collect additional reinsurance contributions must describe the purpose of the additional collection and the additional contribution rate.

- We have clarified that a State that modifies the reinsurance parameters from those published in the annual HHS notice of benefit and payment parameters must apply those parameters uniformly throughout the State.

Subpart C—State Standards Related to the Reinsurance Program (§ 153.200–§ 153.250)

- We have clarified that States that establish an Exchange are not required to establish a reinsurance program.

- We have revised the process for collection of contributions so that HHS will collect contributions from self-insured plans, while the State has the option to collect from fully insured plans. We have required States to notify HHS by December 1, 2012, if they elect to collect reinsurance contributions from fully insured plans for the 2014 benefit year, and by September 1 of the calendar year that is two years prior to the applicable benefit year if they elect to collect reinsurance contributions from fully insured plans for any benefit year after 2014.

- We have directed each State to notify HHS of the percentage of reinsurance contributions received by HHS allocated to each applicable reinsurance entity, if applicable.

- We have added provisions specifying that if a State elects to collect additional reinsurance contributions, HHS will only collect additional amounts for administrative expenses, and will not collect additional amounts for reinsurance payments.

- We are no longer requiring that reinsurance payments be linked to essential health benefits.

Subpart D—State Standards Related to the Risk Adjustment Program (§ 153.300–§ 153.350)

- We have added a deadline for States to notify issuers of payments and charges.

- We have added a provision that States must submit annual risk adjustment program summary reports to HHS.

- We have clarified the standards for publication of risk adjustment methodology in HHS and State notices of benefit and payment parameters.

- We have modified the proposed approach to risk adjustment data collection, as follows: When HHS operates a risk adjustment program, it will use a distributed approach so that individual data remains with the issuer.

When a State operates a risk adjustment program, it may choose the approach that best suits its program.

- We have modified the privacy and security standards applicable when a State is operating risk adjustment.

- We have adjusted the data validation standards to account for the new approach to risk adjustment data collection.

Subpart E—Health Insurance Issuer and Group Health Plan Standards Related to the Reinsurance Program (§ 153.400 and § 153.410)

- We have clarified that contributing entities must make reinsurance contributions to HHS and the applicable reinsurance entity, if the State elects to collect reinsurance contributions.

- We have clarified which contributing entities must make reinsurance contributions.

- We have clarified issuer standards for States that elect to collect additional funds.

- We have specified a collection timeframe for submission of reinsurance contributions to HHS.

- We have clarified that reinsurance contributions data must be submitted to HHS and each applicable reinsurance entity, if the State elects to collect reinsurance contributions.

Subpart F—Health Insurance Issuer Standards Related to the Risk Corridors Program (§ 153.500–§ 153.530)

- We added the defined terms “administrative costs” and “premiums earned” to be consistent with the MLR regulations.

- We revised the defined term “allowable administrative costs” to include a 20 percent cap on such costs.

- We revised the defined term “allowable costs” to include quality improvement and health information technology expenditures under the MLR regulations.

- We revised the defined term “direct and indirect remuneration” to conform with the MLR regulations.

- We revised the provision regarding attribution of reinsurance payments based on the date on which the reinsurance claim was submitted. The final rule specifies that reinsurance payments and contributions and risk adjustment payments and charges be allocated to the benefit year for which they apply.

- We added a number of provisions clarifying how revenue and expense items not typically plan-specific are to be allocated and attributed to plans.

- We revised the provisions concerning after-the-fact adjustments to allowable costs to more clearly reflect the relevant statutory requirements.

Subpart G—Health Insurance Issuer Standards Related to the Risk Adjustment Program (§ 153.610 and § 153.620)

- We have modified issuers’ data submission standards to reflect the flexibility afforded to States in collecting risk adjustment data.

- We have included a requirement that issuers that offer risk adjustment covered plans store all required risk adjustment data in accordance with the risk adjustment data collection approach established by HHS, or the State.

- We have specified that issuers remit risk adjustment charges within 30 days.

IV. Collection of Information Requirements

This final rule includes requirements that differ from those included in the proposed rule. The following provisions of provisions this final rule involve changes from the information collection requirements set forth in the proposed rule:

- As described in § 153.210(a), we have added a new provision to the final rule under which a State that contracts with more than one applicable reinsurance entity must notify HHS of the percentage of reinsurance contributions received from HHS for the State to be allocated to each applicable reinsurance entity.

- As described in § 153.220(b), we have added a new standard to the final rule under which a State electing to collect reinsurance contributions from issuers in the fully insured market must notify HHS of its intention to do so.

- As described in § 153.310(d), we have added a new standard to the final rule under which a State operating a risk adjustment program must submit annual summary reports of risk adjustment operations to HHS.

- As described in § 153.340(b)(1), we have modified the risk adjustment data collection standards from the proposed rule. A State operating a risk adjustment program must collect or calculate individual risk scores generated by the risk adjustment model in the Federally certified risk adjustment methodology.

- As described in § 153.400(d), we have modified the data standards applicable to contributing entities with respect to contribution amounts so that a contributing entity in the individual and fully insured market is no longer required to submit enrollment and premium data and a contributing entity in the self-insured market is no longer required to submit data on covered lives and total expenses. Instead, a contributing entity is required to submit

data necessary to substantiate the contribution amounts for the contributing entity.

- As described in § 153.520(c), we have added a new standard to the final rule under which a QHP issuer must submit to HHS a report with detailed description of the methods and specific bases used to attribute revenues and expenses in allowable costs and target amount to each QHP and across plans.

- As described in § 153.520(e), we have added a new standard to the final rule under which a QHP issuer must maintain for ten years and make available to HHS upon request the data used to make certain attributions and allocations of items of revenue or expenses, together with all supporting information required to determine that these methods and bases were accurately implemented.

In addition, this final rule describes some information collections for which HHS plans to seek approval at a later date. For these information collections, HHS will issue future **Federal Register** notices to seek comments on those information collections, as required by the Paperwork Reduction Act. Included among such information collections for which HHS plans to seek later approval are the following requirements:

- As described in § 153.310(d), a State operating a risk adjustment program must submit annual summary reports of risk adjustment operations to HHS.

- As described in § 153.400(d), a contributing entity must submit data required to substantiate the contribution amounts for the contributing entity.

- As described in § 153.410(b), issuers of reinsurance-eligible plans, in order to receive reinsurance payments, must make requests for payment in accordance with the standards of the annual HHS notice of benefit and payment parameters for the applicable benefit year or the applicable State notice of benefit and payment parameters.

- As described in § 153.520(c), a QHP issuer must submit to HHS a report with a detailed description of the methods and specific bases used to attribute revenues and expenses in allowable costs and target amount to each QHP and across plans.

- As described in § 153.530, a QHP issuer must submit to HHS data on premiums earned, allowable costs, and allowable administrative costs with respect to each QHP that the QHP issuer offers.

- As described in § 153.610(a)–(b) and § 153.620(b), an issuer that offers risk adjustment covered plans must submit or make accessible, and must

store, all risk adjustment data for those risk adjustment covered plans.

- As described in § 153.620, an issuer that offers risk adjustment covered plans must comply with data validation requests by the State or HHS on behalf of the State.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a control number assigned by OMB.

V. Summary of Regulatory Impact Analysis

The following section focuses on the benefits and costs of the requirements included in this final rule, summarizing analysis from the detailed Regulatory Impact Analysis, available at <http://cciio.cms.gov> under “Regulations and Guidance.” That Regulatory Impact Analysis evaluates the impacts of this final rule and a second final rule, titled “Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers.” The second final rule was made available for public inspection at the Office of the Federal Register on March 12, 2012.

A. Introduction

HHS has examined the impacts of the final rule under Executive Orders 12866 and 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits (both quantitative and qualitative) of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated an “economically” significant rule, under section 3(f)(1) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Few insurance issuers offering comprehensive health insurance policies fall below the size thresholds for “small” business established by the SBA. HHS concludes that this rule will not have a significant impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is approximately \$136 million, using the most current (2011) Implicit Price Deflator for the Gross Domestic Product. Because States are not required to establish a reinsurance program or operate a risk adjustment program, the final rule does not impose a mandate to incur costs above the \$136 million threshold on State, local, or tribal governments. Because operational details on how health insurance issuers and entities that must participate in the reinsurance program have not been finalized, we are not able to estimate whether the final rule imposes a mandate to incur costs above the \$136 million threshold on the private sector.

B. Need for This Regulation

This rule implements standards for States related to reinsurance and risk adjustment, and for health insurance issuers related to reinsurance, risk corridors, and risk adjustment consistent with the Affordable Care Act. These programs will mitigate the impacts of potential adverse selection and stabilize the individual and small group markets as insurance reforms and the Exchanges are implemented, starting in 2014. The transitional State-based reinsurance program serves to reduce the uncertainty of insurance risk in the individual market by making payments for high-cost enrollees. The temporary federally administered risk corridors program serves to protect against rate-setting uncertainty for QHPs by limiting the extent of issuer losses (and gains). On an ongoing basis, the State-based risk adjustment program is intended to protect health insurance issuers that attract higher-risk populations (such as individuals with chronic conditions).

C. Summary of Costs and Benefits

Two regulations are being published to implement components of the Exchange and health insurance premium stabilization policies in the Affordable Care Act. The detailed Regulatory Impact Analysis evaluates the impacts of both proposed rules, while this summary focuses on the benefits and costs of the requirements in this final rule.

Methods of Analysis

This regulatory impact analysis references Congressional Budget Office (CBO) estimates relating to the Affordable Care Act and CMS estimates published in the FY 2013 President's Budget relating to the Affordable Care Act and the proposed form of this rule. The CBO estimates remain the most comprehensive accounting of all the interacting provisions pertaining to the Affordable Care Act, and contain cost estimates of certain provisions that have not been independently estimated by

CMS. We expect that the requirements in this final rule will significantly alter neither CBO's estimates nor CMS's estimates. Our review and analysis of the requirements of the final rule indicate that the impacts are within the margin of error of CBO's and CMS's models.

Summary of Costs and Benefits

CBO estimated program payments and receipts for reinsurance and risk adjustment. As those programs do not begin operation until 2014, there are no

outlays for reinsurance and risk adjustment in 2012 and 2013. CBO estimates that risk adjustment payments and collections are equal in the aggregate, but that risk adjustment payments lag revenues by one quarter. CBO did not score the impact of the risk corridors program, but assumed collections would equal payments to plans in the aggregate. The payments and receipts in risk adjustment and reinsurance are financial transfers between issuers and the entities running those programs.

TABLE 1—ESTIMATED OUTLAYS AND RECEIPTS FOR REINSURANCE AND RISK ADJUSTMENT PROGRAMS FY2012–FY2016, IN BILLIONS OF DOLLARS

Year	2012	2013	2014	2015	2016
Reinsurance and Risk Adjustment Program Payments ^a			11	18	18
Reinsurance and Risk Adjustment Program Receipts ^a			12	16	18

^a Risk-adjustment payments lag receipts by one quarter. Note that although the estimates above are based upon CBO analyses, CBO did not account for reinsurance collections payable to the U.S. Treasury. Consequently, the receipts in the President's Fiscal Year 2013 Budget are higher than those estimated by CBO, though not appreciably different.

Source: CBO. 2011. *Letter to Hon. Nancy Pelosi*. March 20, 2010.

Benefits. Payments through reinsurance, risk adjustment, and risk corridors reduce the increased risk of financial loss that health insurance issuers might otherwise expect to incur in 2014. Insurers charge premiums for expected costs plus a risk premium, in order to build up reserve funds in case medical costs are higher than expected. Reinsurance, risk adjustment, and risk corridors payments reduce the risk to the issuer, reducing the risk premium.

Costs. There are administrative costs to States and Exchanges to set up and administer these premium stabilization programs. However, States may use Exchange Planning and Establishment Grant funding awarded pursuant to section 1311 of the Affordable Care Act to develop these programs. There are also reporting costs for issuers to submit data and financial information.

Regulatory Options Considered

Options considered for the reinsurance, risk adjustment, and risk corridor programs parallel the options considered for Exchanges. These programs aim to mitigate the impacts of

potential adverse selection and stabilize the individual and small group markets as insurance reforms and the Affordable Insurance Exchanges are implemented, starting in 2014. The Affordable Care Act structures reinsurance and risk adjustment as State-based programs with Federal guidelines on methodology, while it establishes risk corridors as a federally run program.

HHS identified two regulatory options to the approach set forth in this final rule, as required by Executive Order 12866.

Uniform Standards for Reinsurance and Risk Adjustment: Under this option, HHS would have set a single standard for State operation of reinsurance and risk adjustment. This option would have restricted State flexibility.

State Flexibility for Reinsurance and Risk Adjustment: Under this option, States would have had a great deal of flexibility around whether and how to implement reinsurance and risk adjustment programs. This option would have allowed States to develop these programs to fit their State-specific characteristics. The programs would

have been subject to few Federal standards.

Summary of Estimate Costs for Each Option

A single standard for State operations of reinsurance and risk adjustment could have resulted in reduced Federal oversight cost. However, this option could also have reduced innovation and limited the diffusion of successful policies. On the other hand, while State flexibility could have allowed for State innovation, it would have increased the administrative burden on the Federal government and multi-State issuers, as policies and procedures could have varied significantly between States. HHS has adopted a middle course that aims to limit administrative costs, especially for the transitional reinsurance program, while also ensuring that the policy aims of the premium stabilization programs are met. These costs and benefits are discussed more fully in the detailed Regulatory Impact Analysis.

D. Accounting Statement

Category	Primary estimate	Year dollar	Unit discount rate (percent)	Period covered
Benefits:				
Annualized Monetized (\$millions/year)	Not estimated	2011	7	2012–2016
	Not estimated	2011	3	2012–2016
Costs:				
Annualized Monetized (\$millions/year)	Not estimated	2011	7	2012–2016
	Not estimated	2011	3	2012–2016
Transfers:				

Category	Primary estimate	Year dollar	Unit discount rate (percent)	Period covered
Federal Annualized Monetized (\$millions/year).	9925	2011	7	2012–2016
	9633	2011	3	2012–2016
Qualitative	Risk Adjustment transfers funds among individual and small group market health plan issuers. Reinsurance collects funds from all issuers and distributes it to individual market issuers.			

Note: For full documentation and discussion of these estimated costs and benefits see the detailed Regulatory Impact Analysis, available at <http://ccio.cms.gov> under “Regulations and Guidance.”

VI. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of the proposed rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The RFA generally defines a “small entity” as (1) A proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of “small entity.” HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent.

As discussed above, this final rule is necessary to implement standards for States related to reinsurance and risk adjustment, and for health insurance issuers related to reinsurance, risk corridors, and risk adjustment consistent with the Affordable Care Act. For purpose of the regulatory flexibility analysis, we expect entities offering health insurance plans, including fully insured health plan issuers and self-insured health plan issuers, to be affected by this proposed rule. We believe that health insurers would be classified under the North American Industry Classification System (NAICS) Codes 524114 (Direct Health and Medical Insurance Carriers) According to SBA size standards, entities with average annual receipts of \$7 million or less would be considered small entities for this NAICS code. Health issuers could also be classified in NAICS code 621491 (HMO Medical Centers), in which case the SBA size standard for small entities would be annual receipts of \$10 million or less.

HHS examined the health insurance industry in depth in the Regulatory Impact Analysis we prepared for the proposed rule on establishment of the

Medicare Advantage program (69 FR 46866, August 3, 2004). In that analysis, we determined that there were few insurance firms underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) that fell below the size thresholds for “small” entities established by the SBA.

Additionally, as discussed in the Medical Loss Ratio interim final rule (75 FR 74918), HHS used 2009 National Association of Insurance Commissioners (NAIC) Health and Life Blank annual financial statement data to develop an updated estimate of the number of small entities that offer comprehensive major medical coverage in the individual and group markets. For purposes of that analysis, HHS used total Accident and Health (A&H) earned premiums as a proxy for annual receipts. HHS estimated that there were 28 small entities with less than \$7 million in A&H earned premiums offering individual or group comprehensive major medical coverage; however, this estimate may overstate the actual number of small health insurance issuers offering such coverage, since it does not include receipts from these companies’ other lines of business.

This final rule contains standards for premium stabilization programs required of health plan issuers including the risk adjustment program as well as the transitional reinsurance program and temporary risk corridors programs. Because we believe that few insurance firms offering comprehensive health insurance policies fall below the size thresholds for “small” entities established by the SBA, we conclude that this final rule will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 45 CFR Part 153

Administrative practice and procedure, Adverse selection, Health care, Health insurance, Health records, Organization and functions (Government agencies), Premium Stabilization, Reporting and recordkeeping requirements,

Reinsurance, Risk adjustment, Risk corridors, Risk mitigation, State and local governments.

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR subtitle A, subchapter B, by adding part 153 to read as set forth below:

Subtitle A—Department of Health and Human Services

Subchapter B—Requirements Relating To Health Care Access

PART 153—STANDARDS RELATED TO REINSURANCE, RISK CORRIDORS, AND RISK ADJUSTMENT UNDER THE AFFORDABLE CARE ACT

Subpart A—General Provisions

Sec.

153.10 Basis and scope.

153.20 Definitions.

Subpart B—State Notice of Benefit and Payment Parameters

153.100 State notice of benefit and payment parameters.

153.110 Standards for the State notice of benefit and payment parameters.

Subpart C—State Standards Related to the Reinsurance Program

153.200 [Reserved]

153.210 State establishment of a reinsurance program.

153.220 Collection of reinsurance contribution funds.

153.230 Calculation of reinsurance payments.

153.240 Disbursement of reinsurance payments.

153.250 Coordination with high-risk pools.

Subpart D—State Standards Related to the Risk Adjustment Program

153.300 [Reserved]

153.310 Risk adjustment administration.

153.320 Federally certified risk adjustment methodology.

153.330 State alternate risk adjustment methodology.

153.340 Data collection under risk adjustment.

153.350 Risk adjustment data validation standards.

Subpart E—Health Insurance Issuer and Group Health Plan Standards Related to the Reinsurance Program

- 153.400 Reinsurance contribution funds.
 153.410 Requests for reinsurance payment.

Subpart F—Health Insurance Issuer Standards Related to the Risk Corridors Program

- 153.500 Definitions.
 153.510 Risk corridors establishment and payment methodology.
 153.520 Attribution and allocation of revenue and expense items.
 153.530 Risk corridors data requirements.

Subpart G—Health Insurance Issuer Standards Related to the Risk Adjustment Program

- 153.600 [Reserved]
 153.610 Risk adjustment issuer requirements.
 153.620 Compliance with risk adjustment standards.

Authority: Secs. 1321, 1341–1343, Pub. L. 111–148, 24 Stat. 119.

Subpart A—General Provisions**§ 153.10 Basis and scope.**

(a) *Basis.* This part is based on the following sections of title I of the Affordable Care Act (Pub. L. 111–148, 24 Stat. 119):

(1) Section 1321. State flexibility in operation and enforcement of Exchanges and related requirements.

(2) Section 1341. Transitional reinsurance program for individual market in each State.

(3) Section 1342. Establishment of risk corridors for plans in individual and small group markets.

(4) Section 1343. Risk adjustment.

(b) *Scope.* This part establishes standards for the establishment and operation of a transitional reinsurance program, temporary risk corridors program, and a permanent risk adjustment program.

§ 153.20 Definitions.

The following definitions apply to this part, unless the context indicates otherwise:

Alternate risk adjustment methodology means a risk adjustment methodology proposed by a State for use instead of a Federally certified risk adjustment methodology that has not yet been certified by HHS.

Applicable reinsurance entity means a not-for-profit organization that is exempt from taxation under Chapter 1 of the Internal Revenue Code of 1986 that carries out reinsurance functions under this part on behalf of the State. An entity is not an applicable reinsurance entity to the extent it is carrying out reinsurance functions under subpart C of this part on behalf of HHS.

Attachment point means the threshold dollar amount for claims costs incurred by a health insurance issuer for an enrolled individual's covered benefits in a benefit year, after which threshold the claims costs for such benefits are eligible for reinsurance payments.

Benefit year has the meaning given to the term in § 155.20 of this subchapter.

Calculation of payments and charges means the methodology applied to plan average actuarial risk to determine risk adjustment payments and charges for a risk adjustment covered plan.

Calculation of plan average actuarial risk means the specific procedures used to determine plan average actuarial risk from individual risk scores for a risk adjustment covered plan, including adjustments for variable rating and the specification of the risk pool from which average actuarial risk is to be calculated.

Coinsurance rate means the rate at which the applicable reinsurance entity will reimburse the health insurance issuer for claims costs incurred for an enrolled individual's covered benefits in a benefit year after the attachment point and before the reinsurance cap.

Contributing entity means a health insurance issuer or a third party administrator on behalf a self-insured group health plan.

Contribution rate means, with respect to a benefit year, the per capita amount each contributing entity must pay for a reinsurance program established under this part with respect to each reinsurance contribution enrollee who resides in that State.

Exchange has the meaning given to the term in § 155.20 of this subchapter.

Federally certified risk adjustment methodology means a risk adjustment methodology that either has been developed and promulgated by HHS, or has been certified by HHS.

Grandfathered health plan has the meaning given to the term in § 147.140(a) of this subchapter.

Group health plan has the meaning given to the term in § 144.103 of this subchapter.

Health insurance coverage has the meaning given to the term in § 144.103 of this subchapter.

Health insurance issuer or issuer has the meaning given to the term in § 144.103 of this subchapter.

Health plan has the meaning given to the term in section 1301(b)(1) of the Affordable Care Act.

Individual market has the meaning given to the term in § 144.103 of this subchapter.

Individual risk score means a relative measure of predicted health care costs

for a particular enrollee that is the result of a risk adjustment model.

Large employer has the meaning given to the term in § 155.20 of this subchapter.

Qualified employer has the meaning given to the term in § 155.20 of this subchapter.

Qualified health plan or QHP has the meaning given to the term in § 155.20 of this subchapter.

Qualified individual has the meaning given to the term in § 155.20 of this subchapter.

Reinsurance cap means the threshold dollar amount for claims costs incurred by a health insurance issuer for an enrolled individual's covered benefits, after which threshold, the claims costs for such benefits are no longer eligible for reinsurance payments.

Reinsurance contribution enrollee means an individual covered by a plan for which reinsurance contributions must be made pursuant to § 153.400.

Reinsurance-eligible plan means, for the purpose of the reinsurance program, any health insurance coverage offered in the individual market, except for grandfathered plans and health insurance coverage not required to submit reinsurance contributions under § 153.400(a).

Risk adjustment covered plan means, for the purpose of the risk adjustment program, any health insurance coverage offered in the individual or small group market with the exception of grandfathered health plans, group health insurance coverage described in § 146.145(c) of this subchapter, individual health insurance coverage described in § 148.220 of this subchapter, and any other plan determined not to be a risk adjustment covered plan in the annual HHS notice of benefit and payment parameters.

Risk adjustment data means all data that are used in a risk adjustment model, the calculation of plan average actuarial risk, or the calculation of payments and charges, or that are used for validation or audit of such data.

Risk adjustment data collection approach means the specific procedures by which risk adjustment data is to be stored, collected, accessed, transmitted, validated and audited and the applicable timeframes, data formats, and privacy and security standards.

Risk adjustment methodology means the risk adjustment model, the calculation of plan average actuarial risk, the calculation of payments and charges, the risk adjustment data collection approach, and the schedule for the risk adjustment program.

Risk adjustment model means an actuarial tool used to predict health care

costs based on the relative actuarial risk of enrollees in risk adjustment covered plans.

Risk pool means the State-wide population across which risk is distributed.

Small group market has the meaning given to the term in section 1304(a)(3) of the Affordable Care Act.

State has the meaning given to the term in § 155.20 of this subchapter.

Subpart B—State Notice of Benefit and Payment Parameters

§ 153.100 State notice of benefit and payment parameters.

(a) *General requirement for reinsurance.* A State establishing a reinsurance program must issue an annual notice of benefit and payment parameters specific to that State if that State elects to:

(1) Modify the data requirements or data collection frequency for health insurance issuers to receive reinsurance payment from those specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year;

(2) Collect reinsurance contributions pursuant to § 153.220(a)(1);

(3) Collect additional reinsurance contributions pursuant to § 153.220(g);

(4) Use more than one applicable reinsurance entity; or

(5) Modify any reinsurance payment parameters from those specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year.

(b) *Risk adjustment requirements.* A State operating a risk adjustment program must issue an annual notice of benefit and payment parameters specific to that State setting forth the risk adjustment methodology and data validation standards it will use.

(c) *State notice deadlines.* If a State is required to publish an annual State notice of benefit and payment parameters, it must do so by March 1 of the calendar year prior to the benefit year for which the notice applies.

(d) *State failure to publish notice.* Any State establishing a reinsurance program or operating a risk adjustment program that fails to publish a State notice of benefit and payment parameters within the period specified in paragraph (c) of this section must—

(1) Adhere to the data requirements and data collection frequency for health insurance issuers to receive reinsurance payments that are specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year;

(2) Forgo the collection of reinsurance contributions pursuant to § 153.220(a);

(3) Forgo the collection of additional reinsurance contributions pursuant to § 153.220(g);

(4) Forgo the use of more than one applicable reinsurance entity;

(5) Adhere to the reinsurance parameters specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year; and

(6) Adhere to the risk adjustment methodology and data validation standards published in the annual HHS notice of benefit and payment parameters for use by HHS when operating risk adjustment on behalf of a State.

§ 153.110 Standards for the State notice of benefit and payment parameters.

(a) *Data requirements.* If a State that establishes a reinsurance program elects to modify the data requirements or data collection frequency for health insurance issuers to receive reinsurance payment from those specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year, the State notice of benefit and payment parameters must specify those modifications.

(b) *Reinsurance collection.* If a State that establishes a reinsurance program elects to collect reinsurance contributions pursuant to § 153.220(a), then the State must announce its intention to do so in the State notice of benefit and payment parameters.

(c) *Additional collections.* If a State that establishes a reinsurance program elects to collect additional funds pursuant to § 153.220(g), the State must publish the following:

(1) A description of the purpose of the additional collection, including whether it will be used to cover reinsurance payments, administrative costs, or both; and

(2) The additional contribution rate at which the funds will be collected.

(d) *Multiple reinsurance entities.* If a State plans to use more than one applicable reinsurance entity, the State must publish in the State notice of benefit and payment parameters, for each applicable reinsurance entity—

(1) The geographic boundaries for that entity;

(2) An estimate of the number of enrollees in fully insured plans within those boundaries;

(3) An estimate of the number of enrollees in the individual market within those boundaries;

(4) An estimate of the reinsurance contributions that will be collected by the applicable reinsurance entity;

(5) The percentage of reinsurance contributions received from HHS for the

State to be allocated to the applicable reinsurance entity; and

(6) An estimate of the amount of reinsurance payments that will be made to issuers with respect to enrollees within those boundaries.

(e) *Reinsurance payment.* If a State that establishes a reinsurance program intends to modify the attachment point, reinsurance cap, or coinsurance rate from the corresponding parameters specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year, the State must—

(1) Describe those modified parameters in the State notice of benefit and payment parameters; and

(2) Apply the modified parameters uniformly throughout the State.

(f) *Risk adjustment content.* A State operating a risk adjustment program must provide the information set forth in § 153.330(a) and the data validation standards set forth pursuant to § 153.350 in the State notice of benefit and payment parameters.

Subpart C—State Standards Related to the Reinsurance Program

§ 153.200 [Reserved]

§ 153.210 State establishment of a reinsurance program.

(a) *General requirement.* Each State is eligible to establish a reinsurance program for the years 2014 through 2016.

(1) If a State establishes a reinsurance program, the State must enter into a contract with one or more applicable reinsurance entities to carry out the provisions of this subpart.

(2) If a State contracts with more than one applicable reinsurance entity, the State must:

(i) Ensure that each applicable reinsurance entity operates in a distinct geographic area with no overlap of jurisdiction with any other applicable reinsurance entity;

(ii) Use the same payment parameters with respect to each applicable reinsurance entity; and

(iii) Notify HHS in the manner and timeframe specified by HHS of the percentage of reinsurance contributions received from HHS for the State to be allocated to each applicable reinsurance entity.

(3) A State may permit an applicable reinsurance entity to subcontract specific administrative functions required under this subpart and subpart E of this part.

(4) A State must review and approve subcontracting arrangements to ensure efficient and appropriate expenditures

of administrative funds collected under this subpart.

(5) A State must ensure that the applicable reinsurance entity completes all reinsurance-related activities for benefit years 2014 through 2016 and any activities required to be undertaken in subsequent periods.

(b) *Multi-State reinsurance arrangements.* Multiple States may contract with a single entity to serve as an applicable reinsurance entity for each State. In such a case, the reinsurance programs for those States must be operated as separate programs.

(c) *Non-electing States.* HHS will establish a reinsurance program for each State that does not elect to establish its own reinsurance program.

(d) *Oversight.* Each State that establishes a reinsurance program must ensure that the applicable reinsurance entity complies with all provisions of this subpart and subpart E of this part throughout the duration of its contract.

§ 153.220 Collection of reinsurance contribution funds.

(a) *Collections.* If a State establishes a reinsurance program, then—

(1) The State may elect to—

(i) Have the applicable reinsurance entity collect contributions for reinsurance contribution enrollees who reside in that State directly from issuers of health plans; or

(ii) Ensure that the applicable reinsurance entity accepts contributions for reinsurance contribution enrollees who reside in that State with respect to issuers of health plans from HHS.

(2) The State must ensure that the applicable reinsurance entity accepts contributions for reinsurance contribution enrollees who reside in that State with respect to all contributing entities other than issuers of health plans from HHS.

(b) *Notification of election to collect.* If a State establishes a reinsurance program, then that State must notify HHS by December 1, 2012, if the State elects to collect reinsurance contributions from fully insured plans for the 2014 benefit year, and by September 1 of the calendar year that is two years prior to the applicable benefit year if the State elects to collect reinsurance contributions from fully insured plans for any benefit year after 2014, in each case pursuant to paragraph (a)(1)(i) of this section. The State's notification will be effective for the applicable benefit year and each subsequent benefit year during which activities related to the transitional reinsurance program continue.

(c) *Contribution funding.* Reinsurance contributions collected must fund the following:

(1) Reinsurance payments that will total, on a national basis, \$10 billion in 2014, \$6 billion in 2015, and \$4 billion in 2016;

(2) U.S. Treasury contributions that will total, on a national basis, \$2 billion in 2014, \$2 billion in 2015, and \$1 billion in 2016; and

(3) Administrative expenses of the applicable reinsurance entity or HHS when performing reinsurance functions under this subpart.

(d) *Distribution of reinsurance contributions.* If a State establishes a reinsurance program, HHS will distribute funds collected for reinsurance contribution enrollees who reside in a State to the applicable reinsurance entity for that State (or the applicable reinsurance entities, if more than one, in accordance with the allocation specified by the State pursuant to § 153.210(a)(2)(ii)), less:

(1) The State's pro rata share of the U.S. Treasury contribution described in paragraph (c)(2) of this section; and

(2) The State's pro rata share of administrative expenses incurred by HHS when performing reinsurance functions under this subpart.

(e) *National contribution rate.* HHS will set in the annual HHS notice of benefit and payment parameters for the applicable benefit year the national contribution rate and the proportion of contributions collected under the national contribution rate to be allocated to:

(1) Reinsurance payments;

(2) Payments to the U.S. Treasury as described in paragraph (c)(2) of this section; and

(3) Administrative expenses of the applicable reinsurance entity or HHS when performing reinsurance functions under this subpart.

(f) *State collections.* If a State elects to have the applicable reinsurance entity collect contributions pursuant to paragraph (a)(1)(i) of this section, the State must ensure that:

(1) The applicable reinsurance entity for the State collects contributions for reinsurance contribution enrollees who reside in that State directly from issuers of health plans in the amounts required under the national contribution rate.

(2) Reinsurance contributions are allocated as required in the annual HHS notice of benefit and payment parameters for the applicable benefit year, such that:

(i) Contributions allocated for reinsurance payments are only used for reinsurance payments; and

(ii) Contributions allocated for payments to the U.S. Treasury are paid to the U.S. Treasury in a timeframe to be established by HHS.

(g) *Additional State collections.* If a State establishes a reinsurance program, it may elect to collect more than the amounts that would be collected based on the national contribution rate set forth in the annual HHS notice of benefit and payment parameters for the applicable benefit year to provide:

(1) Funding for administrative expenses of the applicable reinsurance entity; or

(2) Additional funding for reinsurance payments.

(h) *Administration of additional State collections.* If a State elects to collect additional amounts pursuant to paragraph (g) of this section for administrative expenses or reinsurance payments, then:

(1) The State must notify HHS within 30 days after publication of the draft annual HHS notice of benefit and payment parameters for the applicable benefit year of the additional contribution rate that it elects to collect for additional administrative expenses. The State must ensure that the State's applicable reinsurance entity—

(i) Collects these additional amounts for additional administrative expenses from issuers of health plans when the State elects to collect contributions from such issuers under paragraph (a)(1) of this section; and

(ii) Accepts additional amounts for additional administrative expenses from HHS from all contributing entities from which HHS collects in accordance with the State's election under paragraph (a)(1) of this section.

(2) Notwithstanding paragraphs (a)(1) and (a)(2) of this section, the State must ensure that the applicable reinsurance entity collects all additional reinsurance contributions for the purpose of reinsurance payments from all contributing entities.

§ 153.230 Calculation of reinsurance payments.

(a) *General requirement.* A health insurance issuer of a non-grandfathered individual market plan becomes eligible for reinsurance payments when its claims costs for an individual enrollee's covered benefits in a benefit year exceed the attachment point.

(b) *Reinsurance payment parameters.* If a State establishes a reinsurance program, the State must use, subject to any modifications made pursuant to paragraph (d) of this section, the payment formula and values for the attachment point, reinsurance cap, and coinsurance rate for each year

commencing in 2014 and ending in 2016 established in the annual HHS notice of benefit and payment parameters for the applicable benefit year.

(c) *Reinsurance payments.* If a State establishes a reinsurance program, the State must ensure, subject to § 153.240(b)(1), that the reinsurance payment represents the product of the coinsurance rate multiplied by the health insurance issuer's claims costs for an individual enrollee's covered benefits that the health insurance issuer incurs between the attachment point and the reinsurance cap.

(d) *State modification of reinsurance payment formula.* If a State establishes a reinsurance program, the State may modify the reinsurance payment formula in accordance with the following:

(1) The State may only use one or more of the following methods to modify the reinsurance payment formula:

- (i) Increasing or decreasing the attachment point;
- (ii) Increasing, decreasing, or eliminating the reinsurance cap; or
- (iii) Increasing or decreasing the coinsurance rate.

(2) The State must publish any such modification to the reinsurance payment formula and parameters in a State notice of benefit and payment parameters as described in subpart B of this part.

(3) Any State modification to the reinsurance payment formula pursuant to paragraph (d)(1) of this section must be reasonably calculated to ensure that reinsurance contributions received toward reinsurance are sufficient to cover payments that the applicable reinsurance entity is obligated to make under that State formula for the given benefit year for the reinsurance program.

(4) The State must use a uniform attachment point, coinsurance rate, and reinsurance cap throughout the State.

§ 153.240 Disbursement of reinsurance payments.

(a) *Data collection.* If a State establishes a reinsurance program, the State must ensure that the applicable reinsurance entity collects from health insurance issuers of reinsurance-eligible plans data required to calculate payments described in § 153.230, according to the data requirements and data collection frequency specified by the State in the notice of benefit and payment parameters described in subpart B of this part.

(b) *Reinsurance entity payments.* If a State establishes a reinsurance program,

the State must ensure that each applicable reinsurance entity does not make payments to health insurance issuers that exceed contributions received to date by the applicable reinsurance entity.

(1) If a State, or HHS on behalf of the State, determines that reinsurance payments requested for a benefit year will likely exceed the reinsurance contributions that will be received for the year, the State may require that the applicable reinsurance entity reduce (or HHS on behalf of the State may reduce) reinsurance payments, so long as the manner in which payments are reduced is fair and equitable for all health insurance issuers in the individual market.

(2) The State must ensure that an applicable reinsurance entity makes payment to the health insurance issuer of a reinsurance-eligible plan after receiving a valid claim for payment from that health insurance issuer in accordance with the requirements of § 153.410.

(c) *Maintenance of records.* If a State establishes a reinsurance program, the State must maintain books, records, documents, and other evidence of accounting procedures and practices of the reinsurance program for each benefit year for at least 10 years.

§ 153.250 Coordination with high-risk pools.

(a) *General requirement.* The State must eliminate or modify any State high-risk pool to the extent necessary to carry out the reinsurance program established under this subpart.

(b) *Coordination with high-risk pools.* The State may coordinate the State high-risk pool with the reinsurance program to the extent that the State high-risk pool conforms to the provisions of this subpart.

Subpart D—State Standards Related to the Risk Adjustment Program

§ 153.300 [Reserved]

§ 153.310 Risk adjustment administration.

(a) *State eligibility to establish a risk adjustment program.* (1) A State that elects to operate an Exchange is eligible to establish a risk adjustment program.

(2) Any State that does not elect to operate an Exchange, or that HHS has not approved to operate an Exchange, will forgo implementation of all State functions in this subpart, and HHS will carry out all of the provisions of this subpart on behalf of the State.

(3) Any State that elects to operate an Exchange but does not elect to administer risk adjustment will forgo implementation of all State functions in

this subpart, and HHS will carry out all of the provisions of this subpart on behalf of the State.

(b) *Entities eligible to carry out risk adjustment activities.* If a State is operating a risk adjustment program, the State may elect to have an entity other than the Exchange perform the State functions of this subpart, provided that the entity meets the standards promulgated by HHS to be an entity eligible to carry out Exchange functions.

(c) *Timeframes.* A State, or HHS on behalf of the State, must implement risk adjustment for the 2014 benefit year and every benefit year thereafter. For each benefit year, a State, or HHS on behalf of the State, must notify issuers of risk adjustment payments due or charges owed annually by June 30 of the year following the benefit year.

(d) *State summary reports.* Each State operating a risk adjustment program must submit to HHS an annual summary of risk adjustment program operations in the manner and timeframe specified by HHS.

§ 153.320 Federally certified risk adjustment methodology.

(a) *General requirement.* Any risk adjustment methodology used by a State, or HHS on behalf of the State, must be a Federally certified risk adjustment methodology. A risk adjustment methodology may become Federally certified by one of the following processes:

(1) The risk adjustment methodology is developed by HHS and published in an annual HHS notice of benefit and payment parameters; or

(2) An alternate risk adjustment methodology is submitted by a State in accordance with § 153.330, reviewed and certified by HHS, and published in an annual HHS notice of benefit and payment parameters.

(b) *Publication of methodology in notices.* The publication of a risk adjustment methodology by HHS in an annual HHS notice of benefit and payment parameters or by a State in an annual State notice of benefit and payment parameters described in subpart B of this part must include:

(1) A complete description of the risk adjustment model, including—

(i) Factors to be employed in the model, including but not limited to demographic factors, diagnostic factors, and utilization factors, if any;

(ii) The qualifying criteria for establishing that an individual is eligible for a specific factor;

(iii) Weights assigned to each factor; and

(iv) The schedule for the calculation of individual risk scores.

(2) A complete description of the calculation of plan average actuarial risk.

(3) A complete description of the calculation of payments and charges.

(4) A complete description of the risk adjustment data collection approach.

(5) The schedule for the risk adjustment program.

(c) *Use of methodology for States that do not operate a risk adjustment program.* HHS will specify in the annual HHS notice of benefit and payment parameters for the applicable year the Federally certified risk adjustment methodology that will apply in States that do not operate a risk adjustment program.

§ 153.330 State alternate risk adjustment methodology.

(a) *State request for alternate methodology certification.* (1) A State request to HHS for the certification of an alternate risk adjustment methodology must include:

(i) The elements specified in § 153.320(b);

(ii) The calibration methodology and frequency of calibration; and

(iii) The statistical performance metrics specified by HHS.

(2) The request must include the extent to which the methodology:

(i) Accurately explains the variation in health care costs of a given population;

(ii) Links risk factors to daily clinical practice and is clinically meaningful to providers;

(iii) Encourages favorable behavior among providers and health plans and discourages unfavorable behavior;

(iv) Uses data that is complete, high in quality, and available in a timely fashion;

(v) Is easy for stakeholders to understand and implement;

(vi) Provides stable risk scores over time and across plans; and

(vii) Minimizes administrative costs.

(b) *State renewal of alternate methodology.* If a State is operating a risk adjustment program, the State may not implement a recalibrated risk adjustment model or otherwise alter its risk adjustment methodology without first obtaining HHS certification.

(1) Recalibration of the risk adjustment model must be performed at least as frequently as described in paragraph (a)(1)(ii) of this section;

(2) A State request to implement a recalibrated risk adjustment model or otherwise alter its risk adjustment methodology must include any changes to the parameters described in paragraph (a)(1) of this section.

§ 153.340 Data collection under risk adjustment.

(a) *Data collection requirements.* If a State is operating a risk adjustment program, the State must collect risk adjustment data.

(b) *Minimum standards.* (1) If a State is operating a risk adjustment program, the State may vary the amount and type of data collected, but the State must collect or calculate individual risk scores generated by the risk adjustment model in the applicable Federally certified risk adjustment methodology;

(2) If a State is operating a risk adjustment program, the State must require that issuers offering risk adjustment covered plans in the State comply with data privacy and security standards set forth in the applicable risk adjustment data collection approach; and

(3) If a State is operating a risk adjustment program, the State must ensure that any collection of personally identifiable information is limited to information reasonably necessary for use in the applicable risk adjustment model, calculation of plan average actuarial risk, or calculation of payments and charges. Except for purposes of data validation, the State may not collect or store any personally identifiable information for use as a unique identifier for an enrollee's data, unless such information is masked or encrypted by the issuer, with the key to that masking or encryption withheld from the State.

(4) If a State is operating a risk adjustment program, the State must implement security standards that provide administrative, physical, and technical safeguards for the individually identifiable information consistent with the security standards described at 45 CFR 164.308, 164.310, and 164.312.

§ 153.350 Risk adjustment data validation standards.

(a) *General requirement.* The State, or HHS on behalf of the State, must ensure proper implementation of any risk adjustment software and ensure proper validation of a statistically valid sample of risk adjustment data from each issuer that offers at least one risk adjustment covered plan in that State.

(b) *Adjustment to plan average actuarial risk.* The State, or HHS on behalf of the State, may adjust the plan average actuarial risk for a risk adjustment covered plan based on errors discovered with respect to implementation of risk adjustment software or as a result of data validation conducted pursuant to paragraph (a) of this section.

(c) *Adjustment to charges and payments.* The State, or HHS on behalf of the State, may adjust charges and payments to all risk adjustment covered plan issuers based on the adjustments calculated in paragraph (b) of this section.

(d) *Appeals.* The State, or HHS on behalf of the State, must provide an administrative process to appeal findings with respect to the implementation of risk adjustment software or data validation.

Subpart E—Health Insurance Issuer and Group Health Plan Standards Related to the Reinsurance Program

§ 153.400 Reinsurance contribution funds.

(a) *General requirement.* Each contributing entity must make reinsurance contributions at the national contribution rate (and any additional contribution rate if the State has elected to collect additional contributions pursuant to § 153.220(g)) for the reinsurance program for all reinsurance contribution enrollees who reside in a State, in a frequency and manner determined by HHS or the State, to HHS or the applicable reinsurance entity, as applicable.

(1) A contributing entity must make reinsurance contributions on behalf of its group health plans and health insurance coverage, except as set forth in paragraph (a)(2) of this section.

(2) A contributing entity is not required to make contributions on behalf of plans or health insurance coverage that consist solely of excepted benefits as defined by section 2791(c) of the PHS Act.

(b) *Multiple reinsurance entities.* If the State establishes or contracts with more than one applicable reinsurance entity, the contributing entity must make reinsurance contributions to each applicable reinsurance entity for the reinsurance contribution enrollees who reside in the applicable geographic area.

(c) *Timeframe for Federal collections.* Each contributing entity must submit contributions to HHS on a quarterly basis beginning January 15, 2014.

(d) *Data requirements.* Each contributing entity must submit to HHS and each applicable reinsurance entity, if the State elects to collect reinsurance contributions, data required to substantiate the contribution amounts for the contributing entity, in the manner and timeframe specified by the State or HHS.

§ 153.410 Requests for reinsurance payment.

(a) *General requirement.* An issuer of a reinsurance-eligible plan may make a

request for payment when an enrollee of that reinsurance-eligible plan has met the criteria for reinsurance payment set forth in the annual HHS notice of benefit and payment parameters for the applicable year or the State notice of benefit and payment parameters described in subpart B of this part, as applicable.

(b) *Manner of request.* An issuer of a reinsurance-eligible plan must make requests for payment in accordance with the requirements of the annual HHS notice of benefit and payment parameters for the applicable benefit year or the State notice of benefit and payment parameters described in subpart B of this part, as applicable.

Subpart F—Health Insurance Issuer Standards Related to the Risk Corridors Program

§ 153.500 Definitions.

The following definitions apply to this subpart:

Administrative costs mean, with respect to a QHP, total non-claims costs incurred by the QHP issuer for the QHP, as described in § 158.160(b) of this subchapter.

Allowable administrative costs mean, with respect to a QHP, administrative costs of the QHP, up to 20 percent of the premiums earned with respect to the QHP (including any premium tax credit under any governmental program).

Allowable costs mean, with respect to a QHP, an amount equal to the sum of incurred claims of the QHP issuer for the QHP, within the meaning of § 158.140 of this subchapter (including adjustments for any direct and indirect remuneration); expenditures by the QHP issuer for the QHP for activities that improve health care quality as set forth in § 158.150 of this subchapter; expenditures by the QHP issuer for the QHP related to health information technology and meaningful use requirements as set forth in § 158.151 of this subchapter; and the adjustments set forth in § 153.530(b).

Charge means the flow of funds from QHP issuers to HHS.

Direct and indirect remuneration means prescription drug rebates received by a QHP issuer within the meaning of § 158.140(b)(1)(i) of this subchapter.

Payment means the flow of funds from HHS to QHP issuers.

Premiums earned mean, with respect to a QHP, all monies paid by or for enrollees with respect to that plan as a condition of receiving coverage, including any fees or other contributions paid by or for enrollees,

within the meaning of § 158.130 of this subchapter.

Risk corridors means any payment adjustment system based on the ratio of allowable costs of a plan to the plan's target amount.

Target amount means, with respect to a QHP, an amount equal to the total premiums earned with respect to a QHP, including any premium tax credit under any governmental program, reduced by the allowable administrative costs of the plan.

§ 153.510 Risk corridors establishment and payment methodology.

(a) *General requirement.* A QHP issuer must adhere to the requirements set by HHS in this subpart and in the annual HHS notice of benefit and payment parameters for the establishment and administration of a program of risk corridors for calendar years 2014, 2015, and 2016.

(b) *HHS payments to health insurance issuers.* QHP issuers will receive payment from HHS in the following amounts, under the following circumstances:

(1) When a QHP's allowable costs for any benefit year are more than 103 percent but not more than 108 percent of the target amount, HHS will pay the QHP issuer an amount equal to 50 percent of the allowable costs in excess of 103 percent of the target amount; and

(2) When a QHP's allowable costs for any benefit year are more than 108 percent of the target amount, HHS will pay to the QHP issuer an amount equal to the sum of 2.5 percent of the target amount plus 80 percent of allowable costs in excess of 108 percent of the target amount.

(c) *Health insurance issuers' remittance of charges.* QHP issuers must remit charges to HHS in the following amounts, under the following circumstances:

(1) If a QHP's allowable costs for any benefit year are less than 97 percent but not less than 92 percent of the target amount, the QHP issuer must remit charges to HHS in an amount equal to 50 percent of the difference between 97 percent of the target amount and the allowable costs; and

(2) When a QHP's allowable costs for any benefit year are less than 92 percent of the target amount, the QHP issuer must remit charges to HHS in an amount equal to the sum of 2.5 percent of the target amount plus 80 percent of the difference between 92 percent of the target amount and the allowable costs.

§ 153.520 Attribution and allocation of revenue and expense items.

(a) *Attribution to QHP.* Each item of revenue or expense in allowable costs or

the target amount with respect to a QHP must be reasonably attributable to the operation of the QHP, with the attribution based on a generally accepted accounting method, consistently applied. To the extent that an issuer utilizes a specific method for allocating expenses for purposes of § 158.170 of this subchapter, the method used for purposes of this paragraph must be consistent.

(b) *Allocation across plans.* Each item of revenue or expense in allowable costs or the target amount must be reasonably allocated across a QHP issuer's plans, with the allocation based on a generally accepted accounting method, consistently applied. To the extent that an issuer utilizes a specific method for allocating expenses for purposes of § 158.170 of this subchapter, the method used for purposes of this paragraph must be consistent.

(c) *Disclosure of attribution and allocation methods.* A QHP issuer must submit to HHS a report, in the manner and timeframe specified in the annual HHS notice of benefit and payment parameters, with a detailed description of the methods and specific bases used to perform the attributions and allocations set forth in paragraphs (a) and (b) of this section.

(d) *Attribution of reinsurance and risk adjustment to benefit year.* A QHP issuer must attribute reinsurance payments and contributions and risk adjustment payments and charges to allowable costs for the benefit year with respect to which the reinsurance payments or contributions or risk adjustment calculations apply.

(e) *Maintenance of records.* A QHP issuer must maintain for 10 years and make available to HHS upon request the data used to make the attributions and allocations set forth in paragraphs (a) and (b) of this section, together with all supporting information required to determine that these methods and bases were accurately implemented.

§ 153.530 Risk corridors data requirements.

(a) *Premium data.* A QHP issuer must submit to HHS data on the premiums earned with respect to each QHP that the issuer offers in the manner and timeframe set forth in the annual HHS notice of benefit and payment parameters.

(b) *Allowable costs.* A QHP issuer must submit to HHS data on the allowable costs incurred with respect to each QHP that the QHP issuer offers in the manner and timeframe set forth in the annual HHS notice of benefit and payment parameters. For purposes of this subpart, allowable costs must be—

(1) Increased by—

(i) Any risk adjustment charges paid by the issuer for the QHP under the risk adjustment program established pursuant to subpart D of this part; and

(ii) Any reinsurance contributions made by the issuer for the QHP under the transitional reinsurance program established pursuant to subpart C of this part.

(2) Reduced by—

(i) Any risk adjustment payments received by the issuer for the QHP under the risk adjustment program established pursuant to subpart D of this part;

(ii) Any reinsurance payments received by the issuer for the QHP under the transitional reinsurance program established pursuant to subpart C of this part; and

(iii) Any cost-sharing reduction payments received by the issuer for the QHP.

(c) *Allowable administrative costs.* A QHP issuer must submit to HHS data on the allowable administrative costs incurred with respect to each QHP that the QHP issuer offers in the manner and timeframe set forth in the annual HHS notice of benefit and payment parameters.

Subpart G—Health Insurance Issuer Standards Related to the Risk Adjustment Program

§ 153.600 [Reserved]

§ 153.610 Risk adjustment issuer requirements.

(a) *Data requirements.* An issuer that offers risk adjustment covered plans must submit or make accessible all required risk adjustment data for those risk adjustment covered plans in accordance with the risk adjustment data collection approach established by the State, or by HHS on behalf of the State.

(b) *Risk adjustment data storage.* An issuer that offers risk adjustment covered plans must store all required risk adjustment data in accordance with the risk adjustment data collection approach established by the State, or by HHS on behalf of the State.

(c) *Issuer contracts.* An issuer that offers risk adjustment covered plans may include in its contract with a provider, supplier, physician, or other practitioner, provisions that require such contractor's submission of complete and accurate risk adjustment data in the manner and timeframe established by the State, or HHS on behalf of the State. These provisions may include financial penalties for failure to submit complete, timely, or accurate data.

(d) *Assessment of charges.* An issuer that offers risk adjustment covered plans

that has a net balance of risk adjustment charges payable, including adjustments made pursuant to § 153.350(c), will be notified by the State, or by HHS on behalf of the State, of those net charges, and must remit those risk adjustment charges to the State, or to HHS on behalf of the State, as applicable.

(e) *Charge submission deadline.* An issuer must remit net charges to the State, or HHS on behalf of the State, within 30 days of notification of net charges payable by the State, or HHS on behalf of the State.

§ 153.620 Compliance with risk adjustment standards.

(a) *Issuer support of data validation.* An issuer that offers risk adjustment covered plans must comply with any data validation requests by the State or HHS on behalf of the State.

(b) *Issuer records maintenance requirements.* An issuer that offers risk adjustment covered plans must retain any information requested to support risk adjustment data validation for a period of at least ten years after the date of the report.

Dated: March 14, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: March 14, 2012.

Kathleen Sebelius,
Secretary.

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EXHIBIT 9



Report to Congressional Requesters

April 2015

PATIENT PROTECTION AND AFFORDABLE CARE ACT

Despite Some Delays,
CMS Has Made
Progress
Implementing
Programs to Limit
Health Insurer Risk

GAO Highlights

Highlights of [GAO-15-447](#), a report to congressional requesters

Why GAO Did This Study

PPACA resulted in significant changes to the private individual and small group health insurance markets in 2014 that expanded the availability and affordability of coverage. However, some of these provisions reduced issuers' ability to mitigate the risk of high-cost enrollees by limiting their ability to deny coverage or charge higher premiums based on individuals' health risks and other factors. Issuers also faced increased risk starting in 2014 because these provisions were expected to result in the enrollment of many previously uninsured individuals, who have unknown and potentially higher medical costs than the broader population. To limit these risks, PPACA required the establishment of three risk mitigation programs.

GAO was asked to provide information on the design and development of these three programs and on issuer perspectives on them. In this report, GAO describes: (1) the factors that guided CMS's design of these programs, (2) the data collection systems CMS developed for these programs, (3) CMS's plans to monitor and evaluate the programs, and (4) issuer experiences with the programs. GAO reviewed regulations, guidance, and documentation about design and implementation activities and interviewed CMS officials. GAO also interviewed officials from a non-representative sample of 12 issuers that offered individual market coverage in 2014 and were selected based on variation in enrollment, location, and market experience.

View [GAO-15-447](#). For more information, contact John Dicken at (202) 512-7114 or dickenj@gao.gov.

April 2015

PATIENT PROTECTION AND AFFORDABLE CARE ACT

Despite Some Delays, CMS Has Made Progress Implementing Programs to Limit Health Insurer Risk

What GAO Found

The Centers for Medicare & Medicaid Services (CMS) considered market characteristics and program duration in designing the three programs mandated by the Patient Protection and Affordable Care Act (PPACA) to mitigate the risks issuers of health insurance faced starting in 2014. Each of the three programs—risk adjustment, reinsurance, and risk corridors—was intended to account for a different source of issuer risk, such as enrollee health status or high-cost medical claims. CMS considered a range of market characteristics—including demographics and the availability of data—in making decisions about how to design each of the programs. CMS's design decisions also reflected the temporary status of the reinsurance and risk corridors programs, which are set to expire after 3 years. While CMS considered similar Medicare risk mitigation programs during the design process, key differences in the markets served by Medicare and the PPACA programs resulted in different approaches to their design.

CMS considered privacy and security concerns in developing systems for collecting issuer data for the risk mitigation programs and experienced multiple implementation delays. For example, for the risk adjustment and reinsurance programs, CMS elected to use a system that allows sensitive enrollee claims data to remain with issuers while providing CMS with only summary data. However, CMS delayed implementation of data collection systems for these programs by nearly a year as it revised its plans to reduce administrative burden and accommodate issuer preferences. Therefore, CMS was unable to provide issuers with most of the periodic, interim reports it had originally planned to generate throughout 2014.

CMS developed or had plans to develop data verification or audit procedures for all three programs. CMS had also initiated efforts to evaluate the permanent risk adjustment program but had not finalized the details of the evaluation. In November 2014, CMS issued a request for contractors to submit bids to conduct a range of services, including research and development tasks for the risk adjustment program such as: analyze the impact of market and enrollee factors on the model; evaluate the accuracy of the program; and conduct research to support adaptation of the model. As of April 2015, CMS officials expected to award the contract in the spring of 2015, although the agency had not finalized a date for completing that evaluation. CMS's continued effort to carry out this evaluation will be important to assessing the program's success.

Most of the 12 issuers GAO interviewed said that the three risk mitigation programs encouraged their participation in the individual health insurance market, and two of the programs allowed them to lower their premiums. Issuers identified design concerns specific to each PPACA risk mitigation program and provided mixed responses regarding the effect of CMS's implementation delays and technical assistance.

In commenting on a draft of this report, the Department of Health and Human Services described CMS's data collection strategy for these programs and its efforts to ensure the appropriate level of technical support for issuers.

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Abbreviations

CCIIO	Center for Consumer Information & Insurance Oversight
CMS	Centers for Medicare & Medicaid Services
CO-OP	Consumer Operated and Oriented Plan
EDGE	External Data Gathering Environment
HIOS	Health Insurance Oversight System
HHS	Department of Health and Human Services
MLR	medical loss ratio
PPACA	Patient Protection and Affordable Care Act
SHOP	Small Business Health Options Program

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April 30, 2015

The Honorable Lamar Alexander
Chairman
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Bob Corker
United States Senate

The Patient Protection and Affordable Care Act (PPACA), signed into law on March 23, 2010, contained a number of provisions that resulted in significant changes to the private individual and small group health insurance markets.¹ Provisions took effect in 2014 to make coverage in these markets more available and affordable. However, some of these provisions reduced issuers' ability to mitigate the risk of high-cost enrollees by establishing new rules that limit how much issuers can vary the premiums they charge certain individuals or groups.² PPACA also introduced new requirements that prohibit issuers from denying coverage based on an individual's health status.

¹See, e.g., Pub. L. No. 111-148, §§ 1201, 1563(c)(1), formerly 1562(b)(1), 10103(a), 10107(b)(1), 124 Stat. 119, 154, 264, 892, 911 (adding to and amending provisions in the Public Health Service Act pertaining to certain individual and small group plans, including requirements for premiums, availability of coverage, benefits and cost sharing) (codified as amended at 42 U.S.C. § 300gg et seq.).

The private health insurance market includes individual and group coverage—including small and large group health plans. It does not include public health insurance coverage provided by the government, such as Medicare and Medicaid. Insurance offered by small employers is known as small group insurance and insurance offered by large employers is known as large group insurance. Some employers have self-funded coverage—where they pay health claims directly rather than purchase coverage through an insurance company—which may be operated by a third party administrator. Under PPACA, until 2016, states have the option to define a “small employer” either as having from 1 through 100 full-time equivalent employees or having from 1 through 50 full-time equivalent employees. Beginning in 2016, a “small employer” will be defined in all states as those with 100 or fewer full-time equivalent employees. Pub. L. No. 111-148, §§ 1304(b), 124 Stat. 171 (codified at 42 U.S.C. § 18024(b)).

²An issuer is an insurance company, insurance service, or insurance organization that is required to be licensed to engage in the business of insurance in a state.

To limit the increased risk that that issuers could face starting in 2014, PPACA also required the establishment of three risk mitigation programs: a permanent “risk adjustment” program and two temporary programs—“reinsurance” and “risk corridors”—set to expire after 3 years.³ These three programs have also been referred to as “premium stabilization” programs by the Center for Medicare & Medicaid Services (CMS) and as “risk-sharing” programs by others, including by the American Academy of Actuaries.⁴ Each of these programs uses a different mechanism intended to both improve the functioning of the health insurance markets and stabilize the premiums that issuers charge for health coverage. CMS is responsible for designing and implementing the programs within the parameters set by PPACA and for monitoring their operation.

Given the focus of these three risk mitigation programs on improving the functioning of insurance markets, it is important that they be designed and implemented effectively, especially during the 3 years following their introduction. You asked that we provide information on CMS’s design and development of these programs and on issuer perspectives on them. In this report, we describe:

1. the factors that guided CMS’s design of the three PPACA risk mitigation programs,
2. CMS’s development of systems for issuers to submit data needed for these three risk mitigation programs,
3. CMS’s plan to monitor and evaluate these three risk mitigation programs, and
4. issuer experiences with these three risk mitigation programs during the first year of operation.

To examine the factors that guided CMS’s design of the three PPACA risk mitigation programs, we reviewed CMS’s proposed and final regulations and other agency guidance and documents that describe design decisions. In addition, we interviewed CMS officials about their rationale for these design decisions; use of internal analyses, external experts, and consultants; and the extent to which the risk mitigation programs in

³See Pub. L. No. 111-148, §§ 1341, 1342, 1343, and 10104(r), 124 Stat. 208, 211, 212 and 906 (codified at 42 U.S.C. §§ 18061-18063).

⁴CMS is an agency within the Department of Health and Human Services (HHS).

Medicare Advantage and the Medicare prescription drug program informed their design decisions.⁵ In addition, to obtain contextual information on the design of risk mitigation programs, we interviewed experts from organizations with expertise in insurance-related issues, such as the National Association of Insurance Commissioners and the American Academy of Actuaries.

To examine CMS's development of data submission systems for these three risk mitigation programs, we reviewed regulations, guidance, and other agency documentation about implementation activities to date, including timelines for data collection and reporting of estimates of program payments and contributions. We also interviewed CMS officials about the schedule and decisions involved in implementation, as well as about their plans for issuing data and information related to these programs.

To examine CMS's plan to monitor and evaluate these three risk mitigation programs, we reviewed agency documentation and interviewed CMS officials. We also reviewed CMS's evaluations of the risk mitigation programs in Medicare.

To examine issuer experiences with these three risk mitigation programs during the first year of operation, we interviewed a non-generalizable sample of 12 issuers. We selected our sample of issuers from the 291 issuers that we determined sold a health plan in 2014 on the individual exchanges—marketplaces in each state where individuals can compare and select among insurance plans offered by participating private

⁵The Medicare program provides health coverage for persons age 65 or over, certain individuals with disabilities, and individuals with end-stage renal disease. Traditional fee-for-service Medicare includes Part A, which generally covers hospital inpatient services, and Part B, which generally covers certain services not covered by Part A, such as physician and outpatient services. Beneficiaries enrolled in Parts A and B may choose to enroll in a managed care Medicare Advantage plan in lieu of Medicare fee-for-service. Also, since 2006, Medicare Part D—prescription drug coverage—has been available to Medicare beneficiaries.

issuers.⁶ In selecting issuers, we sought to achieve variation across a number of factors that could influence their experience with the three risk mitigation programs. Specifically, we selected larger and smaller issuers, as determined by beneficiary enrollment.⁷ We also considered whether the issuer operated in a state that had private insurance market protections prior to 2014 that were similar to those in PPACA.⁸ In addition, we ensured that our sample contained some issuers that were new to the 2014 individual market,⁹ including issuers that were newly established through the federally funded Consumer Operated and Oriented Plan (CO-OP) program.¹⁰ Of the 12 issuers that we interviewed, 4 were issuers new to the individual insurance market in 2014, of which 2 were CO-OPs. The other 8 issuers that we interviewed had provided

⁶We selected issuers from among those offering coverage on the exchanges because plans in the exchanges are covered by all three of the risk mitigation programs, whereas plans offered outside of the exchanges vary in terms of which PPACA risk mitigation programs apply to them. We identified issuers offering coverage on individual exchanges in 2014 using data from CMS and individual states. For a full description of this methodology, see GAO, *Patient Protection and Affordable Care Act: Largest Issuers of Health Coverage Participated in Most Exchanges, and Number of Plans Available Varied*, [GAO-14-657](#) (Washington, D.C.: Aug. 29, 2014).

⁷We defined beneficiary enrollment using covered life-years, which represent the average number of lives insured, including dependents, on a pre-specified day over the 12 months in the reporting year. This information was developed based on issuer-reported medical loss ratio (MLR) data, which include enrollment data provided to CMS beginning in 2011, as required by PPACA. Pub. L. No. 111-148, §§ 1001(5), 1004, 10101(f), 124 Stat. 130, 136, 140, 885 (adding § 2718 to the PHSA) (codified at 42 U.S.C. § 300gg-18). The MLR standards set by PPACA require issuers to spend a minimum percentage of plan premiums towards their enrollees' medical care costs or issue rebates to those enrollees. Issuers must report these data to CMS every June and these data are based on the issuers' experience for the prior calendar year. CMS Medical Loss Ratio Data, Public Use File for 2012, as of Aug. 1, 2013, downloaded from <http://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html>.

⁸In 2012, we reported that Maine, Massachusetts, New Jersey, New York, and Vermont were the only states that reported having insurance market protections similar to those established in PPACA. See GAO, *Private Health Insurance: Estimates of Individuals with Pre-Existing Conditions Range from 36 million to 122 Million*, [GAO-12-439](#) (Washington, D.C.: Mar. 27, 2012).

⁹We determined whether an issuer in the individual exchange was new to the individual market in 2014 based on whether it had submitted individual market enrollment data to CMS as part of its 2012 MLR submission.

¹⁰PPACA required the establishment of the CO-OP program, which provides loans to encourage consumer-governed, nonprofit issuers to offer health plans in the individual and small group exchanges. Pub. L. No. 111-148, §§ 1322, 10104(l) 124 Stat. 187, 902 (codified at 42 U.S.C. § 18042).

health insurance in the individual market prior to 2014, including 4 larger issuers and 4 smaller issuers. We assessed the reliability of the data from CMS and the states by reviewing documentation and performing data reliability checks, such as examining the data for missing values and obvious errors. After taking these steps, we determined the data were sufficiently reliable for our purpose of selecting a non-generalizable sample of issuers. We developed a structured interview protocol to gather consistent information from these 12 issuers about their perspectives on the three risk mitigation programs. In order to inform the development of the structured protocol, we interviewed officials from relevant organizations, such as America's Health Insurance Plans, the Blue Cross Blue Shield Association of America, and the Association for Community Affiliated Plans. The interview protocol included questions about the design of the risk mitigation programs, the effect of these programs on issuer decisions to participate in the individual market and set premiums, and issuer experiences with the programs during the first year. Our findings are limited to those 12 issuers we spoke with and are not representative of the perspectives of all issuers.

We conducted this performance audit from August 2014 through April 2015 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Insurance Risk in Health Care

When issuers set their premiums, they consider a number of factors, such as trends in the cost of paying providers for medical services and data on the utilization of services in the population they are serving. Issuers are able to more accurately predict these costs when they have historic claims data for the population eligible to purchase coverage.¹¹ However, issuers must also consider the risk that the cost of the healthcare

¹¹Historic claims data is generally available for populations covered under public programs such as Medicare and Medicaid, as well as for populations that have had coverage over time through employer-based health plans.

delivered to their enrollees will exceed the premiums that they developed based on historic claims data.

Prior to the implementation of PPACA, issuers offering individual and small group market health insurance plans generally mitigated risks for unexpectedly high health care costs by tailoring premiums to specific individuals and small groups through a process known as medical underwriting and, in the individual market, by denying coverage to certain individuals based on factors such as health status.¹² Issuers generally were not subject to uniform federal requirements in regards to rules for setting premiums and guaranteed issuance of coverage for individuals,¹³ and therefore consumer protections varied among states.¹⁴ For example, we reported that, prior to the passage of PPACA, the majority of states did not prohibit issuers from denying enrollment of individuals because of their health status and issuers in many states were able to vary premiums based on the individual's health status, gender, and age.¹⁵

PPACA Provisions

Several PPACA provisions that became effective January 1, 2014, limited the ability of issuers to deny coverage or charge higher premiums to individuals and small groups based on health risks or certain other factors. For example, PPACA requires that issuers offering individual and small group market plans guarantee coverage regardless of the existence

¹²Medical underwriting is a process through which issuers consider the age, gender, health status, and other factors about individuals or small groups when determining their premium rate.

¹³The Health Insurance Portability and Accountability Act of 1996 set certain minimum federal standards, such as guaranteed issuance of coverage in the small group market and guaranteed renewal of coverage in both the small group and individual markets. See Pub. L. No. 104-191, §§ 102(a), 111(a), 110 Stat. 1936, 1955, 1978 (pertinent provisions formerly codified at 42 U.S.C. §§ 300gg-11(a), 300gg-12(a) and currently codified at 42 U.S.C. § 300gg-42(a)).

¹⁴States have primary responsibility for regulating issuers' premiums and coverage. For example, they may oversee premium setting by issuers and establish requirements for the amount of funds that an issuer must have to try to ensure that they can cover the expected medical needs of their enrollees.

¹⁵[GAO-12-439](#).

of a person's pre-existing conditions.¹⁶ Further, issuers are restricted in the amount they can vary premiums based on age and tobacco use, and they cannot set premiums for individual and small group plans based on an individual's health status, gender, or other characteristics.¹⁷ As a result, issuers may have an incentive to try to attract healthier individuals through certain marketing practices, benefit designs, drug formularies, and provider networks, leaving to other issuers those individuals who are in worse health and likely to require costly medical care.

PPACA also included a requirement that most individuals purchase health insurance or pay a tax penalty if coverage meeting affordability standards is available (this is known as the "individual mandate").¹⁸ As a result, many previously uninsured individuals entered the insurance market, possibly for the first time, and issuers lacked historical information about their health care and use of medical services.¹⁹ In addition, previously uninsured individuals who are most in need of health care may be more likely than others to purchase insurance during the transition, resulting in a pool of enrollees that have unknown and potentially higher medical costs than the broader population. In this situation, issuers might set plan premiums higher than they would otherwise due to uncertainty about enrollees' health status.

¹⁶Pub. L. No. 111-148, §§ 1201, 1563(c), formerly 1562(c)(1), 10107(b)(1), 124 Stat. 154, 264, 911 (amending SSA § 2704) (codified as amended at 42 U.S.C. § 300gg-3). A pre-existing condition is a health condition that exists before someone applies for or enrolls in a new health insurance plan.

¹⁷Pub. L. No. 111-148, §§ 1201, 10103(a), 124 Stat. 154, 892 (adding SSA § 2701) (codified at 42 U.S.C. § 300gg). Issuers' use of age in setting premiums is limited by the requirement that the premium for an older adult can be no greater than three times the premium they charge to a younger adult. Similarly, PPACA does not allow issuers to charge tobacco users more than 1.5 times what they charge those who do not use tobacco. Premiums may also vary based on whether a plan covers an individual or family and on geographic area.

¹⁸Pub. L. No. 111-148, §§ 1501, 10106, 124 Stat. 242, 907, as amended by Pub. L. No. 111-152, §§ 1002, 1004, 124 Stat. 1029, 1032 (codified as amended at 26 U.S.C. § 5000A and 42 U.S.C. § 18091).

¹⁹The Congressional Budget Office projected in April 2014 that 12 million more nonelderly people would have health insurance in 2014 than would have had it in the absence of the PPACA. They also projected that 19 million more people would be insured in 2015, 25 million more in 2016 and 26 million more in each year from 2017 through 2024 than would have been the case without the PPACA. Congressional Budget Office, *Updated Estimates of the Effects of the Insurance Coverage Provisions of the Affordable Care Act, April 2014* (Washington, D.C.: April 2014).

PPACA also required the creation in all states of health insurance exchanges—marketplaces where individuals and small employers can compare and select among insurance plans offered by participating private issuers.²⁰ To participate on the exchanges issuers must offer plans that meet certain state and PPACA requirements for benefit design, rate setting, and other factors. Approved plans are referred to as qualified health plans. It is through the exchanges that qualifying individuals may apply for premium tax credits and cost-sharing reductions, and certain small employers may apply for small business health insurance tax credits. Issuers participating in an exchange must meet certain criteria; for example, criteria related to marketing, provider networks, and accreditation.

PPACA does not require issuers offering coverage in the individual and small group markets to offer plans through the exchanges but, with limited exceptions, issuers in these markets are required to comply with other provisions, such as requiring coverage of specified benefit categories at standardized levels of cost-sharing and prohibitions on annual and lifetime limits on the dollar value of required benefits. Some of these market reforms do not apply to “grandfathered plans.”²¹

PPACA Risk Mitigation Programs

To mitigate issuer risk in the individual and small group health insurance markets, PPACA required the creation of the permanent risk adjustment program and temporary reinsurance and risk corridors programs. States have the option to either establish their own state-run risk adjustment and reinsurance programs or allow the federal government to administer

²⁰Pub. L. No. 111-148, §§ 1311, 1321, 10104(e)-(h), 10203(a), 124 Stat. 173, 186, 900, 901, 927 (codified at 42 U.S.C. §§ 18031 and 18041). The exchanges for small employers are referred to as Small Business Health Options Program (SHOP) exchanges.

²¹A grandfathered health plan refers to an existing plan in which at least one individual has been enrolled since March 23, 2010. These plans are subject to fewer requirements than plans established later. To maintain grandfathered status, a plan must avoid certain changes to benefits, cost-sharing and employer contributions. Grandfathered plans generally cannot enroll new groups or individuals.

these programs.²² The Department of Health and Human Services (HHS) is required to administer the risk corridors program.

Each of the risk mitigation programs applies to a different group of issuers. For example, the risk adjustment program transfers funds among individual and small group market issuers, while the reinsurance program collects funds from all issuers and third party administrators on behalf of group health plans and distributes it to only individual market issuers. Further, issuers do not have to comply with these requirements for certain types of plans. Specifically, grandfathered plans do not participate in the risk adjustment program, and they do not receive reinsurance payments. Similarly, HHS determined in 2013 that states could decide whether to allow enrollees to continue coverage under certain non-grandfathered plans established prior to 2014.²³ These plans—referred to as transitional plans—did not have to comply with all PPACA provisions and do not participate in the reinsurance or risk adjustment programs.²⁴

For a summary of each program's key functions, years of operation, and the issuers required to participate, see table 1.

²²Only states that operate their own individual or small group exchanges have the option to establish a risk adjustment program, while any state could choose to establish a reinsurance program. According to CMS officials, Massachusetts is the only state that elected to administer its own risk adjustment program, and Connecticut is the only state that elected to administer its own reinsurance program.

²³Centers for Medicare & Medicaid Services, Center for Consumer Information & Insurance Oversight Letter to Insurance Commissioners (Washington, D.C.: Nov. 14, 2013). The Center for Consumer Information & Insurance Oversight (CCIIO), within CMS, is responsible for overseeing the implementation the provisions of PPACA related to private health insurance.

²⁴Transitional plans must comply with PPACA provisions that started immediately after the law's passage—such as preventive care with no cost-sharing and no annual limits. However they do not have to comply with provisions that began on January 1, 2014, such as guaranteed issuance of coverage, adjusted community rating, and a single risk pool. In March 2014, CMS extended this policy, allowing transitional plans to be renewed until October 1, 2016, meaning that some transitional plans could persist through September 2017. Also, student health plans and self-funded plans do not participate in the risk adjustment program. Centers for Medicare & Medicaid Services, Center for Consumer Information & Insurance Oversight Letter to Insurance Commissioners (Washington, D.C.: Mar. 5, 2014).

Table 1: PPACA Risk Mitigation Program Key Function, Time Frame, and Participating Issuers

Program	Risk adjustment	Reinsurance	Risk corridors
Key function	Transfers funds from issuers with lower-risk enrollees to those with higher-risk enrollees	Makes payments to issuers that incur high claims costs for enrollees	Limits issuer losses and profits
Time frame	Permanent	Three years: 2014 through 2016	Three years: 2014 through 2016
Issuers required to participate	Issuers with individual and small group market plans, both inside and outside the exchanges, with the exception of grandfathered, transitional, and self-funded plans.	All issuers and third party administrators on behalf of group health plans contribute funding. Issuers of individual market plans both inside and outside the exchanges are eligible to receive payments, with the exception of grandfathered and transitional plans.	Issuers of qualified health plans in the individual and small group markets both inside and outside the exchanges.

Source: GAO analysis of PPACA, HHS regulations, and information from the Henry J. Kaiser Family Foundation and the Commonwealth Fund. | GAO-15-447

Risk Adjustment Program

Risk adjustment provides a way to correct for market imbalances that occur when some issuers attract a larger share of enrollees at low risk for expensive claims and other issuers attract a larger share of enrollees at high risk for expensive claims. Risk adjustment programs have previously been used in Medicare Advantage—the managed care option for Medicare beneficiaries—and Medicare Part D—the Medicare prescription drug program. PPACA’s requirements for the design of the risk adjustment program allowed for discretion by CMS in the design of the program. Under the program designed by CMS, payments are transferred from issuers with a larger share of enrollees at low risk for expensive claims to those with a larger share of enrollees at high risk for expensive claims. The amount to be transferred between issuers is determined using the following steps:

- determine individual enrollee risk scores—for example, how much more or less costly each enrollee is expected to be relative to the average enrollee—based on demographic and diagnostic information;
- determine the average risk score for each plan based on individual enrollee risk scores plus adjustments for a variety of factors, such as the extent of enrollee cost-sharing in the plan;
- compare each plan’s average risk score to the average risk score of the market within its geographic area; and
- calculate the amount that CMS will transfer between issuers.

Reinsurance Program

Reinsurance programs are designed to limit issuer risks for enrollees with very high-cost claims. Such reinsurance coverage has traditionally been available to issuers in the private insurance market, Medicare Part D, and through state-subsidized programs. Generally, a provider of reinsurance assumes full or partial liability when costs for any single enrollee during a year exceed a specified dollar threshold, while the issuer is usually required to retain at least some liability for costs so that it will have an incentive to continue managing the enrollee's care.

Under the PPACA reinsurance program, CMS expects that premium increases that might otherwise occur in the individual health insurance market because of the increased enrollment of higher risk individuals will be limited.²⁵ CMS collects contributions from all issuers and third party administrators based on the size of their enrollment and then transfers payments to issuers in the individual market, both inside and outside the exchanges, that have enrollees with high claims costs. PPACA specified the total amount issuers are to contribute each year to cover payments for enrollees with high claims costs.²⁶ For example, the amount of reinsurance funds that was to be collected from and distributed to issuers for the 2014 benefit year was \$10 billion. Each year CMS specifies the per-enrollee contribution issuers must make and the parameters for determining the amount to be paid to issuers for their high cost enrollees. These payment parameters define the two elements that are used to calculate issuers' reinsurance payments: "attachment point," which is the dollar value above which an enrollee is considered high-cost and when reinsurance payments would begin, and the "coinsurance rate", which is the percentage of issuer cost above the attachment point and below the cap of \$250,000 that is eligible for reimbursement. For example, for 2014, CMS determined an attachment point of \$45,000 and a coinsurance rate

²⁵According to CMS, increased enrollment of higher risk individuals in 2014 potentially included those previously enrolled in high-risk pools that offered health insurance to individuals unable to purchase affordable coverage in the private market because of pre-existing conditions. PPACA established a temporary federal high-risk pool program to provide coverage when PPACA provisions prohibiting issuers from denying coverage based on an individual's health status became effective in 2014.

²⁶Pub. L. No. 111-148, §§ 1341, 10104(r), 124 Stat. 208, 90642 (pertinent provision codified at U.S.C. § 18061(b)(3)(B)). The contribution amount may include an additional amount to fund the administrative expenses of the applicable reinsurance entity. In addition to the annual total contribution amounts specified, each issuer's contribution amount will reflect a proportionate share of an additional specified amount for calendar years 2014 through 2016.

of 80 percent, which means that CMS reimburses issuers for 80 percent of an enrollee's medical costs above \$45,000 and up to \$250,000. Costs above the \$250,000 cap are fully paid by the issuer. For the reinsurance program contribution amounts and payment parameters for 2014 through 2016, see table 2.

Table 2: Contribution Amounts and Payment Parameters for the PPACA Reinsurance Program, 2014-2016

Contribution amounts or payment parameter	Benefit year		
	2014	2015	2016
Total contribution amounts for reinsurance payments	\$10 billion	\$6 billion	\$4 billion
Total additional contribution amounts	\$2 billion	\$2 billion	\$1 billion
Contribution rate per enrollee ^a	\$63	\$44	\$27
Attachment point	\$45,000	\$45,000	\$90,000
Coinsurance rate	80%	50%	50%
Cap	\$250,000	\$250,000	\$250,000

Sources: GAO analysis of PPACA and HHS regulations. | GAO-15-447

Notes: The attachment point is the dollar value threshold above which an enrollee is considered "high-cost." The coinsurance rate is the percentage of issuer costs above the attachment point and below the cap that is eligible for reimbursement.

^aThe contribution rate issuers pay per enrollee is determined each year based on dividing the sum of the total contribution amounts and total additional contributions amounts and estimated administrative expenses by the estimated number of enrollees in plans that make reinsurance contributions.

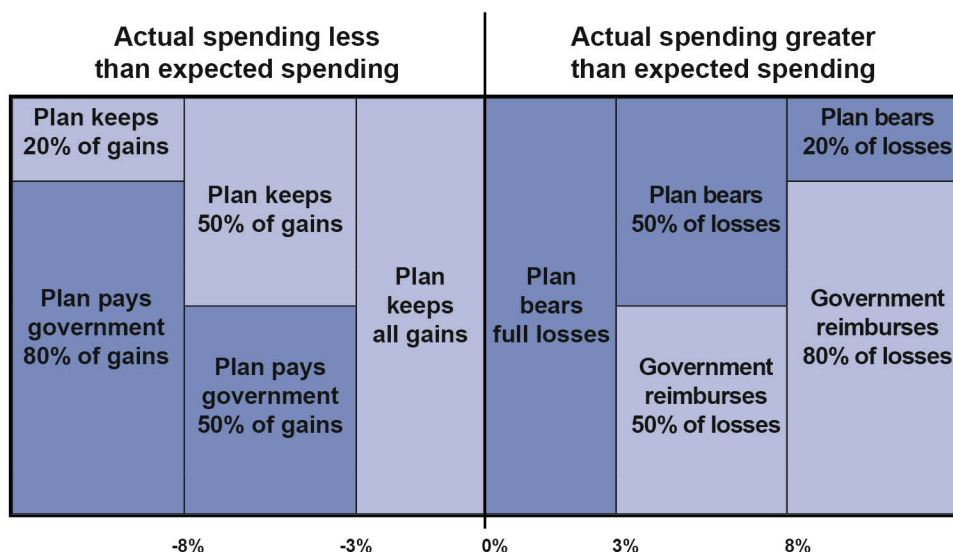
Risk Corridors Program

A risk corridors program, as has been used in Medicare Part D, helps limit excessive issuer profits or losses that may result from market volatility or inaccurate rate setting. Under the PPACA risk corridors program, CMS and issuers of qualified health plans may share in profits and losses that exceed a certain threshold. The program determines profits and losses by comparing an issuer's actual spending to its expected spending. The actual spending is known as "allowable costs"—costs for medical care claims, quality improvement, and health information technology. The expected spending is known as the "target amount"—premiums collected less certain administrative costs and profits.

CMS will make program payments to an issuer if its losses exceed a certain threshold, and issuers whose profits exceed a certain threshold will make program payments to CMS. The amount of that payment depends on the extent of the losses or profits. Issuers with allowable costs within a specified range, or corridor, of the target amount do not make or receive any payments. In total, the program has three corridors: one for issuers whose costs are within the specified range, and two others for issuers with relatively greater or lesser costs compared to the

target amount. When an issuer's costs are within 3 percent of its target amount, between 97 and 103 percent, the issuer makes no payments and receives no payments. Issuers whose profit or loss is greater than 3 percent of its target amount share in that profit or loss with CMS. An issuer whose profit or loss is greater than 8 percent of its target amount will pay a greater portion of its profit or will be reimbursed for a greater portion of its loss. (See fig. 1.)

Figure 1: PPACA Risk Corridors Program Payment Thresholds for Issuers of Qualified Health Plans



Difference between actual medical spending and expected medical spending
(as a percent of expected medical spending)

Source: © 2013 American Academy of Actuaries. Used with permission. | GAO-15-447

Risk Mitigation Programs in Medicare

PPACA directed HHS to consider the design of the Medicare risk mitigation programs in developing the PPACA risk mitigation programs, although it also set requirements that differed from the Medicare programs.²⁷ While PPACA established the risk corridors and reinsurance

²⁷ PPACA indicates that for risk adjustment, HHS "may utilize" criteria and methods similar to those used under Medicare Advantage and Medicare Part D. For the risk corridors program, PPACA indicates that the risk corridors program "shall be based on" that used in Medicare Part D. See PPACA, Pub. L. No. 111-148, §§ 1342(a) and 1343(b), 124 Stat. 211, 212 (codified at 42 U.S.C. §§ 18062(a) and 18063(b)) (pertaining to risk corridors and risk adjustment, respectively).

programs as temporary programs for the 3-year period 2014 through 2016, the Medicare Part D programs were not required to be temporary and have operated since 2006. In addition, according to CMS, the PPACA risk adjustment and reinsurance programs are budget neutral, in that payments to issuers will be adjusted to reflect, and not exceed, contributions. CMS originally indicated that the PPACA risk corridors program would not be operated in a budget neutral manner but subsequently indicated its intent to operate the program as budget neutral in 2014 and 2015, and then in 2016, if collections are insufficient to make payments, it would use other sources of funding subject to availability. For the Medicare Advantage and Medicare Part D risk mitigation programs, the payments that CMS makes to issuers are not limited to issuer contributions.

CMS Considered Market Characteristics and Program Duration When Designing PPACA's Three Risk Mitigation Programs

CMS considered a range of insurance market characteristics—such as demographics and the availability of market data—in making decisions about how to design PPACA's three risk mitigation programs. CMS's design decisions also reflected the temporary status of the reinsurance and risk corridors programs.

CMS's Design of the Risk Adjustment Program Reflects Multiple Factors That Influence Cost Variation in the Individual and Small Group Markets under PPACA

While the Medicare risk adjustment programs served as the basis for the PPACA risk adjustment program, CMS's design of the PPACA program reflects key differences that exist between Medicare and PPACA markets, including differences in demographics, the availability of enrollee data, and each program's benefit design and premium-setting structure.²⁸ For example, while Medicare primarily serves the elderly and certain individuals with disabilities, the markets covered by the PPACA risk adjustment program provide coverage for the general non-elderly population. Therefore, while both the Medicare and PPACA risk adjustment programs incorporate information about enrollee age when estimating risk, the PPACA program includes separate analyses for infants, children, and adults to reflect the inherent differences in the medical needs and costs of these three population groups. On the other hand, the PPACA risk adjustment program does not incorporate certain demographic characteristics that are important for the Medicare population, such as Medicaid enrollment, and whether an individual resides in a nursing home.²⁹

In designing the PPACA risk adjustment program, CMS also had to account for uncertainty surrounding the population that would enroll in 2014 health plans and for the lack of historical claims data for this population. Therefore, to develop risk adjustment rates for different age, sex, and diagnostic categories, CMS used claims data from private health plans including employer-based plans for a population that was similar to those individuals expected to enroll in individual and small group coverage in 2014.³⁰ CMS also chose to develop a concurrent risk adjustment program model, which uses enrollees' diagnoses during the current benefit year as the basis for developing the risk scores for that same year. In contrast, historical claims data was available on the

²⁸CMS used multiple approaches to obtain input on how to design a risk adjustment program for enrollees in the individual and small group markets both on and off the health insurance exchanges. For example, the agency obtained comment through the rule making process between 2011 and 2014; issued a white paper in September 2011 introducing design options to obtain feedback; and held a major meeting with stakeholders in May 2012.

²⁹Medicaid is a federal-state health financing program for low-income and medically needy individuals.

³⁰The PPACA risk adjustment model was calibrated using data from the Truven Health Analytics 2010 MarketScan Commercial Claims and Encounters database for individuals living in all states, aged 0 to 64, enrolled in private health insurance plans.

Medicare population and its risk adjustment program is a prospective model, which uses data from a prior year to calculate the risk adjustment score in the current benefit year.³¹

CMS also considered other market characteristics in designing the PPACA risk adjustment program, such as the option for issuers to offer different benefit levels and the availability of subsidies that may affect enrollees' use of health services. As with demographics and the availability of enrollee data, these characteristics are different in the Medicare and PPACA markets. See table 3 for additional information about key market characteristics and design features of the Medicare Advantage and PPACA risk adjustment programs.³²

³¹Generally, a concurrent approach to risk adjustment places greater weight than does a prospective model on acute conditions that occur in a given year, while the prospective approach emphasizes ongoing chronic conditions that persist from the prior year into the current year.

³²Since the Medicare Part D risk adjustment program is built on the Medicare Advantage risk adjustment program and is limited to coverage for prescription drugs, it is not separately described in this table.

Table 3: Medicare Advantage and PPACA Market Characteristics and Risk Adjustment Program Features

Market Characteristics	Risk Adjustment Program Features	
	Medicare Advantage (MA)	PPACA
Population demographics	- Serves the elderly and certain individuals with disabilities. - Calculates relative risk for enrollees based on age, sex, and other factors such as Medicaid enrollment, disability status, and whether an individual resides in a nursing home. - Is based on groupings of diagnostic categories that reflect the health experiences of elderly population.	- Serves the general non-elderly population. - Includes separate risk adjustment models for adults, children and infants. Is based on groupings of diagnostic categories that reflect the health experiences of the non-elderly population.
The availability and use of market data	- Developed using available diagnostic data from the Medicare population. - Uses prior-year diagnostic information to estimate relative costs for the current benefit year. This type of model emphasizes the impact of ongoing chronic conditions on costs. - Does not use prescription drug data to capture diagnostic information.	- Is based on claims data from private insurance market for a population that was expected to be similar. - Uses current-year information to estimate relative costs. This type of model tends to emphasize the impact of current year acute health events on costs. - Does not use prescription drug data to capture diagnostic information.
Benefit and premium options	MA plans must provide a minimum basic set of benefits and charge all plan enrollees the same premium.	- Issuers may offer different benefit levels within certain actuarial guidelines and they may charge different premiums and have different levels of cost-sharing (deductibles and co-pays). - Different levels of cost-sharing may affect an enrollee's use of health services and the plan's costs, which is factored into the risk adjustment calculation.
Subsidies	Not applicable	- Income-based subsidies are provided to some enrollees, which may affect their use and cost of health services. - An adjustment for enrollee subsidies is thus factored into the risk adjustment program.
Issuer payment and budget neutrality	- Uses enrollee risk scores to determine the risk-adjusted capitation payment from the Medicare program to the plan. Risk adjustment is incorporated into payments made to issuers in the current benefit year. - No risk transfers among Medicare plans. Risk adjustment is not inherently budget neutral.	- Calculates retroactively a "transfer" payment in the year following the benefit year, charging plans with relatively lower average risk and paying plans with relatively higher average risk. - The transfer calculation is designed to be budget neutral—charges and payment transfers sum to zero—within a market, within a state.

Source: GAO analysis of HHS documents. | GAO-15-447

CMS's Design of the PPACA Reinsurance and Risk Corridors Programs Reflects Their Temporary Nature and Specific Characteristics of the Insurance Market under PPACA

PPACA Reinsurance Program

CMS indicated that it designed the PPACA reinsurance program to minimize administrative burden for issuers and maximize simplicity, in part because the program is temporary. For example, CMS initially proposed basing the amount an issuer contributes to the reinsurance pool on a percent of the premiums paid by each of its enrollees. CMS indicated that this would be the fairest method as it would ensure that issuers with higher premiums and costs—and thus potentially higher reinsurance claims—contribute additional funds towards reinsurance. However, because of the temporary nature of the reinsurance program, and after reviewing comments from rule-making, which included comments from issuers, CMS ultimately chose to base contributions on a flat per-enrollee amount because it is more straightforward for issuers and less complex for CMS to administer.³³ Additionally, in establishing the basis for identifying enrollees as high-cost, CMS chose to use actual claims costs incurred by the plan for each enrollee, rather than a list of medical conditions identified as high risk. Although CMS acknowledged that payments made solely on the basis of actual claims costs may not as strongly encourage efficient care, CMS chose this approach because issuers would still be responsible for costs above the reinsurance cap and because it was simpler and consistent with the structure of other reinsurance programs.³⁴ CMS also initially proposed that issuers determine whether an enrollee's costs exceeded the attachment point based on claims for essential health benefits in order to ensure that

³³PPACA: Standards Related to Reinsurance, Risk Corridors and Risk Adjustment, HHS final rule, 77 Fed. Reg. 17220, 17227 (Mar. 23, 2012) (preamble, II.C.3.).

³⁴CMS acknowledged the concern that there may be less incentive for issuers to control costs after the attachment point is reached if they are not responsible for paying the claims after that point. However, the agency noted that because reinsurance will only reimburse a portion of the costs above the attachment point, and no costs above the reinsurance cap, there will still be incentives for issuers to encourage efficient care.

reinsurance payments are based on a comparable set of benefits across issuers.³⁵ However, CMS subsequently decided to use all covered benefits—not only essential health benefits—because of the administrative burden for issuers of distinguishing claims for essential health benefits from other claims.

CMS also considered specific characteristics of the insurance market under PPACA when designing the reinsurance program. For example, CMS developed a model to estimate market enrollment and expenditures in 2014 to help it set the rate that each issuer must contribute per enrollee in order for CMS to collect the full amount authorized by PPACA.³⁶ CMS also used the model to estimate what payment parameters—the attachment point, coinsurance rate, and cap—would allow it to distribute the full collected amount.³⁷ In addition, when deciding how to allocate

³⁵PPACA: Standards Related to Reinsurance, Rick Corridors and Risk Adjustment, HHS proposed rule, 76 Fed. Reg. 41930, 41935 (July 15, 2011) (preamble, II.C.4.). PPACA defines essential health benefits as 10 broad categories of health care services, which include ambulatory patient services, emergency services, hospitalization, maternity and newborn care, mental health and substance abuse disorder services, prescription drugs, rehabilitative and habilitative services and devices, laboratory services, preventive services and chronic disease management, and pediatric services (including dental and vision). In addition to essential health benefits, issuers may offer additional benefits as part of a plan, such as state-required benefits.

³⁶The Affordable Care Act Health Insurance Model uses Current Population Survey data and was developed with reference to existing models such as those of the Congressional Budget Office and the CMS Office of the Actuary to characterize medical expenditures and enrollment choices across the 2014 market place. The model predicts coverage status of individuals and incorporates the effects of state and federal policy choices. See PPACA: HHS Notice of Benefit and Payment Parameters for 2014, CMS final rule, 78 Fed. Reg. 15410, 15461 (Mar. 11, 2013)(preamble.III.C.3.a).

³⁷Because the issuer contribution rate for 2014 was based on an estimate of the total number of enrollees in the 2014 market, it is possible that the total amount actually collected may vary from the target amount if the estimate is inaccurate. Similarly, because the payment parameters are based on estimated expenditures for 2014, actual requests for payment by issuers may be greater or less than \$10 billion. CMS has indicated that if reinsurance contributions do not equal the requests for reinsurance payments, it will make a proportional adjustment up or down to be applied to all requests from issuers for reinsurance payments for high-cost cases. CMS can adjust the coinsurance rate in any benefit year and has indicated that for the final program year of 2016, if there are excess contributions, it will increase the coinsurance rate up to 100 percent. CMS has determined that it will collect reinsurance contributions for benefit year 2014 in two installments. The first installment, due on January 15, 2015, is intended to cover reinsurance payments to issuers. The second installment, due on November 15, 2015, is intended to cover the additional contribution amount required in PPACA and administrative costs. Payments to issuers that reported high cost enrollees during 2014 will be made beginning in July 2015.

reinsurance payments, CMS considered the variation among states in the relative size of the individual and group insurance markets that could affect the balance of contributions and payments. CMS determined that the availability of reinsurance contributions to make payments will vary significantly between states, and some states may not have sufficient contributions to meet the need for all reinsurance payments in that state. Therefore, after initially proposing that contributions would remain in each state, CMS determined that contributions would be pooled nationally and then distributed to issuers. CMS also modified the reinsurance program to accommodate market changes resulting from its policy allowing states to renew certain transitional plans until October 2, 2016. As a result of this policy, CMS was concerned that healthier individuals were more likely to remain enrolled in these non-PPACA compliant transitional plans, leaving less healthy and higher-cost individuals to enroll in PPACA-compliant plans. Because the policy was implemented in November 2013, after issuers had set their premiums for 2014, there was an increased risk that the premiums would not be adequate to cover higher than anticipated claims costs. Therefore, in March 2014, CMS lowered the attachment point for 2014 from \$60,000 to \$45,000 to provide increased protection to plans that enrolled individuals with high costs.

PPACA Risk Corridors Program

While various aspects of the risk corridors program were prescribed in statute, CMS officials told us that, due to the temporary nature of the program, they sought to minimize issuer burden for the elements of the program that were left to the agency's discretion. Specifically, CMS aligned the risk corridors program formula with the definition of allowable costs under the medical loss ratio (MLR) requirements that issuers have been required to meet since 2011.³⁸ For example, under both programs, the cost of certain health care quality improvement activities—such as developing quality data reporting—and certain health information technology activities are included in “allowable costs” and profits are included in “allowable administrative costs.”

CMS modified the risk corridors program for the 2014 and 2015 benefit years to account for changes to the insurance market resulting from its policy to let states allow continued coverage by non-PPACA compliant transitional plans. CMS noted that issuers may incur increased claims

³⁸For more information about MLR requirements, see GAO, *Private Health Insurance: Early Effects of Medical Loss Ratio Requirements and Rebates on Insurers and Enrollees*, [GAO-14-580](#) (Washington, D.C.: Jul. 10, 2014).

costs because of this policy, but were not able to incorporate assumptions about additional costs into their premium rates because the policy was initiated after issuers had set their premiums. Therefore, CMS made certain adjustments to the risk corridors calculation to allow issuers to retain a larger share of profits. For benefit year 2014, CMS planned to make adjustments based on the number of enrollees in each state's transitional plans. For benefit year 2015, CMS established a national adjustment to the risk corridors program formula, regardless of the presence of transitional plans in the state.

CMS guidance to issuers about how it will manage the risk corridors program if collections do not cover required payments changed significantly over time:

- In March 2013, CMS confirmed that it would make payments to issuers as required under PPACA, and would not operate the risk corridors program in a budget neutral manner.³⁹
- In March 2014, after issuers had set 2014 premiums and after the start of the benefit year, CMS indicated that it would seek to operate the risk corridors program in a budget neutral manner by making all risk corridors payments with risk corridors collections.⁴⁰ In April 2014 it issued further guidance explaining that if collections were insufficient for one year, the agency would reduce risk corridors payments to issuers proportionately and later use funds collected in the next year to make full payments. CMS also noted that it would issue future guidance indicating what it would do if collections did not cover payments as of the final year of the risk corridors program.⁴¹
- In February 2015 CMS clarified what it would do in the event that risk corridors program collections for the three years of the program were

³⁹PPACA: 78 Fed. Reg. 15410, 15472 (Mar. 11, 2013) (preamble, III.D.1.) (discussion of definition of "profits"). The Medicare Part D risk corridors program has generally resulted in net payments to the government: Medicare Part D plans have overestimated their costs under this program and have returned funds to the federal government in most years. See Congressional Research Service, *Risk Corridor Provisions under Medicare Part D, the Medicare Advantage Regional Program, and ACA Private Health Insurance Market Reforms* (Washington, D.C. July 2014).

⁴⁰PPACA: HHS Notice of Benefit and Payment Parameters for 2015, CMS final rule, 79 Fed. Reg. 13744, 13787 (Mar. 11, 2014) (preamble, I, III.C.4.d.).

⁴¹Centers for Medicare & Medicaid Services, *Memo on Risk Corridors and Budget Neutrality* (Washington, D.C.: April 11, 2014).

not sufficient to cover payments to issuers. CMS indicated that “in the unlikely event of a shortfall in the 2016 benefit year, HHS will use other sources of funding, subject to availability of appropriations.”⁴²

CMS Considered Privacy and Security in Developing Systems for Collecting Issuer Risk Mitigation Data and Experienced Significant Delays

CMS chose data collection systems for the risk mitigation programs that were intended to address privacy and security concerns and maximize efficiencies. CMS delayed implementation of the new data collection system for the risk adjustment and reinsurance programs by nearly a year as it revised its plans for implementing the distributed data approach. Because of these changes, the agency was not able to adhere to its original timeline for collecting and reporting data to issuers.

CMS Considered Privacy, Security, and Efficiency When Developing Data Collection Systems for PPACA’s Risk Mitigation Programs

CMS chose a data collection system for the risk adjustment and reinsurance programs that was intended to address privacy and security concerns and to maximize efficiencies across the programs. According to CMS, the system it developed—known as the distributed data approach—allows enrollee claims data, which are needed to calculate risk adjustment payments and charges and reinsurance payments and contributions, to remain on the issuers’ own servers. CMS provides each issuer with software to calculate contributions but only the summary reports generated by CMS’s software are sent to the agency and not the actual claims data. CMS told us that the system was designed to (1) address privacy and data security concerns by minimizing the number of transfers and amount of enrollee health information transferred, (2) ensure that issuers’ proprietary data remains with the issuer, and (3) standardize software processes, timing, and rules uniformly across issuers.

CMS elected to use the distributed data approach after considering comments from the industry through its rule-making process. In particular, CMS initially considered three data collection options: a centralized data collection system in which issuers send individual enrollee claims data

⁴²PPACA: HHS Notice of Benefit and Payment Parameters for 2016, CMS final rule, 80 Fed. Reg. 10750, 10779 (Feb. 27, 2015) (preamble, III.C.4.b.).

directly to CMS, a state-level approach in which states collected enrollee claims data on behalf of CMS, and the distributed data approach. CMS indicated that it received many comments in favor of the distributed data approach because of the increased privacy and the fact that it eliminated the administrative complexity of issuers transmitting claims data to CMS.

In selecting the distributed data approach, however, CMS identified potential tradeoffs. Specifically, it noted that this approach raises the possibility that issuers could make errors when calculating their risk scores. To address this concern, the agency said that it would augment its data audit processes. CMS also indicated that some issuers, particularly smaller companies, may be challenged by the administrative complexity of the distributed data approach, and therefore this approach may require more resources from CMS to support issuers with implementation.

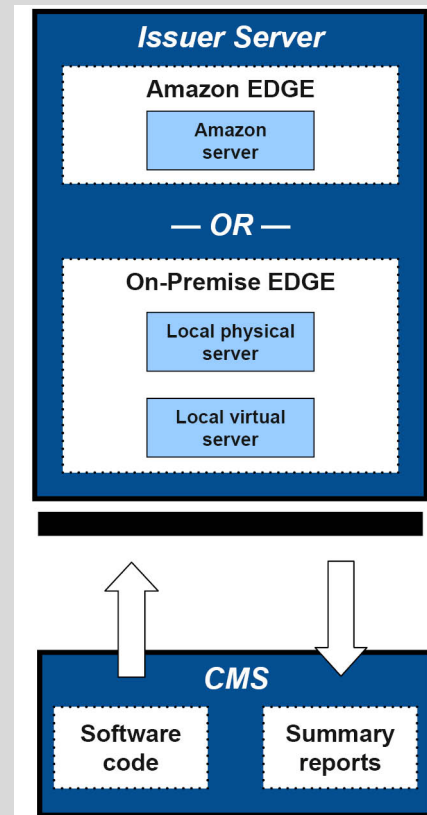
CMS decided to leverage the distributed data approach to collect data for both the risk adjustment and reinsurance programs in order to maximize efficiency. As reinsurance is a temporary program, agency officials believed it was not worth the resource investment for issuers or CMS to develop a separate data collection system. As a result, the distributed data approach is used for both programs, and issuers submit data to CMS on the same schedule for both programs.

For the risk corridors program, CMS officials said that the agency is using an existing data system in an effort to maximize efficiency. Issuers will submit data to CMS for calculating payment transfers through CMS's Health Insurance Oversight System (HIOS), which issuers already use to submit MLR data. Specifically, issuers use HIOS to submit data on their total medical claims costs, expenses for quality improvement activities, premiums, taxes and fees, and non-claims costs, which CMS will then use to calculate whether issuers qualify for risk corridors payments or owe contributions. As the calculations for the risk corridors program do not require transmitting enrollee claims data, CMS did not have the same privacy and security concerns related to data submission that they had for the risk adjustment and reinsurance programs.

CMS Delayed Data Collection and Reporting for the Risk Adjustment and Reinsurance Programs

CMS delayed implementation of data collection for the risk adjustment and reinsurance programs by nearly a year as it revised its plans for implementing the distributed data approach. An initial delay occurred when CMS changed the server requirements due to its concerns about the administrative burden for the agency and to accommodate issuer preferences. The servers used for the distributed data approach are called the external data gathering environment (EDGE) servers. CMS initially decided in May 2012 that each issuer would set up and maintain its own physical EDGE servers, with the issuer downloading CMS software to a server located on its premises. However, according to CMS officials, when the agency tested these servers with a small sample of issuers in late 2012 and early 2013, it found that it took the agency longer than expected to load the necessary software onto each issuer's individual server. CMS officials also said that the issuers involved in the initial testing requested that CMS consider a virtual approach, in which another entity would host the server rather than the issuers themselves. In response to these concerns, CMS officials said that the agency decided to develop a virtual EDGE server for issuers in late 2013 and early 2014, furnished by Amazon Web Services. Once issuers uploaded their claims data on to the virtual EDGE server, CMS's software would generate detailed and summary reports to be transmitted to CMS.

CMS's timeline for implementing the EDGE servers was delayed again when it changed its plan for these servers a second time. After CMS made the switch to the virtual EDGE server, some issuers that had already purchased a physical on-premise server to comply with CMS's initial requirements requested that CMS allow them to use those servers. Therefore, in May 2014, CMS decided to allow issuers to use either option, as well as an option to use a virtual server provided by an entity other than Amazon Web Services—known as a virtual on-premise server. All three options allow issuers to maintain their data on private servers that are only accessible to the issuer and use CMS software to generate summary reports that are sent to the agency (see side bar). CMS officials said that in addition to being responsive to issuer requests for flexibility, they wanted to create multiple approaches to reflect the variation in issuer size. For example, smaller issuers might find the virtual server option

EDGE Server Options

Source: GAO analysis of CMS information. | GAO-15-447

more appealing if they do not have the administrative resources available to purchase and maintain a physical on-premise server.⁴³

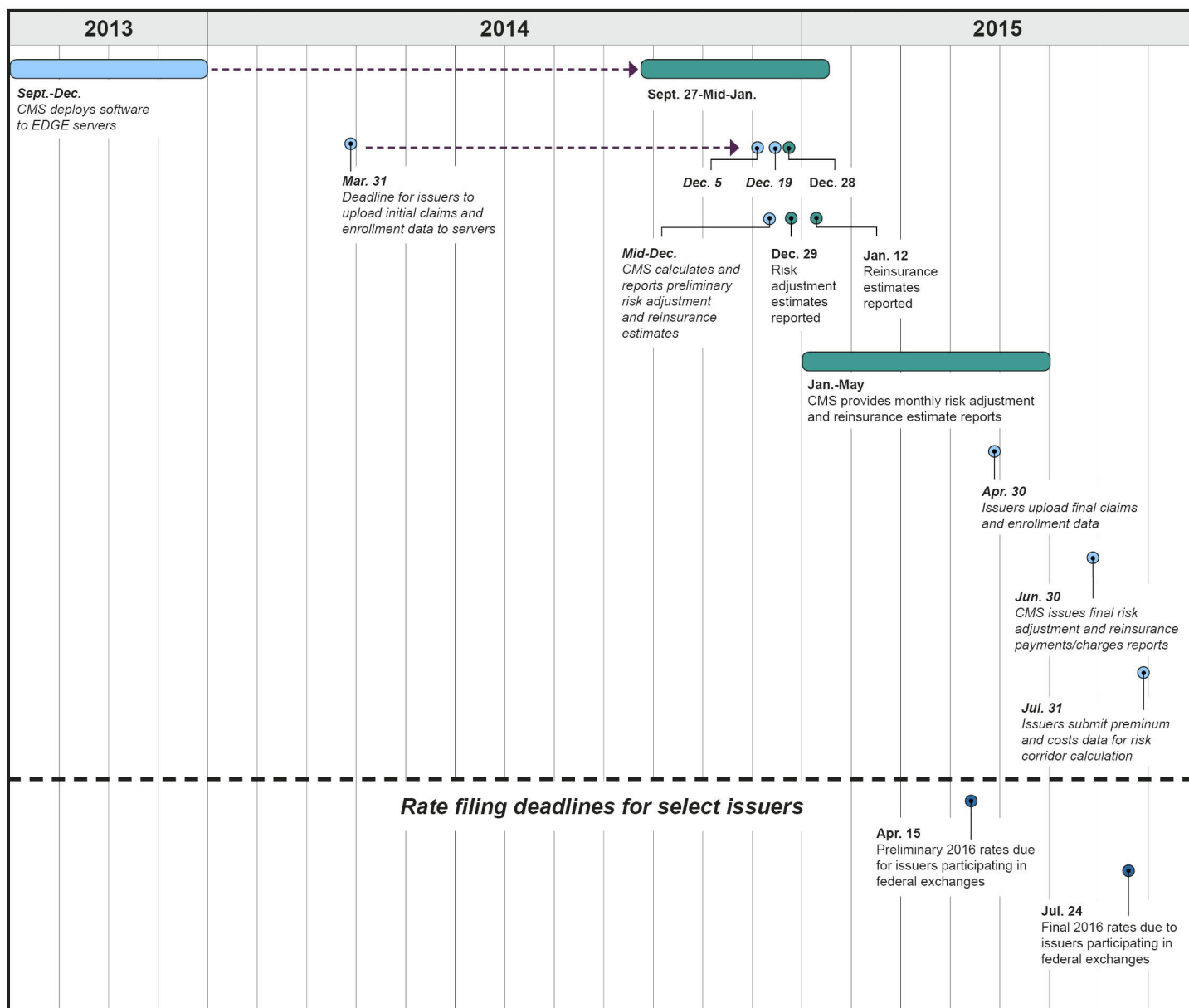
Because of these changes in CMS's EDGE server requirements, the agency was not able to adhere to its original timeline for uploading data and providing program reports to issuers. CMS initially planned to have issuers acquire and set up their servers in the first part of 2013 and to then load software and configure the servers in the latter part of 2013. This would have allowed issuers to upload enrollment and claims data on a monthly basis starting in January 2014, and CMS planned to use these data to generate issuer reports during 2014:

- CMS planned to provide quarterly reports to issuers with the estimated amount of reinsurance program payments they would receive for benefit year 2014. CMS officials said that these estimates would allow issuers to more accurately account for reinsurance payments when setting their premiums for benefit year 2015 and beyond, as issuers set premiums in the year prior to the benefit year.
- CMS planned to provide interim estimate reports on risk adjustment calculations throughout the benefit year as it did with the reinsurance program. These reports were to include preliminary calculations of an issuer's average risk score for each of its plans but not any data about how an issuer's score compared to other issuers in its market, which would be necessary for an issuer to estimate its potential contribution or payment. CMS officials said that they did not plan to provide relative market data to issuers in the estimate reports because CMS may not have complete or correct data for all the issuers in a market until the final data submission deadline on April 30 of the year following the benefit year. They said that relative market data risk scores based on incomplete data could present a misleading estimate of an issuer's potential contribution or payment.

⁴³According to CMS officials, in 2015 the majority of PPACA-compliant EDGE servers are on-premise as opposed to those furnished by Amazon Web Services. Specifically, 699, or 83 percent of these 846 EDGE servers, are on-premise. The remaining 147 are furnished by Amazon Web Services; of which a majority belong to a single large company.

However, CMS's plans for data collection and reporting were delayed. As issuers were not able to begin loading data onto the EDGE servers until September 27, 2014, CMS was not able to provide either quarterly reinsurance reports or interim risk adjustment reports for benefit year 2014. Therefore, issuers did not have estimates of reinsurance payments available from CMS to incorporate into their 2015 premium calculations. CMS next planned to produce two risk adjustment estimate reports for issuers, one in mid-December 2014 and one in May 2015. However, CMS experienced further delays as issuers began uploading their data to the EDGE servers. CMS officials noted that they were implementing a new technology in a compressed timeframe, and that there were ongoing fixes as they deployed the new software. As a result, CMS postponed the deadline for issuers to upload their data to the EDGE servers from the beginning to the end of December 2014, thus delaying CMS's issuance of the first risk adjustment estimate reports to December 29, 2014, and the first reinsurance estimate report to January 12, 2015 (see fig. 2). CMS announced in January 2015 that it would provide monthly risk adjustment and reinsurance estimate reports for the remainder of the data collection period for benefit year 2014, which runs through April 30, 2015. Officials said that the purpose of these monthly estimate reports is to allow CMS to look at data discrepancies and quality issues before issuers upload their final data. After benefit year 2014, CMS officials said the agency plans to provide periodic risk adjustment and reinsurance estimate reports throughout each benefit year.

Figure 2: The Centers for Medicare & Medicaid Services' (CMS) Planned and Actual Timeline for Implementing the External Data Gathering Environment (EDGE) Servers and Calculating Payments for the Three Risk Mitigation Programs



Planned activity Actual activity Rate filing deadlines for select issuers -----> Length of delay

Source: GAO analysis of CMS information. | GAO-15-447

For the risk corridors program, CMS indicated that it expects to propose and finalize a data collection tool from January to May 2015. Although CMS is using an existing data system, HIOS, CMS officials said the agency must still develop a new data collection tool within HIOS, which will include new fields specifically for the risk corridors program. However, the timeline for collecting these data is later, relative to the other two programs. The calculation of risk corridors payments, as is also the case with MLR rebates, incorporates risk adjustment program transfers and reinsurance program payments and therefore must take place after CMS makes those other calculations. Issuers must annually submit data for both the risk corridors program and MLR payments by July 31 of the year following the benefit year—for example, July 31, 2015, for the 2014 benefit year. CMS plans to collect risk corridors program contributions from issuers that are required to make them beginning in mid-September 2015 and to issue payments to eligible issuers beginning in mid-October 2015.

CMS Established Some Processes to Monitor the Accuracy of Issuer Data for the Three Risk Mitigation Programs and Initiated Efforts to Evaluate the Permanent Risk Adjustment Program

To a varying extent, CMS has developed or has plans to develop data verification checks or audit procedures for each of PPACA's three risk mitigation programs. In addition, CMS has initiated efforts to evaluate the permanent risk adjustment program but has not finalized the details of the evaluation.

CMS Established Some Data Verification Processes and Audit Procedures for the Risk Mitigation Programs, and Others Are under Development

For the reinsurance and risk adjustment program data that issuers upload to the EDGE server, the software on the EDGE server allows issuers to conduct data verification checks to identify errors. Issuers are able to run test reports to identify errors in what is called the test zone. Each record included on the four files submitted to the EDGE server—enrollment, medical, pharmacy, and supplemental diagnoses—is either accepted or rejected, and records that are rejected are given an error code and a description of the erroneous field. For instance, a record may be rejected if it has a value that is not the correct data type or the value is outside the

permitted range. The software on the EDGE server produces detailed error reports—with information on the errors in specific records—for issuers and provides summary error reports to CMS that aggregate the number of records that were submitted, accepted, and rejected by plan, year, and month. CMS plans to use the summary error reports to understand if issuers have submitted data for all of their plans and whether the data submission includes claims and enrollment data for all months of the benefit year. CMS officials said that the reports will also be used to identify software problems and particular issuers that may need additional support. Going forward, the agency plans to use the reports for additional analyses, such as analyses of the type and volume of issuer claims for the risk adjustment program. Issuers are also supposed to report data discrepancies to CMS for benefit year 2014 as they receive monthly estimate reports from January through May 2015, including if the results of the calculations in the reports are inconsistent with either the risk adjustment or reinsurance payment methodologies, or if any claims or enrollment data were incorrectly excluded from the calculations. For the risk corridors program, CMS officials told us that the agency was in the process of developing data verification procedures at the time of our report, including automatic data checks that were going to be built into the data collection system. Officials said that they are applying lessons learned from the MLR data verification procedures to the data verification procedures for the risk corridors program.

In addition to automatic data verification checks, CMS requires issuers to conduct a third-party risk adjustment data validation audit of their risk adjustment program, starting with a 2015 audit of 2014 benefit year data. The third-party audits address individual claims data that CMS does not receive in the summary reports generated by issuers in the distributed data approach. CMS will require issuers to conduct the data audits annually in two phases. For the first phase, each issuer must have a sample of its risk adjustment data, as selected by CMS, audited by an independent party. The audit must include validation of all enrollment, demographic, and medical data for enrollees in the data sample. For the second phase, CMS will audit a sub-sample of validated data from the initial audit. Beginning with 2016 benefit year data, CMS will adjust the amount issuers owe or receive under the risk adjustment program based on the audit results. Given the complexity of the risk adjustment program and the audit process, the agency was concerned that adjusting payments and charges without first gathering information on the prevalence of data errors could lead to a costly and potentially ineffective audit program.

CMS officials told us that they are in the process of developing standard operating procedures for auditing the reinsurance and risk corridors programs. They said that they are developing a contract for auditing issuers' reinsurance and risk corridors data submissions. The audits will review a variety of things, such as compliance with definitions of terms used to identify issuers that are required to make reinsurance contributions and accurate enrollment reporting for reinsurance contributions.

CMS Has Initiated Efforts to Evaluate the Risk Adjustment Program

CMS officials told us that an evaluation of the risk adjustment program would be conducted under contract by an organization with expertise in design and evaluation of risk adjustment models.⁴⁴ A permanent risk adjustment program that accurately predicts the expected costs of enrollees is a critical factor in ensuring the long-term stability of health insurance markets under PPACA. If certain groups of enrollees are not accurately scored under the program, it could undermine the program's integrity and result in issuers seeking to avoid enrolling sicker individuals or deciding to leave the market. In November 2014, CMS issued a request for contractors to submit bids to conduct a range of services related to Medicare and the PPACA insurance market reforms, including research and development for the PPACA risk adjustment program. The bid request identified general research and development tasks for the risk adjustment program, such as analysis of the impact of market and enrollee factors on the model, evaluation of the accuracy of the risk adjustment program, and research to support adaptation of the model. The bid request also required the contractor to develop the specific details of the evaluation.

⁴⁴CMS officials indicated that the PPACA risk adjustment program is different than the two temporary programs in that it required significantly more development work and is a more complex model for estimating relative issuer risk. CMS officials did not identify specific plans to evaluate the long-term impacts of the temporary reinsurance and the temporary risk corridors programs, but noted that they modified the payment parameters for reinsurance and the accounting definitions for risk corridors in response to policy changes. CMS officials told us that that reinsurance is intended to put downward pressure on premiums and suggested that premium trends would be a source of information about the impact of this program. Officials also said that, given that the risk corridors program is meant to mitigate the risk of inaccurately pricing premiums during the early years of the health insurance exchanges, they expect the overall amount of risk corridor contributions and payments to decrease over time. They added that they will monitor these amounts throughout the duration of the program.

At the time of this report, CMS was reviewing contract bids to evaluate the PPACA risk adjustment program. As of April 2015, CMS expected to award this contract in the spring of 2015, although the agency had not specified the timing and scope of the evaluation. In addition, CMS was in the process of procuring an audit contractor and expected to award the audit contract near the end of fiscal year 2015.

Past evaluations of the Medicare risk adjustment program have improved the predictive accuracy of that model. Specifically, evaluations for Medicare Advantage and Medicare Part D have identified areas for improvement in these programs' risk adjustment models and have led to greater predictive accuracy, which refers to how well the models predict the cost of enrollees. CMS contracted for five evaluations of the predictive accuracy of the Medicare risk adjustment models between 2004 and 2012—three of the Medicare Advantage program and two of the Medicare Part D program—and CMS officials told us that these evaluations have had important implications for the programs.⁴⁵ It is critical that CMS similarly understands whether or not the new PPACA risk adjustment model is accurately reflecting costs, and CMS's continued effort to carry out this evaluation will be important to the program's success.

Interviewed Issuers Described Benefits of the PPACA Risk Mitigation Programs, Although Some Had Concerns Related to Design and Implementation

Most of the 12 issuers we interviewed said that the three risk mitigation programs encouraged their participation in the individual health insurance market, and two of the programs allowed them to lower their premiums. Issuers identified design concerns specific to each PPACA risk mitigation program and provided mixed responses regarding the effect of CMS's implementation delays and technical assistance.

⁴⁵For instance, a 2012 evaluation of the risk adjustment model in Medicare Part D found that modifications made to the model improved overall predictive accuracy by better matching payments to actual costs.

Most Issuers Interviewed Said That All Three Risk Mitigation Programs Encouraged Their Participation in the Individual Health Insurance Market, and Two Programs Affected Their Premiums

Most of the 12 issuers we interviewed said that, beginning in 2014, the PPACA risk adjustment program positively influenced their participation in the individual health insurance market and that the PPACA reinsurance and risk corridors programs positively influenced their participation in the market and also led them to set lower premiums than they otherwise would have offered. (See table 4 for specific counts for each program.) Results for each program are as follows:

- Risk adjustment:** Eight issuers said that the risk adjustment program positively influenced their decision to participate in the individual market; for example, one issuer that was new to the market said that it would not have participated without the risk adjustment program because it believed that established issuers would seek to attract the healthiest individuals.⁴⁶ With respect to premiums, seven issuers (six of which cited an influence on participation) said that the risk adjustment program had no impact on the premiums they offered for 2014. Some of these issuers indicated that the lack of market-wide risk score data limited the influence of risk adjustment on their premiums because issuers were only able to calculate estimates of their own risk scores and not relative market-wide risk scores. Without knowing its relative market-wide risk score, an issuer does not know whether it will be a payer or receiver under the risk adjustment program and therefore cannot incorporate such information into its financial planning and accounting processes. Two issuers specifically suggested that CMS should provide periodic risk adjustment reports that contain relative market-wide information.⁴⁷ Another issuer said that such information would be useful, but that they would not rely on the information if it was incomplete—for example, if it was based on data from a portion of the year or did not include data for all issuers in the market.

⁴⁶Of the four issuers that reported that the program did not influence their participation, three were based in states that had already implemented some provisions similar to PPACA and, in some cases, had relatively high rates of coverage.

⁴⁷Of the five issuers that reported that the program influenced their premiums, two operate in Massachusetts, which administers its own risk adjustment program and provided issuers with both issuer-specific and market-wide risk adjustment data on a periodic basis throughout benefit year 2014. A third issuer that said the program affected their premiums to some extent; however, the issuer noted that one of the risk adjustment program's weaknesses is that it does not provide interim updates that include market risk score information.

-
- **Reinsurance:** Seven issuers said that the reinsurance program positively influenced their decision to participate in the individual market, including two issuers which described the reinsurance program as the most influential of the three risk mitigation programs on their decision to participate.⁴⁸ With respect to premiums, ten issuers said that the reinsurance program allowed them to offer lower premiums in 2014 and 2015. Seven of these issuers reported this reduction to be in the range of 8 to 13 percent lower than they would have otherwise set for 2014. Five of these seven issuers indicated a smaller reduction for 2015, with some explaining that this smaller reduction reflects the decrease in funding statutorily available to pay reinsurance claims.⁴⁹
 - **Risk corridors:** Nine issuers said that the risk corridors program positively influenced their decision to participate in the individual market in 2014. However, one of these issuers characterized the program as the least influential of the three risk mitigation programs for this decision. Three issuers that credited the program with encouraging their participation nevertheless expected that the program's effect would diminish over time as they gain more experience. With respect to premiums, seven issuers said that the program influenced their premiums in 2014; five of these issuers said that the program allowed them to set lower premiums than they otherwise would have due to the mitigation of potential financial loss. Two issuers noted that their state regulators do not allow itemized references to the risk corridors program when the issuers submit their premiums to the states' insurance regulators.

⁴⁸Of the issuers that reported that the program did not influence their participation, two were Massachusetts-based issuers, and another two issuers said the program did not influence their participation but allowed them to offer lower premiums.

⁴⁹Four of these five issuers estimated premium reductions in 2015 ranging from 4 to 8 percent.

Table 4: Influence of Risk Mitigation Programs on Issuers' Decision to Participate in the Individual Health Insurance Market Beginning in 2014 and on Premiums for 2014

Risk mitigation program	Influence on...	No	Yes	Total
Risk adjustment	Participation	4	8	12
	Premiums	7	5	12
Reinsurance	Participation	5	7	12
	Premiums	2	10	12
Risk corridors	Participation	3	9	12
	Premiums	5	7	12

Source: GAO Interviews with 12 issuers. | GAO-15-447

Issuers Identified Design Concerns Specific to Each PPACA Risk Mitigation Program, Including Concerns about Data Sources, Funding Availability, and Program Tenure

Issuers identified concerns with specific aspects of each of the three risk mitigation programs, including concerns about the sources of data used for the risk adjustment program and about the availability of funding for and temporary tenure of the reinsurance and risk corridors programs.

Risk Adjustment: All 12 issuers we interviewed said that they would prefer the risk adjustment model to include prescription drug data in its risk score calculations.⁵⁰ One issuer noted that such data provides useful information about enrollee diagnoses, is available quickly, and would improve the accuracy of risk adjustment calculations and payments to issuers. Other issuers commented that prescription drug data is less prone to errors and misreporting and is administratively straightforward for issuers to manage, compared to other sources of diagnostic data. However, 2 issuers acknowledged that the inclusion of pharmacy data in the risk score calculation would pose an additional administrative burden on CMS.

Reinsurance: Most of the 12 issuers we interviewed expressed concerns about the availability of funding and about the timing of reinsurance payments and payment estimate reports. Six issuers expressed uncertainty about whether the program will receive its planned contributions. For example, 1 issuer said that because the contribution

⁵⁰In March 2014, CMS indicated its intent to consider whether and how to include prescription drug data in future PPACA risk adjustment models. At the same time it noted that it was important to maintain model stability in the initial years of risk adjustment, and therefore, it did not intend to recalibrate the model for this purpose in the initial years of the program. 79 Fed. Reg. 13744, 13753 (Mar. 11, 2014) (preamble, III.C.2.b.).

amount and the payment parameters are based on an estimate made by CMS, it is possible that CMS may collect less than it targeted if the estimate is incorrect.⁵¹ Eight issuers said that more frequent payments from CMS would improve cash flow. However, 2 other issuers said that more frequent payments would increase the temporary program's administrative burden. With regards to the quarterly reports of estimated payments and contributions that CMS could not provide in 2014 due to the EDGE server implementation delays, 6 issuers said that these reports would have provided them with information to incorporate into their financial planning and reporting processes. However, several issuers noted that these reports are less important than those in the risk adjustment program, because issuers do not need additional data or modeling from CMS to generate their own reinsurance payments estimates.

Risk Corridors: Most of the 12 issuers we interviewed cited uncertainty about the extent to which funds would be available. Ten issuers said that they did not support the agency's decision to manage the risk corridors program in a budget neutral manner. One of these issuers described CMS's decision to operate the program as budget neutral in 2014 and 2015 as a reversal of previous guidance, but noted that CMS has since been clear about operating in a budget neutral manner by limiting risk corridors payments for 2014 and 2015 to available collections.⁵² Two issuers described scenarios in which a budget neutral policy would not be sufficient to make needed payments; if an issuer priced premiums very low, that issuer may have significant losses and the remaining issuers may not have sufficient profit to cover those losses. Another 2 of these

⁵¹For 2014, CMS required a per enrollee contribution from issuers, intended to attain the aggregate total amount specified in PPACA for that year—\$10 billion for reinsurance payments, \$2 billion in additional collections—and for administrative expenses. On April 14, 2015, CMS released guidance indicating that, as of March 31, 2015, it had collected approximately \$8.7 billion in reinsurance contributions for the 2014 benefit year and expected to collect approximately \$1 billion more by November 15, 2015. CMS indicated in the guidance that, because this is less than the \$12 billion the agency expected to collect, it would allocate the first \$10 billion in contributions to issuers and allocate any additional contributions collected up to the total of \$12 billion for additional purposes.

⁵²CMS is prohibited from using its Program Management lump sum appropriation for fiscal year 2015 for risk corridor payments. See, Pub. L. No. 113-235, Div. G, Tit. II, § 227, 128 Stat. 2130 (2014). This restriction is limited to the fiscal year 2015 lump sum appropriation and does not affect CMS's authority to make payments under the program from user fees collected.

issuers indicated that the status of the program's funding as budget neutral and the possibility that there will not be enough funds collected to pay for losses will have a material impact on their premium decisions for 2016.

Tenure of Temporary Programs: Eleven of the 12 issuers we interviewed said that the 3-year timeline for the temporary reinsurance and risk corridors programs may not afford enough time for issuers to adjust to the market changes under PPACA. Some issuers said that this was particularly true given ongoing policy changes and delays that contributed to lower than expected enrollment and limited the availability of data on new enrollees. They said that without these data, they do not have sufficient information to confidently set premiums. For example, 6 issuers described lower than expected enrollment rates in their market due to CMS policy changes, such as delaying implementation of a requirement that certain employers provide health insurance to their employees,⁵³ and allowing transitional plans.⁵⁴ As a result of this lower than expected enrollment, issuers may have less information on the population that may eventually enroll under PPACA. When the programs expire, issuers will have less enrollee data than they originally expected with which to formulate their premiums. Two issuers who were new to the individual market in 2014 said that extending the temporary programs would provide more time for them to gather additional data. Otherwise, they will be at a disadvantage when the temporary programs expire in 2016 in contrast to more established issuers that already possess prior claims data.

⁵³PPACA requires large employers to pay penalties under certain circumstances if they do not offer coverage to their employees. Pub. L. No. 111-148, § 1513, 124 Stat. 253, amended by Pub. L. No. 111-152 § 1003, 124 Stat. 1029, 1033 (2010) (pertinent provision codified as amended at 26 U.S.C. 4980H). However, this requirement and other related employer coverage and reporting requirements were delayed until 2015. See, Shared Responsibility for Employers Regarding Health Coverage, Internal Revenue Service final regulations, 79 Fed. Reg. 8544, 8577 (Feb. 12, 2014) (codified at 26 C.F.R. §§ 54.4980H-0 - 54.4980H-6).

⁵⁴One issuer indicated that the existence of transitional plans may have caused higher than anticipated costs in the exchanges and PPACA-compliant plans, because healthier individuals were more likely to remain in the transitional plans while higher cost individuals were likely to find relatively lower premium rates on the exchanges and in PPACA compliant plans.

Due to concerns about the adequacy of the 3-year time period, 10 of the 12 issuers suggested extending the reinsurance program beyond its scheduled expiration. Nine of the 12 issuers suggested that the temporary reinsurance program be extended for 1 or 2 years and 5 of these issuers noted that they expect that premiums will rise significantly in 2017 in response to the expiration of the program at the end of 2016. Seven of the 12 issuers suggested extending the risk corridors program, with 5 of them specifying that the program be extended for either 1 or 2 years.

Issuers Provided Mixed Responses Regarding the Effect of CMS's Implementation Delays and Technical Assistance

Most of the 12 issuers we interviewed supported CMS's choice of the distributed data collection approach for the risk adjustment and reinsurance programs, although they offered mixed responses about how they were affected by CMS's decision to change how it implemented the EDGE servers and the resulting delays in implementation:

- Six of the issuers we interviewed said that the delays in implementing the EDGE servers were exceedingly disruptive or significant to them. They indicated that CMS's policy changes resulted in wasted time and resources and required them to redevelop their plans for procuring and launching the servers. Although noting that the policy changes caused problems for them, five of these six issuers said that they supported CMS's final decision to allow issuers to use either virtual or on-premise EDGE servers.
- The other six issuers—four of whom were new to the individual market in 2014, including two COOPs—said that EDGE server delays did not affect them. Three of these issuers told us that they had already purchased a physical server when CMS announced that all issuers had to use the Amazon Web Services option. However, they said that they were able to repurpose the physical servers and chose to use the Amazon option; therefore, CMS's decision did not have a significant negative effect on their companies.

In addition, 8 of the 12 issuers we interviewed expressed concerns about CMS's ongoing implementation of data collection systems. For example, these issuers noted that they have continued to experience challenges uploading data using the EDGE servers and incorporating CMS's ongoing corrections to its software code. For instance, 1 issuer described how CMS released software code for issuers to use the following morning to run risk adjustment calculations, but then rescinded the code the following afternoon because of an error. The issuer said that this example illustrates how CMS was releasing software before conducting the necessary quality assurance checks and was correcting problems as it

went. This issuer also described how CMS released software that was missing 7,000 diagnostic codes. Five issuers raised concerns about another aspect of CMS's implementation of data collection systems. Specifically, these issuers noted that the small window of time CMS allotted between when it informs issuers of estimated payments and contributions and when issuers' final data submissions are due could be problematic if there is a need for significant reconciliations between CMS's and issuers' calculations.

Finally, nearly all 12 issuers said that they experienced challenges obtaining technical assistance from CMS during implementation of the EDGE servers. However, with respect to CMS's ongoing technical assistance and timeliness in responding to requests, they reported both positive and negative experiences:

- **EDGE server implementation.** Ten issuers reported challenges with CMS technical assistance during EDGE server implementation, including several issuers who reported an extended period of time when CMS did not provide any guidance to issuers. Issuers reported that during the period from the fall of 2013 through the spring of 2014, they received no guidance from CMS about the EDGE servers. One issuer noted that previously active user groups were disabled, and therefore they had to put their implementation plans on hold. It was during part of this period that individuals were first able to enroll in health plans available on the health care exchanges.
- **Ongoing technical assistance.** Issuers noted both positive and negative experiences in terms of their ongoing efforts to get technical assistance from CMS. For instance, four issuers told us that CMS assigned individual account managers to each issuer in December 2014 to help with technical assistance, and two of these issuers said that the account managers have helped them get more timely responses from CMS. Another issuer said it had mixed results with this manager, who sometimes provided useful information and other times provided information that was contradicted by another source. With regard to other forms of technical assistance, five issuers said they were participating in regular calls and webinars with CMS officials, and three of these issuers said they found these sessions to be useful. However, some of these issuers also said that it was very difficult to get their questions answered during these sessions due to the high volume of questions being submitted to the agency.

-
- **Timeliness.** Issuers provided mixed responses about CMS's timeliness in responding to current requests for assistance. Two issuers told us that the timeliness had improved. However, two other issuers told us that there were still unresolved requests related to data submission issues, even though the relevant submission deadline had passed.

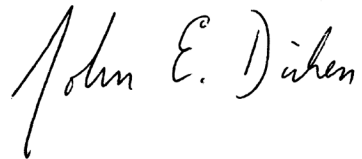
Agency Comments

We provided a draft copy of this report to HHS for its review and HHS provided written comments, which are reprinted in appendix I. HHS explained that CMS implemented the data collection strategy for these programs utilizing new innovative technology as well as existing data systems, and carried out the implementation in a phased approach. HHS indicated that issuer data submissions through the EDGE server began in September 2014 and CMS was on target to meet the regulatory deadline of April 30, 2015, to upload final submissions by issuers of claims and enrollment data for benefit year 2014. Further, HHS described CMS's efforts to ensure the appropriate level of technical support, including the use of cross-functional teams that include software developers and dedicated account managers for each issuer. HHS noted that CMS solicited feedback directly from issuers and provided technical guidance and multiple trainings.

In addition, HHS provided technical comments, which we incorporated where appropriate.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the Secretary of Health and Human Services, the Administrator of the Centers for Medicare & Medicaid Services, and other interested parties. In addition, the report will be available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staffs have any questions about this report, please contact me at (202) 512-7114, or dickenj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of our report. Key contributors to this report are listed in appendix II.

A handwritten signature in black ink that reads "John E. Dicken". The signature is written in a cursive style with a large initial 'J' and a distinct 'E'.

John E. Dicken
Director, Health Care

Appendix I: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

APR 16 2015

John Dicken
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Mr. Dicken:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "*Patient Protection and Affordable Care Act: CMS Has Made Progress Implementing Programs to Limit Health Insurer Risk, Despite Some Delays*" (GAO-15-447).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

A handwritten signature in black ink, reading "Jim R. Esquea".

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

Appendix I: Comments from the Department of Health and Human Services**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: PATIENT PROTECTION AND AFFORDABLE CARE ACT: CMS HAS MADE PROGRESS IMPLEMENTING PROGRAMS TO LIMIT HEALTH INSURER RISK, DESPITE SOME DELAYS (GAO-15-447)**

The U.S. Department of Health and Human Services (HHS) appreciates the opportunity from Government Accountability Office (GAO) to review and comment on this draft report.

The Affordable Care Act created the risk adjustment, reinsurance and risk corridors programs which are also referred to as the premium stabilization programs. The programs reduce the impacts of potential adverse selection, reduce incentives for health insurance issuers to avoid enrolling sicker people, and stabilize premiums in the individual and small group health insurance markets inside and outside the Marketplaces. The risk corridor and reinsurance programs are designed to be temporary by helping protect health insurance issuers against uncertainty in setting premium rates and helping reduce premiums and ensure market stability when the new federal consumer protections were implemented in 2014. The permanent risk adjustment program will assist health insurance issuers that provide coverage to those with higher health care costs. HHS has implemented these programs utilizing innovative technology in a transparent and collaborative manner.

To protect the privacy and security of individuals' personal and health information and address issuer concerns, HHS implemented a data collection strategy for the premium stabilization programs utilizing new innovative technology and existing data systems. The phased delivery approach of the premium stabilization software included an early deployment of an initial build which was launched in August of 2014. Later releases offered additional install options and customizations designed to make the system more administratively streamlined. Data submissions for the premium stabilization programs began in September of 2014 with issuers submitting data through the External Data Gathering Environment (EDGE) server and are on target to meet the regulatory deadline of April 30, 2015. In addition, HHS is actively monitoring and evaluating the quality of issuers' data submissions to ensure issuers will have sufficient time to review and modify their data submissions prior to the close of the reporting window.

Implementation of the premium stabilization programs is a collaborative effort between HHS and issuers, and HHS takes its obligation to assist issuers during this process seriously. To ensure issuers are getting the appropriate level of technical support that is needed, cross functional teams, which include developers of the submission code and dedicated account managers for each issuer, conduct outreach to issuers experiencing technical or support issues. HHS has actively engaged in soliciting feedback directly from the issuers that are submitting data through the systems to ensure all questions are being answered. Through our technical guidance and multiple trainings, HHS has supported issuers with their requests and data issues. Additionally, HHS has provided targeted outreach to a sub-set of issuers that have not yet submitted data to ensure resolution of issues prior to the deadline. HHS is committed to providing issuers assistance in successfully completing the data submission process and will continue to offer support and outreach.

Appendix II: GAO Contact and Staff Acknowledgments

GAO Contact

John E. Dicken, (202) 512-7114 or dickenj@gao.gov

Staff Acknowledgments

In addition to the contact named above, William Hadley, Assistant Director; George Bogart; Keara Castaldo; Julianne Flowers; Mary Giffin; Sarah-Lynn McGrath; Laurie Pachter; Vikki Porter; and Leslie Powell made key contributions to this report.

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EXHIBIT 10



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Part II

Department of Health and Human Services

45 CFR Parts 144, 147, 153, et al.

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2015; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES**45 CFR Parts 144, 147, 153, 155, 156 and 158****[CMS-9954-F]****RIN 0938-AR89****Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2015****AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Final rule.

SUMMARY: This final rule sets forth payment parameters and oversight provisions related to the risk adjustment, reinsurance, and risk corridors programs; cost sharing parameters and cost-sharing reductions; and user fees for Federally-facilitated Exchanges. It also provides additional standards with respect to composite premiums, privacy and security of personally identifiable information, the annual open enrollment period for 2015, the actuarial value calculator, the annual limitation in cost sharing for stand-alone dental plans, the meaningful difference standard for qualified health plans offered through a Federally-facilitated Exchange, patient safety standards for issuers of qualified health plans, and the Small Business Health Options Program.

DATES: These regulations are effective on May 12, 2014.

FOR FURTHER INFORMATION CONTACT:

For general information: Sharon Arnold, (301) 492-4286; Laurie McWright, (301) 492-4311; or Jeff Wu, (301) 492-4305.

For matters related to student health insurance coverage and composite premiums: Jacob Ackerman, (301) 492-4179.

For matters related to the risk adjustment program: Kelly Horney, (410) 786-0558.

For general matters related to the reinsurance program: Adrienne Glasgow, (410) 786-0686.

For matters related to reinsurance contributions: Adam Shaw, (410) 786-1019.

For matters related to risk corridors: Jaya Ghildiyal, (301) 492-5149.

For matters related to medical loss ratio: Christina Pavlus, (301) 492-4172.

For matters related to cost-sharing reductions and netting of payments and charges: Pat Meisol, (410) 786-1917.

For matters related to the premium adjustment percentage: Johanna Lauer, (301) 492-4397.

For matters related to Federally-facilitated Exchange user fees: Michael Cohen, (301) 492-4277.

For matters related to the annual limitation on cost sharing for stand-alone dental plans, privacy and security of personally identifiable information, the annual open enrollment period for 2015, and the meaningful difference standard: Leigha Basini, (301) 492-4380.

For matters related to the Small Business Health Options Program: Christelle Jang, (410) 786-8438.

For matters related to the actuarial value calculator: Allison Yadsko, (410) 786-1740.

For matters related to patient safety standards for issuers of qualified health plans: Nidhi Singh Shah, (301) 492-5110.

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Acronyms

Affordable Care Act The collective term for the Patient Protection and Affordable Care Act (Pub. L. 111–148) and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152)

AV Actuarial Value

CFR Code of Federal Regulations

CMS Centers for Medicare & Medicaid Services

EHB Essential Health Benefits

ERISA Employee Retirement Income Security Act of 1974 (Pub. L. 93–406)

FFE Federally-facilitated Exchange

FF–SHOP Federally-facilitated Small Business Health Options Program

FPL Federal poverty level

HCC Hierarchical condition category

HHS United States Department of Health and Human Services

HIPAA Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191)

IRS Internal Revenue Service

MLR Medical Loss Ratio

OMB Office of Management and Budget

OPM United States Office of Personnel Management

PHS Act Public Health Service Act

PII Personally identifiable information

PSO Patient Safety Organization

PRA Paperwork Reduction Act of 1995

PSES Patient safety evaluation system

QHP Qualified health plan

SADP Stand-alone Dental Plan

SHOP Small Business Health Options Program

The Code Internal Revenue Code of 1986

TPA Third party administrator

I. Executive Summary

Qualified individuals and qualified employers are now able to purchase private health insurance coverage through competitive marketplaces called Affordable Insurance Exchanges, or “Exchanges” (also called Health Insurance Marketplaces, or “Marketplaces”).¹ Individuals who enroll in qualified health plans (QHPs) through individual market Exchanges may be eligible to receive premium tax credits to make health insurance more affordable and reductions in cost-sharing payments to reduce out-of-pocket expenses for health care services. In 2014, HHS began operationalizing the premium stabilization programs established by the Affordable Care Act. These programs—the risk adjustment, reinsurance, and risk corridors programs—are intended to mitigate the potential impact of adverse selection and stabilize the price of health insurance in the individual and small

group markets. We believe that these programs, together with other reforms of the Affordable Care Act, will make high-quality health insurance affordable and accessible to millions of Americans.

HHS has previously outlined the major provisions and parameters related to the advance payments of the premium tax credit, cost-sharing reductions, and premium stabilization programs. This rule finalizes additional provisions related to the implementation of these programs, including certain oversight provisions for the premium stabilization programs, as well as key payment parameters for the 2015 benefit year.

The HHS Notice of Benefit and Payment Parameters for 2014 final rule (78 FR 15410) (2014 Payment Notice) finalized the risk adjustment methodology that HHS will use when it operates risk adjustment on behalf of a State. This final rule establishes updates to the risk adjustment methodology for 2014 to account for certain private market Medicaid expansion alternative plans. It also establishes the counting methods for determining small group size for participation in the risk adjustment and risk corridors programs.

Using the methodology set forth in the 2014 Payment Notice, we establish a 2015 uniform reinsurance contribution rate of \$44 annually per capita, and the 2015 uniform reinsurance payment parameters—a \$70,000 attachment point, a \$250,000 reinsurance cap, and a 50 percent coinsurance rate. We are also finalizing our proposal to decrease the attachment point for 2014 from \$60,000 to \$45,000. Additionally, in order to maximize the financial effect of the transitional reinsurance program, we provide that if reinsurance contributions collected for a benefit year exceed total requests for reinsurance payments for the benefit year, we will increase the coinsurance rate on our reinsurance payments for that benefit year up to 100 percent, rolling over any remaining funds for use as reinsurance payments for the subsequent benefit year.

We also finalize several provisions related to cost sharing. First, we establish a methodology, with certain modifications described below, for estimating average per capita premium and for calculating the premium adjustment percentage for 2015, which is used to set the rate of increase for several parameters detailed in the Affordable Care Act, including the maximum annual limitation on cost sharing and the maximum annual limitation on deductibles for health plans in the small group market for 2015. We are establishing the reduced maximum annual limitations on cost

sharing for the 2015 benefit year for cost-sharing reduction plan variations. We are relaxing the requirement that a QHP and its plan variations have the same out-of-pocket spending for non-EHBs. We are finalizing our proposal to modify the methodology for calculating advance payments for cost-sharing reductions for the 2015 benefit year. We are also finalizing parameters for updating the AV Calculator.

For 2015, we are finalizing the FFE user fee rate of 3.5 percent of premium. Additionally, with respect to the FFE user fee adjustment set forth under the Coverage of Certain Preventive Services Under the Affordable Care Act final rule, published in the July 2, 2013 **Federal Register** (78 FR 39870) (Preventive Services Rule), we are finalizing an allowance for administrative costs and margin associated with the payment for contraceptive services. We are also finalizing proposed modifications to the risk corridors program for the 2014 benefit year.

The success of the premium stabilization programs depends on a robust oversight program. This final rule expands on the provisions of the Premium Stabilization Rule (77 FR 17220), the 2014 Payment Notice (78 FR 15410), and the first and second final Program Integrity Rules (78 FR 54070 and 78 FR 65046). We are finalizing HHS’s authority to audit State-operated reinsurance programs, contributing entities, and issuers of risk adjustment covered plans and reinsurance eligible plans. We also finalize participation standards for the risk corridors program, and outline a process for validating risk corridors data submissions and enforcing compliance with the provisions of the risk corridors program.

We also finalize several aspects of our methodology for the HHS-operated risk adjustment data validation process. On June 22, 2013, we issued “The Affordable Care Act HHS-operated Risk Adjustment Data Validation Process White Paper”² and on June 25, 2013, we held a public meeting to discuss how to best ensure the accuracy and consistency of the data we will use when operating the risk adjustment program on behalf of a State. In this final rule, we establish certain standards for risk adjustment data validation, including a sampling methodology for the initial validation audit and detailed audit standards. These standards will be used and evaluated for 2 years before

¹ The word “Exchanges” refers to both State Exchanges, also called State-based Exchanges, and Federally-facilitated Exchanges (FFE). In this rule, we use the terms “State Exchange” or “FFE” when we are referring to a particular type of Exchange. When we refer to “FFEs,” we are also referring to State Partnership Exchanges, which are a form of FFE.

² Available at: https://www.regtap.info/uploads/library/ACA_HHS_OperatedRADVWhitePaper_062213_5CR_062213.pdf.

they are used as a basis for payment adjustments.

This rule also includes a reduction in the time period for which a State electing to operate an Exchange after 2014 must have in effect an approved, or conditionally approved, Exchange Blueprint and operational readiness assessment from at least 12 months to 6.5 months prior to the Exchange's first effective date of coverage. We also finalize certain provisions related to the privacy and security of personally identifiable information (PII) in the Exchange, the Exchange annual open enrollment period for 2015, the annual limitation on cost sharing for stand-alone dental plans, the meaningful difference standards for QHPs offered through an FFE, the SHOP, patient safety standards for QHP issuers, and composite premiums in the small group market.

II. Background

A. Legislative and Regulatory Overview

The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010. In this rule, we refer to the two statutes collectively as the “Affordable Care Act.”

Section 1201 of the Affordable Care Act added section 2701 of the Public Health Service Act (PHS Act) regarding fair health insurance premiums. Section 2701(a)(1) limits the variation in premium rates charged by a health insurance issuer for non-grandfathered health insurance coverage (including QHPs) in the individual or small group market to four factors: Family size; rating area; age; and tobacco use. Section 2701(a)(4) of the PHS Act requires that any family premium using age or tobacco rating may only apply those rates to the portion of the premium that is attributable to each family member.

Section 1302 of the Affordable Care Act directs the Secretary of Health and Human Services (referred to throughout this rule as the Secretary) to define essential health benefits (EHBs) and provides for cost-sharing limits and actuarial value (AV) requirements. Section 1302(d) of the Affordable Care Act describes the various levels of coverage based on AV. Consistent with section 1302(d)(2)(A) of the Affordable Care Act, AV is calculated based on the provision of EHB to a standard population. Section 1302(d)(3) of the Affordable Care Act directs the

Secretary to develop guidelines that allow for *de minimis* variation in AV calculations.

Section 1311(b)(1)(B) of the Affordable Care Act directs that the SHOP assist qualified small employers in facilitating the enrollment of their employees in QHPs offered in the small group market. Under section 1312(f)(2)(B) of the Affordable Care Act, beginning in 2017, States will have the option to allow issuers to offer QHPs in the large group market through the SHOP.³

Section 1311(c)(6)(B) of the Affordable Care Act states that the Secretary is to set annual open enrollment periods for Exchanges for calendar years after the initial enrollment period.

Section 1311(h)(1) of the Affordable Care Act specifies that a QHP may contract with health care providers and hospitals with more than 50 beds only if they meet certain patient safety standards. For hospitals with more than 50 beds, this includes the use of a patient safety evaluation system and a comprehensive hospital discharge program. Section 1311(h)(2) of the Affordable Care Act also provides the Secretary flexibility to establish reasonable exceptions to these patient safety requirements, and section 1311(h)(3) of the Affordable Care Act allows the Secretary flexibility to issue regulations to modify the number of beds described in section 1311(h)(1)(A) of the Affordable Care Act.

Sections 1313 and 1321 of the Affordable Care Act provide the Secretary with the authority to oversee the financial integrity of State Exchanges, their compliance with HHS standards, and the efficient and non-discriminatory administration of State Exchange activities. Section 1321(a) of the Affordable Care Act provides general authority for the Secretary to establish standards and regulations to implement the statutory requirements related to Exchanges, QHPs, and other components of Title I of the Affordable Care Act.

When operating an FFE under section 1321(c)(1) of the Affordable Care Act, HHS has the authority under sections 1321(c)(1) and 1311(d)(5)(A) of the Affordable Care Act to collect and spend user fees. In addition, 31 U.S.C. 9701 permits a Federal agency to establish a charge for a service provided by the agency. Office of Management and

Budget (OMB) Circular A–25 Revised establishes Federal policy regarding user fees and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public.

Section 1341 of the Affordable Care Act requires the establishment of a transitional reinsurance program in each State to help pay the cost of treating high-cost enrollees in the individual market from 2014 through 2016. Section 1342 of the Affordable Care Act directs the Secretary to establish a temporary risk corridors program that provides for the sharing in gains or losses resulting from inaccurate rate setting from 2014 through 2016 between the Federal government and certain participating health plans. Section 1343 of the Affordable Care Act establishes a permanent risk adjustment program that is intended to provide increased payments to health insurance issuers that attract higher-risk populations, such as those with chronic conditions, and thereby reduce incentives for issuers to avoid higher-risk enrollees. Sections 1402 and 1412 of the Affordable Care Act establish a program for reducing cost sharing for qualified individuals with lower household income and Indians.

Section 1411(g) of the Affordable Care Act requires that any person who receives information specified in section 1411(b) from an applicant or information specified in section 1411(c), (d), or (e) from a Federal agency must use the information only for the purpose of and to the extent necessary to ensure the efficient operation of the Exchange, and may not disclose the information to any other person except as provided in that section. Section 6103(l)(21)(C) of the Code additionally provides that return information disclosed under section 6103(l)(21)(A) or (B) may be used only for the purpose of and to the extent necessary in establishing eligibility for participation in the Exchange, verifying the appropriate amount of any premium tax credit or cost-sharing reduction, or determining eligibility for participation in a health insurance affordability program as described in that section.

Section 1560(c) of the Affordable Care Act provides that nothing in title I of the Affordable Care Act (or an amendment made by Title I of the Affordable Care Act) shall be construed to prohibit an institution of higher education (as such term is defined for purposes of the Higher Education Act of 1965) from offering a student health insurance plan, to the extent that such requirement is

³ If a State elects this option, the rating rules in section 2701 of the PHS Act and its implementing regulations will apply to all coverage offered in such State's large group market (except for self-insured group health plans) pursuant to section 2701(a)(5) of the PHS Act.

otherwise permitted under applicable Federal, State or local law.

1. Premium Stabilization Programs

In the July 15, 2011 **Federal Register** (76 FR 41930), we published a proposed rule outlining the premium stabilization programs. We implemented the premium stabilization programs in a final rule, published in the March 23, 2012 **Federal Register** (77 FR 17220) (Premium Stabilization Rule). In the December 7, 2012 **Federal Register** (77 FR 73118) (proposed 2014 Payment Notice), we published a proposed rule outlining the benefit and payment parameters for the 2014 benefit year to expand the provisions related to the premium stabilization programs and set forth payment parameters in those programs. We published the final rule in the March 11, 2013 **Federal Register** (78 FR 153410) (2014 Payment Notice).

As discussed above, we published a white paper on risk adjustment data validation on June 22, 2013, and hosted a public meeting on June 25, 2013, to discuss the white paper.

2. Program Integrity

In the June 19, 2013 **Federal Register** (78 FR 37032), we published a proposed rule that proposed certain program integrity standards related to Exchanges and the premium stabilization programs (proposed Program Integrity Rule). The provisions of that proposed rule were finalized in two rules, the “first final Program Integrity Rule” published in the August 30, 2013 **Federal Register** (78 FR 54070) and the “second final Program Integrity Rule” published in the October 30, 2013 **Federal Register** (78 FR 65046).

3. Exchanges, Essential Health Benefits, Actuarial Value

A proposed rule relating to EHBs and AV was published in the November 26, 2012 **Federal Register** (77 FR 70644). We finalized standards related to the premium adjustment percentage and AV in the Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation Final Rule, published in the February 25, 2013 **Federal Register** (78 FR 12834) (EHB Rule). We established standards for the administration and payment of cost-sharing reductions and the SHOP in the 2014 Payment Notice and in the Amendments to the HHS Notice of Benefit and Payment Parameters for 2014 interim final rule, published in the March 11, 2013 **Federal Register** (78 FR 15541). The provisions established in the interim final rule were finalized in the second final Program Integrity Rule.

We established standards related to Exchange user fees in the 2014 Payment Notice. We also established an adjustment to the FFE user fee in the Preventive Services Rule.

A Request for Comment relating to Exchanges was published in the August 3, 2010 **Federal Register** (75 FR 45584). An Initial Guidance to States on Exchanges was issued on November 18, 2010. A proposed rule was published in the July 15, 2011 **Federal Register** (76 FR 41866) to implement components of the Exchange. A proposed rule regarding Exchange functions in the individual market, eligibility determinations, and Exchange standards for employers was published in the August 17, 2011 **Federal Register** (76 FR 51202). A final rule implementing components of the Exchanges and setting forth standards for eligibility for Exchanges was published in the March 27, 2012 **Federal Register** (77 FR 18310) (Exchange Establishment Rule).

4. Market Rules

We published a proposed rule relating to the 2014 market reforms in the November 26, 2012 **Federal Register** (77 FR 70584), and a final rule implementing these provisions in the February 27, 2013 **Federal Register** (78 FR 13406) (Market Reform Rule).

5. Medical Loss Ratio

We published a request for comment on PHS Act section 2718 in the April 14, 2010 **Federal Register** (75 FR 19297), and published an interim final rule with a 60-day comment period relating to the medical loss ratio (MLR) program on December 1, 2010 (75 FR 74864). A final rule with a 30-day comment period was published in the December 7, 2011 **Federal Register** (76 FR 76574).

B. Stakeholder Consultation and Input

In addition to seeking advice from the public on risk adjustment data validation, HHS has consulted with stakeholders on policies related to the operation of Exchanges, including the SHOP and the premium stabilization programs. HHS has held a number of listening sessions with consumers, providers, employers, health plans, the actuarial community, and State representatives to gather public input. HHS consulted with stakeholders through regular meetings with the National Association of Insurance Commissioners, regular contact with States through the Exchange Establishment grant and Exchange Blueprint approval processes, and meetings with Tribal leaders and representatives, health insurance

issuers, trade groups, consumer advocates, employers, and other interested parties. We considered all of the public input as we developed the policies in this final rule.

C. Intended Future Rulemaking

Some of the public input suggested changes for 2015 that require additional rulemaking. In the interest of transparency, we describe here the potential policies that we intend to include in such future rulemaking for public comment.

Eligibility & Enrollment: We intend to propose in future rulemaking a limited number of revisions to our rules on eligibility, enrollment, and eligibility appeals. For example, we intend to propose that an appeals entity be required to dismiss an appeal if the employer or employee withdraws the request in writing or by telephone. In future rulemaking, we also intend to propose that an Exchange may establish one or more standard processes for prorating premiums for partial month enrollment, and that the FFE will establish one consistent with the methodology finalized in this rule for the FF-SHOPS.

Index of Premium Growth and Income Growth: To implement section 5000A(e)(1)(D) of the Code, we intend to propose a methodology for determining the excess of the rate of premium growth over the rate of income growth for years after 2014. We are also considering modifying our rounding rules to always round certain cost-sharing parameters down to the next lower multiple of \$50.

Plan Management: In future rulemaking, we intend to propose technical amendments to standards for issuing civil money penalties against QHP issuers and for decertifying QHPs, as currently set forth in 45 CFR 156.805 and 156.810.

Plan Changes: We intend to outline in future guidance the distinction between when a plan is being modified and when it is being terminated for purposes of plan renewal. For example, if an issuer makes changes to a plan that cause it to be in a different metal level, it would in fact be considered to be a new plan. We also intend to propose that issuers utilize standard notices in a format designated by the Secretary when discontinuing a product.

HIPAA Opt-Out for Self-Funded, Non-Federal Governmental Plans: Prior to enactment of the Affordable Care Act, sponsors of self-funded, non-Federal governmental plans were permitted to elect to exempt those plans from certain provisions of title XXVII of the PHS Act. We intend to propose amendments to

the non-Federal governmental plan regulations (45 CFR 146.180) to reflect the amendments made by the Affordable Care Act to these provisions, consistent with previously released guidance.⁴

Fixed Indemnity Insurance in the Individual Market: As indicated in previously released guidance, we intend to propose to amend the criteria for fixed indemnity insurance to be treated as an excepted benefit in the individual health insurance market.⁵

Minimum Essential Coverage: On October 31, 2013, we published guidance indicating that certain types of foreign group coverage are recognized as minimum essential coverage.⁶ We intend to propose amendments to in future rulemaking that would codify the treatment of foreign group coverage as described in the October 31, 2013 guidance. We also intend to clarify that entities other than plan sponsors (for example, issuers) can apply for their coverage to be recognized as minimum essential coverage, pursuant to the process outlined in 45 CFR 156.604 and guidance thereunder.⁷

Navigator, Non-Navigator Assistance Personnel, and Certified Application Counselor Program Standards: We also intend to specify in future rulemaking certain types of State laws applicable to Navigators, non-Navigator assistance personnel, and certified application counselors that HHS would consider to prevent the application of the provisions of title I of the Affordable Care Act. We intend to propose through future rulemaking to update the standards applicable to Navigators and non-Navigator assistance personnel. In addition, we intend to propose standards specific to certified application counselors and certified application counselor designated organizations that would prohibit them

from receiving consideration, directly or indirectly, from health insurance issuers or stop loss insurance issuers in connection with the enrollment of consumers in QHPs or non-QHPs, and that would require certified application counselors to be recertified on at least an annual basis. We further intend to propose that, in specific circumstances, certified application counselor designated organizations may serve targeted populations without violating the broad non-discrimination requirement related to Exchange functions.

Civil Money Penalties for Consumer Assistance Entities: In future rulemaking, we intend to propose that HHS may impose civil money penalties against Navigators, non-Navigator assistance personnel, certified application counselor designated organizations, and certified application counselors in Federally-facilitated and State Partnership Exchanges, if these entities or individuals violate Federal requirements.

Quality: In future rulemaking, we intend to propose quality reporting requirements for Exchanges and QHP issuers, including standards related to the implementation of the quality rating system (QRS), enrollee satisfaction survey (ESS), and a monitoring and appeals process for survey vendors. We intend to propose a beta testing period of the QRS and ESS in 2015 to provide early feedback to Exchanges and QHP issuers and begin public reporting of quality rating information in 2016.

Risk Corridors: In response to our proposed adjustments to the risk corridors program to account for the transitional policy, we received comments urging us to raise the ceiling on allowable administrative costs for QHP issuers in all States. We are carefully analyzing it to consider proposing for the 2015 benefit year, considering its policy and budgetary implications, and would consider making corresponding changes to the risk corridors profit floor and to the MLR regulations at that time. We would implement this policy up to the point of budget neutrality, and may make downward adjustments to parameters if necessary.

SHOP: In future rulemaking, we intend to propose amendments to align the dates for the annual election periods for qualified employers in all SHOPs with the start of open enrollment in the corresponding individual market Exchange for the 2015 benefit year. We also plan to propose to remove the required minimum lengths of both the employer election period and the employee open enrollment period to

provide additional flexibility to SHOPs and qualified employers, which would permit SHOPs to complete the entire election and enrollment processes in fewer than 45 days.

We are considering proposing through future rulemaking specific circumstances under which States could recommend that a SHOP modify the employee choice provision in 2015 if doing so would preserve and promote affordable insurance for employees and small businesses.

Medical Loss Ratio: We intend to propose several amendments to the MLR regulations (45 CFR Part 158). We intend to propose standardized methodologies to take into account the special circumstances of issuers associated with the initial open enrollment and other changes to the market in 2014, including incurred costs due to technical problems during the launch of the State and Federal Exchanges. We also intend to propose amendments that would improve the consistency of MLR and rebate calculations in States that require the individual and small group markets to be merged. In addition, we intend to propose an extension to the period during which issuers may include ICD-10 conversion costs in the MLR numerator and a clarification to the rules for distribution of *de minimis* rebates.

III. Provisions of the Final Regulations and Analysis and Responses to Public Comments

A proposed rule, titled “Patient Protection and Affordable Care Act: HHS Notice of Benefit and Payment Parameters for 2015” was published in the December 2, 2013 **Federal Register** (78 FR 72322) with a comment period ending on December 26, 2013. In total, we received 129 comments from various stakeholders, including States, health insurance issuers, consumer groups, labor entities, industry groups, provider groups, patient safety groups, national interest groups, and other stakeholders. The comments ranged from general support or opposition to the proposed provisions to very specific questions or comments regarding proposed changes. We received a number of comments and suggestions that were outside the scope of the proposed rule and therefore will not be addressed in this final rule.

Another proposed rule, entitled “Patient Protection and Affordable Care Act; Program Integrity: Exchange, SHOP, and Eligibility Appeals” (78 FR 37032), was published in the **Federal Register** on June 19, 2013 with a comment period ending on July 19, 2013. We received a total of 99

⁴ Amendments to the HIPAA opt-out provision (formerly section 2721(b)(2) of the Public Health Service Act) made by the Affordable Care Act (September 21, 2010). Available at: http://www.cms.gov/CCIIO/Resources/Files/Downloads/opt_out_memo.pdf.

⁵ FAQs about Affordable Care Act Implementation (Part XVIII) and Mental Health Parity Implementation, Q11 (January 9, 2014). Available at: http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs18.html and <http://www.dol.gov/ebsa/faqs/faq-aca18.html>.

⁶ See CCIIO Sub-Regulatory Guidance: Process for Obtaining Recognition as Minimum Essential Coverage (October 31, 2013). Available at: <http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/mec-guidance-10-31-2013.pdf>.

⁷ See CCIIO Sub-Regulatory Guidance: Process for Obtaining Recognition as Minimum Essential Coverage (October 31, 2013). Available at: <http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/mec-guidance-10-31-2013.pdf>.

comments from various stakeholders, including States, health insurance issuers, consumer groups, agents and brokers, provider groups, Members of Congress, individuals, Tribal organizations, and other stakeholders. In this final rule, we are only finalizing from that proposed rule provisions related to standards for the SHOP to require all QHP issuers to make any change to rates at a uniform time.⁸ In this final rule, we are finalizing language proposed at § 155.705(b)(6)(ii) at § 155.705(b)(6)(i)(A) instead of at (b)(6)(ii), to make clear that we never intended for this proposal to supersede the language at current § 155.705(b)(6)(ii), and are making a minor change to replace the word FF–SHOP with the term “Federally-facilitated SHOP.”

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the provisions we are finalizing. We note that nothing in these regulations limits the authority of the Office of the Inspector General (OIG) as set forth by the Inspector General Act of 1978 or other applicable law.

Comment: We received a number of comments requesting that the comment period be extended to 60 days.

Response: While we are sympathetic to these concerns, we received numerous detailed, substantive submissions on the contents of the rule. Additionally, the timeline for publication of this final rule accommodates issuer deadlines applicable for the 2015 benefit year.

A. Part 144—Requirements Relating to Health Insurance Coverage

In 45 CFR 144.103, we proposed to amend the definition of “policy year” for student health insurance coverage to mean generally the 12-month period that is designated as the policy year in the policy documents of the student health insurance coverage (rather than a calendar year). This amendment takes into account that student health insurance coverage is traditionally offered on an academic year basis with a policy year other than the calendar year. It is also consistent with our proposal in § 147.145 to exempt student health insurance coverage, a type of individual coverage, from certain calendar year requirements that apply to individual health insurance coverage.

We received comments supporting this proposal. We are finalizing the amendment to the definition of “policy year” with the following minor modification. We remove the word “individual” from the reference to “individual health insurance coverage” so that the terminology is appropriate for both grandfathered individual market and student health insurance coverage. Accordingly, the definition of “policy year” with respect to grandfathered individual health insurance coverage and student health insurance coverage generally now reads as “the 12-month period that is designated as the policy year in the policy documents of the health insurance coverage.”

B. Part 147—Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets

1. Composite Premiums

Section 2701(a)(1) of the PHS Act restricts the variation in premium rating for a particular plan or coverage to four factors: family size, geography, age, and tobacco use (within limits). Section 2701(a)(4) of the PHS Act further requires that any rating variation for age and tobacco use must be applied based on the portion of the premium attributable to each family member covered under a group health plan or health insurance coverage. These rules generally apply to health insurance issuers offering non-grandfathered individual market and small group market coverage, both through and outside an Exchange, for plan or policy years beginning on or after January 1, 2014.⁹

Consistent with the rating rules of section 2701 of the PHS Act, we established in 45 CFR 147.102(c) of the Market Reform Rule that the total premium charged by an issuer to a group health plan (in the small group market) or family (in the individual market) is generally determined by summing the premiums of each individual enrolled in the plan or coverage based on their age and tobacco use. This rating practice is known as per-member rating (also referred to as “list billing”).

In the small group market, section 2701 of the PHS Act regulates the premium “rate” that may be charged by an issuer for a group health plan based on the age and tobacco use of each

enrollee; however the statute does not preclude the possibility that the group could be charged an amount for enrollees based on the average premium per member of the group, rather than their own specific per-member amount. We codified this interpretation in § 147.102(c)(3) of the Market Reform rule, which provides that nothing prevents an issuer in the small group market from dividing the total group premium by the total number of enrollees covered under the plan to develop an average premium amount per enrollee. The preamble to the proposed rule referred to this practice as “composite rating.” However, to avoid unintended confusion with the traditional industry use of that term, we use only the terms “composite premiums” or “average enrollee premium amounts” when referring to average per-enrollee premium amounts in this final rule.¹⁰ An issuer may offer composite premiums in connection with a small group health plan as long as the total group premium calculated at the time of applicable enrollment at the beginning of the plan year equals the amount that is derived from per-member rating.¹¹

In the proposed rule, we proposed to amend § 147.102(c)(3) to specify that if an issuer offers a composite premium in connection with a group health plan in the small group market, the composite premium that was calculated based on applicable enrollment at the beginning of the plan year cannot vary during the plan year. For example, if a new hire enrolls in the plan in the middle of the plan year, the issuer would not adjust the average enrollee premium amount

¹⁰ The term “composite rating” has historically referred to an issuer rating practice that used the rating characteristics of a group as a whole—average employee health risk, average employee age, group size, and industrial code, among others—to determine an average rate per employee and corresponding average rates for different coverage tiers (for example, employee only, employee plus spouse, employee plus one or more children, and family coverage). This rating practice is no longer permitted under section 2701 of the PHS Act.

¹¹ Under 45 CFR 147.102(c)(2), States that do not permit rating for age or tobacco use may require health insurance issuers in the individual and small group markets to use uniform family tiers and corresponding multipliers established by the State. In States that elect this approach, a small group market issuer may offer composite premiums in connection with a group health plan, as long as the total group premium equals the amount that is derived from family-tier rating. For ease of reference, we do not discuss this alternative each time we refer to a total group premium equaling the sum of per-member premiums. However, we note that references in this preamble to the total group premium equaling the sum of per-member premiums also include references to the total group premium equaling the sum of family-tier premiums in States with community rating that have established uniform family tiers.

⁸ Other provisions of that proposed rule were finalized in two rules, the “first final Program Integrity Rule” published in the August 30, 2013 *Federal Register* (78 FR 54070) and the “second final Program Integrity Rule” published in the October 30, 2013 *Federal Register* (78 FR 65046).

⁹ Section 2701(a)(5) of the PHS Act provides that if a State exercises the option of offering large group market QHPs in the SHOP, the rating rules in section 2701 that apply to the small group market will also apply to all coverage offered in that State’s large group market, except for self-insured group health plans.

for the group based on the addition of the new enrollee. Rather, the amount that would be charged to the group for the new hire would be the same average enrollee premium amount that was established at the beginning of the plan year, and that amount would be added to the total group premium. The issuer would recalculate the average enrollee premium amount for the group only upon renewal.

We proposed this policy to ensure that composite premiums for small group coverage—and thus employer contributions to coverage—could remain stable during the plan year even if the composition of the group changes (for example, due to employees adding or dropping coverage). Additionally, we indicated that we were considering establishing a “tiered-composite” premium structure under which a separate composite premium could be calculated for different tiers or categories of enrollees covered under a group health plan (such as employees, adult dependents, and child dependents). We described several possible alternatives for implementing tiered-composite premiums and sought comment on whether and how to establish such approach.

We are finalizing our composite premium proposals with the addition of a tiered-composite premium structure based on one of the alternatives discussed in the preamble to the proposed rule. Specifically, we provide that a composite premium charged to a small group health plan must be based on enrollment of “participants and beneficiaries” at the beginning of the plan year, and may not vary until renewal. We also provide that any rating for tobacco use cannot be included in the composite premium for all enrollees but instead must be applied on a per-member basis. Finally, we specify that an issuer offering composite premiums with respect to a particular product offered in the small group market in a State must do so uniformly for all group health plans enrolling in that product, giving those group health plans the option to pay premiums based on a composite premium methodology (to the extent permitted by applicable State law and except as provided in § 156.285(a)(4) of this final rule when employee choice is offered in the FF–SHOPS).

Comment: In response to the composite premium proposals, we received a few comments that suggested some concern and confusion that per-member rating would no longer be required.

Response: We have not changed the basic per-member rating requirement

under section 2701 of the PHS Act, or the policy that in the small group market, an issuer may convert a group’s per-member premiums into average enrollee premium amounts as long as the total premium owed by the plan to the issuer is the same total produced by per-member rating. The proposed rule and this final rule simply provide clarity about when the per-member rating requirement is satisfied. Specifically, we recognize that, where an issuer offers a composite premium in connection with a group health plan, requiring strict adherence to a per-member buildup at all times throughout the plan year may impose undue administrative burden on issuers and create premium instability for employers and employees. Given that the statute can reasonably be read to support either interpretation, we are finalizing amendments to § 147.102(c)(3) which make clear that the requirement that the sum of composite premiums must equal the sum of per-member premiums is determined at the time of applicable enrollment at the beginning of the plan year.

Comment: Some commenters urged HHS to make compositing premiums mandatory for all small group market issuers. Other commenters emphasized that the decision to offer composite premiums should continue to be voluntary at the option of the issuer (or as required by applicable State law). One commenter noted that issuers historically have offered composite rates to some group health plans but not others (for example, groups with more than ten employees) and requested clarification of whether this practice could continue.

Response: This final rule neither requires nor prohibits the compositing of premiums in connection with a small group health plan (except with respect to employee choice in the FF–SHOPS as discussed below). This decision is within the discretion of the issuer unless applicable State law requires composite premiums. However, in response to comments, we are clarifying that if an issuer elects to offer composite premiums with respect to a particular product offered in the small group market in a State, the issuer cannot do so for only certain group health plans; the issuer must make the option to composite premiums uniformly available to all group health plans enrolling in that product, to the extent permitted by applicable State law and subject to § 156.285(a)(4) of this final rule (prohibiting QHP issuers from offering composite premiums when employers offer employee choice in the

FF–SHOPS). Plan sponsors selecting a product that offers composite premiums may then decide whether to pay premiums based on a per-member or composite premium methodology. This does not affect what portion of the group premium will be paid by the employer or the employee.¹²

Comment: One commenter stated that requiring issuers to accept a premium based on a group’s composite premium at the beginning of the plan year as the standard rate for the entire plan year could affect the premium charged to the group health plan.

Response: Depending on whether a new enrollee added to the plan mid-year is above or below the average age of the group, the composite premium might be higher or lower than the per-member premium that would otherwise be charged for that individual. Consequently, the total group premium would at that point no longer precisely equal the sum of the per-member premiums for each enrollee until the next renewal. Although this policy may thus create some variation from the result that would be produced by calculating premiums based on a strict per-member approach, we do not believe it will result in any material under-rating or over-rating in the market generally, because rates on average should balance out over the issuer’s single risk pool for the small group market. Additionally, as described above, we believe this method of calculating premiums is still based on a per-member rating methodology that is consistent with the statute. However, we will monitor the effects of this policy on the small group market and assess whether future changes may be necessary.

Comment: In response to the request for comment regarding a uniform tiered-composite premium structure, we received comments that both supported and opposed the tiered-composite approach under consideration. Commenters who opposed the suggested alternatives for implementing tiered-composite premiums emphasized the differences between the suggested alternatives and current standard industry practice, which commonly

¹² This separate pricing decision is governed by section 2705(b) of the PHS Act, as amended by the Affordable Care Act and incorporated into ERISA and the Code (providing that a group health plan, and a health insurance issuer offering group or individual health insurance coverage, generally may not require any individual (as a condition of enrollment or continued enrollment under the plan or coverage) to pay a premium or contribution which is greater than the premium or contribution for a similarly situated individual enrolled in the plan or coverage based on any health factor of the individual or a dependent of the individual).

establishes four or five coverage tiers and corresponding premiums that do not vary based on the number of children covered. Some commenters opposed the use of composite premiums altogether, suggested alternative tiered-composite approaches using coverage tiers and corresponding multipliers, or advocated for a “pure” composite that averages the per-member rates of all enrollees in a plan, including the rates of both adults and children. Commenters who supported a tiered-composite methodology generally thought it would ensure that premiums for family coverage appropriately reflect the lower rates of children.

Response: We agree with commenters who suggested a tiered-composite premium approach would benefit families with children enrolled in plans using composite premiums. Based on our analysis, without a tiered approach, the composite premium charged for a family consisting of two adults (both age 24) and three children (all under age 21) would be about 35 to 55 percent higher than the composite premium charged for the same family under a tiered approach, depending on the average age of the group.¹³ Accordingly, this rule establishes a tiered-composite methodology based on one of the alternatives discussed in the preamble to the proposed rule.

The rule creates a two-tiered composite premium structure for small group market issuers that offer composite premiums, effective for plan years beginning on or after January 1, 2015. Under this approach, an issuer offering composite premiums will calculate a composite premium (or average enrollee premium amount) for each individual age 21 and older and a composite premium for each individual under age 21 covered under the plan. We note that an individual’s status as an employee or adult dependent is not relevant for this purpose. To determine the total premium charged by the issuer for a given family composition, the issuer sums the average enrollee premium amount for each covered family member age 21 and older and the average enrollee premium amount for each covered family member under age 21, as applicable, taking into account no more than three covered children under

age 21 and applying any applicable tobacco rating factor on a per-member basis (as discussed below).

For example, suppose the composite premium for a group health plan is \$200 for each covered individual age 21 and older and \$100 for each covered individual under age 21. Also suppose that none of the enrollees uses tobacco. In this example, the premium charged for a single employee (over age 21) would be \$200; the premium charged for an employee and spouse (both over age 21) would be \$400 (\$200 + \$200); and the premium charged for a family consisting of an employee and spouse (both over age 21) and four children (all under age 21) would be \$700 (\$200 + \$200 + \$100 + \$100 + \$100 + \$0). An example of how a tobacco rating factor would be applied is provided below.

We discussed in the proposed rule that, under the approach we were considering, States could establish different tiered-composite premium standards with approval from HHS. We are finalizing this flexibility for States in this final rule. Thus, the tiered-composite premium methodology established in this rule will apply in the small group market in a State, both for coverage offered through a SHOP (subject to the amendments in § 156.285(a)(4) of this final rule that limit the availability of composite premiums in the FF–SHOs when employee choice is offered) and for coverage outside of a SHOP, unless a State establishes and HHS approves an alternate tiered-composite methodology for the State.

Section 147.103 of the Market Reform Rule directs States to report certain information to HHS about State-specific rating requirements, including State-specific standards or requirements concerning average enrollee premium amounts. We interpret § 147.103(a)(5) to include a requirement that States report any State-proposed tiered-composite premium methodology that relates to average enrollee premium amounts. Accordingly, States seeking to adopt tiered-composite premium standards that differ from the Federal standards will submit information about such standards to HHS in accordance with the State reporting provisions set forth in § 147.103 and as further described in guidance. HHS will review a State’s composite premium standards to ensure (1) the State standards are at least as consumer protective as the Federal standards; and (2) the State methodology produces a total group premium that equals the amount that is derived through per-member rating established at the time of applicable

enrollment at the beginning of the plan year.

We believe these composite premium standards will guarantee minimum consumer protections in every State to assure that children are charged only child premium rates, while promoting administrative simplicity for issuers and employers and providing flexibility for States to establish alternative approaches for their health insurance market.

Comment: Tobacco rating is subject to the non-discrimination and wellness provisions under section 2705 of the PHS Act (providing that an issuer in the group market may vary the premium rate based on legal use of tobacco only in connection with a wellness program meeting the standards of section 2705(j) of the PHS Act and its implementing regulations).¹⁴ The preamble to the proposed rule indicates that this is true regardless of whether a tobacco rating factor is applied on a per-member or composite basis.¹⁵ One commenter suggested that including any surcharge for tobacco use in a composite premium was inconsistent with the rationale of ensuring that tobacco rating is applied only to portion of the premium attributable to each individual covered under the plan or coverage.

Response: To ensure that non-tobacco users do not have to pay any portion of a premium that is attributable to tobacco users enrolled in the plan, and to promote consistency with the wellness program requirements, this rule excludes any rating for tobacco use (as defined in § 147.102(a)(1)(iv)) from any enrollee’s composite premium. If an issuer offering composite premiums wishes to rate for tobacco use, consistent with applicable Federal and State law, the issuer must calculate the tobacco rating factor based on the applicable enrollee’s per-member premium, not the composite premium for all enrollees. The resulting tobacco rating factor is added to the composite premium for the enrollee who uses tobacco to create a premium specific to each tobacco user. For example, assume that the rate of a non-tobacco user is \$100 and the issuer does not rate based on age. The issuer imposes a 1.5:1 tobacco rating factor for individuals age 45 and older who use tobacco (that is, a \$50 tobacco surcharge) and a 1.3:1 tobacco rating factor for individuals under age 45 who use tobacco (that is, a \$30 tobacco surcharge). Further, assume that the composite premium for a group health plan is \$100 for each

¹³ For illustration, we assumed per-member premiums for family members of different ages enrolled in employer-group coverage and assumed various average ages for the group. For each average age, we calculated the total composite family premium that would be charged under a pure composite and two-tiered composite approach. The difference in the total composite premium for the family between the pure composite and two-tiered composite approach ranged from 35 to 55 percent, depending on the average age of the group.

¹⁴ 26 CFR 54.9802–1(f); 29 CFR 2590.702(f); and 45 CFR 146.121(f).

¹⁵ 78 FR at 72328, footnote 6.

covered individual age 21 and older. In this example, the premium charged for a single employee (over age 45) who uses tobacco would be \$150 (\$100 + \$50), and the premium charged for a single employee (under age 45) who uses tobacco would be \$130 (\$100 + \$30), subject to the non-discrimination and wellness provisions under section 2705 of the PHS Act.

Comment: Some commenters questioned how a composite premium would be established for adult and child dependents under a two-tiered or three-tiered composite approach if none were enrolled at the time of initial enrollment (or re-enrollment).

Response: This rule establishes a two-tiered rather than a three-tiered composite premium structure in response to these comments. The composite premium calculated at the beginning of the plan year for covered adults applies for all covered individuals age 21 and older regardless of whether they are an employee or adult dependent or when they enroll during the plan year. The composite premium calculated for covered individuals under age 21 is simply the per-member child age rate, which is a single rate for children ages 0 through 20 pursuant to § 147.102(d) and (e), regardless of the total number of children covered under the plan (taking into account no more than three covered children under age 21 with respect to a given family). For these reasons, and because a tobacco rating factor may be applied only on per-member basis, a composite premium will apply for both adult and child dependents who enroll after the start of the plan year (subject to the applicability of the tobacco rating factor).

Comment: Commenters suggested modifying the regulation text to clarify that a composite premium is calculated based on applicable employee “and dependent” enrollment at the beginning of the plan year.

Response: Because composite premiums will be generated for employees and dependents, as well as other types of group health plan enrollees (for example, retirees), we now refer to “participants” and “beneficiaries” in the regulation text for consistency with the terms generally used under the Employee Retirement Income Security Act of 1974 (ERISA).

Comment: The proposed rule provided that the new composite premium provisions would become applicable for plan years beginning on or after January 1, 2015. Some commenters noted that small group policies are issued on a rolling basis throughout the year and recommended

the requirements become effective prior to 2015.

Response: We recognize that issuers have developed the expertise and resources to comply with the per-member rating methodology generally required under the law and regulations and that some issuers might need time to adjust their systems to offer composite premiums in accordance with this rule. Therefore, the rule will take effect as a requirement for plan years beginning on or after January 1, 2015. However, as noted in the preamble to the proposed rule, we encourage issuers to voluntarily adopt the final rule’s composite premium standards for plan years beginning in 2014.

2. Student Health Insurance Coverage

Student health insurance coverage is traditionally offered on an academic year basis with a policy year other than a calendar year. Accordingly, we proposed in § 147.145 to exempt student health insurance from certain calendar year requirements that would otherwise apply to student health insurance coverage as a type of individual health insurance coverage. We proposed to exempt student health insurance coverage from the requirement to establish open enrollment periods and coverage effective dates based on a calendar policy year, and clarified that student health insurance coverage is not required to be offered as a calendar year plan.

We received comments supporting this proposal and are finalizing these provisions as proposed.

C. Part 153—Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment Under the Affordable Care Act

1. Provisions for the State Notice of Benefit and Payment Parameters

Section 1341 of the Affordable Care Act provides that States may elect to operate the transitional reinsurance program. Based on HHS’s communications with States, as of January 31, 2014, Connecticut is the only State that elected to operate a transitional reinsurance program. We indicated in the 2014 Payment Notice that Maryland had elected to operate reinsurance for 2014; however since the publication of the 2014 Payment Notice, Maryland has indicated that it wishes to defer the operation of the transitional reinsurance program to HHS. Because, at this time, taking on the operation of the reinsurance program on behalf of Maryland would not raise operational concerns, we are confirming that HHS

will operate reinsurance on Maryland’s behalf.

Section 153.100(c) provides that a State that operates or establishes a risk adjustment or reinsurance program, and is required to publish a State notice of benefit and payment parameters under § 153.100(a) or (b), must publish an annual State notice of benefit and payment parameters by March 1st of the calendar year prior to the benefit year for which the notice applies. However, because the 2014 Payment Notice was published after March 1, 2013, the 2014 Payment Notice extended this deadline to the 30th day following publication of that final rule. Similarly, we are extending the deadline for publication of a 2015 State notice of benefit and payment parameters until the 30th day following publication of this final rule. Consistent with this policy, we intend to propose in future rulemaking that for future benefit years, the publication deadline for the State notice of benefit and payment parameters be the later of March 1st of the calendar year prior to the applicable benefit year, or the 30th day following publication of the final HHS notice of benefit and payment parameters for the calendar year.

2. Provisions and Parameters for the Permanent Risk Adjustment Program

The risk adjustment program is a permanent program created by section 1343 of the Affordable Care Act that transfers funds from lower risk, non-grandfathered plans to higher risk, non-grandfathered plans in the individual and small group markets, inside and outside the Exchanges. A State that is approved or conditionally approved by the Secretary to operate an Exchange may establish a risk adjustment program, or have HHS do so on its behalf.

In the proposed rule, we proposed a risk adjustment user fee to support HHS operation of the risk adjustment program in 2015. We also considered two adjustments to our risk adjustment methodology: One concerning adjustments for Medicaid alternative plans and the other concerning adjustments relating to the geographic rating areas. We also proposed a default counting method for determining whether a plan is a small group plan for purposes of risk adjustment when a State’s counting method does not account for non-full-time employees. We proposed standards for risk adjustment data validation, including a sampling methodology, audit standards, internal consistency standards, a methodology to adjust risk scores, and actions upon noncompliance. We proposed that HHS have the authority to

conduct audits of issuers of risk adjustment covered plans.

a. Risk Adjustment User Fees

If a State is not approved to operate, or chooses to forgo operating, its own risk adjustment program, HHS will operate a risk adjustment program on the State's behalf. As described in the 2014 Payment Notice, HHS's operation of risk adjustment on behalf of States is funded through a risk adjustment user fee. Section 153.610(f)(2) provides that an issuer of a risk adjustment covered plan must remit a user fee to HHS for each month equal to the product of its monthly enrollment in the plan and the per-enrollee-per-month risk adjustment user fee specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year.

OMB Circular No. A-25R establishes Federal policy regarding user fees, and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public. The risk adjustment program will provide special benefits as defined in section 6(a)(1)(b) of Circular No. A-25R to an issuer of a risk adjustment covered plan because it will mitigate the financial instability associated with risk selection as other market reforms go into effect. The risk adjustment program also will contribute to consumer confidence in the health insurance industry by helping to stabilize premiums across the individual and small group health insurance markets.

For the 2015 benefit year, we proposed to use the same methodology that we used in the 2014 Payment Notice to estimate our administrative expenses to operate the risk adjustment program. That proposed methodology was based upon our contract costs in operating risk adjustment on behalf of States. The contract costs we considered cover development of the model and methodology, collections, payments, account management, data collection, data validation, program integrity and audit functions, operational and fraud analytics, stakeholder training, and operational support. We proposed not to set the user fee to cover costs associated with Federal personnel. We proposed to calculate the user fee by dividing HHS's projected total costs for administering the risk adjustment programs on behalf of States by the expected number of enrollees in risk adjustment covered plans in HHS-operated risk adjustment programs for the benefit year (other than plans not subject to market reforms and student health plans, which are not

subject to payments and charges under the risk adjustment methodology HHS uses when it operates risk adjustment on behalf of a State).

We estimated that the total cost for HHS to operate the risk adjustment program on behalf of States for 2015 would be approximately \$27.3 million, and that the per capita risk adjustment user fee would be no more than \$1.00 per enrollee per year. We are finalizing the proposed methodology for benefit year 2015, and are finalizing a per capita risk adjustment user fee of \$0.96 per enrollee per year, which we will apply as a per-enrollee-per-month risk adjustment user fee of \$0.08.

We received no comments on the risk adjustment user fee, and are therefore finalizing this proposal as proposed.

b. HHS Risk Adjustment Methodology Considerations

In the 2014 Payment Notice, we finalized the methodology that HHS will use when operating a risk adjustment program on behalf of a State in 2014. We proposed to use the same methodology in 2015, but proposed to amend the methodology by applying an adjustment for individuals enrolled in premium assistance Medicaid alternative plans. We proposed to apply the amended methodology beginning in 2014. We also sought comment on potential adjustments to the geographic cost factor to account for rating areas with low populations in the HHS risk adjustment methodology for future years.

We received a number of general comments regarding the HHS risk adjustment methodology.

Comment: Commenters requested that HHS provide additional guidance on the ICD-10 transition for risk adjustment, including the ICD-10 mappings, as soon as possible.

Response: We will publish updated ICD-9 instructions and software and then a combined set of ICD-9 and ICD-10 instructions and software on our Web site, as we did for the original ICD-9 software and instructions.¹⁶ Because ICD-10 codes will be accepted for risk adjustment beginning October 1, 2014, we intend to publish these documents shortly.

Comment: One commenter requested that the risk adjustment model be calibrated for 2015 using the most current data possible. Other commenters suggested that HHS incorporate

pharmacy utilization in the risk adjustment model. One commenter suggested that HHS include transitional plans' data in the risk adjustment model, but exclude them from payments and charges.

Response: We believe it is important to maintain model stability in implementing the risk adjustment methodology in the initial years of risk adjustment, and therefore do not intend to recalibrate the model in the initial years. Similarly, we do not intend to significantly change the model by including pharmacy utilization, though we continue to consider whether and how to include prescription drug data in future models. Finally, as we described in the 2014 Payment Notice (78 FR 15418), under our current methodology, plans not subject to the market reform rules are not subject to risk adjustment charges and do not receive risk adjustment payments. Because under the transitional policy, the Federal government will not consider certain health insurance coverage in the individual or small group market renewed after January 1, 2014, under certain conditions, to be out of compliance with specified 2014 market rules, and requested that States adopt a similar non-enforcement policy, transitional plans are able to set premiums and provide coverage as if they were not subject to market reform rules.¹⁷ For this reason, transitional plans are not subject to risk adjustment payments and charges under our methodology at this time.

Comment: One commenter sought clarification on the risk scoring process. The commenter sought clarification on whether an enrollee's risk score is calculated monthly and aggregated to reflect changes in the receipt of cost-sharing reductions. The commenter also sought clarification on whether diagnoses carry through to the new plan if a qualifying event results in a special enrollment period and an enrollee changes plans, but stays with the same issuer. One commenter questioned whether an issuer would receive credit for the diagnoses on risk adjustment eligible claims paid by the issuer during a grace period if the issuer later processes a retroactive termination because the individual does not pay the premium.

Response: For each enrollee, HHS will use all risk adjustment eligible claims or encounters submitted from across all of the issuer's risk adjustment covered

¹⁶ The HHS-Developed Risk Adjustment Model Algorithm Software is available at: <http://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/index.html> under "Regulations & Guidance" (posted under "Guidance" on May 7, 2013).

¹⁷ Letter to Insurance Commissioners, Center for Consumer Information and Insurance Oversight, November 14, 2013. Available at: <http://www.cms.gov/CCIIO/Resources/Letters/Downloads/commissioner-letter-11-14-2013.PDF>.

plans to calculate a risk score. The diagnoses would be associated with each of the issuer's plans in which the individual enrolls. This means that if the enrollee changes plans within the same issuer, then the claims data from all of the issuer's plans will be utilized to calculate the member's plan-specific risk scores for each of these plans. We note that in accordance with our methodology, the risk score value could change based on cost-sharing reductions received or plan AV. However, to align with our distributed data collection approach, which collects data by issuer, we will not link enrollee data across different issuers, even if the issuers are affiliated with the same insurance company. Diagnoses from risk adjustment eligible claims will only be accepted with dates of service that occur during active enrollment periods. Therefore, claims associated with months during a grace period will be counted toward risk adjustment, so long as the months are not later subject to a retroactive termination.

We are finalizing the use of the 2014 Federal risk adjustment methodology when HHS operates a risk adjustment program on behalf of a State, for 2015, with the modification for the treatment of Medicaid alternative plans discussed below, effective for 2014 risk adjustment.

(i) Incorporation of Premium Assistance Medicaid Alternative Plans in the HHS Risk Adjustment Methodology

Section 1343(c) of the Affordable Care Act provides that risk adjustment applies to non-grandfathered health insurance coverage offered in the individual and small group markets. In some States, expansion of Medicaid benefits under section 2001(a) of the Affordable Care Act may take the form of enrolling newly Medicaid-eligible enrollees into individual market plans. For example, these enrollees could be placed into silver plan variations—either the 94 percent silver plan variation or the zero cost sharing plan variation—with a portion of the

premiums and cost sharing paid for by Medicaid on their behalf. Because individuals in these types of Medicaid alternative plans receive significant cost-sharing assistance, they may utilize medical services at a higher rate. To address this induced utilization in the context of cost-sharing reduction plan variations in the HHS risk adjustment methodology, our methodology increases the risk score for individuals in plan variations by a certain factor. We proposed to use the same factor that we use to adjust for induced utilization for individuals enrolled in cost-sharing plan variations to adjust for induced utilization for individuals enrolled in the corresponding Medicaid alternative plan variations, and to implement these adjustments in 2014. Table 1 shows the cost-sharing adjustments for both 94 percent silver plan variation enrollees and zero cost-sharing plan variation enrollees for silver QHPs as finalized in the 2014 Payment Notice.

TABLE 1—COST-SHARING REDUCTION ADJUSTMENTS

Plan variation	Induced utilization factor
94 Percent Plan Variation	1.12
Zero Cost-Sharing Plan Variation of Silver QHP	1.12

We are finalizing the application of the cost-sharing reduction adjustments to corresponding Medicaid alternative expansion plans as proposed. We plan to evaluate these adjustments in the future, after data from the initial years of risk adjustment is available.

Comment: Commenters agreed with our approach for accounting for Medicaid alternative plans under risk adjustment, with one commenter recommending that we monitor utilization patterns and consider evaluating States' Medicaid alternative plans separately in 2015 and beyond.

Response: We intend to examine the utilization patterns of current Medicaid alternative plans and the benefit structure of future Medicaid alternative plans, and may make appropriate adjustments in the future.

(ii) Adjustment to the Geographic Cost Factor

As finalized in the 2014 Payment Notice, the geographic cost factor is an adjustment in the payment transfer formula to account for plan costs, such as input prices, that vary by geography and are likely to affect plan premiums. For the metal-level risk pool, it is calculated based on the observed

average silver plan premium in a geographic area relative to the Statewide average silver plan premium. It is separately calculated for catastrophic plans in a geographic area relative to the Statewide catastrophic pool. However, as we noted in the proposed rule, several States have defined a large number of rating areas, potentially leading to rating areas with low populations. Less populous rating areas raise concerns about the accuracy and stability of the calculation of the geographic cost factor, because in less populous rating areas, the geographic cost factor might be calculated based on a small number of plans. Inaccurate or unstable geographic cost factors could distort premiums and the stability of the risk adjustment model.

We sought comment in the proposed rule on how to best adjust the geographic cost factors or geographic rating areas in future years to address these potential premium distortions. We also sought comment on how this adjustment should be implemented for a separately risk adjusted pool of catastrophic plans. We stated that we did not intend to make this adjustment for 2014.

Based on comments received, we will continue to implement the geographic cost factor for each rating area established by the State under § 147.102(b) and calculated based on the observed average silver plan premium for the metal-level risk pool, as finalized in the 2014 Payment Notice (78 FR 15433).

Comment: Commenters did not support making additional adjustments to the geographic cost factor. Commenters stated that the time and resources needed to calculate and implement such an adjustment would be considerable, and that any such adjustment would be unlikely to have a material impact on final risk adjustment results.

Response: We will not adjust the geographic cost factors or geographic rating areas, but will monitor 2014 risk adjustment data for any potential premium distortions.

c. Small Group Determination for Risk Adjustment

For a plan to be subject to risk adjustment, according to section 1343(c) of the Affordable Care Act and the definition of a "risk adjustment covered plan" in § 153.20, a plan must be offered

in the “individual or small group market.” The definition of small group market in § 153.20 references the definition at section 1304(a)(3) of the Affordable Care Act.

Section 1304(a)(3) of the Affordable Care Act, in defining “small group market,” references the definition of a “small employer” in section 1304(b)(2) of the Affordable Care Act. That definition provides that an employer with an average of at least 1 but not more than 100 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year will be considered a “small employer.” However, section 1304(b)(3) of the Affordable Care Act provides that, for plan years beginning before January 1, 2016, a State may elect to define “small employer” to mean an employer with at least 1 but not more than 50 employees.

In the 2014 Payment Notice, we stated that we believe that the Affordable Care Act requires the use of a counting method that accounts for non-full-time employees, and that the full-time equivalent method described in section 4980H(c)(2)(E) of the Code is a reasonable method to apply (78 FR 15503). We stated that we believe that the risk adjustment program must also use a counting method that takes employees that are not full-time into account when determining whether a group health plan must participate in that program.

However, we also recognize that, because risk adjustment is intended to stabilize premiums by mitigating pricing uncertainty associated with the rating rules, it is important that the program be available to plans that are subject to the rating rules, to the extent permissible under the Affordable Care Act. We recognize that a number of States, which have primary enforcement jurisdiction over the market rules, may use counting methods that do not take non-full-time employees into account.

Thus, we are finalizing our proposal, with one modification—we are changing the cross-reference to the Code so that it references section 4980H(c)(2). In determining which group health plans participate as small group plans in the risk adjustment program, we will apply the applicable State counting method, unless the State counting method does not take into account employees that are non-full-time. In that circumstance, we will apply the counting method described in section 4980H(c)(2) of the Code and any implementing regulations.¹⁸ We believe that this

approach defers to State counting methods and aligns with State enforcement of rating rules, within the bounds of what is legally permissible under the Affordable Care Act.

Comment: One commenter supported our proposed counting method when a State counting method does not account for non-full-time employees. Some commenters urged us to maintain consistency with other counting methods, noting the administrative burden of having inconsistent counting methods across different Affordable Care Act programs. One commenter suggesting that we codify the average number of employees during the preceding calendar year as the single counting method across Affordable Care Act programs. Some commenters recommended deferring to the State counting method in the transitional years while collaborating with other Federal agencies to issue a uniform counting method in future rulemaking. One commenter recommended that if a group is required to be rated as a small group based on rating rules or SHOP requirements and is part of the single risk pool pricing, it should be included in the small group risk adjustment pool.

Response: We agree that risk adjustment should apply to plans subject to the market reform rating rules, to the extent permissible under the Affordable Care Act. We also agree with commenters that consistency in counting methods across Affordable Care Act programs is important, and we plan to collaborate with other Federal agencies to streamline counting methods in future rulemaking. To better address commenters’ requests for consistency across Affordable Care Act programs, we have changed the Code reference from section 4980H(c)(2)(E) to 4980H(c)(2). This broader cross-reference will incorporate the limit in section 4980H(c)(2)(B) on how certain seasonal employees are counted, and will be consistent with the counting method used by the SHOP, as finalized in the 2014 Payment Notice (78 FR 15503). Prior to streamlining counting methods, because we interpret the employer size definitions in the Affordable Care Act to include non-full-time employees for purposes of determining small group status for purposes of risk adjustment, in States that do not account for non-full-time employees, we believe that requiring the large group counting method described in section 4980H(c)(2) of the Code (which accounts for non-full-time employees) is an appropriate standard

because it is used by other Affordable Care Act programs and will reduce administrative burden for issuers.

d. Risk Adjustment Data Validation

The 2014 Payment Notice established a risk adjustment data validation program that HHS will use when operating risk adjustment on behalf of a State. In the 2014 Payment Notice (78 FR 15436), we specified a framework for this program that includes six stages: (1) Sample selection; (2) initial validation audit; (3) second validation audit; (4) error estimation; (5) appeals; and (6) payment adjustments.

To develop the details of the program, we sought the input of issuers, consumer advocates, providers, and other stakeholders. We issued the “Affordable Care Act HHS-Operated Risk Adjustment Data Validation Process White Paper” on June 22, 2013 (the “white paper”).¹⁹ That white paper discussed and sought comments on a number of potential considerations for the development of the risk adjustment data validation methodology. We received submissions from 53 commenters, including issuers, issuer trade groups, advocacy groups, and consultants. As we noted in the white paper, our overall goals are to promote consistency and a level playing field by establishing uniform audit requirements, and to protect private information by limiting data transfers during the data validation process.

In the proposed rule, we proposed provisions for the risk adjustment data validation process and methodology that reflect our analysis of the white paper comments and our discussions with stakeholders. We again note that a State operating a risk adjustment program is not required to adopt these standards.

We received some general comments about our proposed risk adjustment data validation methodology and process.

Comment: We received comments supporting the risk adjustment data validation methodology and process, noting that data validation is critical to issuer confidence and to encouraging the enrollment of individuals with significant health needs. Another commenter suggested that we model the HHS risk adjustment data validation program after the Medicare Advantage risk adjustment data validation program to the extent possible.

Response: We agree that a robust risk adjustment data validation program is

¹⁸ We note that the IRS has published a final regulation that contains further details that would

apply to this calculation (§ 54.4980H-2(c) (79 FR 8544).

¹⁹ “Affordable Care Act HHS-Operated Risk Adjustment Data Validation Process White Paper.” 22 June 2013. https://www.regtap.info/uploads/library/ACA_HHS_OperatedRADVWhitePaper_062213_5CR_062213.pdf.

critical to ensuring that we effectively promote issuer confidence and the goals of the risk adjustment program. We note that many aspects of the HHS risk adjustment data validation program were modeled after the Medicare Advantage risk adjustment data validation program. For example, we have adopted a sampling strategy modeled on the one used in the Medicare Advantage risk adjustment program. Additionally, we have elected to adopt the medical record as the authoritative source to verify diagnoses, and have required that certified reviewers perform medical record reviews, as discussed below. Both of those program features are modeled on the Medicare Advantage risk adjustment data validation process. However, because our risk adjustment methodology uses a more comprehensive set of data elements, our data collection approach is more robust, and our data validation approach is broader.

(i) Sample Selection

The first stage in the HHS-operated risk adjustment data validation process is the selection of a sample of an issuer's enrollees whose risk adjustment data will be validated. In the final 2014 Payment Notice, we stated that HHS would choose a sample size of enrollees such that the estimated risk score errors would be statistically sound and the enrollee-level risk score distributions would reflect enrollee characteristics for each issuer. We stated that in determining the appropriate sample size for data validation, we recognized the importance of striking a balance between ensuring statistical soundness of the sample, and minimizing the operational burden on issuers, providers, and HHS. Additionally, we stated that we would ensure that the sample would cover critical subpopulations of enrollees for each risk adjustment covered plan, such as enrollees with and without hierarchical condition categories (HCCs). To develop a proposed sample size for the first year of the HHS risk adjustment data validation program, in the proposed rule we proposed to use the methodology outlined in the white paper. We stated in the proposed rule that our goal in determining the enrollee sample size for the initial 2 years of risk adjustment data validation is to use a sample large enough to inform us in a statistically valid manner of the dynamics of the risk adjustment data validation process in operation, and to permit statistically valid estimation of risk score accuracy. As we established in the 2014 Payment Notice, in order to permit HHS to

observe and optimize the risk adjustment data validation process, no payment adjustments will be made based on the risk adjustment data validation process for the initial 2 years of HHS-operated risk adjustment.

In the proposed rule, we proposed selecting the initial validation audit sample for a given benefit year by dividing the relevant population into a number of "strata," representing different demographic and risk score bands. For the initial 2 years of the risk adjustment data validation program, we proposed an initial validation audit sample of 200 enrollees from each issuer. We stated in the proposed 2014 Payment Notice and the proposed rule that the overall sample will reflect a disproportionate selection of enrollees with HCCs. In the proposed rule, we discussed in detail our sampling methodology, including our proposal to group enrollees to account for age characteristics and health status. Some commenters on the white paper suggested that we also consider sampling based on plan types and other characteristics. We will consider other sampling strategies in the future, but believe that we do not yet have enough experience with the risk adjustment process to determine the most appropriate sampling groups at this time. Therefore, we are finalizing a simple age and risk score stratification for the initial 2 years of the program. Following the division of the relevant population into strata, we will use the following formulas to calculate a proposed sample size for the initial validation audit each year. In general, the formula for the overall sample size for an issuer (n) is:

$$n = \frac{\left(\sum_{h=1}^H N_h S_h \right)^2}{\sum_{h=1}^H N_h S_h^2 + \left(\frac{Prec \times Y}{z - value} \right)^2}$$

Where:

H is the number of strata;

N_h is the population size of the h^{th} stratum;

Y is the average risk score of the population, adjusted based upon the estimated risk score error;

S_h represents the standard deviation of risk score error for the h^{th} stratum;

$Prec$ represents the desired precision level (for example, 10 percent, meaning a 10 percent margin of error in the estimated risk score); and

z -value is the z -value associated with the desired confidence level (for example, 1.96 for a two-sided 95 percent confidence level).

We are finalizing a sample size of 200 enrollees from each issuer for the initial 2 years of the program. The formula above will use real data from the HHS-operated risk adjustment program after this initial 2-year period to calculate a more precise, issuer-specific sample size for each issuer.

The formula for calculating the sample size for each stratum (n_h) is:

$$n_h = n \times \frac{N_h S_h}{\sum_{h=1}^H N_h S_h}$$

Where:

N_h is the population size of the h^{th} stratum;

n is the overall sample size; and

S_h represents the standard deviation of risk score error for the h^{th} stratum.

As we described in the proposed rule, for the 2014 benefit year, the parameters listed above were developed using data from two principal sources: Medicare Advantage risk adjustment data validation net error rates and variances; and expenditures data from the Truven Health Analytics 2010 MarketScan® Commercial Claims and Encounters database (MarketScan®). We chose to use Medicare Advantage error rates because Medicare Advantage utilizes an HCC-based methodology similar to the one used for HHS risk adjustment, and because it uses a similar risk adjustment data validation process to determine payment error rates.

We also chose to use the MarketScan® expenditure database because of the comprehensiveness of the database, which was the primary source for calibration for the HHS risk adjustment models. The database contains enrollee-specific claims utilization, expenditures, and enrollment across inpatient, outpatient, and prescription drug services from a selection of large employers and health plans. The database includes de-identified data from approximately 100 payers, and contains more than 500 million claims from insured employees, spouses, and dependents.

We used enrollee predicted expenditure results from our risk adjustment model calibration, which was based on the MarketScan® data, to stratify the population (by age group for enrollees with HCCs, and within a single group for enrollees with no HCCs), then calculated risk scores for the predicted expenditures to relate them to the average expenditures. To estimate a sample size for each issuer, an average issuer size was estimated based on the total expected insured population and the total expected number of issuers. The average issuer

population containing enrollees with and without HCCs was assumed to be split 20 percent with HCCs and 80 percent without HCCs, consistent with the MarketScan® data.

We will group each issuer's enrollee population into 10 strata based on age group, risk level, and presence of HCCs, as follows:

- Strata 1–3 will include low, medium, and high risk adults with the presence of at least one HCC.
- Strata 4–6 will include low, medium, and high risk children with the presence of at least one HCC.
- Strata 7–9 will include low, medium, and high risk infants with the presence of at least one HCC.
- Stratum 10 will include the No-HCC population, which will not be further stratified by age or risk level, because we assume this stratum has a uniformly low error rate.

We calculated a predicted risk score for each individual in each stratum by dividing the predicted expenditures for that individual by the average predicted expenditures for the entire population. Using these individual predicted risk scores, we calculated the overall average risk score for all individuals in each risk-based stratum. This calculation was performed nine times for the HCC population—once for each of the three risk-based strata within each of the three age groups. We set the minimum risk score for enrollees without HCCs in the tenth stratum.

This method of stratification is similar to that used in the Medicare Advantage risk adjustment data validation program, which divides enrollees into three strata, representing low, medium, and high risk expenditures. Error rates and variances are calculated for each of these strata. In the initial year, before error rate and standard deviation data for the population subject to the HHS-operated risk adjustment program are available, we will use the Medicare Advantage error rates and variances to calculate sample sizes. After the initial year, we will evaluate whether sufficient HHS-operated risk adjustment error rate and standard deviation data are available to calculate sample sizes.

We will use the lowest error rate across all HCC strata as the error rate for the stratum of enrollees without HCCs, and we will use the variance associated with that error rate to calculate the standard deviation of the error for the stratum of enrollees without HCCs. If error rates and variances are smaller than assumed for this stratum, the resulting sampling precision may increase.

Because the Medicare Advantage error rates and variances are not calculated

for different age bands, and therefore are available only for three risk-score differentiated subgroups, we will use the same risk score error rates and standard deviation for the age bands for a risk category. Thus, we will use the same risk score error rate and standard deviation assumptions for the adult, child, and infant strata associated with each risk score band. We do not anticipate the expected risk score error rate and variance to be uniform for all age groups; however, in the absence of data, we are making this simplifying assumption. In general, we believe the Medicare Advantage error rates and variances likely overstate the corresponding error rates and assumptions for the HHS risk adjusted population, and therefore, the estimated precision of our error estimates may be understated.

The formulas identified above require data on error rates and standard deviations for the strata, and also a target confidence interval and sampling precision level (or margin of error). For the initial year, as we proposed in the proposed rule, we are finalizing a 10 percent relative sampling precision at a two-sided 95 percent confidence level. That is, we wish to obtain a sample size such that 1.96^{20} multiplied by the standard error, divided by the estimated adjusted risk score, equals 10 percent or less. After actual data are collected from the initial year, we will test and evaluate the data for use in determining the sample size in future years.

Once the overall sample size is calculated, the enrollee count will be distributed among the population based on the second formula above for calculating the sample size of each stratum. Because strata with enrollees with HCCs have a higher standard deviation of risk score error, the overall sample will be disproportionately allocated to enrollees with HCCs (Strata 1–9), helping to ensure adequate coverage of the higher risk portion of the enrollee population.

When data becomes available from the program's first year, we expect to examine our sampling assumptions using actual enrollee data. We anticipate that in the initial 2 years of the risk adjustment data validation program, the stratification design will remain consistent with the design outlined above—nine HCC strata and one No-HCC stratum. However, the specific size and allocation of the sample to each stratum may be refined based on average issuer enrollee risk score distributions. For example, in future years, we are

²⁰ Critical value for the two-sided 95 percent confidence level.

considering using larger sample sizes for larger issuers or issuers with higher variability in their enrollee risk scores, and smaller sample sizes for smaller issuers or issuers with lower variability in their enrollee risk scores. The sampling design may also consist of a minimum and maximum sample size per stratum for each average issuer (large, medium, small) to follow when selecting the sample.

We are finalizing our sampling approach as proposed for the initial 2 years of risk adjustment data validation.

Comment: Several commenters supported reducing the sample size from 300 to 200 enrollees for the initial years of data validation. Commenters supported using sampling experience from the initial years to improve the sampling methodology and target issuer-specific sample sizes in 2016. Other commenters requested that HHS increase the sample size for larger issuers and decrease the sample size for smaller issuers. One commenter requested that we use a nationwide sample to assess error rates for multi-State carriers, while another commenter requested that we combine the risk pools to minimize issuer burden for sample selection. Some commenters did not support the smaller sample size, noting that questionable enrollment data in the initial years may result in erroneous risk scores. One commenter recommended that HHS use a statistically sound method to ensure that there is a proportionate representation of plan metal levels in each issuer sample.

Response: We will use our sampling experience in the initial years of data validation to evaluate how and if we can appropriately establish issuer-specific sample sizes, and whether our sample size is adequate. We believe that lowering the sample size from 300 to 200 will yield a statistically valid sample, while minimizing the burden on all issuers. We also clarify that the enrollee sample totals 200 enrollees per issuer across all risk pools, and not per plan. Our sampling methodology does not separate risk pools within an issuer.

Comment: Commenters generally supported our proposed strata. One commenter suggested that fewer than ten strata are necessary, while another commenter suggested that because our risk adjustment model is calibrated for a standard population, it has significantly lower predictive power when applied to a pediatric-only population.

Response: We believe that the ten strata are appropriate for the initial years of data validation, in order to ensure that the sample targets enrollees

with HCCs of varying ages and health statuses. We intend to use real data as it becomes available to improve our precision in error rate and variance estimation by age and health status.

(ii) Initial Validation Audit

The second stage of the HHS-operated risk adjustment data validation process is the initial validation audit. In this section, we discuss standards and guidelines regarding the qualifications of the initial validation auditor, including conflict of interest standards, standards for the initial validation audit, rater consistency and reliability, and confirmation of risk adjustment errors. As discussed in the white paper and the proposed rule, we considered existing best practices and standards for independent auditors, such as those of Medicare Quality Improvement Organizations and the National Committee for Quality Assurance, when establishing our standards for initial validation auditors.

(1) Initial Validation Auditor

The 2014 Payment Notice established certain standards for the initial validation auditor. In § 153.630(b)(2) and (b)(3), we directed the issuer to ensure that the initial validation auditor is reasonably capable of performing an initial validation audit, and is reasonably free of conflicts of interest, such that it is able to conduct the initial validation audit in an impartial manner with its impartiality not reasonably open to question.

In the white paper, we elaborated on potential options for ensuring that an initial validation auditor meets these criteria, including standardized auditor certification processes and promulgation of best practices. Many commenters sought additional information and guidance regarding initial validation auditor selection and requested that HHS define conflicts of interest between an issuer and the initial validation auditor. In the proposed rule, we proposed the following criteria for assessing conflicts of interest between the issuer and the initial validation auditor:

- Neither the issuer nor any member of its management team (or any member of the immediate family of such a member) may have any material financial or ownership interest in the initial validation auditor, such that the financial success of the initial validation auditor could be seen as materially affecting the financial success of the issuer or management team member (or immediate family member) and the impartiality of the initial validation audit process could reasonably be called

into question, or such that the issuer or management team member (or immediate family member) could be reasonably seen as having the ability to influence the decision-making of the initial validation auditor;

- Neither the initial validation auditor nor any member of its management team or data validation audit team (or any member of the immediate family of such a member) may have any material financial or ownership interest in the issuer, such that the financial success of the issuer could be reasonably seen as materially affecting the financial success of the initial validation auditor or management team or audit team member (or immediate family member) and the impartiality of the initial validation audit process could reasonably be called into question, or such that the initial validation auditor or management or audit team member (or immediate family member) could be seen as having the ability to influence the decision-making of the issuer;

- Owners, directors and officers of the issuer may not be owners, directors or officers of the initial validation auditor, and vice versa;

- Members of the data validation audit team of the initial validation auditor may not be married to, in a domestic partnership with, or otherwise be in the same immediate family as an owner, director, officer, or employee of the issuer; and

- The initial validation auditor may not have had a role in establishing any relevant internal controls of the issuer related to the risk adjustment data validation process when HHS is operating risk adjustment on behalf of a State, or serve in any capacity as an advisor to the issuer regarding the initial validation audit.

In addition, we stated in the proposed rule that we were considering establishing standards under which issuers must verify that no key individuals involved in supervising or performing the initial validation audit have been excluded from working with either the Medicare or Medicaid program, are on the OIG exclusion list or, to its knowledge, are under investigation with respect to any HHS programs.

We noted in the proposed rule that we intend to review the initial validation auditor's qualifications and relationship to the issuer to verify that the initial validation auditor is qualified to perform the audit, and that the issuer and initial validation auditor are free of actual or apparent conflicts of interest, including those stated above. We noted that HHS could gather information

through external reporting to support that review. Although we remain confident that most issuers will exercise diligence in selecting an initial validation auditor that will be able to comply with HHS audit standards, we intend to monitor the performance of initial validation auditors to determine whether certification or additional safeguards are necessary.

In the proposed rule, we proposed to amend § 153.630(b)(1) to specify that the issuer of a risk adjustment covered plan must provide HHS with the identity of the initial validation auditor, and must attest to the absence of conflicts of interest between the initial validation auditor (or the members of its audit team, owners, directors, officers, or employees) and the issuer (or its owners, directors, officers, or employees). We stated that we considered any individual with a significant ownership stake in an entity such that the individual could reasonably be seen to have the ability to influence the decision making of the entity to be an "owner," and considered any individual that serves on the governing board of an entity to be a "director" of the entity. We stated that we were contemplating beginning the initial validation process at the end of the first quarter of the year following the benefit year, with the issuer's submission of the initial validation auditor's identity. We stated that we expected to identify the enrollee sample for the initial validation audit in the summer of the year following the benefit year, and that we were contemplating requiring delivery of the initial validation audit findings to HHS in the fourth quarter of that year. We included a proposed schedule of the risk adjustment data validation process.

Once the audit sample is selected by HHS, we stated that we expect issuers to ensure that the initial validation audit is conducted in the following manner:

- The issuer would provide the initial validation auditor with source enrollment and source medical record documentation to validate issuer-submitted risk adjustment data for each sampled enrollee;

- The issuer and initial validation auditor would determine a timeline and information-transfer methodology that satisfies the data security and privacy requirements at § 153.630(f)(2), and enables the initial validation auditor to meet HHS established timelines;

- The initial validation auditor would validate the status of each enrollee in the sample in accordance with the standards established by HHS; and

- The initial validation auditor would provide HHS with the final results from

the initial validation audit and all requested information for the second validation audit.

We noted in the proposed rule that we did not propose amending § 153.630(f)(2), and that the issuer would be required to ensure that its initial validation auditor comply with the security standards described at §§ 164.308, 164.310, and 164.312 in connection with the initial validation audit.

We are finalizing these standards as proposed, with certain modifications in response to comments to § 153.630(b)(1). Where we had proposed requiring an attestation from the issuer as to the absence of conflicts of interest with the initial validation auditor on the part of the issuer, we are modifying the conflict of interest attestation requirement in § 153.630(b)(1) so that the issuer must attest to the absence of conflicts of interest with the initial validation auditor to its knowledge, following reasonable investigation. Similarly, where we had proposed requiring an attestation from the issuer as to the absence of conflicts of interest on the part of the initial validation auditor, we are modifying the attestation requirement so that the issuer may attest that it has obtained a representation from the initial validation auditor that to its knowledge, following reasonable investigation, there are no conflicts of interest. We are also including a standard under which an issuer must verify that no key individual involved in supervising or performing the initial validation audit appears on the Office of the Inspector General List of Excluded Individuals and Entities or, to the issuer's knowledge, are under investigation with respect to any HHS program.

Comment: One commenter recommended that HHS provide a pre-certified list of auditors to make it easier for issuers to select an independent entity to perform the initial data validation audit. Another commenter suggested that HHS maintain adequate staff to monitor the performance of issuers and their auditors. Commenters suggested that the initial validation auditor, rather than the issuer, certify that the entity meets the conflict of interest standards, since the issuer may be unaware of all potential conflicts. The commenters suggested that the initial validation auditor attest to an absence of conflict to both HHS and the issuer, and that the issuer attest to the absence of conflicts only on the issuer's side. Several commenters recommended that HHS require attestation of an absence of conflict of interest only from senior management teams of the issuer

and the auditor, and permit members of the initial validation audit team to simply disclose any potential conflicts for issuer evaluation, rather than categorically excluding an initial validation auditor. One commenter requested that HHS prohibit vendors that provide risk adjustment services from serving as initial validation auditors.

Response: We believe that members of the initial validation audit team should be subject to the same conflict-of-interest requirements as owners and directors. However, we agree with the commenters that the issuer may not be able to provide the full attestation proposed, and are finalizing a change in our policy in § 153.630(b)(1) so that the issuer is required to attest to the absence of conflicts of interest between the initial validation auditor (or the members of the audit team, owners, directors, officers, or employees) and the issuer (or its owners, directors, officers, or employees), to its knowledge following reasonable investigation, and must attest that it has obtained an equivalent representation from the initial validation auditor.

We do not intend to pre-certify auditors at this time. However, as stated elsewhere in the preamble to this rule, we intend to monitor the performance of initial validation auditors to determine whether additional certification or safeguards are necessary.

Comment: Several commenters suggested that HHS require the initial validation auditor to provide issuers, as well as HHS, with the results of the initial validation audit.

Response: Nothing in our rules prevents the issuer from requiring that the initial validation auditor provide it with the results of the initial validation audit.

(2) Standards for the Initial Validation Audit

In the proposed rule, we proposed that an initial validation audit review of enrollee health status be conducted by medical coders certified after examination by a nationally recognized accrediting agency for medical coding, such as the American Health Information Management Association (AHIMA) or the American Academy of Professional Coders (AAPC). We are finalizing this provision as proposed.

Comment: Several commenters supported requiring nationally accredited medical coders to review an enrollee's health status during an initial validation audit. One commenter recommended that the Practice Management Institute be considered a nationally recognized accrediting

agency for medical coding. Another commenter suggested that reviewers receive certification in the specialty area in which they work and by the appropriate specialized accrediting agency. Another commenter supported coding education and clinical training for medical coders, but suggested that HHS should consider other standards, if available, to enhance consistency among auditors.

Response: We will not recognize certification by the Practice Management Institute as certification by a nationally recognized accrediting agency because we do not believe this organization is nationally recognized for the rigor of its coding training and accreditation practices. By contrast, AHIMA and AAPC certification is intended for a broad group of health providers, issuers, and associated industry groups. At this time, while our risk adjustment data validation standards are relatively new, we will not require specialty certification, but we will consider additional standards in the future.

(3) Validation of Enrollees' Risk Scores

An enrollee's risk score is derived from demographic and health status factors, which requires the use of enrollee identifiable information. Thus, in the proposed rule we proposed to add paragraph (b)(6) to § 153.630, to require an issuer to provide the initial validation auditor and the second validation auditor with all relevant information on each sampled enrollee, including source enrollment documentation, claims and encounter data, and medical record documentation from providers of services to enrollees in the applicable sample without unreasonable delay and in a manner that reasonably assures confidentiality and security of data in transmission. We noted that existing privacy and security standards, such as standards under HIPAA and those detailed at § 153.630(f)(2), will apply. This information would be used to validate the enrollment, demographic, and health status data of each enrollee. Only source documentation for encounters with dates of services within the applicable benefit year would be considered relevant. This would require issuers to collect the appropriate enrollment and claims information from their own systems, as well as from all relevant providers (particularly with respect to medical record documentation). We noted that only a very small percentage of an issuer's records containing personally identifiable information (PII) would be made available to auditors as part of the

risk adjustment data validation process, and that similar transmissions are required today for data validation for the Medicare Advantage program. We also proposed to add paragraph (b)(7) to § 153.630, to describe the standards for validating an enrollee's risk score. Under paragraph (b)(7)(i), we proposed that the initial validation auditor would validate information by reviewing plan source enrollment documentation, such as the 834 transaction,²¹ which is the HIPAA-standard form used for plan benefit enrollment and maintenance transactions. These enrollment transactions reflect the data the issuer captured for an enrollee's age, name, sex, plan of enrollment, and enrollment periods in the plan. We noted that certain identifying information from these enrollment transactions would be used to ensure that the appropriate medical documentation has been provided. We are finalizing these standards as proposed, with the modification to § 153.630(b)(7)(i) that an enrollee's risk score must be validated through enrollment and demographic data in a manner to be determined by HHS. We have made this change because we are exploring an approach under which we would use an automated data validation process for the enrollment and demographic data. We believe that such an approach could lessen the burden of the data validation process on issuers. We will provide further guidance on this topic in the future. We stated in the proposed rule that the sample audit pool would consist of enrollees with and without risk adjustment eligible diagnoses within eligible dates of service. For each enrollee in the sample with risk adjustment HCCs, the initial validation auditor would validate diagnoses through a review of the relevant risk adjustment eligible medical records. We stated we would consider medical record documentation generated with respect to dates of service that occurred during the benefit year at issue to be relevant for these purposes. For enrollees without risk adjustment HCCs for whom the issuer has submitted a risk adjustment eligible claim or encounter, we would require the initial validation auditor to review all medical record documentation for those risk adjustment eligible claims or encounters, as

provided by the issuer, to determine if HCC diagnoses should be assigned for risk score calculation, provided that the documentation meets the requirements for the risk adjustment data validation audits. Documents used to validate all components of the risk score would be required to reflect dates of service during the applicable benefit year. In the initial years of the data validation program, we plan to accept certain supplemental documentation, such as health assessments, to support the risk adjustment diagnosis. We expect to provide additional details on acceptable supplemental documentation in future guidance.²²

Therefore, we proposed in § 153.630(b)(7)(ii) to require that the validation of enrollee health status (that is, the medical diagnoses) occur through medical record review, that the validation of medical records include a check that the records originate from the provider of the medical services, that they align with the dates of service for the medical diagnosis, and that they reflect permitted providers and services. For purposes of § 153.630, "medical record documentation" would mean: "clinical documentation of hospital inpatient or outpatient treatment or professional medical treatment from which enrollee health status is documented and related to accepted risk adjustment services that occurred during a specified period of time." Medical record documentation would be required to be generated in the course of a face-to-face or telehealth visit documented and authenticated by a permitted provider. We expect to provide additional guidance on telehealth services in future guidance.

In § 153.630(b)(7)(iii), we proposed that medical record review and abstraction be performed in accordance with industry standards for coding and reporting. Current industry standards are set forth in the *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9), or the *International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, 4th Edition* (ICD-10) guidelines for coding and reporting.

We are finalizing these standards as proposed, with the modification to § 153.630(b)(7)(i) discussed above.

Comment: One commenter requested that HHS specify documents other than

the "834" plan benefit and enrollment form that could be used to validate demographic data and enrollment information for risk adjustment validation when a plan is not part of a State Exchange. One commenter recommended that HHS adjust its audit standards to rely on medical conditions as described and substantiated in medical claims forms rather than medical records. Several commenters supported our proposal that medical records generated in the course of telehealth encounters be deemed acceptable for risk adjustment data validation, and asked HHS for additional guidance. However, another commenter stated that limiting medical record documentation to face-to-face encounters and telehealth visits would be too restrictive, because of the difficulty in obtaining medical records from providers from prior insurance plans.

Response: HHS will provide further guidance on appropriate sources of plan enrollment data. We believe that the original medical record provides the most complete information on which to assess whether a claim is eligible for risk adjustment. With respect to the challenge of obtaining prior medical documentation when an enrollee changes issuers, we note that the data validation documentation request process for each issuer will be specific to periods during which the issuer reported plan enrollment for the sampled enrollees.

Comment: One commenter stated that the proposed process does not provide adequate recourse for issuers to identify and correct legitimate errors in the provider's medical records. One commenter asked that HHS allow initial validation auditors to use analytic tools to help providers locate overlooked risk adjustment eligible claims.

Response: As part of medical record review, HHS expects that the initial validation auditor will provide the issuer with adequate time to submit accurate medical records from providers. HHS expects that any amendments to medical records will be made in the normal course of business and according to practice protocols. Although we defer to auditors to determine the appropriate tools for their analyses, we encourage issuers to be proactive in identifying risk adjustment eligible claims during the data collection period and, at the same time, to correct for claims identified during data collection that should not be included.

Comment: Another commenter expressed concern that medical

²¹ Issuers and State Exchanges use the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Benefit Enrollment and Maintenance (834), August 2006, ASC X12N/005010X220, as referenced in § 162.1502, or "834 form" to transmit and update enrollment and eligibility to HHS as often as daily but at least monthly. In Federal operations, HHS and the issuer exchange and update data via this same form.

²² See "HHS-Operated Data Collection Policy FAQ" for a discussion of chart review as an acceptable source of supplemental diagnosis codes. Available at: https://www.regap.info/uploads/library/HHS_OperatedDataCollectionPolicyFAQs_062613. Additional detail will be provided in future guidance.

providers may bear the financial burden of data validation audits.

Response: We appreciate that issuers may require more extensive access to provider medical documentation, and expect issuers and providers to negotiate suitable arrangements, as they do today under similar data validation processes.

(4) Confirmation of Risk Adjustment Errors

In the proposed rule, we noted that the data validation audit processes may identify various discrepancies, many of which will have no impact on an enrollee's risk score. For example, if a medical diagnosis underlying an enrollee's HCC was present on a claim but was not supported by medical record documentation, but the same HCC was supported by the medical record for a different diagnosis, no risk adjustment error would be assessed for the enrollee's HCC. However, if none of the medical record documentation supports a particular HCC diagnosis for an enrollee, we proposed that a risk adjustment error be assessed.

We stated that we consider a risk adjustment error to occur when a discrepancy uncovered in the data validation audit process results in a change to the enrollee's risk score. A risk adjustment error could result from incorrect demographic data, an unsupported HCC diagnosis, or a new HCC diagnosis identified during the medical record review. An unsupported HCC diagnosis could be the result of missing medical record documentation, medical record documentation that does not reflect the diagnosis, or invalid medical record documentation (such as an unauthenticated record or a record that does not meet risk adjustment data collection standards for the applicable benefit year).

We proposed in § 153.630(b)(7)(iv) that a senior reviewer be required to confirm any finding of a risk adjustment error. We proposed to define a senior reviewer as a medical coder certified by a nationally recognized accrediting agency who possesses at least 5 years of experience in medical coding.

Comment: Commenters supported requiring senior reviewers to confirm an enrollee risk adjustment error during the initial data validation audit. However, one commenter suggested increasing the experience required for a senior reviewer from 5 years to 7 years; a different commenter recommended that HHS require only 2 years of experience for the senior reviewer. The commenter said it may be difficult to find enough experienced coders. The commenter suggested permitting junior coders with

2 years of experience to act as senior reviewers for the first 2 years of auditing, after which they could obtain certification in their subject area.

Response: As we discussed in the proposed rule, we believe that once risk adjustment data validation is established, 5 years should be the minimum experience necessary for a senior coder, and that all coders should be certified. We believe that, in the long term, this standard appropriately balances the need to assure that senior coders are sufficiently experienced with the need to assure a reasonable supply of senior coders. However, we recognize that in the initial years of risk adjustment data validation, it may be difficult to find experienced coders. In recognition of this difficulty, and because we believe that by 2016, there will be a sufficient supply of coders with 5 years' experience, we are modifying this provision to permit coders who will have sufficient experience by 2016 to act as senior coders—thus, we provide that senior coders are required to have at least 3 years of experience for risk adjustment data validation for the 2014 and 2015 benefit years.

(5) Review Consistency and Reliability

Validation audits typically include methods of evaluating review consistency and reliability. We believe such processes help to ensure the integrity of the data validation process and strengthen the validity of audit results. In § 153.630(b)(8), we proposed that the initial validation auditor measure and report to the issuer and HHS its inter-rater reliability rates among its reviewers. Such processes measure the degree of agreement among reviewers. In the proposed rule, we set the threshold for the acceptable level of consistency among reviewers at 95 percent for both demographic and enrollment data review, and health status data review outcome. We proposed that reviews be performed using rater-to-standard procedures whereby reviews conducted by reviewers with extensive qualifications and credentials are used to establish testing thresholds or standards for consistency. We are amending § 153.630(b)(8) to provide that, for the initial years of risk adjustment data validation (the 2014 and 2015 benefit years), the initial validation auditor may meet an inter-rater reliability standard of 85 percent for validating review outcomes in accordance with the standards established by HHS.

(iii) Second Validation Audit

The initial validation audit will be followed by a second validation audit, which will be conducted by an auditor retained by HHS to verify the accuracy of the findings of the initial validation audit.

In the proposed rule, we proposed to select a subsample of the initial validation audit sample enrollees for review by the second validation auditor. The second validation auditor would perform the data validation audit of the enrollee subsample, adhering to the same audit standards applicable to the initial validation audit described above, but would only review enrollee information that was originally presented during the initial validation audit. In § 153.630(c), we established standards for issuers of risk adjustment covered plans related to HHS's second validation audit. In § 153.630(b)(4), we established that issuers must submit (or ensure that their initial validation auditor submits) data validation information, as specified by HHS, from their initial validation audit for each enrollee included in the initial validation sample. Issuers must transmit all information to HHS or its second validation auditor in a timeframe and manner to be determined by HHS. The second validation auditor would inform the issuer of error findings based on its review of enrollees in the second validation audit subsample. We will provide additional guidance on the manner and timeframe of these submissions in the future.

As discussed in the white paper and in the proposed rule, we would select the second validation audit small subsample using a sampling methodology that would allow for pair-wise means testing to establish a statistical difference between the initial and second validation audit results. If the pair-wise means test results were to suggest that the difference in enrollee results between the initial validation audit and second validation audit is not statistically significant, the initial validation audit error results would be used for error estimation and calculation of adjustments for plan average risk score. If the test results suggest a statistical difference, the second validation auditor would perform another validation audit on a larger subsample of the enrollees previously subject to the initial validation audit. The results from the second validation audit of the larger subsample would again be compared to the results of the initial validation audit using the pair-wise means test. Again, if no statistical difference were to be

found between the initial validation audit and the second validation audit conducted on the larger subsample, HHS would apply the initial validation audit error results for error estimation using all enrollees selected for the initial validation audit sample. However, if a statistical difference were to be found based on the second validation audit on the larger subsample, HHS would apply the second validation audit error results to modify the initial validation sample, which would be used for the error estimate and calculation of adjustments for the plan average risk score. We stated that we were considering using a 95 percent confidence interval for these pair-wise means tests.

As we discussed in the white paper and the proposed rule, we are considering ways to expedite the second validation audit and the subsequent appeals processes. One possibility would be to begin the second validation audit on those enrollees for which the initial validation audit is complete, even if the entire initial validation audit has not been completed.

We are finalizing the second validation audit approach as proposed.

Comment: Commenters stated that it is unclear how and when enrollees will be included in the expedited second validation audit. Commenters expressed concern that the expedited process would permit the initial validation auditor to review its simplest cases first, negating the benefit of additional time for discussion in an expedited second validation audit. One commenter suggested that it would not be realistic to begin the second validation audit in advance because of the time it would take for the health plan to gather the necessary medical documentation.

Response: We will take commenters' suggestions under consideration when we issue guidance on this process in the future.

(iv) Error Estimation

The fourth stage in the HHS risk adjustment data validation process is error estimation. Upon completion of the initial and second validation audits, HHS will derive an issuer-level risk score adjustment and confidence interval. This adjustment will be used to adjust the average risk score for each risk adjustment covered plan offered by the issuer. HHS intends to provide each

issuer with enrollee-level audit results and the error estimates.

In the proposed rule, we proposed to use a two-phase procedure to accept or correct the results of the initial validation audit based on the results of the second validation audit. In phase one, as described above, we would conduct a pair-wise statistical test for consistency between the initial validation and second validation audit results (as described above for second validation audits). In phase two, if we determine that the results of the two audits are inconsistent, we would adjust the initial validation audit results based on the second validation audit results. In the proposed rule, for phase two, we described two options for using second validation audit results to derive an estimate of an overall corrected risk score for each issuer.

Phase One: Consistency Test Between Initial and Second Validation Audit

In phase one, we proposed using a pair-wise statistical test to determine if the initial validation audit sample results should be adjusted using the results of the second validation audit. To illustrate the underlying statistical test, consider the following notations:

$\tilde{x}_i$ is the i th initial validation audit risk score observation in the second validation audit

sample of n_{sva} observations;

y_i is the i th second validation audit risk score observation in the second validation audit

sample of n_{sva} observations;

d_i is the difference between y_i and $\tilde{x}_i$ within the second validation audit sample;

$\bar{d}$ is the mean of all d_i observations within the second validation audit sample; and

s_d is the standard deviation of all d_i observations within the second validation audit sample.

Assume an issuer submits enrollment and claims data to its dedicated distributed data environment that are used to compute a set of "original" risk

scores. As required by the risk adjustment data validation process, the issuer engages an independent validation auditor, who reviews n_{iva}

enrollee records, as sampled by HHS, and validates the original enrollee risk scores.

From the n_{iva} enrollees in the initial validation audit sample, HHS would select a small second validation audit subsample of n_{sva} enrollees. For each second validation audit selected record, HHS calculates the difference, $d_i = y_i - x_i$. HHS would then conduct a pair-wise means test to determine whether the mean difference, $\bar{d}$, is statistically significant (that is, unlikely to be zero). Specifically, HHS would conduct a statistical test to determine if zero (0) is contained within the range, $\bar{d} \pm 1.96 \left(\frac{s_d}{\sqrt{n_{iva}}} \right)$. If so, HHS would conclude that there is no statistically significant difference between risk scores determined by the initial and second validation audit processes, and would accept the results of the initial validation audit.

However, if zero (0) is not contained within this range (that is, the difference between $\bar{d}$ and zero is statistically significant), HHS would expand the second validation audit subsample to select a larger subset of n_{iva} , have the second validation auditor review the enrollee files, and again conduct a pair-wise means test using this larger subsample. If the statistical test shows no statistically significant difference, HHS would accept the results of the initial validation audit. If the statistical test shows a statistically significant

difference between the initial validation audit and larger subsample second validation audit findings, HHS would conduct phase two to adjust the full initial validation audit sample based on the larger subsample second validation audit findings.

Phase Two: Adjustment to the Initial Validation Audit Sample

In phase two, if the difference between the initial and second validation audits is found to be statistically significant, HHS would utilize the risk score error rate

calculated from the larger second validation audit subsample to adjust the full initial validation audit sample, which could in turn be used to adjust the average risk scores for each plan. This approach would adjust the entire initial validation audit sample using a one-for-one replacement for the enrollees reviewed by the second validation audit, and a uniform adjustment for the enrollees that were not.

To illustrate this process, consider the following notations:

M is the total number of enrollees in the risk adjustment covered plans of the issuer;

n_{iva} is the initial validation audit sample size;

n_{sva} is the size of the larger second validation audit subsample;

$\bar{y}_{n_{iva}}$ is the mean of the initial validation audit-adjusted risk scores in the initial validation audit sample n_{iva} ;

$\bar{y}_{n_{sva}}$ is the mean of the second validation audit-adjusted risk scores in the second validation audit sample n_{sva} ;

$\bar{x}_{n_{iva}}$ is the mean of the original risk scores in the initial validation audit sample n_{iva} ;

$\bar{x}_{n_{sva}}$ is the mean of the original risk scores in the second validation audit sample n_{sva} ;

X_M is the original risk score total across all M records;

$\hat{Y}_{n_{iva}}$ is the projected correct risk score across all M records using the initial validation error rate; and

$$\hat{Y}_{n_{iva}} = \frac{\bar{y}_{n_{iva}}}{\bar{x}_{n_{iva}}} X_M$$

$\hat{P}_{n_{sva}}$ is the projected correct risk score across all M records using the error rate from the larger second validation audit subsample.

$$\hat{P}_{n_{sva}} = \frac{\bar{Y}_{n_{sva}}}{\bar{X}_{n_{sva}}} X_M$$

We would undertake the following steps to adjust the risk scores in the initial validation audit samples:

(1) Replace the initial validation audit-adjusted risk scores with the second validation audit-adjusted risk scores in the n_{sva} records that were sampled from n_{iva} (one-for-one risk score adjustment).

(2) Apply a uniform adjustment factor, $\frac{\hat{P}_{n_{sva}}}{\hat{P}_{n_{iva}}}$ to the initial validation audit-adjusted risk scores in the $(n_{iva}-n_{sva})$ records not reviewed by the second validation audit.

Comment: Commenters were supportive of using a pair-wise means test and a larger second validation audit subsample to adjust the initial validation audit sample. One commenter recommended that HHS clarify whether the larger second validation audit subsample will include the small second validation audit sample in the event the second validation audit includes the second, larger review.

Response: The larger subsample will not include the small second validation audit subsample if a larger second validation audit subsample is necessary. However, all enrollees in both the small second validation audit subsample and the larger second validation audit

subsample will be used for the pair-wise test and risk score adjustment, if applicable. We are finalizing this error estimation process as proposed.

Adjusted Risk Score Projections

The results of the initial or second validation audits will be used as the basis for projecting a corrected risk score for each issuer's population. The full initial validation audit sample of 200, whether the initial validation audit sample has been adjusted or not, will be used to calculate adjusted risk score projections. In the proposed rule, we proposed performing the projections described above on a stratum-by-stratum level, weighted to achieve an estimate of the corrected risk score for each issuer.

We proposed to use a stratified separate ratio estimator²³ to estimate the corrected average risk score for each issuer. To compute the stratified separate ratio estimator, HHS would first extrapolate the total correct risk score within each stratum, then sum the stratum-specific projected correct risk scores for all strata, with the total sum divided by the total enrollee count to arrive at the corrected average risk score. The projected risk score error would then be calculated as the difference between the recorded average risk score across the entire population and the point estimate.

The stratified separate ratio estimator of the total correct risk score would be calculated using the following equation:

²³ For a discussion of stratified separate ratio estimators, see Cochran, William G., *Sampling*

Techniques, third edition, John Wiley & Sons, 1977, at 164.

$$\hat{Y}_R = \sum_{h=1}^H \frac{\bar{y}_h}{\bar{x}_h} X_h$$

Where:

$\hat{Y}_R$ is used to estimate the correct total risk score;

$\bar{y}_h$ is the sample mean of the correct risk score in stratum h ;

$\bar{x}_h$ is the sample mean of the original risk score in stratum h ;

X_h is the total sum of the original risk score in stratum h ; and

H is the total number of strata.

$\hat{Y}_R$ would then be normalized by the enrollment count to derive a corrected average risk score for the issuer.

To estimate the variance of the point estimate, HHS would first estimate the variance within each stratum and then sum the stratum-specific variances for all strata. As noted above, the point estimate and variance of the point estimate would be calculated using the full initial validation audit sample of 200, whether the initial validation audit sample has been adjusted or not. The estimated variance of the stratified separate ratio estimate for the correct total risk score would be calculated as follows:

$$\text{Variance } (\hat{Y}_R) = \sum_{h=1}^H \left[\frac{N_h^2 \left(1 - \frac{n_h}{N_h} \right)}{n_h (n_h - 1)} \left(\sum_{i=1}^{n_h} y_{ih}^2 + \hat{R}_h^2 \sum_{i=1}^{n_h} x_{ih}^2 - 2 \hat{R}_h \sum_{i=1}^{n_h} y_{ih} x_{ih} \right) \right]$$

Where:

n_h is the number of enrollees sampled in stratum h ;

N_h is the population frequency in stratum h ;

y_{ih} is the corrected risk score for the i th sampled enrollee in stratum h ;

x_{ih} is the original risk score for the i th sampled enrollee in stratum h ; and

$$\hat{R}_h = \frac{\sum_{i=1}^{n_h} y_{ih}}{\sum_{i=1}^{n_h} x_{ih}}$$

The square root of the estimated variance is the standard error (SE).

We proposed to use the issuer's corrected average risk score to compute an adjustment factor, based on the ratio between the corrected average risk score and the original average risk score that could be applied to adjust plan average risk for all risk adjustment covered plans within the issuer. We considered two options for applying the adjustment factor. Under the first option, we considered directly applying an adjustment factor to all of the issuer's risk adjustment covered plans. Under the second option, we considered

applying this adjustment only if the corrected average risk score and the recorded average risk score are statistically different. We are finalizing the second option, under which a critical parameter of the statistical test is the target confidence interval, which determines the stringency of the test. In the proposed rule, we considered performing the statistical test at the 90, 95, or 99 percent confidence interval. As we noted in the proposed rule, the OIG performs certain similar data validation tests using a 90 percent confidence

interval, while the Medicare Advantage risk adjustment data validation program uses a 99 percent confidence interval.

We are finalizing our proposal to apply an adjustment factor only if the corrected average risk score and recorded risk score are statistically different, using a 95 percent confidence interval. We note that we will use this approach with a 95 percent confidence interval in the initial years of the risk adjustment data validation program but will consider using other error estimation approaches and statistical

tests as risk adjustment data becomes available. Among the approaches that we may consider for future years would be an approach under which risk scores would be corrected only if a statistically significant difference in risk scores was demonstrated, but a more pronounced risk score adjustment would be applied.

Comment: Commenters generally supported applying an adjustment factor only if the corrected average risk score and recorded risk score are statistically different. However, a few commenters supported using a 99 percent confidence interval instead of the proposed 95 percent confidence interval. One commenter recommended using both a 90 percent and a 95 percent confidence interval but having CMS retain the discretion whether to apply an adjustment factor if statistical difference is discovered under the 90 percent confidence interval but not the 95 percent confidence interval. One commenter also recommended that the risk scores for enrollees without HCCs only be adjusted upward, not downward, since enrollees without HCCs are assigned the lowest error rate from among enrollees with HCCs.

Response: We believe that a 99 percent confidence interval could lead to under correction of bias in risk scores, and therefore, are finalizing a 95 percent confidence interval. We believe that this lower confidence interval will encourage issuers to correct practices that may lead to errors in the data validation process. We note that the risk scores of enrollees without HCCs may be adjusted upward or downward based on the review of demographic and medical documentation. For example, if an enrollee's age was incorrectly recorded, validation of that data could change the enrollee risk score, even if the enrollee had no HCCs.

Error Estimation Example

To illustrate the corrected average risk score and error estimation process described above, assume that a sample of 200 enrollees is selected for initial validation audit review for a particular issuer. From this sample, assume that a subsample of 20 enrollees is selected for second validation audit review. Assume the issuer's average recorded population risk score is 1.60 and the projected correct population risk score from the sample of 200 is 1.40, with a two-sided 95 percent confidence interval of 1.30 to 1.50.

The first step in the error estimation process will determine if the initial validation audit results should be corrected based on the second validation audit review or accepted without adjustment. We will perform a

pair-wise means test to compare the projected risk scores for the sample of 200 enrollees and the subsample of 20 enrollees.

For this example, assume that the statistical test fails (that is, there is a statistically significant difference between the projected risk scores in the sample of 200 and the subsample of 20).²⁴ We will then select an expanded subsample from the original sample of 200 enrollees. Assume that the larger subsample is a sample of 80 enrollees. Following selection of the larger second validation audit subsample, we will perform the pair-wise means test again. Assume the test fails again (that is, the pair-wise means test shows a statistically significant difference in the projected risk scores between the initial validation audit and the second validation audit for the sample of 100 enrollees—by assumption, 20 from the first subsample and 80 from the second subsample—selected in the second data validation audit). We will conclude that the risk scores in the sample of 200 enrollees need to be adjusted based on the results of the second validation audit.

In the second step of error estimation, HHS will adjust the risk scores in the sample of 200 using a one-for-one replacement for the risk scores of the 100 enrollees reviewed by the second validation auditor, and a uniform adjustment for the other enrollees in the initial validation audit sample. The one-for-one replacement will replace the risk scores calculated based on initial validation audit findings, with the risk scores calculated based on the second validation audit findings for the 100 enrollees. The remaining 100 enrollees that were not included in the second validation audit subsample will be adjusted based on the ratio of two projections: (1) The projected correct population risk score using the second validation audit findings in the subsample of 100 (assume this projected risk score is 1.50, with a two-sided 95 percent confidence interval of 1.30 to 1.70); divided by (2) the projected correct population risk score using the initial validation audit findings for the sample of 200 enrollees (equal to 1.40 based on the assumption noted above). The adjustment ratio is equal to $1.07 = 1.50/1.40$. Therefore, the risk scores of the remaining 100 enrollees not included in the second validation audit subsample will be increased by 7 percent.

²⁴ If the test passes, then no adjustments would be made to the sample of 200, and the projected results from this sample would be used to adjust average plan liability risk scores.

At that point, the adjusted average risk score of the initial validation sample would be calculated to derive a projected correct population average risk score for the issuer that would be compared to the issuer's recorded average risk score. The plan average risk scores for the issuer would then be adjusted, based on the ratio between the corrected average risk score and the recorded average risk score, as described above, if the issuer's recorded average risk score and the projected correct average risk score are significantly different.

(v) Appeals

We anticipate that the risk adjustment data validation appeals process will occur annually, beginning in the spring of the year in which the error rate will be applied to adjust risk scores and affect risk adjustment payments and charges. Because we are not applying error rates to adjust payments and charges for the initial 2 years of the risk adjustment program, the first year for which error rates will be applied to payments and charges will be 2016. These error rates will be used as the basis for adjustments to the payment transfers for 2017, which will take place in spring 2018. We anticipate the appeals process will begin in the spring of 2018, prior to the 2017 payment transfers. We will provide additional guidance on the appeals process and schedule in future rulemaking.

Comment: Commenters supported beginning the appeals process with the 2016 payment year. They also recommended leveraging existing appeals processes where applicable and providing at least 60 days to file an appeal. We received comments recommending that the individual reviewing the appeal be an independent entity with an appropriate level of coding, medical documentation, and audit experience. One commenter also recommended that the scope of the appeals be expanded to include initial validation audit results.

Response: We will provide additional guidance on the appeals process and schedule in future rulemaking.

(vi) Payment Transfer Adjustments

Risk adjustment payment transfer amounts will be based on adjusted plan average risk scores. The data validation audits will be used to develop a risk score error adjustment for each issuer, as described above. Each issuer's risk score adjustment will be applied to adjust the plan average risk score for each of the issuer's risk adjustment covered plans. This adjustment will be applied on a prospective basis

beginning with the risk adjustment data for benefit year 2016 (that is, the adjustments would take effect in 2018, during payment transfers for 2017). Because an issuer's adjusted plan average risk score is normalized as part of the risk adjustment payment calculation, the effect of an issuer's risk score error adjustment will depend upon its magnitude and direction compared to the average risk score error adjustment and direction for the entire market.

We are considering reporting the following summary findings to issuers for the initial 2 years of the program:

- State- or market-wide error rates.
- Issuer error rates.
- Initial validation audit or error rates.
- Projected financial impact of the proposed risk adjustments, as determined by the initial and second validation auditors.

The 2-year interval before risk adjustment data validation adjustments are applied to risk scores and affect payments and charges will provide initial validation auditors and issuers the opportunity to reform existing processes prior to the implementation of HHS payment transfer adjustments for the 2016 benefit year. We believe that the reports described above will help issuers and initial validation auditors better understand the likely effects of the risk adjustment data validation program in States where HHS operates risk adjustment. We are finalizing these provisions as proposed.

Comment: Commenters requested that HHS provide issuers with reports of their risk scores, as well as market risk scores pre- and post-audit. Commenters also requested that HHS provide issuers with State and market-wide error rates, issuer error rates, initial validation audit error rates, and the projected financial impact of the proposed risk adjustment, as determined by auditors. One commenter requested that HHS publicly report issuer error rates both nationally and for each State for each issuer. Another commenter was opposed to the public reporting of issuer error rates and requested that they be provided individually to issuers.

Response: We plan to publicly report aggregate summaries at the State, market, and initial validation auditor level. However, we will assess whether to publicly report initial validation auditor-level results. We plan to provide issuer-specific reports to the issuer and the initial validation auditor. We will provide further details on the reports in future guidance.

(vii) Oversight

The second final Program Integrity Rule outlined selected oversight provisions related to the premium stabilization programs, such as maintenance of records, sanctions for failing to establish a dedicated distributed data environment, and the application of a default risk adjustment charge to issuers in the individual and small group markets that fail to provide data necessary for risk adjustment. We proposed expanding on these provisions to include oversight related to risk adjustment data validation when HHS operates risk adjustment on behalf of a State, and are now finalizing those proposals.

Section 153.620 provides that an issuer that offers risk adjustment covered plans must comply with any data validation requests by the State or HHS on behalf of the State, and that an issuer that offers risk adjustment covered plans must also maintain documents and records, whether paper, electronic, or in other media, sufficient to enable the evaluation of the issuer's compliance with applicable risk adjustment standards, and must make that evidence available upon request to HHS, OIG, the Comptroller General, or their designee, or in a State where the State is operating risk adjustment, the State or its designee to any such entity.

Based on our authority under section 1321(c)(2) of the Affordable Care Act, we proposed in § 153.630(b)(9) that, when HHS operates risk adjustment on behalf of a State, an issuer of a risk adjustment covered plan that does not engage an initial validation auditor within the timeframe specified by HHS of the year following the benefit year, or that otherwise does not arrange for a risk adjustment initial validation audit that complies with applicable regulations, may be subject to CMPs. We stated that we intend to apply the proposed sanction so that the level of the enforcement action would be proportional to the level of the violation. While we reserve the right to impose penalties up to the maximum amounts proposed in § 156.805(c), as a general principle, we would work collaboratively with issuers to address problems in conducting the risk adjustment data validation process. In our application of the sanction, we would take into account the totality of the issuer's circumstances, including such factors as an issuer's previous record (if any), the frequency and level of the violation, and any aggravating or mitigating circumstances. We stated that our intent is to encourage issuers to address non-compliance and not to

severely affect their business, especially where the issuer demonstrates good faith in monitoring compliance with applicable standards, identifies any suspected occurrences of non-compliance, and attempts to remedy any non-compliance.

We proposed in § 153.630(b)(10) to assign a default risk adjustment charge to an issuer that does not hire an initial validation auditor or that otherwise does not submit initial validation audit results that comply with the regulations in subpart G and subpart H of part 153. We stated that we were considering whether this charge should be the same as the default charge in § 153.740(b) for failure to comply with data requirements, should be based on a default error rate, or should be calculated based on some other methodology. We are finalizing a default risk adjustment charge that will be calculated in the manner provided for in § 153.740(b), which is discussed elsewhere in this final rule.

Issuers may request technical assistance from HHS at any stage of the risk adjustment data validation process. HHS may also offer such assistance directly if we become aware of technical issues arising at any time during the risk adjustment data validation process. We plan to provide further assistance and clarification around the risk adjustment data validation process through a range of vehicles, including additional guidance, training materials, webinars, or user group calls.

Based on the comments received, we are finalizing a default risk adjustment charge at § 153.630(b)(10) for issuers that do not conduct the initial validation audit.

Comment: Commenters agreed with our proposal to impose CMPs if issuers do not engage an auditor within the specified timeframe, do not otherwise arrange for an initial validation audit that complies with applicable regulations, or are repeatedly out of compliance with risk adjustment data validation requirements, including not providing the initial and second validation audit auditors with information. One commenter supported assigning the issuer the highest possible default error rate that guarantees additional charges as a percent of premium or reduced payments as a percent of premium. Another commenter recommended that HHS enforce the initial validation audit requirement with a significant penalty for issuers that do not conduct the initial validation audit, while imposing lesser penalties if the initial validation audit results are not submitted in a timely manner.

Response: We agree that penalties should correspond to the severity of an issuer's non-compliance. We also agree with the commenter who suggested that HHS enforce the initial validation audit requirement with a significant penalty such as the default risk adjustment charge for issuers that do not conduct the initial validation audit, while imposing CMPs if the initial validation audit results are not submitted in a timely manner. As we noted previously and in the proposed rule, we intend to apply any proposed sanction so that the enforcement action would be proportional to the level of the violation.

(viii) Data Security

We recognize that the risk adjustment data validation process outlined here will require the transmission of sensitive data and documents between an issuer and the initial and second validation auditors. HHS takes seriously the importance of safeguarding protected health information and PII. As outlined in the white paper and the proposed rule, we believe that it will be necessary to specify standards for safeguarding this information through proper information storage and transmission methods.

We note that § 153.630(f)(2) currently requires an issuer to ensure that it and its initial validation auditor comply with the HIPAA information security standards described at §§ 164.308, 164.310, and 164.312 (HIPAA Security Rule) in connection with the initial validation audit, the second validation audit, and any appeals. In addition to these requirements, we continue to consider defining standards and expectations that would apply to issuers and initial and second validation auditors pertaining to data security, management, and transmission. These standards could require systems to safeguard and encrypt data "at rest" and "in transit," and to authenticate identities of users. They could also prohibit auditors from using or disclosing the information they receive for any purpose other than the audit and oversight. Similar standards have been implemented under the Medicare Advantage risk adjustment data validation process. We will address these issues and the treatment of initial and second validation auditors under HIPAA in future rulemaking or guidance.

Comment: Several commenters stated that compliance with the current provisions of the HIPAA Security Rule by issuers and their auditors will effectively safeguard the transmission of sensitive data and documents between

the issuer and the initial and second validation auditors. One commenter recommended that HHS adopt additional data security standards. One commenter requested that HHS base data security standards on applicable Medicare Advantage risk adjustment data validation standards, with specific penalties for breaches.

Response: Because of the sensitive nature of the risk adjustment data validation data, we recognize that it is essential that HHS have in place the proper standards and safeguards to ensure data security and privacy protections. We are continuing to evaluate the sufficiency of the current HIPAA Security Rule provisions, as well as the potential effectiveness of requiring additional data security, management, and transmission safeguards, including penalties for breaches. We intend to clarify our data security approach in future rulemaking or guidance.

(ix) Implementation Timeline

For the 2014 benefit year, we expect to implement risk adjustment data validation activities in early 2015. Implementation activities will begin with issuers submitting the identity of their initial validation auditor to HHS in accordance with § 153.630(b)(1). In the spring of 2015, we intend to utilize the data submitted by issuers for risk adjustment payments and charges and apply the sampling methodology described above to select the audit sample for each issuer for the initial validation audit. During the same timeframe, we will train issuers and initial validation auditors on the risk adjustment data validation process and the applicable standards for performing the initial validation audit, which will begin in the summer of 2015. Once the initial validation audit has concluded in the fall of 2015, HHS will begin the second validation audit process, which will continue into 2016. Risk adjustment data validation implementation activities for the 2014 benefit year data will conclude in 2016 after distribution of HHS findings to issuers, processing of appeals, and estimation and reporting of final risk scores. Since the 2014 benefit year is the first year of implementation of risk adjustment data validation, we expect to report on lessons learned from these activities, and to use this information to improve the risk adjustment data validation process.

We expect that risk adjustment data validation implementation activities will follow a similar schedule for each subsequent benefit year. The 2016 benefit year will be the first year when

payments and charges are adjusted. Those adjustments will occur after the conclusion of risk adjustment data validation activities for the 2016 benefit year, in the summer of 2018.

Comment: Commenters supported the reporting of lessons learned from the initial year risk adjustment data validation activities. One commenter was concerned that the initial 2-year time period would be insufficient to analyze error rates or determine the appropriate sampling approach. Several commenters suggested that issuers would need to receive audit results more promptly to be able to improve their processes for the 2017 plan year. One commenter urged HHS to begin the risk adjustment data validation process as soon as possible.

Response: We believe that the initial 2 years of risk adjustment will be sufficient to analyze error rates, determine a more effective sampling approach, and allow issuers to gain experience with the risk adjustment data validation process in time for payment adjustments to occur for the 2016 benefit year. Though final results for the 2014 benefit year will not become available until 2016, we believe issuers should be able to adjust their 2017 processes in time.

e. HHS Audits of Issuers of Risk Adjustment Covered Plans

We proposed in § 153.620(c) that HHS or its designee may audit an issuer of a risk adjustment covered plan, when HHS operates risk adjustment on behalf of a State, to assess the issuer's compliance with the requirements of subparts G and H of 45 CFR part 153. The issuer would also be required to ensure that its relevant contractors, subcontractors, or agents cooperate with the audit. We noted that we anticipate conducting targeted audits of issuers of risk adjustment covered plans informed by, among other criteria and sources, the data provided to HHS through the dedicated distributed data environment and any previous history of noncompliance with these standards. These audits would focus on aspects of the risk adjustment program that are not validated through the risk adjustment data validation program, such as whether a plan was a risk adjustment covered plan.

We also proposed that if an audit results in a finding of material weakness or significant deficiency (as these terms are defined in GAAS issued by the American Institute of Certified Public Accountants, and Government Auditing Standards issued by the Government

Accountability Office (GAO)²⁵ with respect to compliance with any requirement of subparts G or H of 45 CFR part 153, the issuer would be required to: (i) Within 30 calendar days of the issuance of the final audit report, provide a written corrective action plan to HHS for approval; (ii) implement that corrective action plan; and (iii) provide to HHS written documentation of the corrective actions once taken. We proposed that if HHS determines as the result of an audit that the issuer of the risk adjustment covered plan was required to pay additional risk adjustment charges or received risk adjustment payments to which it was not entitled, we may require the issuer to pay such amounts to the Federal government.

We are finalizing the audit provisions as proposed.

Comment: One commenter asked that if an audit identifies repeated noncompliance with the risk adjustment standards and the issuer fails to correct such issues, including failing to implement a corrective action plan, the issuer should be subject to a default risk adjustment charge or CMPs.

Response: Under § 153.620(c), an issuer of a risk adjustment covered plan must provide and implement a corrective action plan to rectify any material weakness or significant deficiency identified by HHS through an audit. Enforcement remedies are provided with respect to the risk adjustment program under § 153.740 when an issuer of a risk adjustment covered plan fails to comply the data requirements in §§ 153.700 through 153.730 or §§ 153.610 through 153.630. Enforcement remedies may be available through other Federal statutes, such as the False Claims Act, as well. While § 153.620(c) does not provide specific remedies for the failure to implement a corrective action plan, we note that HHS will consider the totality of circumstances in assessing penalties for non-compliance with risk adjustment standards under § 153.740, including those that occur in connection with a corrective action plan.

Comment: One commenter suggested that when an audit results in issuers owing risk adjustment, reinsurance, or risk corridors charges, those funds should be paid into the applicable

program and, where applicable, distributed pro rata to issuers of eligible plans in the program. The commenter further suggested that any reinsurance deficiencies identified and rectified after the program has ended should be directed to the risk adjustment program.

Response: As we stated in the proposed rule, if HHS determines as the result of an audit that an entity or issuer was required to pay risk adjustment, reinsurance, or risk corridors charges, HHS has the authority to require the entity or issuer to pay such amounts to the Federal government. We will address the distribution of funding deficiencies, including those identified after a temporary program has ended, in future rulemaking.

Comment: We received a number of comments regarding audit protocols and procedures applicable to the premium stabilization programs. In order to minimize the number and scope of data requests that issuers must respond to, commenters encouraged HHS to identify data elements, sample sizes, and other aspects of the audits in advance, and to streamline and coordinate data requests, given the overlap in data elements supporting the premium stabilization programs and the MLR program. Commenters suggested centralized audits so that auditors can consolidate data requests and follow-up requests for information. Commenters also encouraged HHS to work with States, issuers, contributing entities, and other stakeholders in advance of issuing data requests for audits. Additionally, commenters encouraged HHS to provide significant lead time for data collection and submission, and suggested that HHS limit its audits to samples of data when possible and expand those sample audits only upon a finding of material non-compliance. Commenters also suggested that HHS limit issuer audits to one per year.

Response: As stated in the proposed rule, to reduce the burden on issuers and HHS, to the extent practical, we intend to coordinate any audits of issuers and contributing entities with related audits of Exchange financial programs and premium stabilization programs, in order to limit the number of potential audits that an organization would experience. We intend to provide further details on the audit program, including timelines, procedures, and substantive requirements, in future rulemaking and guidance. We will consider the comments we received to this proposed rule and further feedback from stakeholders to ensure that our audit program is transparent and effective.

Comment: Some commenters asked that HHS perform audits from a centralized location, with no on-site audits.

Response: While we reserve the right to conduct on-site audits, as noted above, we intend to provide further details on the audit program in future rulemaking and guidance.

f. State-Submitted Alternate Risk Adjustment Methodology

For 2015, we are recertifying the alternate risk adjustment methodology submitted by Massachusetts and certified in the 2014 Payment Notice (78 FR 15439–15452). We are not certifying any other alternate risk adjustment methodologies for 2015.

3. Provisions and Parameters for the Transitional Reinsurance Program

The Affordable Care Act directs that a transitional reinsurance program be established in each State to help stabilize premiums for coverage in the individual market from 2014 through 2016. In the 2014 Payment Notice, we expanded on and modified the standards set forth in subparts C and E of the Premium Stabilization Rule, and established the reinsurance payment parameters and a uniform contribution rate for the 2014 benefit year. In this final rule, we finalize provisions from the proposed rule, including: additional standards regarding reinsurance contributions, the 2015 reinsurance payment parameters and uniform contribution rate, modifications to the 2014 reinsurance payments parameters, and certain oversight provisions for the reinsurance program.

a. Major Medical Coverage

Section 1341(b)(3)(B)(i) of the Affordable Care Act states that “the contribution amount for each issuer [must] proportionally reflect each issuer’s fully insured commercial book of business for all major medical products . . .” To provide additional clarification for contributing entities, we proposed to define “major medical coverage” in § 153.20 to mean health coverage for a broad range of services and treatments provided in various settings that provides minimum value in accordance with § 156.145. We noted in the proposed rule that this definition of major medical coverage only applies for the purpose of determining reinsurance contributions under section 1341 of the Affordable Care Act.

We are finalizing this provision as proposed, with one modification—we are modifying the definition of major medical coverage to include a specific reference to catastrophic plans and

²⁵ See Government Auditing Standards (2011 Revision), available at: <http://www.gao.gov/yellowbook>. For public companies, the Public Company Accounting Oversight Board (PCAOB) sets audit standards. See <http://pcaobus.org/Standards/Auditing/Pages/default.aspx>. For non-public companies, the AICPA sets audit standards. See <http://www.aicpa.org/Research/Standards/AuditAttest/Pages/SAS.aspx>.

individual and small group market plans subject to actuarial value requirements under § 156.140.

Comment: Several commenters supported our proposed definition of major medical coverage, stating that the reference to minimum value is a reasonable method to provide a consistent definition for major medical coverage. Other commenters asked that we exclude the reference to minimum value and continue to classify fully insured major medical coverage as that which provides hospitalization and medical services, or retain the definition of major medical coverage as it was defined in the preamble to the 2014 Payment Notice (78 FR 15456). One commenter stated that coverage before 2014 was not evaluated for minimum value and retroactive testing would be difficult to implement, administratively burdensome, difficult to audit, and that this definition could exclude a fairly large population from reinsurance contributions. Another commenter suggested that minimum value is confusing because it is not a concept that generally applies to individual health coverage and is only relevant for determining whether employer-sponsored coverage provides minimum value. One commenter noted that because the safe harbor method of calculating minimum value has not yet been finalized, minimum value cannot yet be determined.

Response: We believe that codification of this definition of major medical coverage will help issuers and group health plans more accurately determine their reinsurance contribution obligations. As noted in the proposed rule, we believe that minimum value is a reasonable way to clarify the definition of major medical coverage and reduce uncertainty as to whether reinsurance contributions are required of certain unique plan arrangements. In addition, we believe that the concept of minimum value will be familiar to issuers and group health plans, and believe that the minimum value calculator will enable the calculation of minimum value with minimal burden, regardless of when the coverage was first offered. In the event that the minimum value calculator is unsuitable for use in determining whether a particular plan provides minimum value (and, therefore, major medical coverage), the contributing entity may seek certification by an actuary consistent with § 156.145(a)(3) to establish whether the plan provides minimum value.

Comment: One commenter asked that we include in the definition of major medical coverage any coverage subject

to the actuarial value requirements because this would eliminate the need for plans subject to actuarial value requirements to also calculate minimum value.

Response: We agree with the commenter that this additional clarification would be helpful to eliminate this unneeded complexity, and are therefore finalizing a definition of major medical coverage to include explicit references to catastrophic plans and individual and small group market plans subject to the actuarial value requirements under § 156.140. As noted in the proposed rule (78 FR 72340), the minimum value standards established under 45 CFR 156.145 deem any coverage that meets any of the levels of coverage requirements described in 45 CFR 156.140 to satisfy minimum value requirements. The levels of coverage, in turn, are determined through calculation of AV between 60 to 90 percent. As such, plans that meet the AV requirements in accordance with 45 CFR 156.140 would not need to also calculate minimum value. We further note that catastrophic plans, as well as coverage offered in the individual and small group markets that are subject to the Affordable Care Act AV requirements, would be considered part of a contributing entity's "commercial book of business." Therefore, contributing entities must make reinsurance contributions on behalf of their enrollees with catastrophic coverage, as well as individual market coverage and small group coverage subject to the AV requirements under 45 CFR 156.140, absent another exception in § 153.400.

Comment: One commenter suggested that HHS clarify that short-term limited duration insurance, which is excluded from the definition of "individual health insurance coverage" under section 2791(b)(5) of the PHS Act,²⁶ is not major medical coverage and is therefore not required to make reinsurance contributions.

Response: In general, section 1341(b)(3)(B)(i) of the Affordable Care Act requires reinsurance contributions for "major medical coverage" that is considered to be part of a "commercial book of business," absent an applicable exemption. We are interpreting the term "major medical coverage" solely in the context of the obligation under the Affordable Care Act to make reinsurance

contributions. The question of whether coverage is subject to the rules that apply to "individual health insurance coverage" is separate from the question of whether it is "major medical coverage" for purposes of reinsurance contributions.

As we noted in the preamble to the 2014 Payment Notice (78 FR 15456), for purposes of whether a reinsurance contribution is required, we interpret the term "major medical coverage" in terms of the scope and extent of the coverage offered, not in terms of what other Federal requirements may apply to the coverage. Specifically, in the 2014 Payment Notice, we indicated that we interpreted "major medical coverage" to be coverage of a wide range of services not limited in scope (for example, vision or dental coverage) or extent (for example, coverage with very low annual dollar limits). Therefore, reinsurance contributions would be required with respect to a contributing entity's enrollees in a short-term limited duration plan to the extent the plan provides "major medical coverage," as we have interpreted that term. In this final rule, we are adopting as final the language in proposed § 153.20 that sets forth a specific standard for implementing our interpretation of "major medical coverage," as set forth in the 2014 Payment Notice. Specifically, under § 153.20, coverage will be considered "major medical coverage" for reinsurance contribution purposes if it covers a wide range of services, is not limited in scope, and provides a level of coverage that meets the minimum value test under § 156.145. While we are finalizing this standard in this final rule, because it implements our interpretation of "major medical coverage" as set forth in the 2014 Payment Notice, this standard will be applied in determining a contributing entity's reinsurance contribution liability for the 2014, 2015, and 2016 benefit years.

We recognize that the non-standard features of a short-term limited duration plan may make the minimum value calculator unsuitable for use with the plan in determining whether the plan provides minimum value (and, therefore, "major medical coverage"). In such an event, the contributing entity may seek certification by an actuary consistent with § 156.145(a)(3) to establish whether the plan provides minimum value.

b. Self-Administered, Self-Insured Plans

Following comments submitted with respect to the 2014 Payment Notice and the proposed Program Integrity Rule, we proposed to modify the definition of a

²⁶ Section 2791(b)(5) of the PHS Act provides: "The term 'individual health insurance coverage' means health insurance coverage offered to individuals in the individual market, but does not include short-term limited duration insurance." Available at: http://www.nadp.org/Libraries/HCR_Documents/phsa027.sflb.ashx.

“contributing entity” for the 2015 and 2016 benefit years to exclude self-insured group health plans that do not use a third party administrator (TPA) in connection with the core administrative functions of claims processing or adjudication (including the management of internal appeals) or plan enrollment. The preamble to the proposed rule discussed how section 1341(b) of the Affordable Care Act can reasonably be interpreted in more than one way with respect to whether a self-insured, self-administered plan is a contributing entity. The proposed modification recognized that some self-insured group health plans, which we believe would generally not be considered to be using the core services of a TPA, may use third parties for ancillary administrative support, and we noted that we would consider these plans to be self-administered for purposes of the reinsurance program. For purposes of the definition of “contributing entity,” we proposed to consider a TPA to be, with respect to a self-insured group health plan, an entity that is not under common ownership or control with the self-insured group health plan or its sponsor that provides administrative functions to the self-insured group health plan in connection with the core administrative services noted above. We sought comment on this definition, and whether certain types of service providers should be considered a TPA for these purposes.

In addition, we sought comment on whether the core administrative functions are the appropriate criteria for this revised definition, and what other administrative functions, such as medical management services, provider network development, or other support tasks, should be considered in determining whether a self-insured group health plan uses a TPA. We also sought comment on whether certain benefits or services, such as pharmaceutical benefits or behavioral health benefits, or a *de minimis* or small percentage of all benefits and services, may be performed by an unaffiliated service provider, which benefits or services should be excluded, and how such a *de minimis* amount or small percentage should be measured.

We are finalizing the proposed definition of “contributing entity” as proposed, with minor modifications to permit the use of unrelated third parties for provider network development and related services, and to provide for a *de minimis* exception.

Comment: Some commenters agreed with the proposed exemption, and stated that it had adequate statutory support and also accurately reflected

Congressional intent. Some commenters urged an expanded exemption. Some commenters disagreed with the proposed exemption as not required or supported by the statute, inconsistent with HHS’s prior position on the issue, or not supported by a clear policy rationale.

Response: Section 1341(b)(1)(A) of the Affordable Care Act can reasonably be interpreted in more than one way with respect to the applicability of reinsurance contributions to self-insured, self-administered plans. After receipt of comments submitted in response to the 2014 Payment Notice and the proposed Program Integrity Rule, we reconsidered this issue. Following this in-depth review, our view is that the better reading of section 1341 is that a self-insured, self-administered plan should not be a contributing entity, but in order to avoid disruption to contributing entities, we proposed to retain the prior definition of contributing entity for the 2014 benefit year. Section 1341(b)(1)(A) of the Affordable Care Act states that health insurance issuers and TPAs on behalf of group health plans are required to make reinsurance contributions, but does not refer to self-insured, self-administered plans. The provision’s reference to group health plans administered by TPAs, coupled with the omission of self-insured, self-administered plans, supports the proposed exemption. We also note that section 1341 of the Affordable Care Act supports the distinction between self-insured, self-administered plans and self-insured plans that use a TPA, since sections 1341(b)(1) and (b)(3)(B)(i) specifically refer to self-insured plans with TPAs and are silent as to self-insured, self-administered plans. Further support for this reading is found under section 1341(b)(3)(B) of the Affordable Care Act and § 153.400(a)(1)(ii), which provide that reinsurance contributions are to reflect a “commercial book of business.” While a group health plan administered by a TPA would normally be considered part of a “commercial book of business,” a self-insured, self-administered plan would not normally be considered part of an entity’s “commercial book of business.” For the reasons set forth above, HHS is finalizing the proposed exemption, with certain modifications discussed below.

Comment: Some commenters stated that adopting the proposed exemption would set a precedent permitting other contributing entities to seek exemptions from reinsurance contributions. Several commenters stated that the proposed exemption inappropriately treats self-insured plans with TPAs differently

from self-insured, self-administered plans, and will inequitably shift reinsurance costs from self-insured, self-administered plans to self-insured plans with TPAs and health insurance issuers. Several commenters stated that the proposed exemption inappropriately favors “union plans.”

Response: Self-insured, self-administered plans are a unique subset of potential contributing entities. The proposed exemption is narrowly drawn so that only a self-insured plan that does not use a TPA to perform its claims processing, claims adjudication, and enrollment functions would qualify for the exemption. As discussed in the preamble to the proposed rule, section 1341 of the Affordable Care Act supports the distinction between self-insured, self-administered plans and self-insured plans that use a TPA, since sections 1341(b)(1)(A) and (b)(3)(A) of the Affordable Care Act specifically refer to self-insured plans with TPAs and are silent as to self-insured, self-administered plans. In addition, section 1341(b)(3)(B) of the Affordable Care Act and § 153.400(a)(1)(ii) provide that reinsurance contributions are to reflect a “commercial book of business.” A self-insured, self-administered plan is fundamentally different from a health insurance issuer as well as a self-insured plan that uses a TPA, in that an insured plan and a self-insured plan with a TPA both involve an external commercial entity (the issuer or the TPA, which may itself be an issuer or an issuer affiliate). There will be no shifting of costs for 2014 because the exemption for self-insured, self-administered plans will only apply to the 2015 and 2016 benefit years. Based on comments received, our understanding is that relatively few plans will be eligible for the exemption. In addition, reinsurance payments will decrease substantially for the 2015 and 2016 benefit years, so all contributing entities will be responsible for substantially lower contributions for those years.

Finally, any self-insured plan that does not use a TPA for the core administrative functions of claims processing, claims adjudication (including the management of internal appeals), or enrollment may claim the exemption for the 2015 and 2016 benefit years, irrespective of whether the plan is jointly sponsored by a union and an employer or any other type of employer.

Comment: Several commenters urged HHS to expand the exemption significantly. For example, a number of commenters stated that all self-insured plans should be exempt from reinsurance contributions, or that self-

insured plans that use non-issuer TPAs should be exempt. Additionally, some of the commenters stated that it was inappropriate to have a different definition of contributing entity for the 2014 benefit year, and that the proposed exemption should apply for all three benefit years. According to these commenters, there is adequate time for contributing entities to make the necessary adjustments, and consequently, the change would not be disruptive in the 2014 benefit year.

Response: For the reasons discussed above and in the preamble to the 2014 Payment Notice (78 FR 15455), all self-insured plans are not exempt from reinsurance contributions. HHS also does not believe it has the authority to differentiate between TPAs that are issuers or issuer affiliates and non-issuer TPAs for purposes of the exemption. This is because sections 1341(b)(1)(A) and (b)(3)(A) of the Affordable Care Act only refers to issuers and TPAs, and does not distinguish between issuer TPAs and non-issuer TPAs. Exempting only non-issuer TPAs would treat similarly situated TPAs that perform comparable services for similar clients differently solely because one TPA is an issuer or issuer affiliate. In addition, we continue to believe that making the proposed exemption effective for the 2014 benefit year at this late stage would be disruptive to plans and issuers that have already set contribution rates and premiums, and could upset settled estimates with respect to expected reinsurance payments and contribution obligations. Therefore, we are retaining the proposal that this exemption only apply for the 2015 and 2016 benefit years.

Comment: Some commenters agreed with the proposed exemption, including the core functions test for determining when a self-insured plan uses a TPA. Some commenters objected to the proposed core functions approach on the grounds that it lacked clarity, was ambiguous, overly complex, or took the wrong factors into account. Some commenters stated that the proposed test was too broad in that it would be too easy for self-insured plans that use outside service providers to be deemed to be using a TPA, with the result that very few plans would be able to claim the proposed exemption. Another commenter indicated that the core functions test was unclear, and that too many plans would be able to claim the exemption. Some commenters suggested other tests to ascertain when a self-insured plan is self-administered or uses a TPA. For example, some commenters suggested a test which looks to whether

a self-insured plan is using a third party for a “full complement” of administrative functions or all services in connection with administering the plan. Another commenter suggested that the proper test was whether a plan retains legal responsibility to adjudicate claims and decide appeals. Some commenters urged limiting the exclusion to self-insured plans that do not utilize the services of third parties in any way to facilitate or assist in the proper administration of the plan.

Response: After a thorough review of the comments, we are generally retaining the proposed core functions analysis as a reasonable and objective indicator of which self-insured plans should be properly classified as self-administered for the limited purpose of determining whether such plans are contributing entities for reinsurance contribution purposes. In response to comments, we are clarifying that a self-insured plan must retain responsibility for claims payment, claims adjudication (including internal appeals), and enrollment in order to be regarded as self-administered during the 2015 and 2016 benefit years. Thus, subject to the exceptions described below, if a self-insured plan uses a third party for claims payment, claims adjudication, or enrollment, it would not be treated as self-administered for purposes of reinsurance contributions during the 2015 and 2016 benefit years. As suggested in comments, we are adopting certain modifications to our proposal regarding such issues as leasing of networks and *de minimis* use of third party services.

Comment: In the preamble to the proposed rule, HHS sought comment as to whether any other administrative functions should be considered in determining whether a self-insured plan uses a TPA for core administrative functions, including medical management, provider network development, and other support tasks.

Numerous commenters noted that self-insured plans very rarely develop and manage their own provider networks, and typically “lease” such networks from issuers. In these arrangements, the self-insured plan pays a fee to the issuer (or other entity) for the use of its provider network. The issuer (or other entity) bears the costs of developing and maintaining the networks, and also “reprices” the self-insured plan’s claims to take into account provider discounts the issuer has negotiated with members of its network. These commenters suggested that a self-insured plan that leases a network should not lose self-

administered status for reinsurance contributions purposes.

Response: HHS agrees with the commenters’ suggestion, and is clarifying in regulation text that if a self-insured plan “leases” a network from an unrelated third party and also obtains provider network development, claims repricing, and similar services, the plan will not lose self-administered status as a result.

Comment: In the preamble to the proposed rule, HHS sought comment as to whether a self-insured plan may outsource specific services, such as those relating to pharmaceutical benefits, without losing self-administered status, or whether an unaffiliated service provider may provide a *de minimis* or small percentage of all services for the plan. Commenters requested that a self-insured, self-administered plan be able to obtain prescription drug benefits provided by a pharmacy benefits manager (PBM), as well as services from specialized vendors for behavioral health, vision/dental benefits, or benefits with respect to which Medicare is the primary provider. The commenters noted the prevalence of these arrangements in the market, and that some of the outsourced benefits are exempt from reinsurance contributions. Commenters were divided as to whether a self-insured plan should be permitted to receive a *de minimis* percentage of all benefits and services from an unrelated third party without the plan losing self-administered status.

Response: In response to comments, we are clarifying the following in regulation text. First, a self-insured plan may outsource core administrative functions (claims processing, claims adjudication, and enrollment services) to an unrelated third party such as a PBM without losing self-administered status, provided that the underlying benefits are pharmacy benefits or excepted benefits as defined by section 2791(c) of the PHS Act. We clarify that medical benefits, other than pharmacy benefits or excepted benefits, cannot be outsourced by a self-insured, self-administered plan if the plan wants to retain its exemption from the definition of contributing entity. For example, if a self-insured plan enters into a separate contract for more than a *de minimis* amount of services related to mental health or substance abuse benefits, this contractual arrangement would disqualify the plan from the exemption. We also clarify that a self-insured plan may outsource a *de minimis* amount of core administrative services for benefits other than excepted benefits or pharmacy benefits to an unrelated party.

For this purpose, we clarify that a *de minimis* amount means up to 5 percent, as measured by the amount of enrollment or claims processing transactions for non-pharmacy and non-excepted benefits which are outsourced, or by the value of the outsourced enrollment or claims processing transactions for non-pharmacy and non-excepted benefits (measured by the cost of the outsourced services compared to the sum of those costs plus the fully loaded costs—that is, including an appropriate share of indirect costs, such as fixed and overhead expenses—reasonably allocated, borne by the self-insured plan for such services).

Comment: In certain multiemployer funds, the fund may use an administrator for certain purposes that is an affiliate of certain, but not all, sponsors. Several commenters requested clarification that this structure would not result in the fund losing otherwise applicable self-administered status.

Response: We are clarifying that a service provider that is affiliated with one or more sponsors other than the sponsor that is the contributing entity in the context of a multiemployer fund will not be a TPA, and would therefore not lose its self-administered status for purposes of reinsurance contributions in the 2015 and 2016 benefit years.

Comment: One commenter asked that HHS clarify whether a self-insured plan or its TPA is a contributing entity that must make reinsurance contributions.

One commenter stated that any entity providing services to plans subject to reinsurance should be required to submit contributions for their benefits.

Response: As noted in the preamble of the 2014 Payment Notice (78 FR 15455), pursuant to the definition of a contributing entity in § 153.20, “a self-insured group health plan that is a contributing entity is responsible for the reinsurance contributions, although it may use a TPA or administrative services-only contractor for transfer of the reinsurance contributions.”

Comment: One commenter stated that exempting self-insured, self-administered plans from making reinsurance contributions would increase the 2015 contribution rate by \$3 for all other contributing entities, and exempting these health plans has an unfair impact on those remaining entities subject to reinsurance contributions.

Response: Because we expect few entities to qualify for it, we estimate that the exclusion of self-insured, self-administered plans will have a small effect on the 2015 uniform contribution rate.

c. Uniform Reinsurance Contribution Rate

(i) Uniform Reinsurance Contribution Rate for the 2015 Benefit Year

Section 153.220(c) requires HHS to publish in the annual HHS notice of

benefit and payment parameters the uniform reinsurance contribution rate for the upcoming benefit year. Section 1341(b)(3)(B)(iii) of the Affordable Care Act specifies that \$10 billion for reinsurance contributions are to be collected from contributing entities in 2014, \$6 billion in 2015, and \$4 billion in 2016 (reinsurance payment pool). Additionally, sections 1341(b)(3)(B)(iv) and 1341(b)(4)(B) of the Affordable Care Act direct that \$2 billion in funds are to be collected for contributions to the U.S. Treasury in 2014, \$2 billion in 2015, and \$1 billion in 2016. Finally, section 1341(b)(3)(B)(ii) of the Affordable Care Act allows for the collection of additional amounts for administrative expenses. Taken together, these three components make up the total dollar amount to be collected from contributing entities for each of the 3 years of the reinsurance program under the uniform reinsurance contribution rate.

As discussed in the 2014 Payment Notice (78 FR 15459), each year, the uniform reinsurance contribution rate will be calculated by dividing the sum of the three amounts (the reinsurance payment pool, the U.S. Treasury contribution, and administrative costs) by the estimated number of enrollees in plans that must make reinsurance contributions:

Uniform Reinsurance Contribution Rate

$$= \frac{\text{Reinsurance payment pool} + \text{Treasury contribution} + \text{Administrative costs}}{\text{Estimate of enrollees in plans required to make reinsurance contributions}}$$

We proposed collecting \$25.4 million for administrative expenses for the 2015 benefit year (or 0.4 percent of the \$6 billion to be dispersed). Therefore, the total amount to be collected would be approximately \$8.025 billion. Our estimate of the number of enrollees in plans that must make reinsurance contributions yields a 2015 annual per capita contribution rate of \$44, about \$3.67 per month. We are finalizing this contribution rate as proposed.

Comment: One commenter asked that HHS implement a two-tiered contribution rate, charging issuers more since they benefit from the program and self-insured group health plans less. Other commenters suggested that only issuers be required to make contributions allocated for the U.S. Treasury.

Response: The statute does not differentiate between the contribution amounts required from issuers and third party administrators on behalf of self-insured group health plans. As noted in the Premium Stabilization Rule (77 FR 17227), we are using a national, per capita contribution rate because it is a simpler approach that minimizes the administrative burden of collections.

(ii) Timing of Collection of Reinsurance Contributions

We proposed modifying our collection schedule for the reinsurance program, so that we collect the reinsurance contribution amounts for reinsurance payments and for administrative expenses earlier in the calendar year following the applicable benefit year, approximately in accordance with the schedule in

§ 153.405(c), but collect the reinsurance contribution amounts for payments to the U.S. Treasury in the last quarter of the calendar year following the applicable benefit year.

Under proposed § 153.405(c)(1), following submission of the annual enrollment count, HHS would notify a contributing entity of the reinsurance contribution amount allocated to reinsurance payments and administrative expenses to be paid for the applicable benefit year. If the enrollment count is timely submitted, HHS would notify the contributing entity by December of benefit year 2014, 2015, or 2016, as applicable. We note that, due to our desire to align the notification of reinsurance contributions due with our monthly payment and collections cycle, this schedule differs slightly from the schedule currently set

forth in § 153.405(c), which provides for notification by the later of 30 days of the submission of the annual enrollment count or by December 15. Under proposed § 153.405(c)(3), the contributing entity must remit this amount within 30 days after the date of the first notification.

The second installment covers the portion of the reinsurance contribution amount allocated to the payments for the U.S. Treasury to be paid for a benefit year. Under proposed § 153.405(c)(2), in the fourth quarter of the calendar year following the applicable benefit year, HHS would notify the contributing entity of the portion of the reinsurance contribution amount allocated for payments to the U.S. Treasury for the applicable benefit year. In accordance with proposed § 153.405(c)(3), a contributing entity would remit this amount within 30 days after the date of this second notification. We note that the contributing entity is required to submit an annual enrollment count only once for each benefit year under § 153.405(b), by not later than November 15th of the benefit year.

For the 2014 benefit year, of the \$63 annual per capita contribution rate, \$52.50 would be allocated towards reinsurance payments and administrative expenses, and \$10.50 towards payments to the U.S. Treasury. Therefore, if a contributing entity submits its enrollment count by November 15, 2014, a reinsurance contribution payment of \$52.50 per covered life would be invoiced in December 2014, and payable in January, 2015. Another reinsurance contribution payment of \$10.50 per covered life would be invoiced in the fourth quarter of 2015, and payable late in the fourth quarter of 2015. For the 2015 benefit year, the \$44 annual per capita contribution rate would be allocated \$33 towards reinsurance payments and administrative expenses, and \$11 towards payments to the U.S. Treasury. These amounts would similarly be payable in January 2016 and late in the fourth quarter of 2016, respectively.

In order to leave the MLR and risk corridors calculations unchanged, we clarified in the proposed rule that the two installment payments would be

included with 2014, 2015, and 2016 data, for purposes of the risk corridors and MLR reports due July 31, 2015, 2016, and 2017, respectively, despite the fact that the later installment would not have been paid at that time.

We are finalizing the bifurcated contribution collection schedule as discussed above.

Comment: Several commenters supported our proposal to collect reinsurance contributions via two collections. Many commenters supporting our proposal asked that contributing entities have the option to pay the entire contribution in one payment while other commenters asked that we return to one annual collection schedule, citing the increased administrative burden of making two collections. One commenter supporting the bifurcated collection schedule specifically supported our proposal that the full 2014 reinsurance contribution be included with 2014 MLR reporting, despite the fact that the second payment would not have occurred by the MLR reporting deadline.

Response: We recognize that the reinsurance collections provided for in the Affordable Care Act will result in substantial upfront payments from contributing entities for the reinsurance program. Therefore, in consideration of the comments received, we are finalizing our proposal to collect contributions via two payments. We will not permit contributing entities to choose between collection schedules for operational reasons.

Comment: One commenter expressed concern that the bifurcation of the collection of the 2014 contribution rate of \$63 per enrollee would not evenly divide into a per enrollee per month charge when split into payments of \$52.50 and \$10.50. The commenter suggested that we revise the 2014 contribution rate to require \$52.44 in the first payment (\$4.37 per enrollee per month) and \$10.56 in the second payment (\$0.88 per enrollee per month).

Response: We do not believe it is necessary that the contribution amounts divide evenly into a per enrollee per month charge and further note that certain of the permitted counting methods set forth in 45 CFR 153.405

will yield fractional enrollment counts, whether tallied at the annual or monthly level.

Comment: One commenter sought clarification on when HHS would invoice contributing entities if enrollment counts are submitted by November 15th of the applicable benefit year pursuant to § 153.405(b). The commenter asked that HHS invoice contributing entities by December 1st.

Response: As noted in the proposed rule, if a contributing entity submits its enrollment count for the 2014 benefit year by November 15, 2014, a reinsurance contribution payment of \$52.50 per covered life would be invoiced in December 2014, and payable in January, 2015. We anticipate that these invoices will align with our monthly payment and collections schedule. We will provide more specific timelines in future guidance.

Comment: One commenter asked that HHS defer the collection of contributions allocated to the U.S. Treasury until 2016.

Response: Sections 1341(b)(3)(B)(iv) and 1341(b)(4)(B) of the Affordable Care Act specify \$2 billion in funds are to be collected for contributions to the U.S. Treasury in 2014, \$2 billion in 2015, and \$1 billion in 2016. As noted in the 2014 Payment Notice (78 FR 15460), we do not believe HHS has authority under the statute to defer this collection.

(iii) Allocation of Uniform Reinsurance Contribution Rate

Section 153.220(c) provides that HHS is to set in the annual HHS notice of benefit and payment parameters for the applicable benefit year the proportion of contributions collected under the uniform reinsurance contribution rate to be allocated to reinsurance payments, payments to the U.S. Treasury, and administrative expenses. In the 2014 Payment Notice (78 FR 15460), we stated that reinsurance contributions collected for 2014 will be allocated pro rata to the reinsurance pool, administrative expenses, and the U.S. Treasury, up to \$12.02 billion. Similar to the pro rata approach set forth in the 2014 Payment Notice, in Table 2, we specify the proportions for 2015 (or amounts, as applicable):

TABLE 2—PROPORTION OF REINSURANCE CONTRIBUTIONS COLLECTED UNDER THE UNIFORM REINSURANCE CONTRIBUTION RATE FOR THE 2015 BENEFIT YEAR FOR REINSURANCE PAYMENTS, PAYMENTS TO THE U.S. TREASURY, AND ADMINISTRATIVE EXPENSES

	If total contribution collections under the uniform reinsurance contribution rate are less than or equal to \$8.025 billion	If total contribution collections under the uniform reinsurance contribution rate are more than \$8.025 billion
Proportion or amount for:		
Reinsurance payments	74.8 percent (\$6 billion/\$8.025 billion).	The difference between total collections and those contributions allocated to the U.S. Treasury and administrative expenses.
Payments to the U.S. Treasury	24.9 percent (\$2 billion/\$8.025 billion).	\$2 billion.
Administrative expenses	0.3 percent (\$25.4 million/\$8.025 billion).	\$25.4 million.

As shown in Table 2, if the total amount of contributions collected is less than or equal to \$8.025 billion, we will allocate approximately 74.8 percent of the reinsurance contributions collected to reinsurance payments, 24.9 percent of the reinsurance contributions collected to the U.S. Treasury, and 0.3 percent of the reinsurance contributions collected to administrative expenses.

To provide that all reinsurance contributions collected for a benefit year are paid out for claims for that benefit year, we proposed to amend § 153.230(d) to provide that if HHS determines that the amount of all reinsurance payments requested under the uniform payment parameters from all reinsurance-eligible plans in all States for a benefit year will not be equal to the amount of all reinsurance contributions collected for reinsurance payments under the uniform contribution rate in all States for an applicable benefit year, HHS will determine a uniform pro rata adjustment (up or down) to be applied to all such requests for reinsurance payments for all States. We proposed that each applicable reinsurance entity, or HHS on behalf of a State, reduce or increase the reinsurance payment amounts for the applicable benefit year by any adjustment required under that paragraph.

We sought comment on the proposal to use excess funds in a current benefit year, including whether any excess collections should be allocated to increasing coinsurance rates above 100 percent, or whether such funds should be used instead to change other reinsurance parameters, or used for future benefit years.

Because our proposed changes noted above would provide that all reinsurance contributions collected for a benefit year are paid out for claims for that benefit year, we proposed to delete and reserve § 153.235(b), which currently provides that any excess reinsurance contributions collected from contributing entities for any benefit year but unused for the applicable benefit year *must* be used for reinsurance payments in subsequent benefit years. We are finalizing our proposal to use excess contributions for reinsurance payments for the current benefit year by increasing the coinsurance rate up to 100 percent before rolling over any remaining funds to the next year. Therefore, we are not finalizing our proposal to delete and reserve § 153.235(b). We are finalizing our modification to § 153.230(d) to provide that if HHS determines that the amount of reinsurance payments requested under the uniform payment parameters will not be equal the amount of reinsurance contributions collected for reinsurance payments, HHS will determine a uniform adjustment (up or down) to be applied to all requests for reinsurance payments.

Comment: Some commenters supported our proposal to use excess funds in the current benefit year. Others asked that we roll over excess funds to potentially lower the contribution rate in future benefit years, or that excess funds be refunded to contributing entities. Some commenters who supported the use of excess funds in the current benefit year suggested that we only increase the coinsurance rate up to 100 percent and then roll over any additional funds to a subsequent benefit year, in order to avoid perverse

incentives to incur claims costs. One commenter supported increasing the coinsurance rate above 100 percent.

Response: We are finalizing our proposal to use excess reinsurance contributions for reinsurance payments in the current benefit year by increasing the coinsurance rate up to 100 percent before rolling over any remaining funds to the next year. We believe that a 100 percent ceiling on the coinsurance rate is appropriate, and will permit us to increase reinsurance payments in subsequent years if we collect more in contributions than are requested in payments.

(iv) Administrative Expenses

In the 2014 Payment Notice (78 FR 15460), we estimated that the Federal administrative expenses of operating the reinsurance program would be \$20.3 million, based on our estimated contract and operational costs. We proposed to use the same methodology to estimate the administrative expenses for the 2015 benefit year. These estimated costs would cover the costs related to contracts for developing the uniform reinsurance payment parameters and the uniform reinsurance contribution rate, collecting reinsurance contributions, making reinsurance payments, and conducting account management, data collection, program integrity and audit functions, operational and fraud analytics, training for entities involved in the reinsurance program, and general operational support. We proposed to exclude from these administrative expenses the costs associated with work performed by Federal personnel. To calculate our proposed reinsurance administrative expenses for the 2015 benefit year, we

divided HHS's projected total costs for administering the reinsurance programs on behalf of States by the expected number of covered lives for which reinsurance contributions are to be made for the 2015 benefit year.

We estimated this amount to be approximately \$25.4 million for the 2015 benefit year. The 2015 estimate has increased from the 2014 estimate because we will be making reinsurance payments in 2015 for the 2014 benefit year, and as discussed below, will engage in program integrity and audit-related activity in 2015 to oversee the reinsurance program. We believe that this figure reflects the Federal government's significant economies of scale, which helps to decrease the costs

associated with operating the reinsurance program. Based on our estimate of covered lives for which reinsurance contributions are to be made for the 2015 benefit year, we proposed a uniform reinsurance contribution rate of \$0.14 annually per capita for HHS administrative expenses. We provide details below on the methodology we used to develop the 2015 enrollment estimates.

For the 2014 benefit year, we allocated the administrative expenses equally between contribution and payment-related activities. Because we anticipate that our additional activities in the 2015 benefit year, including our program integrity and audit activities, will also be divided approximately

equally between contribution and payment-related activities, we again proposed to allocate the total administrative expenses equally between these two functions. Therefore, as shown in Table 3, we will apportion the annual per capita amount of \$0.14 of administrative expenses as follows: (a) \$0.07 of the total amount collected per capita for administrative expenses for the collection of contributions from health insurance issuers and group health plans; and (b) \$0.07 of the total amount collected per capita for administrative expenses for reinsurance payment activities, supporting the administration of payments to issuers of reinsurance-eligible plans.

TABLE 3—BREAKDOWN OF ADMINISTRATIVE EXPENSES

[Annual, per capita]

Activities	Estimated expenses
Collecting reinsurance contributions from health insurance issuers and group health plans	\$0.07
Calculation and disbursement of reinsurance payments	0.07
Total annual per capita expenses for HHS to perform all reinsurance functions	0.14

If HHS operates the reinsurance program on behalf of a State, HHS will retain the annual per capita fee to fund HHS's performance of all reinsurance functions, which would be \$0.14. If a State establishes its own reinsurance program, HHS will transfer \$0.07 of the per capita administrative fee to the State for purposes of administrative expenses incurred in making reinsurance payments, and retain the remaining \$0.07 to offset the costs of collecting contributions. We note that the administrative expenses for reinsurance payments will be distributed to those States that operate their own reinsurance program in proportion to the State-by-State total requests for reinsurance payments made under the uniform reinsurance payment parameters. We received no comments on our proposed 2015 administrative expenses and are finalizing this provision as proposed.

d. Uniform Reinsurance Payment Parameters for 2015

Section 1341(b)(2)(B) of the Affordable Care Act directs the Secretary, in establishing standards for the transitional reinsurance program, to include a formula for determining the amount of reinsurance payments to be made to issuers for high-risk individuals that provides for the equitable allocation of funds. In the Premium Stabilization Rule (77 FR 17228), we provided that reinsurance payments to eligible issuers

will be made for a portion of an enrollee's claims costs paid by the issuer (the coinsurance rate) that exceeds an attachment point (when reinsurance would begin), subject to a reinsurance cap (when the reinsurance program stops paying claims for a high-cost individual). The coinsurance rate, attachment point, and reinsurance cap together constitute the uniform reinsurance payment parameters.

Given the smaller pool of reinsurance contributions to be collected for the 2015 benefit year, as directed by the statute, we proposed that the 2015 uniform reinsurance payment parameters be established at an attachment point of \$70,000, a reinsurance cap of \$250,000, and a coinsurance rate of 50 percent. We estimate that these uniform reinsurance payment parameters will result in total requests for reinsurance payments of approximately \$6 billion for the 2015 benefit year.

As discussed in the 2014 Payment Notice (78 FR 15461), to assist with the development of the uniform reinsurance payment parameters and the premium adjustment percentage index, HHS developed the Affordable Care Act Health Insurance Model (ACAHiM). The ACAHiM estimates market enrollment, incorporating the effects of State and Federal policy choices, and accounting for the behavior of individuals and employers. The outputs of the ACAHiM, especially the estimated enrollment and

expenditure distributions, were used to analyze a number of policy choices relating to the proposed 2015 reinsurance contribution rate and 2015 uniform reinsurance payment parameters.

The ACAHiM generates a range of national and State-level outputs for 2015, including the level and composition of enrollment across markets given the eligible population in each State. The ACAHiM is described below in two sections: (1) The approach for estimating 2015 enrollment; and (2) the approach for estimating 2015 expenditures. The ACAHiM uses recent Current Population Survey (CPS) data adjusted for small populations at the State level, exclusion of undocumented immigrants, and population growth in 2015 to assign individuals to the various coverage markets.

Specifically, the ACAHiM assigns each individual to a single health insurance market as his or her baseline (pre-Affordable Care Act) insurance status. In addition to assuming that individuals currently enrolled in Medicare, TRICARE, or Medicaid will remain in such coverage, the ACAHiM takes into account the probability that a firm will offer employment-based coverage based on the CPS distribution of coverage offers for firms of a similar size and industry. Generally, to determine the predicted insurance enrollment status for an individual or family (the "health insurance unit" or

“HIU”), the ACAHIM calculates the probability that the firm will offer insurance, then models Medicaid eligibility, and finally models eligibility for advance payments of the premium tax credit and cost-sharing reductions under the Exchange. Whenever a transition to another coverage market is possible, the ACAHIM takes into account the costs and benefits of the decision for the HIU and assigns a higher probability of transition to those with the greatest benefit. The ACAHIM assumptions of the rate at which uninsured individuals will take-up individual market coverage are based on current take-up rates of insurance across States, varied by demographics and incomes and adjusted for post-Affordable Care Act provisions, such as advance payments of the premium tax credit and cost-sharing reductions.

Estimated expenditure distributions from the ACAHIM are used to set the uniform reinsurance payment parameters so that estimated contributions from all contributing entities equal estimated payments for all reinsurance-eligible plans. The ACAHIM uses the Health Intelligence Company, LLC (HIC) database from calendar year 2010, with the claims data trended to 2015 to estimate total medical expenditures per enrollee by age, gender, and area of residence. The expenditure distributions are further adjusted to take into account plan benefit design, or “metal” level (that is, “level of coverage,” as defined in § 156.20) and other characteristics of individual insurance coverage in an Exchange. To describe a State’s coverage market, the ACAHIM computes the pattern of enrollment using the model’s predicted number and composition of participants in a coverage market. These estimated expenditure distributions were the basis for the uniform reinsurance payment parameters. We are finalizing the 2015 reinsurance payment parameters as proposed.

Comment: Some commenters suggested that HHS keep the reinsurance payment parameters consistent between 2014 and 2015, and delay increasing the attachment point to \$70,000 and decreasing the coinsurance rate to 50 percent until 2016, or keep the 2014 and 2015 attachment points as close as possible. One commenter asked HHS to increase the contribution rate to account for increased costs during 2014 and 2015. Other commenters supported lowering the 2015 contribution rate and uniform reinsurance payment parameters.

Response: Section 1341(b)(3)(B)(iii) of the Affordable Care Act directs HHS to collect \$6 billion for reinsurance

payments in 2015. This is \$4 billion less than will be collected in 2014 for reinsurance payments. We believe that the lower coinsurance rate and higher attachment point we have proposed appropriately accounts for this smaller reinsurance payment pool. We also believe that maintaining the reinsurance cap for the 2015 benefit year will make it easier for issuers to estimate the effects of reinsurance, and reduce interference with the traditional commercial reinsurance market. As discussed above, to the extent that reinsurance contributions for 2015 exceed reinsurance payments requested, our policy of increasing the coinsurance rate up to 100 percent will help assure that the excess contributions are used to offset claims for high-cost individual market enrollees.

e. Adjustment Options

In the 2014 Payment Notice, we finalized the following uniform reinsurance payment parameters for the 2014 benefit year—a \$60,000 attachment point, a \$250,000 reinsurance cap, and an 80 percent coinsurance rate. However, updated information, including the actual premiums for reinsurance-eligible plans, as well as recent policy changes, suggest that our prior estimates of the uniform reinsurance payment parameters overestimated the total covered claims costs of individuals enrolled in reinsurance-eligible plans in 2014. To account for this, we proposed to decrease the 2014 attachment point to \$45,000. We are finalizing our proposal to decrease the 2014 attachment point to \$45,000.

Comment: Several commenters asked that HHS consider alternative relief for the transitional policy announced on November 14, 2013²⁷ that does not increase the burden on large employers and self-insured group health plans.

Response: The lowering of the 2014 attachment point will not result in additional contributions being collected from contributing entities. As noted in the proposed rule, we believe that our prior estimates of the 2014 uniform payment parameters overestimated the total covered claims costs of individuals enrolled in reinsurance-eligible plans in 2014, allowing these additional payments to be made from within the amount already being collected.

Comment: Several commenters supported lowering the 2014 attachment point to \$45,000. One commenter

suggested lowering the attachment point to \$20,000. Other commenters opposed lowering the attachment point, asking that HHS return to the finalized 2014 payment parameters, and urging that any excess funds should be rolled over to the subsequent benefit year and used to lower the contribution rate for all contributing entities. Some commenters who objected to the lowering of the attachment point stated that HHS should instead increase the reinsurance cap to \$500,000 to reimburse issuers for larger claims costs.

Response: As discussed above, the ACAHIM, which estimates market enrollment, incorporates the effects of State and Federal policy choices and accounts for the behavior of individuals and employers. These assumptions and projections, as well as the transitional policy announced in November 2013, resulted in an updated estimate of the 2014 individual and employer-sponsored insurance markets and expenditures, and permitted us to update our estimate of the 2014 uniform reinsurance payment parameters. We believe that lowering the attachment point to \$45,000 would allow the reinsurance program to make more payments for high-cost enrollees without increasing the contribution rate. We are not increasing the reinsurance cap to avoid interfering with traditional commercial reinsurance, which typically has attachment points in the \$250,000 range.

Comment: One commenter asked that the proposed modifications to the reinsurance program for the transitional policy be applied consistently in all States.

Response: These modifications will be applied consistently in all States.

f. Reinsurance-Eligible Plans

In this final rule, we clarify that in accordance with the policy established in the 2014 Payment Notice, student health plans are not eligible to receive reinsurance payments. Under § 147.145(b)(3), student health plans are not subject to the single risk pool requirement of section 1312(c) of the Affordable Care Act and § 156.80. Under § 153.234, a reinsurance-eligible plan’s covered claims costs for an enrollee incurred prior to the application of the following provisions do not count towards either the uniform reinsurance payment parameters or the State supplemental reinsurance payment parameters: § 147.102 (fair premiums); § 147.104 (guaranteed availability); § 147.106 (guaranteed renewability); § 156.80 (single risk pool); and subpart B of part 156 (essential health benefits). However, we note that a student health

²⁷ Letter to Insurance Commissioners, Center for Consumer Information and Insurance Oversight, November 14, 2013. Available at: <http://www.cms.gov/CCIIO/Resources/Letters/Downloads/commissioner-letter-11-14-2013.PDF>.

plan would be considered part of a contributing entity's "commercial book of business" and, to the extent that the plan provides major medical coverage, as defined in § 153.20, a contributing entity must make reinsurance contributions on behalf of their enrollees, absent another exception in § 153.400.

In response to this proposed rule, we received several comments asking that certain plans or coverage be eligible for reinsurance payments.

Comment: Several commenters requested that we permit State high-risk pools to be eligible for reinsurance payments for their high-risk enrollees. One commenter asked that the Federal government extend the Federal high-risk pool until all funds are depleted.

Response: As stated in the 2014 Payment Notice (78 FR 15455), under the definition of a reinsurance-eligible plan at § 153.20, State high-risk pools are not eligible to receive reinsurance payments for their enrollees because high risk pool coverage is not subject to the 2014 market reforms outlined under § 153.234 (that is, § 147.102 (fair premiums); § 147.104 (guaranteed availability); § 147.106 (guaranteed renewability); § 156.80 (single risk pool); and subpart B of part 156 (essential health benefits)). Therefore, claims costs incurred by high risk pools would not be eligible for reinsurance payments. Funding for the Federal high risk pool, also known as the Pre-Existing Condition Insurance Plan program, is not addressed in this rule.

Comment: One commenter asked that HHS expand the reinsurance program to encompass transitional plans covered by the transitional policy outlined in the November 14, 2013 guidance,²⁸ while another commenter asked that HHS clarify that only plans that are subject to all of the 2014 market reforms established under the Affordable Care Act are eligible for reinsurance payments.

Response: As discussed above, under § 153.234, a reinsurance-eligible plan's covered claims costs for an enrollee incurred prior to the application of §§ 147.102, 147.104 (subject to 147.145), 147.106 (subject to 147.145), 156.80, and subpart B of part 156 do not count towards either the uniform reinsurance payment parameters or the State supplemental reinsurance payment parameters. Therefore, a transitional plan is not eligible for reinsurance payments. For the purpose of

reinsurance contributions, we note that contributing entities are required to make reinsurance contributions for their major medical coverage that is considered to be part of a "commercial book of business," subject to certain exceptions provided for in our regulations. As such, a contributing entity must make reinsurance contributions on behalf of its enrollees in transitional plans that provide major medical coverage, as defined in § 153.20, unless one of the exceptions provided under 45 CFR 153.400 applies to such coverage.

g. Deducting Cost-Sharing Reduction Amounts From Reinsurance Payments

Subpart H of 45 CFR part 153 governs the submission of medical and pharmacy claims to an issuer's dedicated distributed data environment. Under § 156.410, if an individual is determined eligible to enroll in an individual market Exchange QHP and elects to do so, the QHP issuer must assign the individual to a standard plan or cost-sharing plan variation based on the enrollment and eligibility information submitted by the Exchange. Issuers of individual market Exchange QHPs will receive cost-sharing reduction payments for enrollees that have effectuated coverage in cost-sharing plan variations. Therefore, in the 2014 Payment Notice (78 FR 15499), we stated that the enrollee-level data submitted by an issuer of a reinsurance-eligible plan must include claims data and data related to determining cost-sharing reductions provided through a cost-sharing plan variation to permit HHS to calculate an issuer's plan paid amounts on behalf of an enrollee. In the proposed rule, we explained the methodology HHS proposed to use to deduct the amount of cost-sharing reductions paid on behalf of an enrollee enrolled in a QHP in an individual market through an Exchange.

As specified in § 153.230, HHS will calculate reinsurance payments by applying the uniform reinsurance payment parameters for the applicable benefit year to the issuer's plan paid amounts on behalf of each enrollee in a reinsurance-eligible plan for the benefit year. However, this calculation may not always account for the cost-sharing reduction payments the QHP issuer receives for an enrollee, resulting in an issuer receiving payments twice for the same enrollee's total costs. In the proposed rule, we stated that we believe that the cost-sharing payment amounts provided by HHS to a QHP issuer for an enrollee in a plan variation should be deducted from the total plan paid amounts to avoid "double payment" to

the QHP issuer of the reinsurance-eligible plan because the QHP issuer is already being reimbursed for the value of the cost-sharing reductions provided.

Under the Secretary's authority under section 1341(b)(2)(B) of the Affordable Care Act to establish a payment formula for the reinsurance program that provides for the equitable allocation of available funds, we proposed a method through which HHS intends to account for cost-sharing reduction payments when calculating reinsurance payments for QHP issuers for reinsurance-eligible plans offered in an individual market. We proposed that for each enrollee enrolled in a QHP plan variation, we would subtract from the QHP issuer's total plan paid amounts for the enrollee in a reinsurance-eligible plan the difference between the annual limitation on cost sharing for the standard plan and the annual limitation on cost sharing for the plan variation. Because reinsurance payments are made for enrollees only when the issuer's total plan paid amounts exceed the attachment point (for example, \$45,000 in the 2014 benefit year), we believe that it is highly unlikely that an enrollee for which a QHP issuer is eligible for reinsurance payments will not have reached the annual limitation on cost sharing. Therefore, the difference between the two annual limitations on cost sharing is likely to be an accurate estimate of cost-sharing reduction payments provided by HHS to the QHP issuer. We proposed to apply this approach to calculating the amounts of cost-sharing reductions provided for an enrollee in a silver plan variation or a zero cost sharing plan variation.

For policies with multiple enrollees, such as family policies, we proposed to allocate the difference in annual limitation in cost sharing across all enrollees covered by the family policy in proportion to the enrollees' QHP issuer total plan paid amounts.

In contrast, we proposed not to reduce the QHP issuer's plan paid amounts for purposes of calculating reinsurance payments for an Indian in a limited cost sharing plan variation. We are finalizing these provisions as proposed.

Comment: Several commenters supported our proposed approach to account for cost-sharing reduction payments. One commenter asked, in the case of a policy with multiple enrollees, that the allocation be made in proportion to each family member's share of costs subject to cost sharing rather than to total costs.

Response: We appreciate the reasoning behind the comment, but believe that it will be operationally simpler to consider total plan paid

²⁸ Letter to Insurance Commissioners, Center for Consumer Information and Insurance Oversight, November 14, 2013. Available at: <http://www.cms.gov/CCIIO/Resources/Letters/Downloads/commissioner-letter-11-14-2013.PDF>.

amounts when accounting for cost-sharing reductions.

Comment: Several commenters recommended that HHS re-evaluate the methodology for family policies where each individual has a separate annual limitation on cost sharing, suggesting that HHS treat individuals with separate annual limitations on cost sharing as if they had each enrolled in an individual policy for the purposes of accounting for cost-sharing reduction payments in calculating reinsurance payments.

Response: For operational reasons, we believe it will be easier to allocate a family annual limitation on cost sharing across enrollees rather than make individual calculations.

Comment: One commenter sought clarification on how HHS's proposal to calculate the amount of cost-sharing reductions provided for an enrollee in a silver plan variation or a zero cost sharing plan variation would apply if an individual moves between plan variations during the benefit year.

Response: Because cost sharing accumulates over the benefit year across plan variations of the same standard plan, we will apply the adjustment for cost-sharing reductions based on the annual limitation on cost sharing applicable to the plan variation in which the enrollee was last enrolled during the benefit year.

Comment: One commenter asked for clarification regarding the following footnote set forth in the proposed rule (78 FR 72345, n. 16): "We note that because the annual limitation on cost sharing applies only to in-network services, it is possible that an enrollee could incur additional cost-sharing reductions on out-of-network services. However, except in the case of zero cost sharing plan variations, an issuer is not required to reduce cost sharing out-of-network, and we believe that an issuer will rarely choose to do so because the AV Calculator does not recognize any change in AV due to a reduction in out-of-network cost sharing. Although it is possible that an enrollee in a zero cost sharing plan variation could incur significant out-of-network cost-sharing reductions beyond the standard plan's annual limitation on cost sharing, we believe such a circumstance will be relatively rare because of the substantial out-of-pocket costs an enrollee would likely incur in the form of balance billing."

Response: We proposed the methodology described above to avoid reimbursing an issuer through reinsurance payments for claims costs for which it will be otherwise reimbursed through cost-sharing reduction payments. The footnote

explains that this methodology does not take into account cost-sharing reductions on out-of-network services because we believe that issuers have little incentive to provide cost-sharing reductions on out-of-network services for silver plan variations, and that it will be relatively rare that an enrollee in a zero cost sharing plan will incur substantial out-of-pocket costs beyond the standard plan's annual limitation on cost sharing. Thus, we stated that we believed that the effect of this limitation in our methodology would be small.

h. Audits

(i) HHS Audits of State-Operated Reinsurance Programs

We proposed in § 153.270(a) authority for HHS or its designee to conduct a financial and programmatic audit of a State-operated reinsurance program to assess compliance with the requirements of subparts B and C of 45 CFR part 153. We proposed that a State that establishes a reinsurance program be required to ensure that its applicable reinsurance entity and any relevant contractors, subcontractors, or agents cooperate with an audit of its reinsurance program by HHS or its designee. We stated that HHS anticipates conducting targeted audits of State-operated reinsurance programs based on the State summary report provided to HHS for each benefit year described in § 153.260(b), the results of the independent external audit conducted for each benefit year under § 153.260(c), and issuer input, among other factors.

We proposed in § 153.270(b) that if an audit by HHS results in a finding of material weakness or significant deficiency (as these terms are defined in GAAS issued by the American Institute of Certified Public Accountants, and Government Auditing Standards issued by the Government Accountability Office (GAO) ²⁹) with respect to the State-operated reinsurance program's compliance with any requirement of subparts B or C of 45 CFR part 153, the State would be required to ensure that its applicable reinsurance entity provide a written corrective action plan to HHS for approval within 60 calendar days of the issuance of the final audit report. The State would ensure that the applicable reinsurance entity

implements the plan and provides to HHS written documentation of the corrective actions once taken.

(ii) HHS Audits of Contributing Entities

We proposed in § 153.405(i) that HHS or its designee have the authority to audit a contributing entity to assess its compliance with the requirements of subpart E of 45 CFR part 153. We stated that we anticipated conducting targeted audits of contributing entities based on, among other criteria and sources, data provided to HHS through the annual enrollment count submitted under § 153.405(b), and any previous history of noncompliance with these standards. We proposed that if HHS determines as the result of an audit that a contributing entity was required to pay additional reinsurance contributions, we might require the contributing entity to pay such amounts to the Federal government.

(iii) HHS Audits of Issuers of Reinsurance-Eligible Plans

We proposed in § 153.410(d) authority for HHS or its designee to audit an issuer of a reinsurance-eligible plan to assess its compliance with the requirements of subparts E and H of 45 CFR part 153. We also proposed that if an audit results in a finding of material weakness or significant deficiency (as these terms are defined in GAAS issued by the American Institute of Certified Public Accountants, and Government Auditing Standards issued by the Government Accountability Office (GAO) ³⁰) with respect to compliance with any requirement of subpart E or H of 45 CFR part 153, the issuer be required to: (i) Within 30 calendar days of the issuance of the final audit report, provide a written corrective action plan to HHS for approval; (ii) implement that corrective action plan; and (iii) provide to HHS written documentation of the corrective actions once taken. We proposed that if HHS determines as the result of an audit that the issuer of a reinsurance-eligible plan has received reinsurance payments to which it was not entitled, we might require the issuer to pay such amounts back to the Federal government.

In the proposed rule, we noted that we anticipate conducting targeted audits of issuers of reinsurance-eligible plans based on, among other criteria and

²⁹ See Government Auditing Standards (2011 Revision), available at: <http://www.gao.gov/yellowbook>. For public companies, the Public Company Accounting Oversight Board (PCAOB) sets audit standards. See <http://pcaobus.org/Standards/Auditing/Pages/default.aspx>. For non-public companies, the AICPA sets audit standards. See <http://www.aicpa.org/Research/Standards/AuditAttest/Pages/SAS.aspx>.

³⁰ See Government Auditing Standards (2011 Revision), available at: <http://www.gao.gov/yellowbook>. For public companies, the Public Company Accounting Oversight Board (PCAOB) sets audit standards. See <http://pcaobus.org/Standards/Auditing/Pages/default.aspx>. For non-public companies, the AICPA sets audit standards. See <http://www.aicpa.org/Research/Standards/AuditAttest/Pages/SAS.aspx>.

sources, the data provided to HHS through the dedicated distributed data environment and any previous history of noncompliance with these standards. We stated that we anticipate that this audit will focus on claims records validating the requests for reinsurance payments submitted to the dedicated distributed data environments, as well as records indicating the plan was a reinsurance-eligible plan.

We addressed the general comments received on the proposed audit provisions in the preamble discussion of § 153.620(c) above, and address comments specific to the transitional reinsurance program audit provisions below. We are finalizing these provisions as proposed.

Comment: One commenter asked that audits of contributing entities be delayed until after the first year of the reinsurance program to enable issuers and self-insured group health plans to focus on compliance. Other commenters stressed the importance of prioritizing audits of contributing entities.

Response: We believe that audits of contributing entities may be necessary to ensure that the reinsurance program has sufficient funds to effectively stabilize premiums during the initial years of Exchange operation, particularly with respect to the 2014 benefit year, for which the largest amount of contributions will be collected. We are therefore not adopting the commenter's suggestion.

Comment: One commenter suggested audit processes that would reduce the burden on contributing entities. Specifically, the commenter asked that audit protocols include sufficient, advance written notice of the audit, and that requests for supporting documentation be limited to enrollment data maintained by or on behalf of the contributing entity and information related to whether the plan provides major medical coverage. The commenter also asked that contributing entities be able to satisfy requests for information in a reasonable manner and format, and that an audited contributing entity be granted appeal rights.

Response: We agree that any audit of a contributing entity should focus on records relating to enrollment in the applicable self-insured or insured plan, to confirm that the number of covered lives was correctly calculated and that the correct amount of reinsurance contributions was paid. Additionally, these audits may be used to identify entities that were required to but did not make reinsurance contributions. We will consider these comments when developing the protocols and procedures of our audits, such as

timeframes for notification, formats for submitting supporting documentation, and appeals of audit findings, as part of future rulemaking and guidance.

i. Same Covered Life

In the second final Program Integrity Rule (78 FR 65057), we stated that it is our intent not to require payment of reinsurance contributions more than once for the same covered life. We stated that we recognize that certain complex group health plan arrangements can lead to situations in which lives are covered by multiple arrangements, where it is unclear whether more than one health plan or issuer must make reinsurance contributions, and that we intended to provide clarity on the matter in future rulemaking. In the proposed rule, in § 153.400(a)(1), we clarified the general principle that reinsurance contributions are required for major medical coverage that is considered to be part of a commercial book of business, but are not required to be paid more than once with respect to the same covered life.

In addition, we proposed to add paragraph (vi) to § 153.400(a)(1), which provided that no reinsurance contributions would be required in the case of employer-provided group health coverage where (A) such coverage applies to individuals who are also enrolled in individual market health insurance coverage for which reinsurance contributions are required; or (B) such coverage is supplemental or secondary to group health coverage for which reinsurance contributions must be made for the same covered lives. This provision was proposed to address situations in which a person covered under a group health plan also obtains individual market coverage, and in which multiple group health plans cover the same lives. It also addressed a situation in which two spouses are each covered as dependents by the respective group health plans offered by their two independent employers. We are finalizing these provisions as proposed.

Comment: Several commenters supported our proposal that a contribution not be required with respect to the same life more than once, and our proposal at § 153.400(a)(1)(vi). Other commenters objected to our proposals, stating that information regarding whether coverage is supplementary or secondary is not available to the employer or issuers, and that therefore this proposal would be expensive to administer. One commenter asked if guidance would be forthcoming on how issuers are to

validate this exclusion if the coverage occurs among different issuers.

Response: As noted in the proposed rule, if it is not clear from the terms of the health plans which group health plan is supplemental, in keeping with § 153.400(a)(3), the group health plan that offers the greater portion of inpatient hospitalization benefits is deemed the primary health plan. If it is not clear from the terms of the health plans which group health plan is primary and which is secondary, we would defer to the arrangements on primary and secondary liability set forth by the respective plan sponsors, in accordance with applicable State coordination of benefit laws and regulations. In such a situation, we would hold a plan sponsor harmless from non-compliance actions for failure to pay reinsurance contributions to the extent the sponsor relied in good faith upon a written representation by the other sponsor that the other sponsor's coverage has primary liability for claims for particular covered lives (and is responsible for making reinsurance contributions with respect to those covered lives).

Comment: One commenter suggested an operational process of reporting under which plans that provide supplemental and secondary coverage to a participant must identify these participants to the primary major medical coverage and pay a portion of the reinsurance contribution for such participant.

Response: Under our proposal, if employer-provided group health coverage is secondary or supplemental coverage, the group health plan offering such supplemental or secondary coverage is not required to make partial or full contributions on behalf of participants who are also enrolled in a primary major medical plan. We do not wish to require an additional information disclosure in connection with this exemption.

Comment: One commenter suggested that we codify an exception permitting a contributing entity to automatically exclude coverage for any enrollee for which the coverage is secondary under coordination of benefit rules.

Response: Our rule would not extend this exception to coverage which is determined to be secondary under coordination of benefit rules if the entity that provides the primary coverage is not required to make reinsurance contributions. The intent of the rule and accompanying exceptions is to avoid double-counting of contributions, but the commenter's automatic exclusion (if adopted) could incorrectly result in no

reinsurance contributions being made with respect to a covered life.

Comment: One commenter asked that HHS clarify that with respect to supplemental or secondary coverage, any time a participant's spouse is covered as an employee by another group health plan, the participant's plan may exclude that spouse from the count of covered lives and could assume without written representation that the entity that covers the spouse as an employee would be responsible for paying the contribution without further verification.

Response: We decline to make that clarification because our rule would not extend the exception if the entity that provides the primary coverage is not required to make reinsurance contributions. The adoption of the commenter's automatic assumption could incorrectly result in no reinsurance contributions being made with respect to a covered life. As such, the entity covering the spouse as an employee would need to represent that it was responsible for making reinsurance contributions on behalf of the covered lives in order for the entity covering the spouse as a dependent to avail itself of the exemption.

Comment: Several commenters asked that the general principle that reinsurance contributions are not required to be paid more than once with respect to the same covered life be extended to the Patient-Centered Outcomes Research Institute fee for 2015 and beyond by the Treasury Department.

Response: The U.S. Department of the Treasury is responsible for administration of the Patient-Centered Outcomes Research Institute fee, and regulation of that fee is outside the scope of this rulemaking.

Comment: One commenter requested that HHS modify § 153.400 to provide that the secondary coverage exemption in § 153.400(a)(1)(vi) be determined based on the coverage a participant is enrolled in at the time of enrollment regardless of whether this coverage is terminated during the benefit year.

Response: A contributing entity must consider an enrollee's status throughout the benefit year such that if an enrollee in secondary coverage loses his or her primary medical coverage, the secondary coverage will have to account for that enrollee using one of the counting methods under § 153.405 when calculating its reinsurance contributions.

Comment: Several commenters asked that HHS clarify that certain types of coverage, even when provided in combination, are not subject to the

contribution requirement. Specifically, they asked that all dental and vision coverage be exempt from the contribution requirement because it is not major medical coverage. The commenters also asked that excepted benefits, prescription drug coverage, and other ancillary benefits such as hearing aid coverage may be offered by the same plan without that combination of coverage becoming subject to the reinsurance contribution requirement.

Response: Any plan not satisfying the definition of major medical coverage as set forth in § 153.20 is not required to make reinsurance contributions.

Comment: One commenter asked HHS to permit contributing entities to submit reinsurance contributions and comply with reporting requirements electronically. The commenter also asked HHS to allow contributing entities flexibility in correcting inadvertent errors when making reinsurance contributions.

Response: We will provide further details on how contributing entities should submit enrollment counts and reinsurance contributions in future guidance. We will work with contributing entities in establishing these operational processes.

j. Reinsurance Contributions and Enrollees Residing in the Territories

Section 1323(a)(1) of the Affordable Care Act provides that a U.S. territory may establish an Exchange, and any territory that elects to establish an Exchange will be "treated as a State" for purposes of the Exchange standards in sections 1311 through 1313 of the Affordable Care Act. In a letter dated December 10, 2012 to the governors of the U.S. territories, HHS stated that "if a territory establishes an approved Exchange, it may elect to establish a transitional reinsurance program . . . consistent with the provisions in section 1341 . . . of the Affordable Care Act." That letter further stated that if a territory does not establish a transitional reinsurance program, HHS would not do so on the territory's behalf, and that in order to operate a reinsurance program for the 2014 benefit year, the territory was required to notify HHS of its intention to do so by March 1, 2013. No territory has notified HHS of an intention to operate a reinsurance program.

We proposed in § 153.400(a)(1)(v) the following exception for when a contributing entity must make reinsurance contributions for its self-insured group health plans and health insurance coverage: To the extent that the coverage applies to enrollees with primary residence in a territory when

that territory does not operate a reinsurance program, the contributing entity would not be required to make reinsurance contributions for those enrollees. We proposed that a contributing entity be permitted to use any reasonable method to determine the primary residence of an enrollee, including using the last-known mailing address of the principal subscriber on the enrollee's policy. We are finalizing this provision as proposed.

Comment: Several commenters supported our proposal to exempt from the reinsurance contribution obligation enrollees who reside in a territory that does not operate a reinsurance program. One commenter asked that HHS amend the proposal to exempt enrollees in a major medical plan that is based or administered in a territory.

Response: We are finalizing this provision as proposed. It is possible that a major medical plan based or administered in a territory that does not operate a reinsurance program may have enrollees in the 50 States and the District of Columbia. As noted in the proposed rule, this provision aligns with the goals of the reinsurance program because reinsurance contributions would only be required with respect to those jurisdictions that benefit from the premium stabilization effects of the reinsurance program. Additionally, we note that a contributing entity is not required to allocate its covered lives by primary residence between the territories, on the one hand, and the 50 States and the District of Columbia, on the other hand, and must do so only if it wishes to exclude covered lives from reinsurance contributions under § 153.400(a)(1)(v).

k. Form 5500 Counting Method

In the 2014 Payment Notice (78 FR 15463), we established counting methods for calculating the annual enrollment for determining reinsurance contributions for self-insured group health plans, fully insured health plans, and plans that are partially insured and partially self-insured. One of the allowable methods for a self-insured group health plan is the Form 5500 counting method in § 153.405(e)(3). In the proposed rule, we amended § 153.405(e)(3), by changing the references from "benefit year" to "plan year" to clarify that a self-insured group health plan may use the enrollment set forth in the Form 5500 even if the group health plan is based on a plan year (as defined for the purposes of the Form 5500) other than the benefit year. Therefore, a self-insured group health plan that chooses to use the Form 5500 counting method and offers self-only

coverage would calculate the number of lives covered by adding the total participants covered at the beginning and end of the most current plan year, as reported on the Form 5500, then dividing by two. A self-insured group health plan that offers both self-only coverage and coverage other than self-only coverage would calculate the number of lives covered by adding the total participants covered at the beginning and the end of the most current plan year, as reported on the Form 5500. We are finalizing this amendment as proposed.

Comment: Several commenters supported our proposed amendment to the Form 5500 counting method. One commenter suggested modifying this amendment to make clear that a self-insured group health plan that offers both self-only coverage and coverage other than self-only coverage would calculate the number of lives covered by adding the numbers of total participants covered at the beginning and at the end of the most current plan year, as reported on the Form 5500 and then dividing by two to avoid double counting enrollees.

Response: We are finalizing this technical amendment as proposed. The Form 5500 counting method does not result in the double counting of enrollees. As discussed in the “2013 Instructions for Form 5500, Annual Return/Report of Employee Benefit Plan”³¹ a “participant” does not include covered dependents, accounting for the counting method used for coverage other than self-only.

4. Provisions for the Temporary Risk Corridors Program

a. Definitions

In the first final Program Integrity Rule, we provided that, in 45 CFR part 153, subpart F regarding risk corridors, any reference to a “qualified health plan” or “QHP” includes plans that are the “same” as a QHP or “substantially the same” as a QHP. We noted that plans that are substantially the same as a QHP will continue to be considered substantially the same even if they differ in terms of benefits, premiums, provider networks, or cost-sharing structure, provided that the differences are tied directly and exclusively to Federal or State requirements or prohibitions on the coverage of benefits that apply differently to plans depending on whether they are offered through an Exchange or outside of an Exchange. In the first final Program Integrity Rule, we recognized that OPM might issue

additional standards for multi-State plan (MSP) issuers in the future (for example, standards related to provider networks) that could create situations analogous to the ones we discuss above. In the proposed rule, we considered whether a plan that differs from a QHP (as defined at § 155.20) based on OPM standards would be considered to be “substantially the same” as a QHP for the purposes of participating in the risk corridors program, and stated that we were considering amending the definition of a QHP at § 153.500 in response. Because OPM has not issued MSP standards that create such analogous situations, in this final rule, we are not amending the definition of a plan that is substantially the same as a QHP in § 153.500, though we will consider doing so in the future.

Comment: One commenter recommended that any difference in QHPs offered off-Exchange that result from a requirement imposed by OPM, including differences in provider networks, should not disqualify a QHP from participation in the risk corridors program. The commenter also requested that HHS allow plans that include an optional rider to be included in the definition of “substantially the same.”

Response: The first final Program Integrity rule provided that a plan offered outside of an Exchange is substantially the same as an Exchange QHP, and thus will participate in the risk corridors program, if it differs from an Exchange QHP with respect to benefits, premiums, cost-sharing structure, and provider networks, provided that such differences are tied directly and exclusively to Federal or State benefit requirements that apply differently to plans depending on whether they are offered through or outside an Exchange. As discussed above, we will consider amending this standard if OPM promulgates standards that require analogous differences between QHPs offered through or outside Exchanges. We are not amending this definition to include optional riders to the extent these riders are not a result of differing Federal or State requirements with respect to Exchange and off-Exchange plans.

b. Compliance With Risk Corridors Standards

In the proposed rule, we outlined our proposed process for validating risk corridors data submissions and enforcing compliance with the risk corridors requirements in subpart F of 45 CFR part 153. Because the MLR and risk corridors programs will require similar data, we proposed to closely align the data submission, data

validation, audit provisions, and sanctions for the two programs.

For the 2014 benefit year, we proposed to collect risk corridors data through the same form used for MLR data collection, at the same time (July 31st of the year following the applicable benefit year). We noted that we would modify the collection instrument and adjust the operational aspects of data submission as necessary to ensure that the data collection process adheres to the requirements for both programs. We would leverage the data validation procedures that are used by the MLR program to uncover data inconsistencies, and would add additional validation steps that would allow us to identify QHP issuers and verify QHP-specific premium information. In addition, we stated that we were considering conducting an internal quality check of risk corridors data to ensure that the information submitted is consistent with information submitted for other programs (for example, premiums and claims data reported on the dedicated distributed data environment). We stated that, similar to the MLR process, we anticipate requiring issuers to resubmit corrected data after risk corridors data errors are identified.

To ensure the integrity of risk corridors data reporting, we proposed in § 153.540(a) to establish HHS authority to conduct post-payment audits of QHP issuers. Because similar data is used in the risk corridors and MLR calculations, we proposed to conduct the risk corridors audits using the existing MLR auditing process set forth at § 158.402 to reduce the time and expense (for both HHS and issuers) of conducting multiple audits on similar data.

The second final Program Integrity Rule provides that a QHP issuer on an FFE that fails to comply with the risk corridors provisions may be subject to decertification or CMPs, but does not extend this remedy to a QHP issuer on a State Exchange. In § 153.540(b), we proposed that HHS have the authority to assess CMPs on QHP issuers in State Exchanges in accordance with the same enforcement and sanction procedures that apply to QHP issuers on FFEs, under § 156.805. We noted that, consistent with our general approach relating to the application of sanctions, we would take various factors into account when determining the amount of a CMP, including an issuer's record of prior compliance with risk corridors requirements, the gravity and the frequency of the violation, and the issuer's demonstrated success in correcting violations that HHS has identified (for example, errors identified

³¹ Available at: <http://www.dol.gov/ebsa/pdf/2013-5500inst.pdf>.

in corrective action plans).³² We received no comments on our proposal. Because we are still developing our enforcement and audit programs for the risk corridors and MLR programs, we are not finalizing our proposed enforcement policy with regard to CMPs at this time. We note that noncompliance with risk corridors data submission requirements may be subject to enforcement actions under the False Claims Act, and that any failure to pay risk corridors charges may be subject to our debt collection rules.

In this final rule, we are finalizing our policy with respect to risk corridors data submission, data validation, and audits, as proposed.

Comment: Some commenters opposed our proposal to combine MLR and risk corridors data submission, data validation, and auditing processes. One commenter disagreed with the proposal to use the same form for reporting MLR and risk corridors data. The commenter stated that MLR and risk corridors calculations and reporting requirements are based upon different definitions and requirements, which would rule out the use of a single form. For example, the commenter noted, the programs use different definitions of group size, and require aggregation to different levels—QHP versus legal entity. The commenter also opposed the proposal to validate risk corridors data with data from the dedicated distributed data environment, because risk corridors data are based upon total claims, including capitation amounts, whereas the dedicated distributed data will include derived encounter values. Another commenter also advised against validating risk corridors data with data from the dedicated distributed data environment because of concerns that the dedicated distributed data environment would not be ready in time or would face short-term operational challenges that would prevent it from being a reliable source of claims data.

Response: We are finalizing our proposal to use data validation procedures that are employed by the MLR program to uncover data inconsistencies, and to add validation steps that would allow us to identify QHP issuers and verify QHP-specific premium information. We do not believe that differences in standards and requirements between the risk corridors and MLR programs preclude the use of a single form because similar data will be collected at the issuer and State level

for both programs. We also note that we will make some modifications to the form to capture any additional data, such as QHP-specific premium, that is specific to any one program. We believe that this approach is less burdensome for issuers and will prevent the submission of duplicative information.

We are also finalizing our proposal to conduct an internal quality check of risk corridors data to ensure that the information submitted is consistent with information submitted for other programs. However, in response to comment regarding the appropriateness of validating risk corridors information against data collected through the dedicated distributed environment, we are clarifying that we will only validate risk corridors data against other data sources if the data from the other data sources is sufficiently reliable and can be appropriately compared, including with respect to any data submitted through the dedicated distributed data environment for 2014.

Comment: One commenter was concerned that the proposed data collection program is geared toward fee-for-service payment systems and would not accommodate the unique challenges faced by organizations that operate, at least in part, through capitated or integrated health systems.

Response: We disagree that the data collection program established for the MLR program would not accommodate the experience of capitated or integrated health systems. The MLR data submission template that would be used for the submission of risk corridors data currently accommodates data submission from a variety of insurance and provider models.

Comment: We received several comments that supported our proposal to combine MLR and risk corridors audits as a way to reduce burden for issuers. One commenter additionally suggested that HHS use enrollment weighted selection criteria, identify outliers, and employ pooling methods similar to those used by the IRS for its auditing strategy. Another commenter encouraged HHS to coordinate risk corridors audits with those performed by State Departments of Insurance.

Response: In § 153.540, we are finalizing our proposal to conduct post-payment risk corridors audits using the existing MLR auditing process set forth at § 158.402. We agree that a combined data submission and audit process will reduce burden on issuers. We appreciate commenters' suggestions on the risk corridors audit process. We intend to work closely with State Departments of Insurance to share knowledge and coordinate our audit approach to the

extent practicable, in order to prevent duplicative audits in States that review information related to MLR reporting. We intend to issue detailed guidance on the auditing process in the future.

c. Participation in the Risk Corridors Program

Because the premium stabilization programs, including the risk corridors program, are intended to mitigate pricing uncertainty associated with the 2014 market reforms, particularly the rating rules at section 2701 of the PHS Act and § 147.102, we believe that the protections of these programs should be limited to plans that are subject to the premium rating rules. In the proposed rule, we proposed to amend the risk corridors rules to provide that a plan that is not subject to the market reform rules and premium rating rules would not participate in the risk corridors program. We proposed to add paragraph (f) to § 153.510 to provide that the risk corridors program would apply only to QHPs, as defined in § 153.500, including all plans offered through the individual market Exchange or SHOP, regardless of employer size, that are subject to the following provisions within title 45 of the CFR:

- § 147.102 (fair health insurance premiums).
- § 147.104 (guaranteed availability of coverage).
- § 147.106 (guaranteed renewability of coverage).
- § 147.150 (essential health benefits).
- § 156.80 (single risk pool) and subpart B of 45 CFR part 156 (essential health benefits package).

We also proposed that the employee counting method applicable under State law would determine whether a plan is considered to be offered in the small group market for purposes of the risk corridors program, even if the State definition does not take non-full-time employees into account, and thus could include some employers that would be large employers under the Federal definition. We noted that, for purposes of the risk corridors program, permitting the use of a State employee counting method that is inconsistent with the counting method set forth in Federal law differs from the approach taken under the MLR program and the proposed counting method for the risk adjustment program that is described elsewhere in this final rule. Under these programs, non-full-time employees must be counted. We also noted that the State's employee counting method would also be used to determine whether a plan that is not a QHP is part of the non-grandfathered individual or small group market within a State, and

³² We note that the good faith provision at 45 CFR 156.800(c) will not be applicable in this context because risk corridors activities, such as data submission and payment, begin in 2015.

would, therefore, be part of a QHP issuer's risk corridors data submission under § 153.530.

In this final rule, we are finalizing the risk corridors participation rules as proposed to exclude plans that are not subject to market rules and premium rating rules from participating in the risk corridors program. We are also finalizing our proposal that the employee counting methodology used for the purposes of determining which plans participate in the risk corridors program will be the State employee counting method.

Comment: We received three comments recommending that the experience of plans not compliant with the Affordable Care Act, including transitional plans, should be excluded from the risk corridors calculation, since those plans are not in the same risk pool.

Response: QHP issuers are required to submit risk corridors data for all of their non-grandfathered plans in a market within a State. We are clarifying that this data submission requirement excludes the experience of plans that are not subject to the Affordable Care Act market reform rules, and plans being offered pursuant to the transitional policy announced on November 14, 2013.³³ This is consistent with our single risk pool policy, which bases rate setting on the predicted EHB claims experience of all of an issuer's non-grandfathered plans within the individual or small group market (or merged markets in states that require merging the risk pools) that are subject to the Affordable Care Act's market reform rules, including the single risk pool requirement. As described in this section, only QHPs (as defined in § 153.500) are subject to risk corridors charges and eligible for risk corridors payments, and only if they are plans that are required to comply with specified Affordable Care Act market reform rules previously discussed.

Comment: Some commenters recommended that HHS expand the types of plans that would be subject to the risk corridors program. Some commenters suggested that we expand risk corridors to all plans compliant with the Affordable Care Act, not just plans that are the same or substantially the same as a QHP. One commenter suggested that the risk corridors program should apply to an off-Exchange plan that would otherwise qualify as an Exchange QHP.

Response: Consistent with our current policy, only plans that are QHPs, the same as a QHP, or substantially the same as a QHP (as defined at § 153.500) will make or receive risk corridors payments. We believe that our existing policy preserves the intent of the risk corridors program, which is to share risk and stabilize premiums for QHPs, whether offered through or outside the Exchange. We believe that our expanded definition of a QHP for purposes of risk corridors serves to maintain the program's focus on QHPs while permitting these plans to be offered outside the Exchange, with only such minor variations as are required by law.

Comment: We received several comments that the definition of the small group market should be consistent between the premium stabilization programs, and that the State employee counting method should be used for all Affordable Care Act programs.

Response: As noted earlier in this final rule, we agree that consistency in counting methods across Affordable Care Act programs is important, and we plan to collaborate with other Federal agencies to develop a streamlined counting method in future rulemaking. For purposes of the risk corridors program, we interpret section 1342 of the Affordable Care Act to permit us to defer to State counting methodologies. However, as noted above, we interpret the employer size definitions in the Affordable Care Act to include non-full-time employees for purposes of determining small group status for purposes of risk adjustment. We therefore are finalizing our proposal that the employee counting methodology used for the purposes of determining which plans participate in the risk corridors program will be the State employee counting method.

d. Adjustment for the Transitional Policy

As previously noted, on November 14, 2013, the Federal government announced a transitional policy under which it will not consider certain health insurance coverage in the individual or small group markets that is renewed for a policy year starting after January 1, 2014, under certain conditions to be out of compliance with specified 2014 market rules, and requested that States adopt a similar non-enforcement policy.³⁴ CMS noted in a letter to the insurance commissioners of the 50 States and the District of Columbia that

while the transitional policy would not have been anticipated by issuers in setting rates for 2014, the risk corridors program should help ameliorate unanticipated changes in premium revenue as a result of this policy. We also stated that we intended to explore ways to modify the risk corridors program to address any unanticipated effects of this policy.

In our proposed rule, we considered an adjustment to the risk corridors formula for the 2014 benefit year that would help to further mitigate any unexpected losses for issuers of plans subject to risk corridors attributable to the effects of the transitional policy, and noted that we were considering approaches that would limit the impact of the policy on the Federal budget. We considered implementing an adjustment to the risk corridors formula set forth in subpart F of part 153 for each of the individual and small group markets by increasing the profit margin floor (from 3 percent of after-tax profits) and the allowable administrative costs ceiling (from 20 percent of after-tax profits) in an amount sufficient to offset the effects of the transitional policy upon the claims costs of a model plan. We stated that this adjustment could increase a QHP issuer's risk corridors ratio and its risk corridors payment amount to help offset losses that might occur under the transitional policy as a result of increased claims costs not accounted for when setting 2014 premiums. We stated that we were considering applying this adjustment only to plans whose allowable costs (as defined at § 153.500) are at least 80 percent of their after-tax premiums, because issuers under this threshold would generally be required to pay out MLR rebates to consumers. We stated that because we believed that the Statewide effect on this risk pool would increase with an increase in the percentage enrollment in transitional plans in the State, we were considering having the State-specific percentage adjustment to the risk corridors formula also vary with the percentage enrollment in these transitional plans in the State. To estimate this State-specific effect of the transitional policy on average claims costs, we proposed to require all issuers participating in the individual and small group markets in a State to submit to HHS a member-month enrollment count for transitional plans and non-transitional plans in the individual and small group markets prior to the risk corridors July 31, 2015 data submission.

In the proposed rule, we stated we were also considering calculating the State-specific percentage adjustment by analyzing the effects of the transitional

³³ Letter to Insurance Commissioners, Center for Consumer Information and Insurance Oversight, November 14, 2013. Available at: <http://www.cms.gov/CCIIO/Resources/Letters/Downloads/commissioner-letter-11-14-2013.PDF>.

³⁴ Letter to Insurance Commissioners, Center for Consumer Information and Insurance Oversight, November 14, 2013. Available at: <http://www.cms.gov/CCIIO/Resources/Letters/Downloads/commissioner-letter-11-14-2013.PDF>.

policy upon a plan with the following specified characteristics: allowable costs (including claims) equal to 80 percent of premiums, Federal income taxes equal to 35 percent of pre-tax profits, other tax liability equal to 7.5 percent of premiums, and other administrative costs equal to 8 percent of premiums. We proposed to estimate the effect of the transitional policy upon the model plan's claims costs by assuming that allowable costs (including claims) among the transitional plans are 80 percent of the allowable costs that would have resulted from the broad risk pool, in the absence of the transitional policy. HHS would analyze that data, and publish the State-specific adjustments that issuers would use in the risk corridors calculations for the 2014 benefit year.

Finally, in the proposed rule, we stated that we were considering modifying the MLR formula to ensure that the proposed adjustment to the risk corridors program does not distort the implementation of MLR requirements, so that the rebates that would be owed absent the transitional policy and this adjustment would not substantially change.

We are finalizing the risk corridors adjustment policy as proposed. Consistent with our proposal, we are adding a definition of "adjustment percentage" to § 153.500, and are amending the definitions of risk corridors "profits" and "allowable administrative costs" in § 153.500 to account for the adjustment percentage. We are also adding a definition of "transitional State" to § 153.500. Finally, we are adding paragraph (e) to § 153.530 to require health insurance issuers in the individual and small group markets to submit enrollment data for the risk corridors adjustment. We are making a conforming change to § 153.530(d) to clarify that the July 31st submission deadline for risk corridors data does not apply to the enrollment data specified in § 153.530(e). We project that these changes, in combination with the changes to the reinsurance program finalized in this rule, will result in net payments that are budget neutral in 2014. We intend to implement this program in a budget neutral manner, and may make future adjustments, either upward or downward to this program (for example, as discussed below, we may modify the ceiling on allowable administrative costs) to the extent necessary to achieve this goal.

Comment: Several commenters recommended that HHS implement a risk corridors adjustment based on a national calculation instead of State-

level calculations, as we proposed. One commenter noted that the effect of the transitional policy on the State risk pool could vary by factors that we did not propose to account for, such as whether or not the State had a guaranteed issue law prior to 2014, and suggested that a national adjustment would help to mitigate the effect of these differences. Alternatively, the commenter suggested that HHS could provide an adjustment for different categories of States. A few commenters suggested that a national adjustment would reduce administrative burden on issuers and would be simpler to implement. However, several other commenters supported our approach of implementing a State-level adjustment, including the proposed approach of applying the adjustment based on enrollment in non-compliant plans within a State.

Response: We are finalizing our proposed approach to determine the risk corridors adjustment on a State-by-State basis. We believe that a State-based approach provides an appropriate means of accounting for differences in market composition, enrollment in transitional plans, and adoption of the transitional policy between States. Because a national approach would still require issuers to submit enrollment information to HHS in order to determine an accurate national risk corridors adjustment, we do not believe that a State-based approach would prove more burdensome for issuers.

Comment: One commenter recommended that the adjustment be extended through all three years of the temporary risk corridors program. However, another commenter believed that the adjustment should apply for the 2014 benefit year only, since issuers will be able to reflect the effect of the transitional policy in their pricing for subsequent benefit years.

Response: We agree with the comment that issuers will be able to reflect the effect of the transitional policy in their pricing for benefit years following 2014, and thus this specific risk corridors adjustment is needed for the 2014 benefit year only. Therefore, we are finalizing the risk corridors adjustment policy to apply the adjustment to eligible QHP issuers in transitional States for the 2014 benefit year only. However, as we discuss below, we are considering further changes to the risk corridors program.

Comment: Several commenters recommended that we apply the risk corridors transitional adjustment to all plans compliant with the Affordable Care Act, not just QHPs that are subject to the risk corridors program. Some commenters requested that any changes

to the risk corridors formula be applied uniformly to all issuers, including issuers of plans that are not compliant with Affordable Care Act requirements, rather than limited to issuers offering transitional policies. One commenter supported defining "transitional plans" to include "early renewal" plans that have been renewed in late 2013 and that will not be required to comply with the Affordable Care Act until the end of 2014.

Response: Because, as described above, the risk corridors program is intended to share risk and stabilize premiums for QHPs and substantially similar off-Exchange plans that differ only due to legal requirements, we decline to expand the participation criteria for the risk corridors transitional adjustment. Consistent with our existing regulations set forth in subpart F of part 153, any risk corridors payment or charge amount, including any adjusted payment or charge amount resulting from this transitional policy, will be calculated for a QHP issuer in proportion to the premium revenue that the issuer receives from its QHPs, as defined in § 153.500. Plans that do not comply with the Affordable Care Act market reforms will not participate in the risk corridors program, and data from these plans will not be included in a QHP issuer's risk corridors calculation, or the calculation of its risk corridors adjustment percentage.

We are also finalizing our proposal that a QHP issuer in a transitional State will receive the risk corridors adjustment only if its allowable costs are above 80 percent of after-tax premiums, and will receive that adjustment irrespective of whether the issuer offers transitional policies. Because the transitional policy may affect the overall risk pool in a transitional State, we believe that it is appropriate to provide the adjustment to a QHP issuer in that State even if the issuer does not offer a transitional policy.

Comment: Some commenters recommended that HHS completely remove the administrative costs ceiling for risk corridors. One of these commenters agreed with HHS's proposal that the allowable costs must be at least 80 percent of after-tax premiums, and another agreed with setting the profit floor according to the methodology outlined in the proposed rule. Another commenter recommended that the risk corridors formula be changed to reflect a standard ceiling of 22 percent for allowable administrative costs.

Response: As we discussed in the proposed rule, the adjustment to the risk

corridors calculation is meant to mitigate the effect of the transitional policy on QHP issuers in transitional States, and not in all States. However, we understand that issuers in all States are experiencing additional administrative costs as a result of transitional issues. We are carefully analyzing this proposal, and may propose implementing it in future rulemaking. If so, this change would apply in all States for the 2015 benefit year. We would also consider making corresponding changes to the risk corridors profit floor and to the MLR regulations.

Comment: We received comments on the interaction between the proposed risk corridors adjustment and MLR reporting. One commenter supported the proposal to modify the MLR formula so that the calculation of MLR rebates would not be affected by the transitional adjustment to the risk corridors program. One commenter believed that there was no need to modify the MLR formula because the formula would automatically account for any distortions, while another commenter recommended that HHS maintain the current structure of the MLR formula in order to prevent issuer confusion. We also received one comment suggesting that issuers should be able to account for administrative expenses that are related to implementing the risk corridors transitional adjustment as part of their MLR calculation for the following year.

Response: We are providing that issuers should exclude the effect of this transitional policy risk corridors adjustment from their MLR calculations. We are making conforming changes to the MLR reporting requirements in §§ 158.130(b)(5), 158.140(b)(4)(ii), and 158.240(c)(2). We note that this policy will not change the existing structure of the MLR or risk corridors formulas. Under this policy, issuers in the transitional States will use unadjusted risk corridors amounts (that is, a risk corridors transfer calculated as if the adjustment percentage, as defined in § 153.500, is equal to zero percent) in their MLR calculations.

Comment: One commenter recommended that HHS collect enrollment counts by the middle of the year so that issuers would be able to estimate their risk corridors transitional adjustment before the end of the year, in time for year-end financial reporting. Another commenter requested that issuers should be permitted to reduce the impact of the transitional policy through mid-year premium rate changes in the small group market that would

allow issuers to file rates as early as April 1, 2014.

Response: We are clarifying that we will collect transitional plan enrollment information and publish each State-specific adjustment in advance of when issuers would need to prepare their year-end financial reports. In response to comments, we are adding § 153.530(e) and making a conforming change to § 153.530(d) to specify that, although the July 31 deadline will continue to apply to the submission of risk corridors data that is necessary to calculate allowable costs and the target amount, the July 31 deadline will not apply to the collection of enrollment data for the risk corridors adjustment. As mentioned above, we intend to collect enrollment information before the July 31st deadline for submitting risk corridors data, so that issuers will know the risk corridors adjustment amount that applies to them before they are required to submit data on allowable costs and the target amount for the purposes of the risk corridors calculation. We currently anticipate conducting this collection at the beginning of 2015.

Comment: One commenter asked HHS to clarify that, for purposes of the target amount calculation, Federal income tax cannot be negative (that is, the Federal income tax amount would have a floor of zero).

Response: We clarify that, because the Federal income tax effects of losses in one plan can be offset by gains in another plan, the risk corridors formula will account for negative Federal income tax, and that we will not apply a floor to the Federal income tax amount used in the risk corridors formula.

5. Distributed Data Collection for the HHS-Operated Risk Adjustment and Reinsurance Programs

a. Discrepancy Resolution Process

(i) Confirmation of HHS Dedicated Distributed Data Environment Reports

We proposed an iterative discrepancy reporting process that would require an issuer of a risk adjustment covered plan or a reinsurance-eligible plan to notify HHS in a timely fashion of data and calculation discrepancies related to the data the issuer uploaded to its dedicated distributed data environment. This process would allow HHS and issuers sufficient time to resolve discrepancies, prior to HHS notifying issuers of final risk adjustment payments and charges and reinsurance payments. This process would also enable HHS to identify and address issues that affect multiple issuers throughout the benefit year.

Interim dedicated distributed data environment reports: In 2014, HHS

anticipates sending interim dedicated distributed data environment reports to issuers of risk adjustment covered plans and reinsurance-eligible plans that have loaded data onto their dedicated distributed data environments. We will also send interim reports to issuers of risk adjustment covered plans and reinsurance-eligible plans that do not load data to verify this result. Issuers of risk adjustment covered plans will receive interim reports that include preliminary risk adjustment information based on this data, and issuers of reinsurance-eligible plans will receive interim reports that include an estimate of the issuer's aggregated total claims eligible for reinsurance payments based on this data. We proposed in § 153.710(d) that within 30 calendar days of the date of an interim report, the issuer would be required either to confirm to HHS that the information in the interim report accurately reflects the data to which the issuer has provided access to HHS through its dedicated distributed data environment in accordance with § 153.700(a) for the timeframe specified in the report, or else to describe to HHS any discrepancy it identifies in the interim report.

Following the identification of a discrepancy in an interim report, HHS would review the evidence submitted by the issuer, along with any other relevant data, and determine if the preliminary risk adjustment information or estimated payment amount at issue was properly calculated using the applicable data.

We note that for the issuer and HHS to effectively address and resolve discrepancies through the proposed interim reporting process, once an issuer's dedicated distributed data environment is established, the issuer will be required under § 153.700(a), on a quarterly basis, to make a complete and current enrollment file accessible to HHS through the dedicated distributed data environment, and make good faith efforts to make accurate and current claims files accessible to HHS through the dedicated distributed data environment. An issuer may later (up until April 30th of the year after the benefit year, as provided for in § 153.730) adjust these files with the most current information to account for changing enrollments or more current adjudications of claims in later periods.

Final dedicated distributed data environment report: We proposed that HHS would provide issuers with a final dedicated distributed data environment report following the applicable benefit year, after the April 30th data submission deadline. The final dedicated distributed data environment

report will include final risk scores and claims amounts eligible for reinsurance payments, each calculated from the issuer's data that was timely loaded onto the dedicated distributed data environment. As with the interim reports discussed above, we proposed in § 153.710(e) that the issuer be required, within 15 calendar days of the date of the final report, to either confirm to HHS that the information in the final dedicated distributed data environment report accurately reflects the data to which the issuer has provided access to HHS through its dedicated distributed data environment in accordance with § 153.700(a) for the benefit year specified in the report, or describe to HHS any discrepancy it identifies in the final report.

Notification of payments and charges:

Last, as required under § 153.310(e) and § 153.240(b)(1)(ii), HHS will provide a notification to issuers specifying the risk adjustment and reinsurance payments due and risk adjustment charges owed for the applicable benefit year by June 30th of the year following the applicable benefit year. We anticipate providing this notification in the form of a report. We also anticipate providing a report on cost-sharing reduction reconciliation payments and charges for that benefit year in the same timeframe. Although we anticipate that the interim and final dedicated distributed data environment reports will permit HHS and issuers to resolve most data and payment discrepancies for risk adjustment and reinsurance before the June 30th report is issued, we recognize that some discrepancies might remain unresolved. Therefore, we proposed in § 153.710(f) that if a discrepancy that is first identified in an interim or final dedicated distributed data environment report in accordance with § 153.710(d)(2) or § 153.710(e)(2) remains unresolved after issuance of the June 30th report, an issuer of a risk adjustment covered plan or reinsurance-eligible plan is permitted to make a request for reconsideration using the process described in § 156.1220(a). To promote the goals of the premium stabilization programs and to ensure that risk adjustment and reinsurance payments are provided to an issuer of a risk adjustment covered plan or reinsurance-eligible plan in a timely fashion, we proposed to assess charges and make payments based on the amounts listed in the June 30th report, whether or not the issuer had submitted a request for reconsideration under § 156.1220(a), and to later correct any charges or payments determined to be

inaccurate under the administrative appeals process.

(ii) Reporting of Payments and Charges Under Reconsideration

We noted in the proposed rule that because risk adjustment payment and charge amounts and reinsurance payment amounts are factors in an issuer's risk corridors and MLR calculations, a delay in resolving final risk adjustment payments and charges and reinsurance payments could make it difficult for issuers to comply with reporting requirements under the risk corridors and MLR programs. Therefore, to clarify how issuers are to comply with these reporting requirements, we proposed in § 153.710(g)(1) that, notwithstanding any discrepancy report made under § 153.710(d)(2) or (e)(2), or any request for reconsideration under § 156.1220(a), unless the dispute has been resolved, an issuer be required to report, as applicable, for purposes of the risk corridors and MLR programs, the risk adjustment or reinsurance payment to be made to the Federal government, or the risk adjustment charge assessed by the Federal government, as reflected in the June 30th report.

If the amount of cost-sharing reductions a QHP issuer has provided is at issue because the issuer requested reconsideration of a cost-sharing reduction reconciliation payment or charge under § 156.1220(a), we proposed that for the purposes of the risk corridors and the MLR program, a QHP issuer would be required to report a cost-sharing reduction amount equal to the amount of the advance payments of cost-sharing reductions paid to the issuer by HHS for the benefit year as reflected in the HHS report on cost-sharing reduction reconciliation payments and charges. Additionally, we proposed that if a QHP issuer requests reconsideration of risk corridors payments or charges under § 156.1220(a), then for purposes of MLR reporting, the QHP issuer would be required to report the risk corridors payment to be made to the Federal government or charge assessed by the Federal government as reflected in the notification provided under § 153.510(d).

Finally, we proposed in § 153.710(g)(2) that an issuer be required to report any adjustment made following any discrepancy report made under paragraph (d)(2) or (e)(2), or any request for reconsideration under § 156.1220(a) with respect to any risk adjustment payment or charge, including an assessment of risk adjustment user fees, reinsurance payment, cost-sharing reconciliation

payment or charge, or risk corridors payment or charge, or following any audit, where the adjustment has not been accounted for in a prior risk corridors or MLR report, in the next following risk corridors and MLR report.

We are finalizing these provisions as proposed.

Comment: Several commenters supported the interim and final dedicated distributed data environment reports and discrepancy process, including the requirement to upload data on a quarterly basis. One commenter requested that HHS require, not merely allow, issuers to notify HHS in a timely fashion of data and calculation discrepancies.

Response: Under § 153.710(d) and § 153.710(e), an issuer will be required to notify HHS of any discrepancies within 30 calendar days of the date of an interim dedicated distributed data environment report and within 15 calendar days of the date of the final dedicated distributed data environment report.

Comment: One commenter stated that the quarterly reporting of data on an issuer's dedicated distributed data environment should not be required until HHS has provided issuers with the necessary documents, software, and support needed to ensure that the dedicated distributed data environment is running properly, with additional time provided for issuers to implement the software and test the system.

Response: We will not require issuers to make data available on the dedicated distributed data environment until we have provided them with the necessary documents, software, support, and time to establish the environment. We will issue future guidance regarding the initiation of quarterly data reporting. At that time, we will ask that issuers make a complete and current enrollment file accessible to HHS through the dedicated distributed data environment on a quarterly basis, while making good faith efforts to make accurate and current claims files accessible to HHS through that environment. As we stated in the proposed rule, an issuer may later (up until April 30th of the year after the benefit year, as provided for in § 153.730) adjust these files with the most current information to account for changing enrollments or more current adjudications of claims in later periods. However, we believe it is critical for issuers to provide quarterly uploads of enrollment and claims files to permit issuers and HHS to monitor data collection.

Comment: Many commenters asked for details on the timing of the interim reports. One commenter recommended

that HHS require quarterly reporting by the issuer to the dedicated distributed data environment one month after the end of each quarter. Commenters stressed the importance of receiving interim reports from HHS in late 2014 to early 2015 because these reports could be used for 2016 pricing and financial reporting obligations which occur prior to the June 30th notification deadline.

Response: We will issue future guidance regarding the timing of the interim reports.

Comment: Several commenters supported receiving interim reports identifying preliminary risk scores and estimates of the issuer's aggregated total claims eligible for reinsurance payments. Many commenters asked that HHS include additional information to enable calculation of risk adjustment payment transfers, and reinsurance payment amounts.

Specifically, commenters requested that the risk adjustment interim reports include: (1) The State average premium; (2) market average risk score; (3) preliminary Statewide risk score; (4) the geographic cost factors; (5) the two market-wide denominators (weighted adjusted risk score and weighted allowed rating factors) needed for the risk adjustment transfer formula; (6) enrollment counts by geographic region; (7) member-level (de-identified) data contributing to the risk score: risk adjusting categories, plan level or plan ID, age, sex, enrollment period, rating area and subsidy information, recommending that such information be displayed for each month included in the interim report; (8) AV; (9) induced demand factor; and (10) average rate factor. One commenter stated that since interim risk score calculations would not reflect true relative risk, HHS should publish statistical reports comparing the issuer with market average demographics, proportion of claims with HCCs, most prevalent HCCs, and other pertinent data.

Regarding the interim report for reinsurance, commenters asked that the interim reports include: (1) Member level claims amounts by month; (2) claim type; and (3) subsidy information necessary to validate the cost-sharing deduction.

Commenters also asked that HHS consult with issuers about the data submission requirements to accommodate diverse market practices due to provider submission patterns, State-specific regulations and different delivery system models.

Response: We will provide more details on the content of the interim

reports in future rulemaking or guidance, as appropriate.

Comment: Several commenters suggested that HHS provide information to issuers regarding data completeness or accuracy, data quality and ways to improve data submission in time for issuers to evaluate and correct such data issues prior to the final data submission deadline.

Response: As stated in the proposed rule, as part of the process for making data available to HHS on a dedicated distributed data environment, we anticipate providing an issuer a transactional process report that will identify data that has been attempted to be uploaded, but that has been rejected along with error codes. To fulfill its obligation to make these files available to HHS, an issuer will be required to either correct or accept the rejection of this data for the submission process to be considered complete. We also intend to provide summarized reports of file processing.

Comment: Some commenters supported the 15-calendar-day deadline to respond to the final dedicated distributed data environment report, while others asked that HHS provide 30 calendar days to respond to the final dedicated distributed data environment report.

Response: The shorter 15-calendar-day reporting timeframe for the final dedicated distributed data environment report is necessary so that HHS can notify issuers of their final risk adjustment payments and charges and final reinsurance payments by June 30th of the year following the applicable benefit year, as required under § 153.310(e) and § 153.240(b)(1)(ii).

Comment: One commenter asked that HHS develop penalties for non-compliance with the standards for the submission of data for the risk adjustment program.

Response: In § 153.740(a), we established HHS's authority to impose CMPs on issuers of risk adjustment covered plans who fail to provide HHS with access to the required data in such environment in accordance with § 153.700(a) or otherwise fail to comply with the requirements of §§ 153.700 through 153.730, or fail to adhere to the risk adjustment data submission and data storage requirements set forth in §§ 153.610 through 153.630.

Additionally, under § 153.740(b), HHS will assess a default risk adjustment charge if an issuer of a risk adjustment covered plan fails to establish a dedicated distributed data environment or fails to provide HHS with access to the required data in such environment in accordance with § 153.610(a),

§ 153.700, § 153.710, or § 153.730 such that HHS cannot apply the applicable Federally certified risk adjustment methodology to calculate the risk adjustment payment transfer amount.

b. Default Risk Adjustment Charge

As described in the second final Program Integrity Rule, if an issuer does not establish a dedicated distributed data environment or submits inadequate risk adjustment data, HHS would not have the required risk adjustment data from the issuer to calculate risk scores or payment transfers for the issuer. As a result, HHS would not be able to properly calculate risk adjustment payments and charges for the entire applicable market for the State. Under § 153.740(b), if an issuer of a risk adjustment covered plan fails to establish a dedicated distributed data environment or fails to provide HHS with access to risk adjustment data in such environment by April 30th of the year following the applicable benefit year in accordance with §§ 153.610(a), 153.700, 153.710, or 153.730 such that HHS cannot apply its Federally certified risk adjustment methodology to calculate the plan's risk adjustment payment transfer amount in a timely fashion, HHS will assess a default risk adjustment charge.

As described in the second final Program Integrity Rule, the total risk adjustment default charge for a risk adjustment covered plan would equal a per member per month (PMPM) amount multiplied by the plan's enrollment.

$$T_n = C_n * E_n$$

Where:

T_n = total default risk adjustment charge for a plan n ;

C_n = the PMPM amount for plan n ; and

E_n = the total enrollment (total billable member months) for plan n .

In the second final Program Integrity Rule, we provided that E_n could be calculated using an enrollment count provided by the issuer, using enrollment data from the issuer's MLR and risk corridors filings for the applicable benefit year, or using other reliable data sources.

We considered several methods to calculate C_n , the PMPM amount for a plan. As discussed in the proposed Program Integrity Rule, one method would be to set a PMPM amount that is equal to the highest PMPM transfer charge that HHS calculates based on risk adjustment data submitted by risk adjustment covered plans in the applicable risk pool in the applicable market in the State. Such a method could yield a PMPM amount that would reflect a PMPM charge that reflects the

high end of the PMPM distribution in certain States. However, in a situation in which the risk adjustment covered plans that provide the necessary risk adjustment data have very similar risk scores, a PMPM amount calculated under this method may yield a relatively low default risk adjustment charge, and fail to provide adequate incentive for prompt establishment of a compliant dedicated distributed data environment.

A second option we considered was to assess a PMPM amount based on the standard deviation of the PMPM charge among all risk adjustment covered plans in the applicable risk pool in the applicable market in the State. The PMPM amount used to calculate the default risk adjustment charge would be an amount equal to the mean PMPM amount plus two such standard deviations. Such an approach could also yield a PMPM amount that is high but reflects the PMPM distribution in certain situations, but, again, low in others. The amount might also be quite unpredictable *ex ante*.

The third option we considered was to assess a charge equal to a fixed percentage of the Statewide average premium, which would be calculated as the enrollment-weighted mean of all risk adjustment covered plan average premiums in the applicable risk pool in the applicable market in the State. This option might be relatively straightforward to implement, but would yield a charge that is not linked to the distribution of PMPM amounts within the relevant risk pool in the market in the State.

We are finalizing an approach in which we will assess a PMPM default charge equal to the product of the Statewide average premium (expressed as a PMPM amount) for a risk pool and the 75th percentile plan risk transfer amount expressed as a percentage of the respective Statewide average PMPM premiums for the risk pool. The nationwide percentile would reflect only plans in States where HHS is operating the risk adjustment program and would be calculated based on the absolute value of plan risk transfer amounts. The PMPM amount determined using the method described here would be multiplied by the non-compliant plan's enrollment, as determined using the sources finalized in the second final Program Integrity Rule, to establish the plan's total default risk adjustment charge.

Comment: Several commenters stated they supported a default risk adjustment charge that would be understood by issuers and that would encourage compliance. Some commenters

supported using the greatest of the three proposed methodologies for calculating the default charge. Those commenters suggested that where there are a limited number of issuers in a market in a State, an alternate approach to the standard deviation-based methodology should be taken, such as one that relies on nationwide data. Another commenter suggested that the default charge be set at the charge that would be two standard deviations above the mean charge in a market for the first instance of noncompliance; and at a higher rate, such as the highest PMPM charge among risk adjustment plans in the risk pool, for a second instance of noncompliance in consecutive benefit years.

Response: We are finalizing an approach in which the default PMPM charge is set at a fixed percentage of the Statewide average premium, which would be calculated as the enrollment-weighted mean of all risk adjustment covered plan average premiums in the applicable risk pool in the applicable market in the State in which the non-reporting plan operates. To calculate the fixed percentage, HHS would calculate the absolute value of the risk transfer PMPM amount of each plan in a State risk pool as a percentage of the Statewide average premium for the State risk pool. These percentages would then be used to rank all transfers as a percentage of Statewide average premium in the same risk pool in all States where HHS operates the risk adjustment program. We would select the fixed percentage of Statewide average premium yielded at the 75th percentile of this distribution of transfers, then multiply this percentage by the Statewide average PMPM premium for the risk pool in which the non-reporting plan operates. We will monitor the default charges resulting from this methodology and may adjust the percentile at which we assess the appropriate fixed percentage to apply the default charge in future rulemaking.

c. Clarification of the Good Faith Safe Harbor

In the second final Program Integrity rule, we finalized § 153.740(a), which permits HHS to impose CMPs upon issuers of risk adjustment covered plans and reinsurance-eligible plans for failure to adhere to certain standards relating to their dedicated distributed data environments. In the preamble to that rule, we stated that if we are able to determine that an issuer of a risk adjustment covered plan or reinsurance-eligible plan is making good faith efforts to comply with the standards set forth in § 153.740(a), consistent with our

policy codified at § 156.800(c),³⁵ we would not seek to impose CMPs for noncompliance with those standards during 2014 (78 FR 65061). We further stated: "However, we note that nothing in this provision prohibits HHS from imposing CMPs in 2015 for noncompliance that occurred in 2014." We seek to clarify that this statement does not mean that HHS takes the position that it could impose CMPs for noncompliance with respect to 2014 standards, even if the issuer attempted in good faith to comply, simply by waiting until 2015.

We intended to convey that the good faith safe harbor does not apply to non-compliance with dedicated distributed data environment standards applicable during 2015, *even if the non-compliance in 2015 relates to data for the 2014 benefit year*. In 2014, issuers must establish dedicated distributed data environments and load data according to a quarterly schedule to be provided by HHS. The good faith safe harbor would apply, for example, to noncompliance with the 2014 schedule for establishing a dedicated distributed data environment and loading data. However, the data loading schedule applicable to 2014 risk adjustment and reinsurance data extends into 2015 (the final loading deadline is April 30, 2015, which will enable HHS to calculate risk adjustment payments and charges and reinsurance payments for the 2014 benefit year by June 30, 2015), and at this time, the good faith safe harbor does not extend to noncompliance with any 2015 obligations, even if those 2015 obligations apply with respect to 2014 data. As we stated in the preamble to the Program Integrity final rules (78 FR 54070 and 78 FR 65046), at the appropriate time, we may consider extending this good-faith compliance safe harbor.

We further note that our clarification of this preamble language does not preclude application of the good faith safe harbor under § 156.800(c) to noncompliance actions that occurred in 2013 with respect to 2014 standards.

D. Part 155—Exchange Establishment Standards and Other Related Standards Under the Affordable Care Act

1. Election To Operate an Exchange After 2014

We proposed to reduce the time that the State must have in effect an approved or conditionally approved Exchange Blueprint and readiness assessment from 12 months to 6.5 months prior to the Exchange's first

³⁵ 45 CFR 156.800(c) was finalized in the first final Program Integrity Final Rule.

effective date of coverage. HHS learned through the process of conditionally approving the first generation of State Exchanges that it is challenging to make an accurate assessment of a State's progress and its ability to complete an Exchange build 10 months prior to open enrollment and a year prior to the first date that insurance coverage for consumers would become effective. In addition, we believe that this amendment will give States more time prior to approval of the Exchange Blueprint to prepare for the transition from an FFE or State Partnership Exchange model to a State Exchange. We proposed to amend § 155.106(a)(2) by moving the deadline for the approval of the Exchange Blueprint for those States electing to establish and operate an Exchange after 2014 to June 15th of the previous plan year rather than January 1st of the previous plan year. We also proposed in the preamble to the proposed rule that the Exchange Blueprint application would be submitted on June 1st instead of on November 15th. This new timeframe will enable HHS to gauge the State's actual technical, business and operational progress as more indicative milestones should be reached by June 15th. We are finalizing the amendment to § 155.106(a)(2) as proposed.

Comment: Several commenters were concerned that moving the date to June 15th will compromise the operational efficiency of issuers planning to offer QHPs in these new Exchanges. Some commenters stated that the June 15th date will give issuers insufficient time to program their systems for State-specific processes and suggested that HHS require newly-electing Exchanges to use a standard file format if the Exchange intends to collect and remit premiums. Other commenters stated that the June 15th date provides insufficient time for plan testing of State systems to ensure a smooth transition from an FFE model to a State Exchange. Other commenters stated that the June 15th date will provide the necessary time and flexibility for States transitioning to a State Exchange.

Response: The June 15th date balances the needs of issuers to prepare products for the Exchanges with the needs of the States that wish to transition to a State Exchange. The QHP certification process of newly electing State Exchanges or transitioning Exchanges should not be delayed, as State DOIs, in the ordinary course of reviewing plans for compliance with State and Federal law, will be conducting their reviews of plans irrespective of the Exchange Blueprint deadline. DOI decisions will therefore

be available to inform certification decisions by a State Exchange, and there should be ample time for issuers to program their system as required by newly electing State Exchanges and as required by those FFE States transitioning to a State Exchange model. We encourage States and new State Exchanges to work with issuers on State-specific requirements and unique processes.

Comment: One commenter suggested that HHS monitor whether the 6.5 month deadline provides adequate time for HHS to assess readiness. In addition, the commenter suggested that 15 days between the Blueprint application due date of June 1st and the decision of approval or conditional approval might not allow for sufficient time for HHS to communicate with States. Finally, the commenter asked HHS to clarify when a State must have full approval as opposed to conditional approval, given the shorter timeframe. One commenter stated that the new deadline would not give HHS enough time to conduct critical IT testing for the Exchange and the health plans.

Response: HHS believes that the June 15th date provides adequate time to assess the readiness of the Exchange. As stated in the preamble, the January 1st date proved difficult for HHS to appropriately assess the readiness of State Exchanges. Fifteen days is sufficient time for communication between the States and HHS, as HHS envisions that States that are applying to become State Exchanges will be communicating with HHS well before June 1st and HHS will provide appropriate support and technical assistance. Finally, the proposed timeframe is sufficient for HHS to approve or conditionally approve the new State Exchanges.

2. Ability of States to Permit Agents and Brokers To Assist Qualified Individuals, Qualified Employers, or Qualified Employees Enrolling in QHPs

We proposed to add new § 155.220(i) to provide that paragraph (c)(3), which addresses enrollment in a QHP through the Exchange via an Internet Web site of an agent or broker, would apply to SHOPs for plan years beginning on or after January 1, 2015, in addition to the individual market Exchanges. Under the proposal, employers that have not traditionally worked with agents and brokers but have, in the past, utilized Internet Web sites of agents and brokers for purchasing insurance would have another option to learn about and participate in SHOP. We proposed to allow SHOPs, in States that allow this activity under State law, to permit

enrollment in a QHP through the SHOP by using an Internet Web site of an agent or broker under the standards outlined in § 155.220(c)(3) if a State SHOP or an FF-SHOP has the technical capability to make this possible. CMS does not currently anticipate that the FF-SHOPs will make this functionality available in 2015. We are finalizing this provision as proposed, but note that we have added a title to the provision.

Comment: A broad range of commenters supported permitting enrollment in a SHOP QHP through the Exchange via the Internet Web site of an agent or broker. While several commenters favored the expanded function for agents and brokers, some commenters also recommended that HHS require compliance with industry and consumer protections. Several commenters recommended that HHS explicitly include consumer protections and prohibit agents and brokers who offer Internet Web sites to help consumers enroll in coverage through the Exchange from using PII, including gender, age, income, or other characteristics, for immediate or future marketing purposes; that the Exchange make consumers aware of these agents' and brokers' financial incentives; and that the Exchange establish a formal system for monitoring agents and brokers who offer Internet Web sites to help consumers enroll in Exchange coverage, enforcing consumer protections against such agents and brokers, and terminating relationships with agents and brokers that violate those protections.

Response: Under § 155.220(c)(3), HHS has established safeguards to protect consumers who are using the Internet Web site of an agent or broker to complete a QHP selection for coverage offered, or to enroll in coverage in the individual market Exchanges. The same safeguards and requirements would also apply when consumers use an Internet Web site of an agent or broker to complete a QHP selection for coverage offered on a SHOP Exchange.

We note that SHOP agents and brokers must comply with section 1411(g) of the Affordable Care Act, which provides that PII may only be used for purposes of, and to the extent necessary in, ensuring the efficient operation of the Exchange. States that are approved to operate SHOP Exchanges must also establish privacy and security standards governing the use of PII by non-Exchange entities consistent with § 155.260, which also prohibits any use or disclosure of PII in violation of section 1411(g) of the

Affordable Care Act.³⁶ We further note that FF–SHOP agents and brokers must sign an agreement with the Exchange (FF–SHOP Agent Broker Agreement) that requires strict adherence to the Exchange’s privacy and security standards established pursuant to 45 CFR 155.260. SHOP agents’ and brokers’ use and disclosure of PII is limited to the specific authorized functions outlined in the FF–SHOP Agent Broker Agreement and that Agreement also explicitly prohibits the use of PII for any purpose that is not identified as an authorized function. The use of PII for marketing purposes is not identified as an authorized function and is therefore prohibited.

Comment: One commenter recommended that HHS require that consumers who enroll in Exchange coverage through the Internet Web site of an agent or broker complete an eligibility application and the enrollment process through the SHOP to assure the SHOP remains the eligibility and enrollment system of record. One commenter further recommended that HHS require the SHOP to transmit enrollment information to a QHP or QDP issuer to ensure an issuer can effectuate enrollment of qualified employees. Another commenter recommended that the proposed rule be expanded to explicitly require that the Exchange retain responsibility for billing and premium aggregation services as required in regulation.

Response: In accordance with CMS regulations, the SHOP, not an agent or broker, will always complete eligibility determinations and the SHOP will remain the system of record for eligibility purposes. Additionally, in accordance with CMS regulations, the SHOP, not an agent or broker, will always be responsible for premium aggregation services as set forth in § 155.705(b)(4). Under § 155.705(b)(4), for plan years beginning on or after January 1, 2015, the SHOP must be responsible for all premium aggregation services and for routing payments from employers to issuers. Specifically, the SHOP must provide each qualified employer with a bill on a monthly basis

that identifies the employer contribution, the employee contribution, and the total amount that is due to issuers from the qualified employer; collect from each qualified employer the total amount due; make payments to QHP and QDP issuers in the SHOP for all enrollees; and maintain books, records, documents, and other evidence of accounting procedures and practices of the premium aggregation program for each benefit year for at least 10 years.

Comment: Several commenters recommended that agents and brokers who offer Exchange enrollment through an Internet Web site be required to list all QHP issuer offerings displayed on the relevant Exchange Web site and that the Exchange provide this information to the agent or broker. Some commenters specifically recommended that HHS specify that agents and brokers using non-Exchange Web sites must refrain from disclosing QHP prices and rates prior to the availability of such data on the SHOP Web site. Other commenters recommended that HHS contract with agents and brokers offering Exchange enrollment through an Internet Web site other than the Exchange Web site to prohibit the early release of data on QHP prices and data to ensure that QHP rates are not shared with competitors prior to the plan data being made public.

Response: As is required at § 155.220(c)(3)(iv) for agents and brokers assisting with enrollment in individual market Exchange coverage, the Internet Web site of the agent or broker used to complete the QHP selection must display all QHP data provided by the Exchange. Agents and brokers must also meet all standards for disclosure and display of QHP information contained in § 155.205(b)(1) and (c). As noted in the proposed Program Integrity Rule (78 FR 37046), we recognize that an Exchange may not be able to provide to agents and brokers certain data elements necessary to meet the § 155.205(b)(1) requirements, such as premium and rate information, depending upon confidentiality requirements, the agent or broker appointment with the QHP issuer, and State laws regarding agent and broker appointments. We therefore provided under § 155.220(c)(3)(i) that if less than all QHP data required under § 155.205(b)(1) is displayed on the agent’s or broker’s Internet Web site, the agent or broker must prominently display a standardized disclaimer provided by HHS stating that all information required under § 155.205(b)(1) for the QHP is available on the Exchange Web site and provide a Web link to the Exchange Web site. In

addition, for States in which HHS is operating an FFM, pursuant to § 155.220(c)(3)(vii), a second disclaimer is required that would include the following notifications: (1) The Internet Web site of the agent or broker is not an FFM Web site, (2) the Internet Web site of the agent or broker may not contain all QHP data available on the FFM Web site, and (3) the agent or broker is required to comply with all applicable Federal laws, including the standards specified in paragraph (c)(3) of § 155.220, and the standards established under 45 CFR 155.260 to protect the privacy and security of PII. The disclaimer must also contain a link to HealthCare.gov. The same requirements would apply to agents and brokers assisting with enrollment in SHOP coverage.

Comment: One commenter recommended that HHS require that the Internet Web site of an agent or broker that is used to complete a QHP selection through the Exchange display available QHPs in a manner that is as consistent with the Exchange Web site as possible.

Response: Under § 155.220(c)(3)(i), all QHP data on the Internet Web site of an agent or broker that is used to complete a QHP selection through the Exchange must be disclosed and displayed consistent with the requirements that apply to the Exchange Web site at 45 CFR 155.205(b)(1) and (c). Section 155.205(b)(1) generally requires that standardized comparative information be provided for each available QHP and 45 CFR 155.205(c) requires that information be displayed in a manner that is accessible to persons with limited English proficiency and persons with disabilities. In addition, as noted above, if an agent or broker Web site does not display all information required under § 155.205(b)(1) for a QHP, it must include the standardized disclaimer established under § 155.220(c)(3)(i). The same requirements would apply to agents and brokers assisting with enrollment in SHOP coverage. State laws and regulations may establish additional standards for this activity.

3. Privacy and Security of Personally Identifiable Information

In § 155.260(a), we proposed allowing the Secretary to determine that additional uses or disclosures of personally identifiable information (PII), which may not be directly connected to Exchange “minimum functions” as currently described in regulation, ensure the efficient operation of the Exchange, subject to privacy and security standards that Exchanges must establish. We proposed a process for

³⁶ 45 CFR 155.105(b)(1) provides that HHS will approve the operation of an Exchange established by the State if the State Exchange is able to carry out the required functions consistent with subparts C, D, E, F, G, H, and K of part 155. For States approved to operate only a SHOP Exchange, the Exchange must perform the minimum functions described in subpart H and all applicable provisions of other subparts referenced therein. 45 CFR 155.705(a) includes a reference to subparts C, E, K, and M of part 155. The privacy and security requirements for Exchanges are codified in subpart C. As such, all Exchanges, including all SHOPs, are subject to the privacy and security requirements at 45 CFR 155.260.

Exchanges to seek the Secretary's approval of other requested uses and disclosures of eligibility and enrollment PII that would ensure the efficient operation of the Exchange; comply with other applicable law and policy; and require the consent of the individual subject of the PII prior to the requested use or disclosure.

We also proposed in § 155.260(b) to clarify that the definition of a "non-Exchange entity" refers to any individual or entity that gains access to PII submitted to an Exchange, or collects, uses, or discloses PII gathered directly from applicants, qualified individuals, or enrollees while that individual or entity is performing functions agreed to with the Exchange. Examples of non-Exchange entities include, but are not limited to, Medicaid and CHIP agencies; Certified Application Counselors; in-person assisters; agents and brokers, including Web-brokers; QHP issuers; and other third parties that contract with the Exchange or other downstream entities that contract with non-Exchange entities.

We proposed to maintain the existing requirement for Exchanges to enter into a contract or agreement with non-Exchange entities, and we specified five required elements to be included in those contracts and agreements. We proposed three criteria that would provide a foundation and flexibility for Exchanges to set privacy and security standards as a condition of contract or agreement with non-Exchange entities while also aligning closely with the wide variety of non-Exchange entities, responsibilities, functions, operational environments, and technical infrastructures. These criteria would provide equivalent or more stringent protection than the standards which the Exchange has established and implemented for itself while aligning to the functions and operating environment of the non-Exchange entity.

The proposed requirement that standards be relevant to non-Exchange entities' duties and activities in relation to the Exchange introduced the concept of "relevant and applicable" and reflected our intent to address the various responsibilities assumed by non-Exchange entities and their associated technical infrastructures. We are finalizing the provisions as proposed.

Comment: Commenters generally expressed support for the proposed substantive and procedural requirements established in § 155.260(a)(1)(iii), including a consent requirement, for data uses and

disclosures not explicitly described in § 155.260(a)(1)(i) or (ii). Certain commenters noted that data required to determine eligibility and premium subsidies is extremely sensitive, necessitating strong privacy and security safeguards. Certain commenters emphasized the need to minimize sharing of PII to the minimum necessary to effectuate implementation of the Affordable Care Act and ensure the efficient operation of the Exchange.

Response: We concur with the commenters' suggestion that the sensitive nature of PII necessitates robust privacy and security safeguards, and we reiterate that the Secretary would review requestors' proposed privacy and security standards as part of the Secretary's proposed review process under § 155.260(a)(1)(iii)(B)(4). The proposed process establishes the requirement for requestors to describe how data will be protected with privacy and security standards that are compliant with § 155.260 and to show that a proposed use or disclosure will ensure the efficient operation of the Exchange consistent with section 1411(g)(2)(A) of the Affordable Care Act. If a requested use or disclosure does not satisfy these requirements, it would not be approved under the proposed process. We further recognize the imperative to maintain safeguards for eligibility and enrollment PII. Once the Secretary approves a proposed use or disclosure of eligibility and enrollment PII, the Exchange would be required to limit the use or disclosure of PII to the extent necessary to accomplish the proposed function, and the individual would need to provide consent before his or her eligibility and enrollment PII could be used or disclosed.

Comment: Some commenters supported our proposal at § 155.260(b)(3), which would require that non-Exchange entities meet privacy and security standards at least as protective as the standards the Exchange establishes and implements for itself. The commenters further recommended that the same standards apply to downstream entities to ensure PII continues to be protected once it reaches the downstream entity. One commenter further recommended that Exchanges form direct agreements with downstream entities rather than relying on non-Exchange entities to ensure their compliance with privacy and security standards. The commenter stressed that this is important because downstream entities may have different duties or operational and technical environments than the non-Exchange entities with which an Exchange has an agreement, and these differences may not be

properly accounted for in the Exchange's agreement with a non-Exchange entity.

Response: We proposed at § 155.260(b)(2) to maintain the existing requirement for Exchanges to enter into a contract or agreement with non-Exchange entities and we provided more details specifying the required elements of these contracts and agreements. We proposed in § 155.260(b)(2)(iv) that such a contract or agreement must require any downstream entities that meet the definition established in § 155.260(b)(1) to comply with the same privacy and security standards with which the non-Exchange entity agrees to comply under its contract or agreement with the Exchange. Further, we proposed in § 155.260(b)(3)(iii)(A) that the privacy and security standards to which non-Exchange entities are bound must consider the operational and technical environment in which the non-Exchange entity operates, and that these environments be assessed in light of the requirement in § 155.260(a)(5) to monitor, periodically assess and update security controls and related system risks to ensure continued effectiveness of those controls. Downstream entities are also subject to this criterion under proposed § 155.260(b)(2)(iv). Our adoption of these requirements in the final rule reflects our concurrence that it is important that the privacy and security standards continue to apply to PII as it moves to additional downstream entities.

Comment: Several commenters suggested that QHP issuers should not be considered non-Exchange entities under the definition proposed in § 155.260(b) because issuers' roles differ fundamentally from the roles and functions of other entities listed as non-Exchange entities in the proposed regulation. Certain commenters specified, as an example, that unlike other entities listed as non-Exchange entities, QHP issuers do not participate in the eligibility determination process because it is conducted entirely through the Exchange.

Response: Because the proposed definition of non-Exchange entities is broad and includes a variety of entities, we recognize that there can be considerable variation among non-Exchange entities. Different non-Exchange entity functions can result in variation in both the amount and type of access to PII and the technical characteristics of the non-Exchange entity's environment. We intended to address the lack of a regulatory mechanism to take these variations into account, and to alleviate potential

operational burdens for non-Exchange entities. We proposed that any individual or entity that gains access to PII submitted to an Exchange or accesses PII directly from individuals should be considered a non-Exchange entity. This approach defines a non-Exchange entity based on the entity's access to PII, not based on the roles or functions of the entity, and QHP issuers would qualify as non-Exchange entities based on this definition. We believe this approach appropriately addresses the fact that a QHP issuer's role may differ from that of other non-Exchange entities.

Comment: Several commenters suggested that QHP issuers should not be subject to the proposed regulatory requirements at § 155.260(b)(2) because they already are subject to the HIPAA Privacy, Security and Breach Notification Rules at 45 CFR Parts 160 and 164, as well as applicable State breach notification standards. Certain commenters requested that if issuers are classified as non-Exchange entities as proposed, we recognize the HIPAA Privacy, Security and Breach Notification Rules as sufficient for Exchange privacy and security standards under § 155.260(b). Certain commenters further explained that, because QHP issuers and their delegated and downstream entities already are subject to comprehensive privacy and security standards under HIPAA, requiring issuers to implement additional privacy and security standards would pose duplicative and potentially conflicting requirements and unnecessary administrative burdens. Certain commenters suggested that the proposed regulatory requirements for non-Exchange entities should not apply to QHP issuers because they already are subject to business associate agreement requirements that the proposed regulatory requirements would duplicate, imposing unnecessary administrative burdens on them.

Response: In its final form, § 155.260(b)(3)(i)–(iii) will allow an Exchange the flexibility to tailor privacy and security standards to particular types of non-Exchange entities so long as those standards remain strong in compliance with § 155.260. With respect to non-Exchange entities that currently are obligated to follow the HIPAA Privacy, Security and Breach Notification Rules, pursuant to written agreements required by § 155.260(b)(3), Exchanges will have the flexibility to deem non-Exchange entities in compliance with the specific privacy and security standards that the Exchange establishes for its non-Exchange entities by virtue of their

compliance with the HIPAA Privacy, Security and Breach Notification Rules or similar standards. This would be permissible so long as the Exchange determines that HIPAA Privacy, Security and Breach Notification Rules or similar standards are at least as protective as the standards the Exchange has established and implemented for itself in compliance with paragraph § 155.260(a)(3), so long as those standards' protections are extended to all PII created, collected, disclosed, accessed, maintained, stored, or used in connection with FFEs, and so long as the Exchange also requires non-Exchange entities to comply with the additional limitations on use and disclosure of PII in section 1411(g) of the Affordable Care Act. It would be incumbent upon the Exchange to evaluate whether such deeming arrangements would satisfy all of the criteria established for privacy and security standards under proposed § 155.260(b)(3). With respect to FFEs, pursuant to written agreements, they also will have the flexibility to deem QHP issuers, and agents and brokers who use QHP issuer information technology systems, to be in compliance with the specific privacy and security standards that the Exchange establishes for its non-Exchange entities by virtue of their compliance with the HIPAA Privacy, Security and Breach Notification Rules or similar standards, so long as the FFEs determine that those standards are at least as protective as the standards the FFEs have established and implemented for themselves in compliance with paragraph § 155.260(a)(3), so long as those standards' protections are extended to all PII created, collected, disclosed, accessed, maintained, stored, or used in connection with FFEs, and so long as the FFEs also require non-Exchange entities to comply with the additional limitations on use and disclosure of PII in section 1411(g) of the Affordable Care Act. We intend to issue guidance that will address in greater detail the applicability of the HIPAA Privacy, Security, and Breach Notification Rules and the additional limitations on use and disclosure of PII in section 1411(g) of the Affordable Care Act.

Comment: Certain commenters more specifically requested that QHP issuers be allowed to comply with the HIPAA Privacy, Security and Breach Notification Rules to satisfy the privacy and security requirements of § 155.260(b) because the enrollment and eligibility PII that QHP issuers receive from an Exchange does not merit a different level of protection than other

non-Exchange-based enrollment information that QHP issuers typically handle. Certain commenters explained that QHP issuers do not participate in the Exchange eligibility determination process, and only receive the results of such determinations in enrollment files that are substantially similar to the enrollment data that health plans and issuers receive or create for non-Exchange-based products that are subject to HIPAA Privacy and Security Rules and State breach notification standards. One commenter also noted that such enrollment files do not contain information from Federal agencies such as IRS and Department of Homeland Security.

Response: Under the final rule, Exchanges will have the flexibility to deem non-Exchange entities in compliance with the specific privacy and security standards that the Exchange establishes for its non-Exchange entities by virtue of their compliance with the HIPAA Privacy, Security and Breach Notification Rules or similar standards, so long as those standards are at least as protective as the standards the Exchange has established and implemented for itself in compliance with paragraph § 155.260(a)(3), and so long as they incorporate the additional limitations on use and disclosure of PII in section 1411(g) of the Affordable Care Act. It would be the responsibility of the Exchange to evaluate whether such deeming arrangements for privacy and security standards for non-Exchange entities would satisfy the criteria proposed in § 155.260(b)(3).

We proposed requirements in § 155.260(b)(3) that are intended to provide a foundation that Exchanges must use to define privacy and security standards for non-Exchange entities that afford a level of protection equal to that provided by the standards the Exchanges adopt for themselves. We proposed three criteria that would have to be met by the privacy and security standards to which an Exchange must bind non-Exchange entities, and we do require that these standards take into specific account the environment in which the non-Exchange entity operates. The first criterion in § 155.260(b)(3)(i) requires that any privacy and security standards must be as protective as the standards the Exchange sets for itself, consistent with all the principles and requirements listed under § 155.260(a). The second criterion requires that any privacy and security standards must also comply with requirements for workforce and contractor compliance, written policies and procedures, compliance with the

Code, and consequences of improper use and disclosure of information established by § 155.260(c), (d), (f) and (g). The third criterion requires that the privacy and security standards to which non-Exchange entities are bound take into consideration several factors, including the operating and technical environment in which the non-Exchange entity operates. These environments and the standards themselves should be assessed in light of the requirement established at § 155.260(a)(5) to monitor, periodically assess, and update security controls and related system risks to ensure the continued effectiveness of those controls. We would expect that an Exchange's contracts and agreements with non-Exchange entities would include privacy and security standards based on these criteria, as well as a proposed requirement at § 155.260(b)(3)(iii)(B) requiring those standards to be relevant and applicable to the non-Exchange entity's duties and activities in relation to the Exchange. We believe these rules allow sufficient flexibility for Exchanges to tailor privacy and security standards to the specific information non-Exchange entities will handle, including that information typically handled by QHP issuers.

Comment: Some commenters expressed concern that under the proposed regulatory language, an Exchange could require a QHP issuer to comply with CMS's "Minimum Acceptable Risk Standard for Exchanges (MARS-E) Suite of Documents: Guidance on Operational, Technical, Administrative, and Physical Safeguards."³⁷ One commenter further explained that because QHP issuers do not conduct eligibility analyses, only receiving eligibility results, requiring issuer compliance with the full suite of MARS-E requirements would have significant operational impacts and increase administrative costs without enhancing data security.

Response: Under the final rule, where an Exchange determines that a non-Exchange entity's compliance with MARS-E requirements are necessary to adequately protect PII and comply with § 155.260(b), it may indeed require such compliance under a written agreement with a non-Exchange entity. For example, FFE agreements with agents and brokers who will assist consumers with applications for determinations of eligibility to enroll in insurance

affordability programs, including QHPs, and/or to receive advance payments of premium tax credit and/or cost-sharing reductions using the FFE Web site, currently require compliance with MARS-E requirements. All agents and brokers providing such assistance through FFEs must comply with the FFE privacy and security standards for non-Exchange entities as a condition of their separate agreements with CMS. Agents and brokers who will use a QHP issuer's computers and work space controlled by a QHP issuer to perform these functions, must ensure those computers and work space are compliant with privacy and security provisions of their agreements with CMS. We believe that QHP issuers typically have procedures already in place to address general computer and work space security.

Comment: One commenter recommended that we clarify that limitations on use and disclosure under section 1411(g) of the Affordable Care Act apply only to PII concerning an "applicant." The commenter further explained that, once an individual is enrolled in a QHP, PII received during the application process should no longer be subject to section 1411(g), but instead should be subject to HIPAA privacy and security standards. The commenter also requested that if an applicant provides information to a QHP issuer, governed by section 1411(g) of the Affordable Care Act, and the applicant does not enroll in a QHP, the issuer should then be able to use and disclose the information consistent with HIPAA privacy and security standards after obtaining the applicant's consent.

Response: We clarify that as proposed in § 155.260(b)(1), any individual or entity that gains access to PII submitted to an Exchange or collects, uses or discloses PII gathered directly from applicants, qualified individuals, or enrollees while that individual or entity is performing the functions agreed to with the Exchange, is considered to be a non-Exchange entity. We proposed in § 155.260(b)(2) to maintain the existing requirement for Exchanges to enter into a contract or agreement with non-Exchange entities. We also state in § 155.260(b)(2)(ii) that in the required contract or agreement, the Exchange must impose a requirement for compliance with privacy and security standards, and specifically list or incorporate by reference the privacy and security standards and obligations with which the non-Exchange entity must comply, including obtaining consent consistent with the principle provided under § 155.260(a)(iv). Under the Final Rule, Exchanges will have the flexibility to deem non-Exchange entities in

compliance with the specific privacy and security standards that an Exchange establishes for its non-Exchange entities by virtue of their compliance with the HIPAA Privacy, Security and Breach Notification Rules or similar standards, so long as the Exchange determines that those standards are at least as protective as the standards the Exchange has established and implemented for itself in compliance with paragraph § 155.260(a)(3), so long as those standards' protections are extended to all PII created, collected, disclosed, accessed, maintained, stored, or used in connection with Exchange, and so long as the Exchange also requires non-Exchange entities to comply with the additional limitations on use and disclosure of PII in section 1411(g) of the Affordable Care Act.

Comment: One commenter expressed concern regarding the proposed requirement that non-Exchange entities inform the Exchange of any change in administrative, technical or operational environments defined as material in the contract. The commenter expressed concern that the definition of material changes that would trigger the reporting requirement could be overly broad in individual Exchange contracts. The commenter recommended that we clarify that the types of changes that would have to be reported be significant and have the possibility of altering the organization's overall security posture.

Response: At § 155.260(b)(2), we proposed to maintain the existing requirement for Exchanges to enter into a contract or agreement with non-Exchange entities, and we proposed five required elements of these contracts and agreements. One of those elements, in § 155.260(b)(2)(iv), would require the non-Exchange entity to inform the Exchange of any change in its administrative, technical or operational environment, as defined within the contract, which would require an alteration of the privacy and security standards within the contract or agreement to ensure those standards remain relevant and aligned with current operating environments. The intent of this requirement is to provide an opportunity for the Exchange and the non-Exchange entity to assess and revise the privacy and security standards to ensure their continued relevance.

4. Annual Open Enrollment Period for 2015

In § 155.410, as finalized in the Exchange Establishment Rule, we set forth provisions for initial and annual open enrollment periods. We proposed amending § 155.410(e) and (f), which pertain to the annual open enrollment

³⁷ The MARS-E suite of documents can be found at the following address: <http://www.cms.gov/ccioo/resources/regulations-and-guidance/index.html#MinimumAcceptableRiskStandards>.

period and effective date for coverage after the annual open enrollment period. These amendments apply to non-grandfathered policies offered through and outside the Exchange.

In paragraph (e), we proposed adding a paragraph that would change the annual open enrollment period for the 2015 benefit year. We proposed that for all Exchanges, annual open enrollment would begin on November 15, 2014 and extend through January 15, 2015. This would give health insurance issuers an additional month in 2014 before they would need to begin accepting plan selections for the upcoming plan year and staggers the start of open enrollment for the Exchange from that for Medicare Advantage. It would give consumers the ability to have coverage starting January 1, 2015, or if they need more time, until January 15, 2015 to shop for, and select a QHP for the 2015 plan year. We also noted that if finalized, all Exchanges would be expected to delay their QHP certification dates by at least one month. This would give health insurance issuers additional time to monitor 2014 enrollments, prior to submitting their 2015 rates. We proposed to retain the October 15th to December 7th open enrollment period for subsequent benefit years.

In paragraph (f), we proposed adding a paragraph to address coverage effective dates for plan selections made during the annual open enrollment period for the 2015 benefit year. We proposed that coverage must be effective January 1, 2015, for plan selections received by the Exchange on or before December 15, 2014. We proposed that coverage must be effective February 1, 2015, for plan selections received by the Exchange from December 16, 2014³⁸ through January 15, 2015. In accordance with § 155.335(j), qualified individuals already enrolled in a QHP through the Exchange in 2014 who remain eligible for enrollment in a QHP would have their coverage continue into 2015, but they would have the ability to change QHPs until January 15, 2015. We also sought comment on whether there should be retrospective coverage to January 1, 2015, for any individual who signs up after December 15, 2014 in the open enrollment period to ensure continuity of coverage. We also proposed January 1st coverage effective dates for open enrollment for benefit years beginning on or after January 1, 2016.

³⁸ We note that the proposed rule contained a typographical error that referred to December 16, 2015, instead of the clearly intended December 16, 2014. This final rule finalizes the provision with the corrected date.

We are finalizing the regulation with an open enrollment end date of February 15, 2015 instead of January 15, 2015, for the benefit year beginning January 1, 2015, and we are adding coverage effective dates for enrollments during the period between January 16–February 15, 2015. We are not finalizing in this rule, the open enrollment period or effective dates for the benefit years beginning on or after January 1, 2016. Finally, for consistency within this section, we are changing the reference to “plans” in subparagraph (f)(1) to “QHPs.”

Comment: Many commenters supported the proposed open enrollment period dates and corresponding coverage effective dates. Some commenters proposed alternate open enrollment period date ranges for both the benefit year beginning on January 1, 2015, and for years beyond 2015. Other commenters opposed the proposed amendments to the rule. Issuers discouraged retroactive effective dates, in response to a solicitation for comments regarding retroactive effective dates.

Response: In response to comments recommending different ranges for the annual open enrollment period, we are finalizing this amendment so that open enrollment for the benefit year beginning January 1, 2015 begins November 15, 2014, and ends February 15, 2015. We are also adding a provision providing for the standard coverage effective date of March 1, 2015 for enrollments taking place between January 16 and 31, 2015. We believe that the additional time before open enrollment will enable the collection of additional rating experience that could have a positive benefit on reducing 2015 rates for consumers. We further believe that extending the open enrollment period to February 15, 2015 instead of January 15, 2015 is beneficial for consumers because it provides additional time to select a plan. We are not adding any requirements for retroactive coverage in connection with this annual open enrollment period. Because some commenters proposed alternate open enrollment period date ranges for benefit years beyond the one year beginning on January 1, 2015, we intend to propose open enrollment dates for the 2016 plan year in the 2016 draft Payment Notice. Finalizing open enrollment dates for the 2016 plan year in the 2016 Payment Notice will allow an additional year's experiences to inform the finalization of realistic enrollment dates.

We note that non-grandfathered individual coverage sold on a date other than January 1st of the calendar year

would still be required to have the plan or policy year end on December 31, 2015 to comply with the requirement to be offered on a calendar policy year under 45 CFR 144.103 and 147.104(b)(2). We also note that this amendment to the open enrollment period applies to the individual health insurance market, both for plans offered through and outside the Exchanges, by virtue of the cross-reference at 45 CFR 147.104(b)(1)(ii), through which the dates of the individual market Exchange open enrollment period also apply to the individual market generally.

5. Functions of a SHOP

We proposed amending § 155.705(b)(1), which lists the rules regarding eligibility and enrollment to which SHOPs must adhere, to include mention of provisions regarding termination of coverage in the SHOPs and SHOP employer and employee eligibility appeals that were finalized in the first final Program Integrity Rule. We are finalizing this amendment with a minor change to replace the list of provisions in the current and proposed versions of the rule with a more general reference to subpart H. The change from the proposed rule text will help HHS keep the provision up to date.

We also proposed adding a new paragraph § 155.705(b)(3) to provide qualified employers with options to offer dental coverage after employee choice becomes available in the FF–SHOPs. We proposed that for plan years beginning on or after January 1, 2015, a FF–SHOP would have two methods by which to offer stand-alone dental plans (SADPs) to its employees and their dependents—either a single SADP or a choice of all SADPs available in an FF–SHOP after employee choice becomes available in the FF–SHOPs. We also noted in the preamble to the proposed 2015 Payment Notice that we were considering allowing qualified employers to offer all SADPs at a given dental AV level option, if the SADP AV level requirements were not eliminated in this rulemaking, and sought comments on this approach. Because we are now not finalizing the elimination of the SADP AV requirements, we are finalizing the policy to reflect this contemplated approach, giving employers the option of offering employees either a single qualified dental plan, or all dental plans at a single dental actuarial value level.

We proposed to re-designate § 155.705(b)(4)(ii) as (b)(4)(iii) and to add new paragraph (b)(4)(ii) to allow all SHOPs to establish one or more standard processes for premium calculation, payment, and collection

after the SHOP makes premium aggregation available. We also proposed provisions related to the processes FF-SHOPs would establish for premium calculation, payment, and collection under proposed § 155.705(b)(4)(ii). Consistent with § 155.720(b), which establishes that all SHOPs must establish a uniform enrollment timeline and process, including a specified list of activities such as establishment of effective dates of employee coverage, for all QHP issuers and qualified employers to follow, and consistent with § 155.720(d), which establishes that all SHOPs must follow the requirements set forth at § 155.705(b)(4), we proposed at § 155.705(b)(4)(ii)(A) that, after premium aggregation becomes available in the FF-SHOPs, employers in the FF-SHOPs would be required to make all premium payments—initial and subsequent—according to a timeline and process that HHS will establish through guidance. We anticipate that this payment timeline would require employers to make a full initial premium payment at least 2 days prior to the employer's desired coverage effectuation date, or perhaps longer, in order to provide a reasonable window of time for the relevant banks to process the payment transaction.

We solicited comments about whether this time frame would be reasonable for employers or issuers, about alternative time frames that might be more appropriate, and about the payment timeline and process for the FF-SHOPs generally, including the consideration that HHS should factor into the development of the payment timeline and process. In developing the premium payment timeline and process, HHS will consider its interest in operating and administering the FF-SHOPs efficiently, as well as issuers' interests in ensuring timely payment of premiums, and issuers' and employers' interests in establishing a fair and workable premium payment process. Section 155.735(c) and the Draft 2015 Letter to Issuers in the Federally-facilitated Marketplaces published on February 4, 2014 contain additional information about the payment timeline and process for payments subsequent to the initial premium payment. Finally, as discussed below in the preamble to § 156.285, we also proposed a conforming amendment to § 156.285(c)(7)(iii) to establish that an FF-SHOP issuer would be required to effectuate coverage unless it has received an enrollment cancellation from the FF-SHOP. We are finalizing these provisions as proposed.

At § 155.705(b)(4)(ii)(B), we proposed a methodology for prorating premiums in FF-SHOPs after premium aggregation

becomes available in those SHOPs in plan years beginning on or after January 1, 2015. We proposed that groups will be charged for the portion of the month for which the enrollee is enrolled. In the FF-SHOPs, premiums for coverage of less than 1 month will be prorated by multiplying the number of days of coverage in the partial month by the premium for 1 month divided by the number or days in the month. Issuers will charge and the FF-SHOP will collect for only the portion of coverage provided for the partial month. We also solicited comments about whether a standardized methodology regarding prorating premiums for partial month enrollment should be adopted across all individual market Exchanges. We are finalizing this provision as proposed, without adopting a standardized methodology across all individual market Exchanges.

We are finalizing in this rule amendments to § 155.705(b)(6) that were proposed in the "Program Integrity Rule" published in the June 19, 2013 *Federal Register* (78 FR 37032) on pages 37051–37052 and 37084. These amendments were proposed in conjunction with the issuer standards regarding the frequency of indexed rate updates that were codified at 45 CFR 156.80, and make explicit that this market-wide policy also applies to SHOPs. Because § 156.80 sets a market standard for mid-year rate updates of no sooner than quarterly, this provision is already in effect small-group-market-wide, including in all SHOPs. Specifically, we proposed to amend paragraph (b)(6)(i) to provide that SHOPs must require QHP issuers to make changes to rates at a uniform time that is no more frequently than quarterly. We also proposed at paragraph (b)(6)(ii) to provide issuers participating in the FF-SHOPs with the maximum amount of flexibility permitted under § 156.80 and the proposed amendment to § 155.705(b)(6)(i), standardize the effective dates for rate updates in the FF-SHOPs, and provide that FF-SHOP issuers must submit rates to HHS 60 days in advance of the effective date. Consistent with technical guidance provided to issuers through the Health Insurance Oversight System on April 8, 2013, issuers will be able to submit updated quarterly rates for the FF-SHOPs no sooner than for the third quarter of 2014, due to current system limitations.³⁹ Comments related to this provision were addressed when the

single risk pool provision was finalized on October 30, 2013 in the Program Integrity final rule. We are finalizing as proposed the amendment to § 155.705(b)(6)(i), but are finalizing the language proposed at § 155.705(b)(6)(ii) at § 155.705(b)(6)(i)(A) instead of at (b)(6)(ii), to make clear that we never intended for this proposal to supersede the language at current § 155.705(b)(6)(ii). We are also making a minor change in the language finalized at § 155.705(b)(6)(i)(A) to replace the word FF-SHOP with the term "Federally-facilitated SHOP."

We proposed at § 155.705(b)(11)(ii)(C) to provide FF-SHOPs, in plan years beginning on or after January 1, 2015, with the option of permitting a qualified employer to define a percentage contribution for full-time employees (as defined in § 155.20 and section 4980H(c)(4) of the Code) that differs from the percentage contribution the qualified employer defines for employees that are not full-time employees under that definition, to the extent permitted by applicable law. This proposal would also allow an FF-SHOP to permit an employer to define different percentage contributions toward premiums for dependent coverage for full-time and non-full-time employees. The FF-SHOPs would be allowed to define up to four different contribution levels: full-time employee-only, full-time employee dependent, non-full-time employee-only and non-full-time employee dependent. We are finalizing the substance of this provision as proposed, but we anticipate that the functionality to implement different contribution levels for full-time versus non-full-time employees and their dependents will not be available in the FF-SHOPs until sometime after January 1, 2015. We will provide adequate notice to issuers and employers before this functionality becomes available.

We also proposed a prohibition on composite premiums in the FF-SHOPs for plan years beginning on or after January 1, 2015, when a qualified employer elects to offer employee choice—that is, when the qualified employer offers its qualified employees all QHPs within the employer's selected level of coverage under § 155.705(b)(3)(iv)(A). To accomplish this objective, we proposed amendments to §§ 155.705(b)(11)(ii)(D) and 156.285(a)(4). While we are finalizing the proposed amendments to § 156.285(a)(4), as discussed below, we are *not* finalizing the proposed amendments to § 155.705(b)(11)(ii)(D), because those amendments would not carry out the intended policy, but would

³⁹ See Rates Changes for Small Group Market Plans and System Processing of Rates (April 8, 2013).

instead limit employers' ability to establish a fixed contribution to employee coverage, which was not an intended outcome of the proposals. We clarify that we have always interpreted § 155.705(b)(11)(ii)(D) to provide that, in an FF-SHOP, a State or employer may require that employer contributions be based on a calculated composite premium, which is, in effect, a composite premium calculated for the sole purpose of establishing a fixed dollar amount employer contribution to employee coverage, and is not a composite premium offered to the group plan by the issuer. When employer contributions are based on a calculated composite premium, this has the effect of equalizing employer contributions for a given plan such that the employer's contribution toward each enrollee's premium does not vary by the enrollee's age, but is instead a fixed dollar amount. In other words, the calculated composite premium described in § 155.705(b)(11)(ii)(D) is a separate concept from the composite premium addressed in § 147.102 and in our proposed amendments to § 156.285(a)(4). Accordingly, the fact that the FF-SHOPS will permit employers to use a calculated composite premium to determine employer contributions does not require issuers that are not otherwise required to offer composite premium rates to do so. Employers may also opt to set their contributions as a percentage of per-member premiums under a calculated composite premium approach or under a per-member premium approach. For these reasons, no modification to § 155.705(b)(11)(ii)(D) is necessary to carry out our intended policy on composite premiums in the FF-SHOPS. We are addressing comments on the proposed policy below, in the preamble section discussion related to final § 156.285(a)(4).

We also asked for comments on whether the calculation of user fees for the FF-SHOPS should be calculated based upon composite premiums or premiums calculated on per-member buildup. The methodology to calculate user fees for the FF-SHOPS will depend on how the group calculates a group's monthly premium. If a group uses a composite premium, the user fee will be based on this methodology. Similarly, if a group uses a per-member buildup approach, the user fee will reflect this methodology.

Comment: We received varying comments on our proposal to allow employers the ability to offer employees a choice of all SADPs available in an FF-SHOP. Several commenters supported our proposal of offering full

choice among all of the SADPs available in an FF-SHOP, and stated that the proposal would allow employees to choose a dental benefit that works best for their family and will lead to an increase in choice and competition in the small group market. Commenters supportive of the proposal also stated that allowing employers the flexibility to select whether to make available a single SADP or to make available all SADPs will encourage employer participation in the Exchanges. However, some commenters were opposed to allowing employee choice of SADPs, specifically requesting that this feature should be revisited in future plan years. Commenters opposed to the proposal stated that this additional choice will provide an additional layer of complexity for both the FF-SHOP Web site and administrative functionality. Some commenters said that it will also increase the risk of adverse selection, negatively affect competition, and increase prices for consumers.

Response: Allowing an employer flexibility to provide its employees and their dependents with a range of stand-alone dental coverage options advances our goal of increased choice and competition in FF-SHOPS. Allowing the option for qualified employers to offer all SADPs at a given dental AV level option (high and low) is similar to employee choice of QHPs in SHOPs, because under employee choice, an employer selects an actuarial value level (or "metal tier") of coverage and employees may select any QHP within that actuarial value level. Accordingly, as discussed in the preamble to the proposed rule, we considered whether to give employers the option of offering one SADP or all SADPs at one of the actuarial value levels set forth at § 156.150, but we did not ultimately propose regulation text reflecting that approach. Instead, we proposed providing employers with the option of offering all SADPs in an FF-SHOP, because another proposed amendment in this rulemaking would have done away with the actuarial value levels for SADPs set forth at § 156.150. Because that proposed amendment to § 156.150 will not be finalized, we can now amend our proposed regulation text to implement this alternative option. This modification would also address some commenters' concerns about too much risk when all SADPs are made available to employees in FF-SHOPS.

Comment: We received some comments stating that issuers should be allowed to price for the employer choice and employee choice for SADPs separately; that is, that issuers should be

permitted to charge a different premium to the employer based on whether the SADP is the only one offered or on whether the SADP is one among many plans being offered. Commenters stated that not allowing issuers to price separately for employer choice and employee choice will adversely affect competition and increase prices for consumers.

Response: 45 CFR 156.255(b) requires that, in order for a plan to be certified as a QHP, the plan's issuer "must charge the same premium rate without regard to whether the plan is offered through an Exchange" This requirement applies to SADP QHPs under § 155.1065(a)(3). If a SADP QHP is priced differently based on whether it is being offered as the only SADP QHP or as one of several SADP QHPs under employee choice that would mean that the SADP QHP would have two different premium rates when offered through the Exchange. This necessarily means that one of these premium rates would be different from the premium rate of the same SADP QHP offered outside the Exchange, resulting in a different premium rate specifically with regard to whether the plan is offered through an Exchange. Therefore, the same SADP QHP cannot be offered at two different premium rates through the Exchange and continue to meet the certification requirement at § 156.255(b). Accordingly, we are not modifying the rule in response to this comment.

Comment: We received some suggestions that HHS require group minimum participation rates for SADPs.

Response: HHS interprets § 155.705(b)(10)(i) and (ii), the minimum participation requirement in the FF-SHOPS, to apply only to comprehensive medical QHPs offered through the FF-SHOPS. HHS did not intend for the FF-SHOP minimum participation requirements to apply to stand-alone dental coverage. Many of the adverse risk selection concerns that exist for medical plans do not apply to SADPs because SADPs, which are typically excepted benefits, are not subject to many of the market reforms applicable to other QHPs, and can therefore address adverse selection with more flexibility, through different premium rating and benefit design methodologies.

Comment: Some commenters supported our proposal to provide options for dental coverage in the FF-SHOPS. However, they believe that an additional option should be taken into consideration which includes allowing employers to offer all SADPs but at a given AV level.

Response: Because we are not removing the AV standards for SADPs as was initially proposed in this rulemaking, we are modifying our proposal to allow employers the option to offer either a single QDP, or all dental plans at a single dental actuarial value level of coverage.

Comment: Several commenters support allowing a SHOP to establish standard processes for premium calculation, premium payment, and premium collection. Further, several commenters believe it should be a requirement of all SHOP Exchanges both FF-SHOPS and State-based SHOPs. Some commenters also stated that the SHOP should involve issuers in the development of the process and that HHS should release a proposed version that is open for comment before it is finalized. Commenters further stated that HHS should build on existing industry models. One commenter also suggested ensuring that timelines are feasible such that employers and employees are not told that coverage will be effectuated on a given date, only to find that processes broke down and coverage was not effectuated due to insufficient processing time.

Response: HHS will provide a premium payment process that is efficient and workable and may, in the future, establish through rulemaking a standard process for all SHOP Exchanges. We will continue to work with issuers and other stakeholders to further refine the timeline and process for premium payments.

Comment: We received several comments on standardizing the pro-rating methodology in FF-SHOPS. Many commenters recognize the need to standardize pro-ration of premiums in an employee choice environment when the FF-SHOP is responsible for billing and payment remittance to multiple issuers for a single group and several commenters supported our proposed methodology of pro-rating premiums. One commenter specifically stated that this policy should only be used for initial enrollment due to birth or adoption and termination and not applied on an ongoing basis. However, some commenters opposed our proposal and suggested we adopt current industry practice of using a mid-month “wash” approach where we would charge for the entire month when the coverage effective date is before the 15th of the month and do not charge for an employee or dependent plan taking effect after the 15th of the month.

Response: FF-SHOPS will be responsible for collecting all premiums from participating qualified employers starting in 2015. It is impractical for the

FF-SHOPS to accommodate the existing variation in pro-rated premium methodologies that exist across States and issuers. We believe our approach is fair for all issuers as they will receive the amount owed them based on the number of days an enrollee is covered. We are finalizing the proposed provision with no changes such that groups would be charged for the portion of the month for which the subscriber is enrolled.

Comment: One commenter supported the approach to adopt a standardized methodology regarding prorating premiums for partial month enrollment across all individual market Exchanges and several commenters expressed concern or sought clarification about such an approach. One commenter believed that setting a standardized methodology was unnecessary because individual market Exchanges do not perform premium aggregation. Another commenter opposed the approach, noting that the commenter believed that it would create gaps in coverage, disruption in other standard enrollment and billing processes designed to operate on a monthly basis, and not align with the U.S. Department of the Treasury regulation concerning the treatment of partial month enrollment for the purpose of minimum essential coverage.

Response: In future rulemaking, we intend to propose that an individual market Exchange may establish one or more standard processes for premium calculation, and that the FFE will establish one consistent with the methodology finalized at § 155.705(b)(4)(ii)(B) of this final rule for the FF-SHOPS. By taking this approach, we would eliminate issues where consumers who transition to Medicaid are charged premiums for days on which they are enrolled in Medicaid, which is effective no earlier than the date of application. It would also be consistent with proposed 26 CFR 1.36B-3(d)(2)⁴⁰ which specifies that when coverage is terminated before the last day of the month, and the issuer reduces or refunds a portion of the monthly premium, the premium tax credit is adjusted using the same methodology described in this final rule for the FF-SHOPS.

Comment: We received several comments on our proposal to give the FF-SHOPS the authority to permit qualified employers to contribute differently to the premiums of full-time

and part-time employees. Some commenters supported our proposal though suggested we let employers determine how many hours constitute a full-time employee. Some commenters opposed our proposal because it would be too complicated to implement. They suggested that the FF-SHOP ask an employer to calculate the percentage or dollar amount of contributions instead of defining a standard contribution level. Other commenters suggested we delay implementing this SHOP feature until after the online portal and premium aggregation services are fully functional. One commenter specifically recommends HHS work with issuers and the premium aggregator to ensure that the FF-SHOP is fully capable of supporting this function.

Response: To ensure we have fully tested this contribution methodology, while we are finalizing the proposed provision giving the FF-SHOPS the option to permit qualified employers to contribute differently in the premiums of full-time and part-time employees, we will not be offering employers this option until sometime after January 1, 2015. We will provide issuers and employers adequate notice before this option becomes available. We further note that it would not be consistent with the definition of a “full-time employee” at 45 CFR 155.20 for the FF-SHOPS to permit employers to determine how many hours constitute a full-time employee.

Comment: Some commenters expressed their preference that FF-SHOP user fees should be based on per-member buildup—even when employers offering a single plan are charged composite premiums pursuant to § 147.102.

Response: The FFE user fee is calculated by multiplying the user fee rate by the premium charged by the issuer for each policy under the plan where enrollment is through a FFE. For issuers participating in an FF-SHOP, the user fee rate is multiplied by the premium calculated under the methodology used to calculate a group’s monthly premium. For example, if a group is using a composite premium, the user fee will be based on the composite premium. If a group uses a per-member buildup approach, the user fee will reflect this methodology.

6. Eligibility Determination Process for SHOP

We proposed to amend paragraph § 155.715(c)(4) to replace a reference to sections 1411(b)(2) and (c) of the Affordable Care Act with a reference to Subpart D of 45 CFR part 155, and to add a reference to eligibility

⁴⁰ Minimum Value of Eligible Employer-Sponsored Plans and Other Rules Regarding the Health Insurance Premium Tax Credit Proposed Rule published in the May 3, 2013 *Federal Register* (78 FR 25915).

verifications as well as to eligibility determinations. The proposed changes would make explicit our interpretation of our current regulations, under which a SHOP is prohibited from performing any individual market eligibility determinations or verifications as described in Subpart D, which, for example, includes making eligibility determinations for advance payments of the premium tax credit and cost sharing reductions in the individual market Exchange. We are finalizing this provision as proposed.

We also proposed amending § 155.715(d) to address when SHOP eligibility adjustment periods would be triggered. We proposed providing eligibility adjustment periods for both employers and employees only when there is an inconsistency between information provided by an applicant and information collected through optional verification methods under § 155.715(c)(2). The proposal would eliminate the potential for unnecessary delay created under the current regulation, while providing SHOP applicants with an opportunity to address inconsistencies between a submitted application and trusted third-party data sources that a SHOP might utilize to verify eligibility under the optional verification process established in § 155.715(c)(2). The applicability of SHOP eligibility adjustment periods would be limited to circumstances where such a discrepancy occurs, and the applicant would be provided an opportunity to submit documentation proving the information submitted on the application is correct without having to initiate a formal eligibility appeal. We also proposed to amend paragraphs (d)(1) and (d)(2) to provide for eligibility adjustment periods when information submitted on an application is inconsistent with information collected through an optional verification process under § 155.715(c)(2).

We are finalizing the provisions as proposed.

Comment: One commenter asked for clarity on how the inconsistency process would work to ensure that eligibility and payment systems are in sync. Issuers and aggregators will need to know immediately when an inconsistency results in a group no longer being eligible for coverage so that they will not continue to provide coverage and so they don't continue to collect premiums.

Response: Enrollment for a group might not begin until any discrepancies being reviewed through the eligibility adjustment process for the employer are resolved, but if it does, there is no

reason why the issuer must terminate enrollment for the group if the employer is not determined eligible. Under guaranteed availability, the issuer generally must make the plan available both inside and outside the SHOP. If the employer is determined ineligible, an issuer may generally continue to offer coverage to a group, and the SHOP will work with the issuer to resolve any concerns related to premium payments that the employer had made to the SHOP.

7. Application Standards for SHOP

We proposed to amend § 155.730 to make explicit our interpretation of our current regulations, under which SHOPS are prohibited from collecting any information on SHOP applications other than what is required to make SHOP eligibility determinations or effectuate enrollment through the SHOP. We proposed to re-designate paragraph § 155.730(g) as paragraph (g)(1) and add new paragraph (g)(2) to provide that a SHOP is not permitted to collect information on the single employer or single employee application that is not necessary to determine SHOP eligibility or effectuate enrollment through the SHOP. We did not receive any comments on this proposal and we are finalizing the provisions as proposed.

E. Part 156—Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges

1. Provisions Related to Cost Sharing

In the proposed rule, we proposed several provisions and parameters for the 2015 benefit year related to cost sharing, including a number of provisions relating to indexing of premium growth. For the reasons described in the proposed rule and considering the comments received, we are generally finalizing these provisions as proposed, with a few modifications. However, we note that with respect to our methodology for indexing premium growth, we will continue to analyze additional methodologies in upcoming years, especially as additional data become available, and may modify these provisions if appropriate.

a. Premium Adjustment Percentage

Section 1302(c)(4) of the Affordable Care Act directs the Secretary to determine an annual premium adjustment percentage, which is used to set the rate of increase for four parameters detailed in the Affordable Care Act: the maximum annual limitation on cost sharing (defined at § 156.130(a)), the maximum annual

limitation on deductibles for plans in the small group market (defined at § 156.130(b)), and the assessable payment amounts under section 4980H(a) and (b) of the Code (finalized at 26 CFR 54.4980H in the “Shared Responsibility for Employers Regarding Health Coverage,” published in the February 12, 2014 **Federal Register** (79 FR 8544)). Section 156.130(e) of 45 CFR provides that the premium adjustment percentage is the percentage (if any) by which the average per capita premium for health insurance coverage for the preceding calendar year exceeds such average per capita premium for health insurance for 2013, and that this percentage will be published annually in the HHS notice of benefit and payment parameters.

We proposed to establish a methodology for estimating average per capita premium for purposes of calculating the premium adjustment percentage. In selecting this methodology, we considered the following four criteria:

(1) *Comprehensiveness*—the premium adjustment percentage should be calculated based on the average per capita premium for health insurance coverage for the entire market, including the individual and group markets, and both fully insured and self-insured group health plans;

(2) *Availability*—the data underlying the calculation should be available by the summer of the year that is prior to the calendar year so that the premium adjustment percentage can be published in the annual HHS notice of benefit and payment parameters in time for issuers to develop their plan designs;

(3) *Transparency*—the methodology for estimating the average premium should be easily understandable and predictable; and

(4) *Accuracy*—the methodology should have a record of accurately estimating average premiums.

Based on these criteria, we proposed that the premium adjustment percentage be calculated based on the projections of average per enrollee private health insurance premiums from the National Health Expenditure Accounts (NHEA), which is estimated by the CMS Office of the Actuary. To calculate the premium adjustment percentage for the 2015 calendar year, we proposed to use the most recent NHEA projections of average per enrollee private health insurance premiums for 2013 and 2014 (\$5,128 and \$5,435, respectively).⁴¹

⁴¹ See <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/>

Under that methodology, the premium adjustment percentage for 2015 would be (5,435–5,128)/5,128, or 6.0 percent.

We also considered several other sources of premium data, and sought comment on additional sources of data we should consider, and our choice of methodology. Several commenters suggested that, at least in the initial years, NHEA projections of per enrollee private health insurance premiums may not be the most appropriate source of data for calculating premium growth because it is influenced by changes in benefit design and market composition. One commenter, who supported the use of NHEA data generally, suggested that premium growth from 2013 to 2014 would be unreliable because those data will reflect issuer uncertainty about the costs of covering a previously uninsured population, and that true premium growth, reflecting any rebates required to be paid after the end of the year, could be lower. Another commenter, who supported using different NHEA data, suggested using an index tied to projected medical costs.

In response to these comments, we will calculate the premium adjustment percentage using different NHEA data—the NHEA projections of per enrollee employer-sponsored insurance (ESI) premiums. This data overlaps very significantly with the private health insurance data—according to the CMS Office of the Actuary, approximately 88 percent of enrollees in 2014 will be covered by employer-sponsored insurance. However, because it will exclude premiums from the individual market, which is likely to be most affected by the significant changes in benefit design and market composition in the early years of implementation of market reforms and is most likely to be subject to risk premium pricing (which, as the commenter noted, may be paid back to consumers after the end of the year in the form of rebates), we believe it will provide a more appropriate measure of average per capita premiums for health insurance coverage for the initial years. And because the data are also from the well-known NHEA, we believe it continues to meet our selection criteria.

Using the ESI data and our proposed methodology, the premium adjustment percentage for 2015 is the percentage (if any) by which the most recent NHEA projection of per enrollee ESI premiums for 2014 (\$5,664) exceeds the most recent NHEA projection of per enrollee

ESI premiums for 2013 (\$5,435), or 4.213431463 percent.⁴² We note that as updated 2013 NHEA data become available, we may update the 2013 estimate for purposes of calculating the premium adjustment percentage for years after 2015.

We further note that after the initial years of implementation of market reforms, once the premium trend is more stable, we may propose to change our methodology. For example we may consider changing our methodology to reflect the broader NHEA per enrollee private health insurance premium data. Additionally, as new data on health insurance premiums become available through the Exchanges and other sources, we intend to review the methodology for calculating the premium adjustment percentage. We also intend to establish consistent methodologies for indexing Affordable Care Act parameters.

In summary, we are finalizing the premium adjustment percentage methodology as proposed, using NHEA projections of per enrollee ESI premiums in place of private health insurance premiums. This premium adjustment percentage will be used to increase the maximum annual limitation on cost sharing, the maximum annual limitation on deductibles for plans in the small group market, and the assessable payment amounts under section 4980H(a) and (b) of the Code. In the preamble to the proposed rule, when calculating the proposed annual limitation on cost sharing for 2015, we rounded to the multiple of \$50 that is higher than the number calculated by the formula. However, we have since learned that the convention for similar language in related tax policies is to round to the multiple of \$50 that is lower than the number calculated by the formula. We strive to align policies wherever possible. As such, in future rulemaking that will be effective prior to the start of the application period for qualified health plans for the 2015 benefit year, we are considering aligning the rounding rules, and rounding to the lower multiple of \$50.

Maximum Annual Limitation on Cost Sharing for Calendar Year 2015. Under § 156.130(a)(2), for the 2015 calendar year, cost sharing for self-only coverage may not exceed the dollar limit for

calendar year 2014 increased by an amount equal to the product of that amount and the premium adjustment percentage for 2015. For other than self-only coverage, the limit is twice the dollar limit for self-only coverage. Using the premium adjustment percentage of 4.213431463 percent for 2015 we established above, and the 2014 maximum annual limitation on cost sharing of \$6,350 for self-only coverage, which was published by the IRS on May 2, 2013,⁴³ the 2015 maximum annual limitation on cost sharing would be \$6,600 for self-only coverage and \$13,200 for other than self-only coverage, if we were to interpret § 156.130(d) and the statute to round the self-only limitation down to the next lower multiple of 50.

Maximum Annual Limitation on Deductibles for Plans in the Small Group Market for Calendar Year 2015.

Under § 156.130(b)(2), for the 2015 calendar year, the annual deductible for a health plan in the small group market may not exceed, for self-only coverage, the maximum annual limitation on deductibles for calendar year 2014 increased by an amount equal to the product of that amount and the premium adjustment percentage for 2015, and for other than self-only coverage, the limit is twice the dollar limit for self-only coverage. Using the premium adjustment percentage for 2015 of 4.213431463 percent we established above and the 2014 maximum annual limitation on deductibles of \$2,000 for self-only coverage, as specified in § 156.130(b)(1)(i), the 2015 maximum annual limitation on deductibles would be \$2,050 for self-only coverage and \$4,100 for other than self-only coverage, if we were to interpret § 156.130(d) and the statute to round the self-only limitation down to the next lower multiple of 50. We note that pursuant to 45 CFR 156.130(b)(3), a health plan's deductible may exceed the 2015 maximum annual limitation on deductibles described above in instances where the plan may not reasonably reach the AV of a given level of coverage without exceeding the annual deductible limit.

Comment: We received three comments in support of our proposal to use data from the National Health Expenditure Accounts. However, we also received several comments expressing concern with the increase in the cost-sharing limits resulting from the proposed premium adjustment percentage methodology, and the

ProjectionsMethodology2012.pdf and Table 17 in <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Proj2012.pdf> for additional information.

⁴² See <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ProjectionsMethodology2012.pdf> and Table 17 in <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Proj2012.pdf> for additional information.

⁴³ See <http://www.irs.gov/pub/irs-drop/rp-13-25.pdf>.

potential impact on affordability and consumer access to care. Commenters noted that because the maximum annual limitation on cost sharing is set based on the premium growth rate for the previous years, consumers could see increased premiums in one year and then increased out-of-pocket costs in the following year (as well as any additional premium increases)—in effect, experiencing impacts twice. Another commenter noted that the proposal would result in the divergence of the maximum annual limitation on cost sharing from the cost-sharing limit set by the IRS for high deductible health plans, which is adjusted based on the Consumer Price Index.⁴⁴ Some commenters stated that the premium adjustment percentage should not be applied until at least 2016, after the Federal government has evaluated consumer experience under the 2014 parameters. Other commenters argued that the premium adjustment percentage should not be affected by the changes in benefit design and market composition that occur between 2013 and 2014. Instead, the commenters argue that the premium adjustment percentage should be based only on the change in the cost of medical services, or on the Consumer Price Index.

Response: In response to comments, as discussed above, we are finalizing our proposed methodology for calculating the premium adjustment percentage, using NHEA projections of per enrollee ESI premiums in place of private health insurance premiums. We believe that NHEA per enrollee ESI premium data will appropriately capture the underlying drivers of premium growth, and reflect the average per capita premium for the majority of health insurance coverage in the United States. In addition, ESI data tends to be more stable and is less influenced by one-time changes in benefit design and market composition.

We do not believe it would be appropriate to use the Consumer Price Index as the basis for estimating premium growth. The Consumer Price Index captures only price changes for a fixed basket of a much broader set of goods, and thus does not reflect the drivers of health insurance premiums. Specifically, the Consumer Price Index would exclude non-price factors that influence medical costs, and thus premiums, such as changes in the utilization or intensity of medical care. Because of this, the Consumer Price Index (both for all items and for medical care) has historically increased at a slower rate than premiums. We are

concerned that consistently constraining the premium adjustment percentage and the cost-sharing limits to a lower rate of growth that is not reflective of the drivers of health insurance premiums may prevent issuers from adequately adjusting plan designs to offset costs, which could result in higher premiums. We clarify that the maximum annual limitation on cost sharing established at § 156.130(a)(2) does not supersede the cost-sharing limit for high deductible health plans established by the IRS under § 223(c)(2)(A)(ii) of the Code.

Comment: One commenter recommended that the premium adjustment percentage be rounded to the nearest tenth of a percentage point, rather than the proposed “nearest decimal point.”

Response: To better align with other tax- and benefit-related indexation provisions, we specify that the premium adjustment percentage will be rounded to ten significant digits. The percentage for calendar year 2015 is 4.213431463 percent.

Comment: We received two comments reporting wide variation in the application across States of the maximum annual limitation on deductibles for plans in the small group market. Commenters acknowledged the need for flexibility in order to meet actuarial value standards, but requested that HHS monitor the application of this policy.

Response: We recognize the need to balance between the required deductible limit and the ability of issuers to offer a variety of cost sharing approaches within the plan designs available to employers. We intend to work with States to assess the need for additional guidance in this area, as the States are the primary enforcers of this limit.

b. Reduced Maximum Annual Limitation on Cost Sharing

Sections 1402(a) through (c) of the Affordable Care Act direct issuers to reduce cost sharing for EHBs for eligible individuals enrolled in a silver level QHP. In the 2014 Payment Notice, we established standards related to the provision of these cost-sharing reductions. Specifically, in 45 CFR part 156 subpart E, we specified that QHP issuers must provide cost-sharing reductions by developing plan variations, which are separate cost-sharing structures for each eligibility category that change how the cost sharing required under the QHP is to be shared between the enrollee and the Federal government. At § 156.420(a), we detailed the structure of these plan variations and specified that QHP issuers must ensure that each silver plan

variation has an annual limitation on cost sharing no greater than the applicable reduced maximum annual limitation on cost sharing specified in the annual HHS notice of benefit and payment parameters. Although the amount of the reduction in the maximum annual limitation on cost sharing is specified in section 1402(c)(1)(A) of the Affordable Care Act, section 1402(c)(1)(B)(ii) of the statute states that the Secretary may adjust the cost-sharing limits to ensure that the resulting limits do not cause the AVs of the health plans to exceed the levels specified in 1402(c)(1)(B)(i) (that is, 73 percent, 87 percent or 94 percent, depending on the income of the enrollee(s)). Accordingly, in the 2014 Payment Notice, we established a process for determining the appropriate reductions in the maximum annual limitation on cost sharing. First, we identified the maximum annual limitation on cost sharing applicable to all plans that will offer the EHB package. Second, we analyzed the effect on AV of the reductions in the maximum annual limitation on cost sharing described in the statute. Last, we adjusted the reductions in the maximum annual limitation on cost sharing, if necessary, to ensure that the AV of a silver plan variation will not exceed the AV specified in the statute. Below, we describe our analysis for the 2015 benefit year and our results, which we finalize as proposed.

Reduced Maximum Annual Limitation on Cost Sharing for Benefit Year 2015. We developed three model silver level QHPs and analyzed the impact on their AVs of the reductions described in the Affordable Care Act to a maximum annual limitation on cost sharing for self-only coverage (\$6,600). The model plan designs are based on data collected for QHP certification for 2014 to ensure that they represent a range of plan designs that we expect issuers to offer at the silver level of coverage through an Exchange. For 2015, the model silver level QHPs include a PPO with a typical cost-sharing structure (\$6,600 annual limitation on cost sharing, \$1,700 deductible, and 20 percent in-network coinsurance rate), a PPO with a lower annual limitation on cost sharing (\$4,500 annual limitation on cost sharing, \$2,000 deductible, and 20 percent in-network coinsurance rate), and an HMO (\$6,600 annual limitation on cost sharing, \$2,100 deductible, 20 percent in-network coinsurance rate, and the following services with copays that are not subject to the deductible or coinsurance: \$500 inpatient stay per

⁴⁴ See section 223(g) of the Code.

day, \$350 emergency department visit, \$25 primary care office visit, and \$50 specialist office visit). All three model QHPs meet the AV requirements for silver health plans.

We then entered these model plans into the AV Calculator developed by HHS, and observed how the reductions in the maximum annual limitation on cost sharing specified in the Affordable Care Act affected the AVs of the plans. We found that the reduction in the maximum annual limitation on cost sharing specified in the Affordable Care Act for enrollees with household incomes between 100 and 150 percent of the FPL (2/3 reduction in the maximum annual limitation on cost sharing), and 150 and 200 percent of the

FPL (2/3 reduction), does not cause the AV of any of the model QHPs to exceed the statutorily specified AV level (94 and 87 percent, respectively). In contrast, the reduction in the maximum annual limitation on cost sharing specified in the Affordable Care Act for enrollees with a household income between 200 and 250 percent of FPL (1/2 reduction), does cause the AVs of two of the model QHPs to exceed the specified AV level of 73 percent. As a result, we are finalizing our proposal that the maximum annual limitation on cost sharing for enrollees in the 2015 benefit year with a household income between 200 and 250 percent of FPL be reduced by approximately 1/5, rather than 1/2, as shown in Table 4.⁴⁵ We are

further finalizing as proposed a requirement that the maximum annual limitation on cost sharing for enrollees with household incomes between 100 and 200 percent of the FPL be reduced by approximately 2/3, in alignment with the statute. As discussed in the proposed rule, these reductions in the maximum annual limitation on cost sharing align with the 2014 reductions and should adequately account for unique plan designs that may not be captured by our three model QHPs. Applying the same parameters as those specified for 2014 will reduce the administrative burden for issuers related to designing new plans, and provide greater continuity for enrollees.

TABLE 4—REDUCTIONS IN MAXIMUM ANNUAL LIMITATION ON COST SHARING FOR 2015

Eligibility category	Reduced maximum annual limitation on cost sharing for self-only coverage for 2015	Reduced maximum annual limitation on cost sharing for other than self-only coverage for 2015
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(i) (that is, 100–150 percent of FPL)	\$2,250	\$4,500
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(ii) (that is, 150–200 percent of FPL)	2,250	4,500
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(iii) (that is, 200–250 percent of FPL)	5,200	10,400

Comment: We received two comments supporting the proposed reductions in the maximum annual limitation on cost sharing for 2015, with the caveat that HHS should monitor provider payments to ensure that cost-sharing reductions do not come at the expense of provider reimbursement. Another commenter stated that HHS should reduce the maximum annual limitation on cost sharing for enrollees with a household income between 200 and 250 percent of the FPL to be more in line with the reduction specified in section 1402(c)(1)(A)(ii) of the Affordable Care Act.

Response: As discussed in the proposed rule, selecting a reduction for the maximum annual limitation on cost sharing that is less than the reduction specified in the statute will not reduce the benefit afforded to enrollees in aggregate because QHP issuers are required to further reduce their annual limitation on cost sharing, or reduce other types of cost sharing, to meet the specified AV for the plan variation. Therefore, we are finalizing the reductions to the maximum annual limitation on cost sharing for 2015 as proposed. We do not address policy

related to provider payments in this rule.

Comment: We also received a comment stating that, in addition to reducing the maximum annual limitation on cost sharing, HHS should require issuers to exempt prescription drugs from any deductibles required under a silver plan variation.

Response: As discussed in the 2014 Payment Notice, we believe the current cost-sharing reduction standards strike the appropriate balance between protecting consumers and preserving QHP issuer flexibility. As a result, we do not intend to propose any additional cost-sharing reduction plan design requirements at this time.

c. Design of Cost-Sharing Reduction Plan Variations

Following our implementation of Exchange operations for 2014, we learned that a number of issuers designed QHPs with cost-sharing parameters that apply to both EHB and benefits that are not EHB. For example, one issuer sought to establish a common deductible across all benefits. For the zero cost sharing plan variation of this QHP, this would result in a substantial

deductible being applied entirely to benefits that are not EHB. As a result, we proposed to remove the standards in § 156.420(c) and (d) that require that a QHP and each of its plan variations have the same out-of-pocket spending for benefits other than EHB. Instead, we proposed that the standard in § 156.420(e)—that cost sharing for EHB from a provider (including a provider outside the plan's network) required of an enrollee in a silver plan variation may not exceed the corresponding cost sharing required in the standard silver plan or any other silver plan variation of that plan with a lower AV—would also apply to out-of-pocket spending required of enrollees in silver plan variations for a benefit that is not an EHB. Similarly, we proposed in § 156.420(d) that the out-of-pocket spending required of enrollees in the zero cost sharing plan variation of a QHP for a benefit that is not an EHB from a provider (including a provider outside the plan's network) may not exceed the corresponding out-of-pocket spending required in the limited cost sharing plan variation of the QHP, which in turn may not exceed the corresponding out-of-pocket spending

⁴⁵ We note that although the revised interpretation of the rounding standard for the maximum annual limitation on cost sharing is not yet finalized, we would not expect a different

interpretation of the rounding standard to result in a significant change in our analysis of the reductions in the maximum annual limitation on cost sharing. As a result, we are finalizing these

reductions in the maximum annual limitation on cost sharing for 2015 in this rule.

required in the QHP with no cost-sharing reductions.

We are finalizing the provisions as proposed, with one modification. To ensure continuity across the plan variations, we clarify in § 156.420(d) that the out-of-pocket spending required of enrollees in the zero cost sharing plan variation of a QHP for a benefit that is not an EHB from a provider (including a provider outside the plan's network) may not exceed the corresponding out-of-pocket spending required in the limited cost sharing plan variation of the QHP and the corresponding out-of-pocket spending required in the silver plan variation of the QHP for individuals eligible for cost-sharing reductions under § 155.305(g)(2)(i), in the case of a silver QHP. This modification responds to commenters' concerns that issuers may use this flexibility to selectively attract certain enrollees, and is consistent with our general policy that an enrollee in a cost-sharing reduction plan variation be provided with plan features, including out-of-pocket spending, provider network, and benefits, that are at least as good as those offered under the standard plan or any other plan variation designed to be less generous.

We also clarify that in the case of an issuer participating in an Exchange that only requires issuers to submit one zero cost sharing plan variation with the lowest premium for a set of standard plans, as described in the 2014 Payment Notice at 78 FR 15494, the issuer must ensure that the out-of-pocket spending requirement for each non-EHB benefit of the submitted zero cost sharing plan variation is less than or equal to the lowest out-of-pocket spending requirement for the same benefit of a silver plan variation for individuals eligible for cost-sharing reductions under § 155.305(g)(2)(i), if the silver plan is included in the set of standard plans.

Under these provisions, each cost-sharing reduction plan variation will continue to provide the most cost savings for which an enrollee is eligible; however, QHP issuers will be able to—though are not required to—reduce out-of-pocket spending for benefits that are not EHB for enrollees in plan variations in order to offer simpler cost-sharing designs that are consistent across EHB and benefits that are not EHB. We note, however, that in accordance with section 1402(d)(4) of the Affordable Care Act, any reductions in out-of-pocket spending for benefits that are not EHB will not be reimbursed by the Federal government because payments for cost-sharing reductions only apply to EHB.

Comment: One commenter strongly supported the proposal, stating that it will allow issuers the flexibility to develop plans that best meet the needs of the low-income population. Conversely, another commenter stated that issuers may use this flexibility to design plans that attract healthier beneficiaries and may offset any costs through premium increases. Several logistical concerns were also raised by commenters about how HHS would ensure that Federal reimbursement is not provided for these reductions, and how issuers would report and implement these reductions.

Response: As described in § 156.430(c), issuers may only submit information on reductions in cost sharing for EHB, and HHS will not provide reimbursement for reductions in out-of-pocket spending for benefits other than EHB. In addition, our changes to § 156.420(d) and (e) provide additional flexibility only with respect to different plan variations, and those provisions do not permit issuers to selectively lower cost sharing in a manner that disadvantages low-income consumers. As a result, we do not believe issuers will have any additional opportunity to attract healthy enrollees. Therefore, we are finalizing this provision as proposed, with the minor modification discussed above. We will provide additional guidance in the future for issuers on how to report out-of-pocket spending for benefits that are not EHB for purposes of QHP certification.

d. Advance Payments of Cost-Sharing Reductions

Section 1402(c)(3) of the Affordable Care Act directs a QHP issuer to notify the Secretary of cost-sharing reductions made under the statute, and directs the Secretary to make periodic and timely payments to the QHP issuer equal to the value of those reductions. Section 1412(c)(3) of the Affordable Care Act permits advance payments of cost-sharing reduction amounts to QHP issuers based upon amounts specified by the Secretary. Under these authorities, we established a payment approach in the 2014 Payment Notice under which monthly advance payments made to issuers to cover projected cost-sharing reduction amounts are reconciled after the end of the benefit year to the actual cost-sharing reduction amounts.

To implement this approach, we specified in § 156.430(a) that a QHP issuer must provide to the Exchange an estimate of the dollar value of the cost-sharing reductions to be provided over the benefit year, calculated in

accordance with the methodology specified by HHS in the annual HHS notice of benefit and payment parameters. We further specified in the 2014 Payment Notice that QHP issuers did not need to submit an estimate of the dollar value of the cost-sharing reductions for the 2014 benefit year, except in the case of a limited cost sharing plan variation.⁴⁶ Instead, the Exchange sent the data that issuers submitted under §§ 156.420 and 156.470, including the AV of the standard plan and plan variation, and the EHB portion of expected allowed claims costs, to HHS for the calculation of the cost-sharing reduction advance payment rates. HHS then approved the rates and sent them back to the Exchange so that the cost-sharing reduction advance payment amounts could be reported as part of the 834 enrollment transactions, pursuant to § 156.340(a). HHS then provided advance payments to QHP issuers.

Based on our experience implementing this process for the 2014 benefit year, we proposed certain modifications to §§ 155.1030, 156.430, and 156.470. We believe these modifications will simplify the process and improve the accuracy of the calculations. Specifically, we proposed to remove the requirement detailed in § 156.430(a) that issuers develop estimates of the dollar value of the cost-sharing reductions to be provided, and instead proposed to modify § 155.1030(b)(3) to provide that an Exchange be required to use the methodology specified in the annual HHS notice of benefit and payment parameters to calculate advance payment amounts for cost-sharing reductions. We also proposed to modify § 155.1030(b)(4) so that the Exchange would no longer be required to submit issuers' advance payment estimates to HHS for approval prior to the start of the benefit year. The Exchange would simply calculate the advance payment amounts and transmit the amounts to HHS via the 834 enrollment transaction, pursuant to § 156.340(a). We then proposed in § 156.430(b)(1) that HHS provide periodic advance payments to QHP issuers based on the amounts transmitted by the Exchange. Lastly, we proposed conforming modifications to §§ 155.1030(b)(1) and 156.470(a), to remove the obligation for QHP issuers to submit, and Exchanges to review, the EHB allocation of the expected allowed

⁴⁶ If an issuer sought advance payments for the cost-sharing reductions provided under the limited cost sharing plan variation of a health plan it offers, we specified in § 156.430(a)(2) that the issuer was required to submit an estimate of the dollar value of the cost-sharing reductions to be provided.

claims costs for the plans, because this data would not be used in the proposed 2015 methodology for calculating cost-sharing reduction advance payments.

Methodology for Calculating Advance Payment Amounts for Cost-Sharing Reductions for 2015. For the 2015 benefit year, we proposed that the Exchanges use a methodology for calculating the advance payment amounts that would not require QHP issuers to submit an estimate of the value of cost-sharing reductions to be provided or the EHB portion of expected allowed claims costs, as previously required under § 156.470(a), and that

would not require Exchanges to transfer data on advance payment amounts to HHS prior to the start of the benefit year. Specifically, we proposed that Exchanges calculate the monthly advance payment amount for a specific policy as the product of (x) the total monthly premium for the specific policy, and (y) a cost-sharing reduction plan variation multiplier. The cost-sharing reduction plan variation multiplier would convert the monthly premium into the appropriate monthly advance payment amount, based on the following formula:

Cost-Sharing Reduction Plan Variation Multiplier = Factor to Remove Administrative Costs * Factor to Convert to Allowed Claims Cost * Induced Utilization Factor * (Plan Variation AV – Standard Plan AV)

Where,

Factor to Remove Administrative Costs = 0.8 for all plan variations, based on the individual market MLR of 80 percent;
Factor to Convert to Allowed Claims Costs = the quotient of 1 and the AV for the standard plan, not accounting for any *de minimis* variation;

Induced Utilization Factor = one of the following factors, depending on the plan variation:

TABLE 5—INDUCED UTILIZATION FACTORS FOR PLAN VARIATIONS

Cost-sharing reduction plan variation	Induced utilization factor
73 percent AV silver plan variation	1.00
87 percent AV silver plan variation	1.12
94 percent AV silver plan variation	1.12
Limited cost sharing plan variation of bronze QHP	1.15
Limited cost sharing plan variation of silver QHP	1.12
Limited cost sharing plan variation of gold QHP	1.07
Limited cost sharing plan variation of platinum QHP	1.00
Zero cost sharing plan variation of bronze QHP	1.15
Zero cost sharing plan variation of silver QHP	1.12
Zero cost sharing plan variation of gold QHP	1.07
Zero cost sharing plan variation of platinum QHP	1.00

Standard Plan AV = the AV specified for each level of coverage at § 156.140(b), not accounting for *de minimis* variation (that is, 60, 70, 80, or 90 percent for a

bronze, silver, gold, or platinum QHP, accordingly); and
Plan Variation AV = one of the following actuarial values, depending on the plan

variation, not accounting for *de minimis* variation:

TABLE 6—ACTUARIAL VALUES FOR PLAN VARIATIONS

Cost-sharing reduction plan variation	Plan variation AV (percent)
73 percent AV silver plan variation	73
87 percent AV silver plan variation	87
94 percent AV silver plan variation	94
Limited cost sharing plan variation of bronze QHP	87
Limited cost sharing plan variation of silver QHP	87
Limited cost sharing plan variation of gold QHP	94
Limited cost sharing plan variation of platinum QHP	94
Zero cost sharing plan variation of bronze QHP	100
Zero cost sharing plan variation of silver QHP	100
Zero cost sharing plan variation of gold QHP	100
Zero cost sharing plan variation of platinum QHP	100

The proposed induced utilization factors would be consistent with the corresponding factors established in the 2014 Payment Notice. For the limited cost sharing plan variations, we derived the induced utilization factors based on the actuarial values proposed above, and the same assumptions used to develop the induced utilization factors for the other plan variations. We proposed to update the induced utilization factors for all plan variations

in future rulemaking as more data becomes available, and stated that at that time we would consider applying them to the risk adjustment methodology that HHS will use when operating risk adjustment on behalf of a State.

The proposed methodology also utilizes the actuarial values of the standard plans and plan variations, not accounting for *de minimis* variation. Although this may slightly reduce the

accuracy of the calculations, we believe it would have little overall impact, and would reduce the administrative burden on Exchanges because Exchanges would not need to develop specific multipliers for each QHP and associated plan variations. However, this approach required us to estimate an actuarial value for each type of limited cost sharing plan variation. We estimated that on average, the AV of the limited cost sharing plan variations of bronze

and silver QHPs would be 87 percent, and the AV of the limited cost sharing plan variations of gold and platinum QHPs would be 94 percent. We developed these estimates based on the data submitted by QHP issuers seeking advance payments for limited cost sharing plan variations that will be offered in benefit year 2014.

We believe the proposed methodology will improve the accuracy of the advance payments because it is based on the total premium for each policy, which in accordance with the rating rules described in §§ 147.102 and 156.80, is based on expected allowed claims costs, adjusted for the plan design and provider network, the number of individuals covered by the policy, rating area, age, and tobacco use. We are finalizing the modifications to §§ 155.1030, 156.430, and 156.470 as proposed, as well as the methodology for calculating advance payment amounts for cost-sharing reductions for 2015.

Comment: We received one comment in support of the proposed changes to the process for calculating advance payments, stating that the changes would reduce the overall administrative burden and streamline reporting requirements for issuers. We also received some comments stating that it is too early to make changes to the process, which commenters stated would require issuers to alter their systems and develop new processes for validating the advance payment amounts. One commenter noted that under the proposed process, each Exchange will be responsible for calculating the advance payment amounts as opposed to one Federal agency, which could create the potential for more errors. The commenter was also concerned with the proposal to base the advance payment amounts on the premium for the policy, as premium data could be inaccurate and subject to a complex reconciliation process. The commenters also stated that the issuer should be allowed to validate the advance payment amounts before they are finalized.

Response: We continue to believe that the modifications to the advance payment calculation process will reduce the administrative burden for all parties because issuers will be required to submit less data, and Exchanges will no longer be required to submit data to HHS prior to the start of the benefit year for the calculation and approval of the advance payment amounts. That approval process will no longer be necessary because the advance payments will be simply calculated based on the product of the cost-sharing

reduction plan variation multiplier specified by HHS and the premium for the policy. This modification to the calculation should also reduce the administrative burden for issuers reviewing the advance payment amounts as part of the discrepancy reporting process because the advance payments will be based on premiums, which we presume issuers would review in connection with the advance payments of the premium tax credit. We also anticipate that FFE issuers will be able to review premium information prior to the start of the benefit year through the plan preview process. In addition, HHS plans to validate that the advance payment amounts reported via the 834 enrollment transaction are calculated in accordance with the methodology specified by HHS. Thus, we believe that this methodology and validation process should ensure the protection of Federal funds, while simultaneously limiting the administrative burden on QHP issuers and Exchanges.

Comment: One commenter expressed concern that the proposed methodology for calculating advance payments would result in lower advance payments amounts that would not cover issuers' costs. Another commenter stated that issuers should be able to request a change to the advance payment amounts mid-year if the amounts do not align with actual cost-sharing reduction amounts provided.

Response: Although we acknowledge that there are some limitations to this methodology (for example, the multiplier does not make a plan-specific adjustment for the cost of non-EHB, or account precisely for costs for large families with children not accounted for in the premium), we believe that a very small number of QHPs would be affected by these limitations, and any inaccuracies in the advance payments would be corrected through the cost-sharing reduction reconciliation process. In addition, as described at § 156.430(b)(2), HHS may adjust the advance payment amount for a particular QHP during the benefit year if the QHP issuer provides evidence that the advance payments are likely to be substantially different than the cost-sharing reduction amounts that the QHP provides.

2. Provisions on FFE User Fees

a. FFE User Fee for the 2015 Benefit Year

Section 1311(d)(5)(A) of the Affordable Care Act contemplates an Exchange charging assessments or user fees to participating health insurance

issuers to generate funding to support its operations. If a State does not elect to operate an Exchange or does not have an approved Exchange, section 1321(c)(1) of the Affordable Care Act directs HHS to operate an Exchange within the State. In addition, 31 U.S.C. 9701 permits a Federal agency to establish a charge for a service provided by the agency. Accordingly, at § 156.50(c), we specified that a participating issuer offering a plan through an FFE must remit a user fee to HHS each month that is equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year and the monthly premium charged by the issuer for each policy under the plan where enrollment is through an FFE.

OMB Circular No. A-25 Revised (Circular No. A-25R) establishes Federal policy regarding user fees, and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public. As in benefit year 2014, issuers seeking to participate in an FFE in benefit year 2015 will receive two special benefits not available to the general public: (1) the certification of their plans as QHPs; and (2) the ability to sell health insurance coverage through an FFE to individuals determined eligible for enrollment in a QHP. Activities performed by the Federal government that do not provide issuers participating in an FFE with a special benefit will not be covered by this user fee.

Circular No. A-25R further states that user charges should generally be set at a level so that they are sufficient to recover the full cost to the Federal government of providing the service when the government is acting in its capacity as sovereign (as is the case when HHS operates an FFE). We proposed to set the 2015 user fee rate for all participating issuers at 3.5 percent. This rate is the same as the 2014 user fee rate.⁴⁷

We are finalizing the 2015 user fee rate as proposed. Because we wish to continue to encourage issuers to offer plans through an FFE, we sought and have received an exception from OMB to the policy in Circular No. A-25R that the 2015 user fee be set to recover full

⁴⁷ OMB granted HHS an exception to the policy in Circular No. A-25R, allowing HHS to set the user fee rate for 2014 at 3.5 percent, rather than a higher rate which would have allowed HHS to recover full costs. This rate was chosen because we wished to encourage issuers to offer plans on FFEs and to align with the administrative cost structure of State Exchanges.

costs. We expect to cover full costs in future years.

Comment: We received several comments stating that both the 2014 and 2015 user fee rate should be lower because of the technical problems associated with FFE operations. Although the FFE performs important functions, issuers have had to take a larger role in supporting the processing of enrollment files and payments. One commenter specifically stated that the FF-SHOP user fee for 2014 should be waived due to the operational delays. Another commenter suggested that the 2014 user fee should be waived to offset issuers' costs resulting from an unbalanced risk pool. For the same reason, the commenter also suggested the annual fee imposed on health insurance providers, described in section 9010 of the Affordable Care Act, should be waived. Some other commenters noted that the 2015 user fee should be lower as a result of gains in operational efficiency and the expected increase in the number of State Exchanges.

Response: As discussed above, Circular A-25R specifies that a user charge should be assessed against recipients of special benefits derived from Federal activities beyond those received by the general public. Despite the 2014 technical issues, participating issuers will continue to receive special benefits through Federal activities. For example, issuers participating in an FF-SHOP will continue to receive the special benefits of the certification of their plans as QHPs and the ability to sell health insurance coverage to employers determined eligible to participate in the SHOP. In addition, we do not expect the cost to the Federal government of providing these special benefits to change appreciably. As a result, we are not changing the 2014 user fee rate. We are also finalizing the 2015 user fee rate at 3.5 percent, as proposed, based on the expected number of Federally-facilitated Exchanges in 2015 and our projected costs.

Changes to the risk pool will be addressed through the premium stabilization programs. Standards regarding the annual fee imposed on health insurance providers were finalized by the IRS on November 29, 2013 (78 FR 71476), and we direct commenters with questions regarding that fee to the IRS. Finally, we agree that over time we expect operational efficiencies and increases in the number of State Exchanges and will continue to take these factors into account when determining the annual FFE user fee rate.

Comment: We received two comments on the underlying structure of the FFE user fee. One commenter recommended that HHS establish broad-based financing for the FFE, such as an assessment on all health care industry entities. If the existing fee structure is kept, the commenter stated that it should only be paid by consumers and small employers that purchase coverage through an FFE. The commenter also stated that the user fee should not be set as a percent of premium, as the cost to run an Exchange is not related to the cost of coverage. In contrast, another commenter stated that the user fee should continue to be calculated as a percent of premium, which ensures the user fee is adjusted based on the size of the issuer's book of business.

Response: The FFE user fee will continue to be assessed as a percent of the monthly premium charged by issuers participating in an FFE. In accordance with Circular A-25R, issuers are charged the user fee in exchange for receiving special benefits beyond those that accrue to the general public. Setting the user fee as a percent of premium ensures that the user fee generally aligns with the business generated by the issuer as a result of participation in an FFE.

Comment: One commenter also recommended that HHS publish cost estimates for the FFE, disclose how funds will be spent, and develop performance metrics for the FFE. The commenter stated that any increase in an issuer's aggregate liability for FFE user fees should be capped at changes in the Consumer Price Index, and that total user fee collections across all issuers should be capped at the level of expended costs. The commenter urged that if user fee collections exceed FFE costs, issuers should receive a rebate or credit against future fees.

Response: HHS will continue to publish cost estimates through the Federal budget process, and performance results from time to time, as has been our practice thus far. We will also continue to set the user fee based on the expected costs to the Federal government of providing the special benefits to issuers; however, for 2015 as noted above, we sought and have received an exception to this policy from OMB because we wish to continue to encourage issuers to offer plans through an FFE. We expect to cover full costs in future years. Because we set the user fee to no more than cover Federal costs (and in the case of 2014 and 2015, at less than our predicted costs), we do not expect user fee collections to exceed the Federal cost of operating the FFE.

b. Adjustment of FFE User Fee

Section 2713(a)(4) of the PHS Act, as added by the Affordable Care Act and incorporated into the ERISA and the Code, directs non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage to provide benefits for certain women's preventive health services without cost sharing.⁴⁸ The Preventive Services Rule (78 FR 39870, July 2, 2013) established accommodations with respect to the contraceptive coverage requirement for health coverage established or maintained or arranged by eligible organizations.⁴⁹

Each organization seeking to be treated as an eligible organization under the Preventive Services Rule is required to self-certify that it meets the definition of an eligible organization. In the case of an eligible organization with a self-insured plan, a copy of the self-certification must be provided to all TPAs with which it or its plan has contracted. Upon receipt of the copy of the self-certification, the TPA may decide not to enter into, or remain in, a contractual relationship with the eligible organization to provide administrative services for the plan. A TPA that receives a copy of the self-certification and that agrees to enter into or remain in a contractual relationship with the eligible organization to provide administrative services for the plan must provide or arrange for separate payments for certain contraceptive services for participants and beneficiaries in the plan without cost sharing, premium, fee, or other charge to plan participants or beneficiaries, or to the eligible organization or its plan. The TPA can provide such payments on its own, or it can arrange for an issuer or other entity to provide these payments. In either case, the payments are not health insurance policies and the TPA can make arrangements with an issuer offering coverage through an FFE to obtain reimbursement for its costs

⁴⁸ The women's preventive health services referenced by PHS Act section 2713(a)(4) are provided for in comprehensive guidelines supported by the Health Resources and Services Administration (HRSA). On August 1, 2011, HRSA adopted and released guidelines for women's preventive health services based on recommendations of the independent Institute of Medicine.

⁴⁹ Under the Preventive Services Rule, an eligible organization is an organization that: (1) Opposes providing coverage for some or all of the contraceptive services required to be covered under section 2713 of the PHS Act and the companion provisions of ERISA and the Code on account of religious objections; (2) is organized and operates as a nonprofit entity; (3) holds itself out as a religious organization; and (4) self-certifies that it satisfies the first three criteria.

(including an allowance for administrative costs and margin) through an adjustment to the FFE user fee paid by the issuer.

At § 156.50(d), we established standards related to the administration of the user fee adjustment. Specifically, in § 156.50(d)(3)(ii), we stated that the user fee adjustment will include an allowance for administrative costs and margin that is no less than 10 percent of the total dollar amount of the payments for contraceptive services, and that HHS would specify the allowance for a particular calendar year in the annual HHS notice of benefit and payment parameters.

For user fee adjustments sought in 2015 for the cost of payments for contraceptive services provided in 2014, we proposed an allowance for administrative costs and margin equal to 15 percent of the total dollar amount of the payments for contraceptive services defined in § 156.50(d)(3)(i).⁵⁰ We proposed this allowance based on our analysis described in the proposed rule of the administrative costs that we expect each entity involved in the arrangement to incur. We are finalizing the allowance for administrative costs and margin at 15 percent, as proposed.

Comment: We received several comments expressing concern that the proposed allowance would not adequately cover administrative costs. One commenter emphasized that the allowance should take into account startup costs, including systems development, contract negotiations, customer service outreach, and provider support. Another commenter stated that there will be wide variation in administrative costs depending on whether the TPA operates in a State with an FFE, or if the beneficiaries live in multiple States. The commenter also noted that TPAs may incur care coordination costs related to contraceptive services, which should be covered by the allowance. As a result, the commenter recommended that HHS permit TPAs to accept either the 15 percent allowance or request a different amount based on expected costs. Another commenter noted that amounts paid for contraceptive services may be low compared to fixed administrative costs, particularly if the payment is for a low cost generic drug. The commenter suggested that HHS provide a greater allowance for administrative costs and margin when the volume of

contraceptive services falls below a set threshold.

Response: As discussed in the proposed rule, the proposed allowance was set to cover the administrative costs and margin for all of the entities involved in the relationship. We recognize that administrative costs may vary between TPAs depending upon their arrangement with an issuer participating in an FFE and the total costs of contraceptive services for which they provide payment. However, we believe that the proposed allowance should adequately cover expected administrative costs for the majority of TPAs and the issuers through which they receive the FFE user fee adjustment. We do not intend to allow TPAs to submit requests for greater allowances for administrative costs and margin, or for different categories of costs, such as startup or overhead costs, because it would be difficult to verify these costs and sufficiently safeguard Federal funds.

Comment: One commenter requested clarification that the FFE user fee adjustment is intended to cover the full cost of the payments for certain contraceptive services, plus an additional 15 percent, for administrative costs and margin.

Response: As described in § 156.50(d)(3), the user fee adjustment will be equal in value to the sum of the dollar amount of the payments for contraceptive services, plus a 15 percent allowance for administrative costs and margin.

Comment: We received several general comments on the accommodation for eligible organizations with a self-insured plan. Commenters noted that there is no requirement for issuers participating in an FFE to enter into arrangements with TPAs of eligible organizations with self-insured plans. As a result, commenters requested that HHS identify an alternative method to reimburse TPAs.

Response: In this final rule, we are specifically establishing the allowance for administrative costs and margin. As discussed in the Preventive Services Rule, we continue to believe the allowance for administrative costs and margin should provide an incentive for issuers to enter into arrangements with TPAs of eligible organizations with self-insured plans.

Comment: One commenter requested that HHS modify the standards related to MLR to align with the accommodations finalized in the Preventive Services Rule.

Response: We do not believe it is necessary to modify the regulations, but instead provided guidance on this topic

in the preamble to the Preventive Services Rule (see 78 FR 39886).⁵¹ Specifically, we noted that under 45 CFR part 158, participating issuers may deduct from premiums as licensing and regulatory fees any amounts paid out to a third party administrator or incurred by or for the issuer in contraceptive claims costs under the accommodations for self-insured group health plans of eligible organizations, plus the allowance for administrative cost and margin allowed under 45 CFR 156.50(d)(3)(ii), along with their net FFE user fee paid to HHS. We further here clarify that an issuer of group health insurance coverage that makes payments for contraceptive services for participants and beneficiaries of its insured health plans under the accommodations for eligible organizations rules may treat those payments as an adjustment to claims costs for purposes of MLR and risk corridors program calculations. As discussed in the Preventive Services Rule, this adjustment would compensate for any increase in incurred claims associated with making payments for contraceptive services.

3. AV Calculation for Determining Level of Coverage

Section 2707(a) of the PHS Act and Section 1302 of the Affordable Care Act direct non-grandfathered health insurance issuers in the individual and small group markets, including QHPs, to ensure that plans meet a level of coverage specified in section 1302(d)(1) of the Affordable Care Act and codified at § 156.140(b). On February 25, 2013, HHS published the EHB Rule implementing section 1302(d) of the Affordable Care Act, which sets forth the requirement that, to determine the level of coverage for a given metal tier level, the calculation of AV be based upon the provision of EHB to a standard population. Section 156.135(a) establishes that AV is to be calculated using the AV Calculator developed and made available by HHS.

HHS recognizes that certain routine changes will on occasion need to be made to facilitate the AV Calculator's ongoing operation by ensuring that it

⁵¹ That guidance stated that “. . . for purposes of the medical loss ratio and the risk corridors program, participating issuers should report the sum of: (1) The net FFE user fee paid to HHS; (2) any amounts paid out to a third party administrator or incurred by or for the participating issuer in contraceptive claims costs under the accommodation for self-insured group health plans of eligible organizations provided in these final regulations; and (3) the allowance for administrative costs and margin provided under 45 CFR 156.50(d)(3)(ii), as licensing and regulatory fees referenced in 45 CFR 158.161(a).”

⁵⁰ We note that the submission of the dollar amount of the payments for contraceptive services is subject to the oversight standards detailed at 45 CFR 156.50(d)(7), as well as the False Claims Act, 31 U.S.C. 3729–3733.

can accommodate changes in the marketplace or product design over time and due to the changing cost of providing health care services in the market. In accordance, we proposed to update certain aspects of the AV Calculator on a regular basis, but no more frequently than annually.

In proposed § 156.140(g), HHS proposed to update the AV Calculator as follows. First, we proposed to update for the annual limit on cost sharing and related functions based on a projected estimate to enable the AV Calculator to comply with § 156.130(a)(2). Second, we proposed to update the continuance tables to reflect more current enrollment data when HHS has determined that the enrolled population has materially changed, defined as more than 5 percent different. Third, we proposed to update the algorithms when HHS has determined the need to adapt the AV Calculator for use by additional plan designs or to allow the AV Calculator to accommodate potential new types of plan designs, where such adaptations can be based on actuarially sound principles and will not have a substantial effect on the AV calculations performed by the then current AV Calculator. To identify new industry practices and technical advances, we proposed a process to consult annually with the American Academy of Actuaries and to take into consideration feedback received through CMS Actuarial Value email address at: actuarialvalue@cms.hhs.gov. Fourth, we also proposed to update the continuance tables to reflect more current claims data no more than every 3 and no less than every 5 years and to annually trend the claims data when the trending factor is more than 5 percent different, calculated on a cumulative basis. To trend the AV Calculator, we proposed to use premium data and/or standard population data in years when the underlying claims data are not being updated in the AV Calculator, and in years where the claims data are being updated, we proposed to trend the Calculator based on the updated claims data. Lastly, we proposed to update the AV Calculator user interface when a change would be useful to a broad group of users of the AV Calculator, would not affect the function of the AV Calculator, and would be technically feasible.

Along with the parameters for updating the AV Calculator, we also proposed to amend § 156.135(a) to clarify that issuers would be required to use the AV Calculator published by HHS for a given benefit year or, in cases where a State has obtained HHS approval to use State specific data in the AV Calculator, issuers would be

required to use that AV Calculator HHS has published for the given benefit year, adjusted to use the State's data (State AV Calculator).

Lastly, we solicited comments on the proposed 2015 AV Calculator and AV Calculator methodology that would replace the 2014 versions of the Calculator and methodology, respectively. For the 2015 AV Calculator, HHS proposed to make minor changes to the design and inputs into the AV Calculator and did not propose updating the claims data, including the trending factor, or the enrollment data, since data were not yet available.

We are finalizing the regulatory provisions as proposed but we are not finalizing the 2015 AV Calculator and 2015 AV Calculator methodology. Rather, under the regulatory parameters for updating the AV Calculator, we are finalizing the 2014 AV Calculator to account for the estimated annual limit on cost sharing of \$6,850 and will update the 2014 AV Calculator methodology accordingly. These materials will also include non-substantive amendments to correct and clarify language, as well as some clarifying frequently asked questions, that do not reflect changes in the functioning of the AV Calculator. Through this final rule, the amended 2014 documents are being finalized as the 2015 AV Calculator and AV Calculator methodology.

Comment: Several commenters recommended that since the proposed version of the 2015 AV Calculator and the parameters to update the AV Calculator in the future can impact the AV of plan designs, CMS should increase the *de minimis* range to prevent issuers from having to make benefit changes in order to be able to continue offering the same plans, including plans for 2015 plans being offered in 2014. Other commenters submitted technical comments on the 2015 AV Calculator updates, as well as recommended that we not update the AV Calculator for 2015 unless other circumstances were met.

Response: We do not intend to change the *de minimis* range. The *de minimis* range is intended to allow plans to float within a reasonable range and is not intended to freeze plan designs preventing innovation in the market.

Because the AV Calculator is a dynamic tool, it is impossible to make changes to the Calculator's algorithms without potentially impacting the AV output. However, we limited the changes in the proposed 2015 AV Calculator to promote stability of the AV Calculator and to help better ensure that

issuers did not have to make benefit changes in 2015 in order to remain within the *de minimis* range. For instance, we did not update the enrollment or claims data because actual data were not available and we did not want to update the AV Calculator based on another projection. In fact, the vast majority of the updates to the proposed 2015 AV Calculator were the direct result of comments that we had received from issuers on improvements in the algorithms and adding additional functionality to the AV Calculator based actuarially sound principles to allow more issuers to use the AV Calculator without adjustment.

Given the limited changes that were being made in the proposed 2015 AV Calculator and that we were not updating the AV Calculator based on the enrollment and claims data for 2015, we are finalizing the 2014 AV Calculator as the 2015 AV Calculator with an updated estimated annual limit on cost sharing to help ensure that issuers do not have to make benefit changes between year 1 and year 2.

Since we are not finalizing the proposed 2015 AV Calculator at this time, with the exception of the updated estimated annual limit on cost sharing, we do not address the technical comments on the proposed 2015 AV Calculator and methodology, but we will take them under consideration if we propose updates to the AV Calculator in the future.

Comment: Commenters wanted the final version of the 2015 AV Calculator to be available early in 2014 and recommended that we ensure that issuers have enough time to work with the final version of the AV Calculator, proposing various annual deadlines.

Response: We recognize that issuers need time to work with the final version of the Calculator to develop their plan designs for a given benefit year. By finalizing the amended 2014 AV Calculator as the 2015 AV Calculator, our intention is to reduce the burden on issuers for 2015 in having to make adjustments to plan designs and do any recalculations with changes to the AV Calculator.

In future years, our intention with finalizing the provisions under § 156.135(g) is to allow us the option to release the final AV Calculator earlier in the year. However, certain updates to the AV Calculator will be dependent on the timeline of availability of the necessary data elements. Thus, while we will work to make the AV Calculator available as early as possible, we intend to release it no later than the end of the first quarter of the preceding the benefit year.

Comment: Some commenters expressed concern about the frequency and potential fluctuations as a result of the updates based on enrollment data, especially given the potential for dramatic changes in the enrolled population in the initial years. Commenters recommended that the enrollment and claims data updates be made as soon as possible or at the same time. Others asked for clarification on the types of statistics being used for the updates and the exact year that we intend to start updating based on enrollment data.

Response: Our policy is to consider updating the AV Calculator, starting with the 2016 AV Calculator, annually based on enrollment data when the combined measurement of the effects of shifts in gender or age statistics are materially different, which we define as more than 5 percent. We are finalizing this threshold for updating based on enrollment data of more than 5 percent to help ensure that updates based on enrollment data are limited. We also recognize the importance of balancing changes in the AV Calculator between ensuring that the AV Calculator is more accurately reflecting the current market and ensuring that any change to the AV Calculator minimizes the disruptions to current plan designs.

Comment: A commenter recommended that we consider updating based on utilization by income. Others expressed concern about the cost sharing limits in the AV Calculator. Comments included a request for additional information on the trending factor update particularly regarding the use of premium data, as well as a recommendation to set a higher threshold for applying the trend factor.

Response: AV is the calculation of a plan's cost sharing generosity that is applied to a standard population and does not take into account utilization by income level. Information on the development of the standard population is included in the AV Calculator methodology document. Income level is factored into other parts of the market, such as the enrollee's eligibility for cost sharing reductions. The cost sharing limits in the AV Calculator are reflective of the requirements under section 1302(c) of the Affordable Care Act, as implemented in regulations codified at § 156.130(a)(2).

When updating the trending factor in the AV Calculator, we will use two sources of data, one to reflect the individual market and one to reflect the small group market, to develop a single trend factor that could be applied to the AV Calculator that could be based on

the premium rate data and/or the standard population data compared from year to year. For premium rate data, these updates will be reflective of a combination of utilization and unit price increases. We intend to use the premium data to trend the Calculator because it is a reliable source of data that is easily accessible and a good indicator of the market cost changes from year to year. This premium rate data will be modified for proper actuarial adjustments to develop the trend factor, including adjustments for the transitional reinsurance program. These adjustments will be detailed in the AV Calculator methodology. As we discussed in the proposed rule, we will consider trending the AV Calculator every year and in cases, where the trend factor is cumulatively more than 5 percent different from the previous time the AV Calculator was updated, we would implement the trend factor.

Comment: Commenters requested additional guidance on a variety of topics related to the AV Calculator as well as analysis of AV policy. Other commenters expressed concern that updates to the algorithms could impact plans' AV. Some commenters requested the opportunity to provide input on future updates to the AV Calculator and requested information about how these updates would apply to the minimum value calculator and any State AV Calculator.

Response: The standard that we will apply in making algorithm adaptations will be to have the minimum impact possible on the outcomes produced by the AV Calculator generally while still allowing it to be adaptable to the new types of plan designs and allowing more types of plan designs to use the AV Calculator. However, as noted above, because the AV Calculator is a dynamic tool, it is impossible to make changes to the Calculator's algorithms without potentially impacting the AV output.

Guidance on the operation and functions of the AV Calculator is included in both the AV Calculator Methodology and the AV Calculator User Guide. As we update the AV Calculator in future plan years, we will revise these documents to provide our analysis and clarification where possible. In addition to taking into consideration stakeholder feedback that is submitted to the CMS Actuarial Value email address at actuarialvalue@cms.hhs.gov during the year, we will consult with the American Academy of Actuaries as well as the National Association of Insurance Commissioners and will intend to release a draft version of the AV Calculator through guidance for comment. This guidance will

include an updated AV Calculator Methodology to explain the changes that were made to the AV Calculator. We also intend to provide future guidance on the parameters for updating a State AV Calculator. The Department of Treasury and the Internal Revenue Service are aware of our updates to the AV Calculator and may consider updates to the minimum value calculator.

Comment: We received two comments on potential data sources for family plans. Other commenters requested additional clarity on incorporating family plans as well as recommending that issuers should not be required to include family coverage in their AV calculation.

Response: We are interested in learning more about the potential for States' all payer claims databases systems to account for family plan cost sharing, but since many of these systems are still in development, we will monitor these systems to consider this option in the future. In the meantime, we will continue to maintain the policy for accounting for family plans that we provided in the "2014 Letter to Issuers on Federally-facilitated and State Partnership Exchanges."⁵²

We believe that determining AV based on the cost sharing applicable to an individual is appropriate for most family plans and that for most plans, the amount of the change in AV due to a more exact calculation of family cost sharing is likely to be within the *de minimis* range. However, if the issuers finds that this approach will not yield an appropriate AV for a specific family plan, then the issuer should use an alternative AV calculation method under § 156.135(b) providing the appropriate documentation. We will continue to consider potential AV calculation modifications in this area.

4. National Annual Limit on Cost Sharing for Stand-Alone Dental Plans in an Exchange

We proposed to impose a specific annual limit on cost sharing for the pediatric dental EHB when offered through a stand-alone dental plan (SADP) of \$300 for one covered child and \$400 for two or more covered children. The annual limit on cost sharing was proposed to apply for SADPs certified by all Exchanges. Further, due to the limited variation in cost sharing with a decreased annual limit on cost sharing, we proposed

⁵² Letter to Issuers on Federally-facilitated and State Partnership Exchanges, April 5, 2013, available at: http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2014_letter_to_issuers_04052013.pdf.

removing the AV requirement applicable to SADPs offered through the Exchanges that had been established previously through rulemaking.

We are finalizing the annual limit on cost sharing with an increase compared to the proposed levels, to apply to SADPs certified by all Exchanges nationally. In response to comments that the actuarial value would still be a valuable standard for SADPs, we are not finalizing our proposal to delete the actuarial value requirement at § 156.150(b).

Comment: Several commenters voiced concerns about a lowered annual limit on cost sharing, primarily related to the anticipated increase in premiums and concerns that a reduced annual limit on cost sharing would result in plan designs that impose deductibles on more of the preventive pediatric dental services. Commenters stated that these higher up-front costs would be a deterrent to consumers purchasing SADPs for their children if the pediatric dental EHB was not included in the QHP. Some commenters suggested that CMS wait to change the limit until more information is available on the first year of experience and to avoid disruption for consumers in the plan designs for year two, and a number suggested that the family to single limit ratio remain 2:1. Other commenters supported the approach for its impact on reducing the total out-of-pocket costs for a consumer enrolled separately in QHPs and SADPs.

Response: We understand that trade-offs exist between the different cost levers in a plan design, such as premiums, deductibles, and annual limits on cost sharing. Accordingly, we requested comment on the proposed annual limits on cost sharing, and specifically whether a higher or lower limit would be appropriate for the pediatric dental EHB. In light of the comments received, we are finalizing the SAMP annual limits on cost sharing with increases of \$50 on the single child limit and \$300 on the limit for two or more children. The national annual limits on cost sharing for the pediatric dental EHB when offered as part of a stand-alone dental plan are \$350 for one covered child and \$700 for two or more covered children. We believe that this will provide more benefit design flexibility to dental issuers, which will reduce the potential impact on premiums and other cost-sharing, while also furthering our originally stated goal in the proposed rule of reducing the total annual limit on cost sharing for consumers who are enrolled in both QHPs and SADPs. The greater increase in the limit for two or more children enrollees is to retain the 2:1 ratio of

family, as suggested by commenters, to be consistent with the ratio for medical plans.

Comment: Regarding the removal of the AV standards, most commenters suggested that CMS return to the previous AV standards so that consumers would continue to have a means of comparison between the relative levels of coverage and out of concern that, without such standards, SADPs could transfer more cost sharing to up-front deductibles that would result in an AV below 70 percent.

Response: We believe that the commenters raised valid points regarding the value to a consumer of an AV level and, accordingly, we will not finalize the deletion of the actuarial value standards for SADPs previously established in the EHB Rule. The standard for SADPs is that they must meet *either* the 70 percent or 85 percent AV level. We understand that with the reduction in the annual limit on cost sharing, the lower of the two limits—70 percent—may be more difficult to meet, but in such cases the SAMP could instead target the 85 percent level.

Comment: A small number of commenters supported the approach to having the annual limit on cost sharing for the pediatric dental EHB in SADPs as a national limit, as opposed to allowing State flexibility.

Response: We agree with the commenter and are finalizing the rule to apply nationally.

5. Additional Standards Specific to SHOP

We proposed adding paragraph (a)(4)(i) to § 156.285 to provide that a qualified employer in the SHOP that becomes a large employer would continue to be rated as a small employer, regardless of whether the QHP being sold through the SHOP is sold in the small group market or the large group market. To assure consistency of pricing within the SHOP, we proposed to require a QHP offered through the SHOP to comply with the rating rules described in § 147.102. Nothing in this proposal prevents such an employer from choosing to buy a guaranteed issue new policy (without small group rating rules) in the large group market outside of the SHOP. We are making a minor change from the proposed rule to add “being sold through the SHOP” to § 156.285(a)(4)(i).

We proposed in amendments to § 156.285(a)(4)(ii) to not allow for composite premiums in the FF-SHOPS when an employer chooses a level of coverage and makes all QHPs within that level available to its employees. In the proposed rule preamble, we also

indicated that we were considering extending the proposed limitation on composite premiums to SADPs in the FF-SHOPS, and invited comment on whether such a prohibition should be adopted. We acknowledge that this proposal would create a limited exception to § 147.102(c)(3) and that it would preempt State laws requiring or permitting composite premiums in the small group market, but we believe this proposal to be limited in scope and tailored to provide for administrative efficiency and uniformity, system compatibility among the FF-SHOPS, and increased competition and choice in the small group market. We are finalizing the provisions with a change reflecting that, in response to comments solicited and received on whether the proposal to limit composite premiums in an employee choice environment should be extended to SADPs, we have decided to extend that limitation to SADPs when an employer opts to offer employees the choice of all SADPs at a dental actuarial value level.

Because the proposed amendments to § 155.705(b)(4) summarized above are being finalized as proposed, all SHOPS will be permitted to establish standard methods for premium payment under § 155.705(b)(4), as part of carrying out the premium aggregation function, and HHS will establish through guidance a process and timeline for employers to follow when remitting premium payments to the FF-SHOPS once premium aggregation becomes available in the FF-SHOPS. We anticipate that after premium aggregation becomes available in the FF-SHOPS, an FF-SHOP would transmit premium payments—both initial and subsequent—to issuers on a regular schedule and anticipate that this would be no more frequently than once a week.

We proposed adding § 156.285(c)(7)(ii) to establish that a QHP issuer offering a QHP through an FF-SHOP would be required to enroll a qualified employee unless it receives a cancellation notice for that employer from the FF-SHOP. This operational scenario would arise only in the case of an employer’s initial premium payment. For regular monthly payments from a participating SHOP employer, the requirements of the payment timeline and process established in accordance with new § 155.705(b)(4)(ii)(A) (as finalized in this rule) and the termination provisions of § 155.735 would apply. We are finalizing this provision as proposed.

Comment: Several commenters supported our proposal to limit composite premiums in FF-SHOPS to employers who choose to offer their

employees a single QHP. In addition to supporting our proposal, many of these commenters stressed that composite premiums should always be optional for issuers participating in FF-SHOPs (unless required by State law or regulation). A few commenters, however, support composite premiums for employee choice and believe it will add to the value-proposition of FF-SHOPs.

Response: As we discussed in the preamble to the proposed rule, our proposal to make composite premiums in the FF-SHOPs unavailable to qualified employers offering employee choice was motivated by our concern that the amendments to § 147.102 finalized in this rule would adversely affect issuers in an employee choice environment, creating an incentive for issuers to avoid participating in the FF-SHOPs and undermining the Affordable Care Act's goals of increased choice and competition in the small group market. That is because, under the composite premium provisions of § 147.102(c)(3), if an issuer offers composite premiums, the average enrollee premium amount established at the time of the initial group enrollment would not change until renewal, even if the composition of the group changes in the interim. For example, if several older employees joined the group or several employees terminated their coverage, the composite premium would remain the same until renewal. Because any risk related to a change in the group's composition is divided among issuers in an employee choice environment, they would be taking on proportionately more risk than in a single plan environment where the issuer would be assuming the risk—good and bad—for the entire group. In light of these concerns, we continue to think the prohibition on composite premiums in an employee choice environment is warranted, and are finalizing this policy as proposed through the amendment to § 156.285(a)(4), so as to not allow for composite premiums in an employee choice environment.

Comment: We received some comments agreeing with our proposal to extend to SADPs in the FF-SHOPs the proposed limitation on composite premiums in an FF-SHOP when an employer selects a level of coverage and makes all QHPs within that level available to its employees.

Response: In response to these comments, we are modifying the final rule to provide that the limitation on composite premiums in an employee choice environment applies to both medical QHPs and SADPs, in circumstances where the employer

offers employees a choice of all plans at a given AV level or dental AV level. As is the case with composite premiums for medical QHPs, we believe composite premiums for SADPs could potentially adversely affect issuers when the employer offers employees all SADPs at a given dental AV level, and could create an incentive for SAMP issuers to avoid participating in the FF-SHOPs and undermine the Affordable Care Act's goals of increased choice and competition in the small group market. Therefore, we have finalized this provision with additional language establishing that the limitation on composite premiums also applies for SADPs when employees are given a choice of SADPs at a given dental AV level.

Comment: We received varying comments on our proposal to require issuers in FF-SHOPs to effectuate coverage unless they receive a cancellation notice for non-payment of premium. Some commenters supported our proposal to require issuers to effectuate coverage if the FF-SHOP does not send a cancellation transaction prior to the coverage effective date. Some commenters opposed our proposal, stating that issuers should not be required to effectuate coverage before receiving the initial premium payment from the FF-SHOP. One commenter stated that issuers typically have payments in hand prior to coverage effectuation, giving issuers time to ensure that member enrollment packets can be sent out prior to the enrollment cut-off date. One commenter took a similar position, though suggested that issuers be allowed to pend claims until the initial payment is received by the FF-SHOP. Another commenter stated that the proposed policy could lead to provider reluctance to participate in Exchange plans. Finally, one comment suggested that a potential solution to this timing issue would be for the FF-SHOP to transmit daily payments to issuers.

Response: This rule does not require issuers to effectuate coverage if the FF-SHOP does not receive a premium payment by the deadline established for the FF-SHOP. If payment is not received by the FF-SHOP prior to that deadline, CMS will issue a cancellation notice, or, in the case of payments subsequent to the initial premium payment, a termination notice to issuers for non-payment of premium. In addition, we anticipate sending issuers weekly premium payments, so the length of time between receipt of payment and premium remittance is not expected to be more than approximately one week. Therefore, we are not

modifying our proposal in response to these comments.

6. Meaningful Difference Standard for QHPs in the FFEs

Section 1311(e)(1)(B) of the Affordable Care Act, codified at § 155.1000(c)(2), sets forth the standard that the Exchange may certify a health plan as a QHP if it determines that making the plan available through the Exchange is in the interests of qualified individuals and qualified employers in the State or States in which such Exchange operates. Therefore, as a means of ensuring that all QHPs offered through an FFE are in the interest of qualified individuals and qualified employers, we proposed that, to be certified as a QHP in an FFE, a plan must be considered “meaningfully different” from all other plans offered by the same issuer through the same Exchange, and we proposed a standard for what is meant by the term “meaningfully different.”

In § 156.298(a), we proposed that the FFEs and FF-SHOPs would impose a meaningful difference requirement when approving a QHP application for certification of multiple QHPs within a service area and level of coverage in the Exchange from a single issuer. Due to the special characteristics of the SAMP market, HHS proposed not to require meaningful difference as a condition for certification among SADPs at this time. We proposed, in § 156.298(b), that a plan within a service area and metal tier (bronze, silver, gold, or platinum, and catastrophic coverage) would be considered meaningfully different from other plans if a reasonable consumer (the typical consumer buying health insurance coverage) would be able to identify at least two material differences among seven⁵³ key characteristics between the plan and other plans to be offered by the same issuer. The key characteristics were proposed in paragraphs (b)(1)–(b)(7), and include (1) cost sharing; (2) provider networks; (3) covered benefits (including prescription drugs); (4) plan type (for example, HMO or PPO); (5) premiums; (6) health savings account eligibility; and (7) self-only, non-self-only, or child-only coverage offerings. We proposed that, at a minimum, a reasonable consumer would have to be able to identify two or more of the characteristics proposed at § 156.298(b) as different in order for the plan to pass the meaningful difference test. Therefore, within a service area and level of coverage in an Exchange, if two

⁵³ We acknowledge that the proposed 2015 Payment Notice listed seven elements, but referred erroneously to eight elements.

plans submitted by a single issuer seeking QHP certification vary among their cost sharing and covered benefits features but have the same premiums, the plans would be deemed as having met the meaningful difference test.

Furthermore, to ensure that consumers have an adequate number of plan options across all metal levels of coverage, we proposed at § 156.298(c), that if HHS determines that the plan offerings at a particular metal level (including catastrophic plans) within a county are limited, plans submitted for certification at that level within that county would not be subject to the meaningful difference requirement.

To provide flexibility for issuers that merge with or acquire another issuer that is a separate legal entity, HHS proposed in § 156.298(d), a 2-year meaningful difference transition period starting from the date on which a QHP issuer (acquiring entity) obtains or merges with another issuer. We proposed in paragraph (d) that during the first 2 plan years after a merger or acquisition, the acquiring entity can offer plans that were recently obtained or merged from another issuer that do not meet the meaningful difference standard.

We are finalizing the provisions with the following modifications. To address concerns with the proposed meaningful difference standard, we have modified § 156.298(b) to have the standard set at one material difference rather than two, and have removed premiums as one of the characteristics among which plans must be different. We are not finalizing the text proposed at § 156.298(b)(5) and are therefore renumbering the provisions proposed at § 156.298(b)(1)–(7) as § 156.298(b)(1)–(6). To be consistent with previous HHS language used for other guidance and regulation, we have modified § 156.298(b)(6) (previously § 156.298(b)(7)) to read “child-only plan offerings” rather than “child-only offerings.”

Comment: Several commenters were supportive of the standard in general, but they also recommended modifying the standard from two differences to one to be consistent with the guidance CMS released for the 2014 coverage year. Furthermore, issuers believed strongly that one material difference (that is, plan type of HMO vs. PPO) would have a large enough impact for consumers to be able to differentiate plans from one another.

Response: Based on the comments received, we agree that one material difference (that is, plan type of HMO vs. PPO) would have a large enough impact for consumers to be able to differentiate plans from one another, which satisfies

our policy goal of ensuring the ability to readily differentiate and compare plan choices, leading to informed decisions. Accordingly, we are finalizing the standard at § 156.298(b) with a modification from two material differences to one.

Comment: Several commenters opposed the inclusion of premiums as a material difference among the key characteristics at the proposed § 156.298(b)(5), to use when determining if the meaningful difference standard is met. Specifically, commenters noted that premiums alone are not indicators of difference in plan design, but rather a function of plan design difference that are already accounted for in the other characteristics included in the proposed list.

Response: We agree based on the strong feedback from commenters that premiums alone are not indicators of difference in plan design. Therefore, we have revised § 156.298(b) so that premium is no longer included as a material difference option. We have renumbered the remaining characteristics accordingly.

Comment: Commenters expressed concern over the vague descriptions of the characteristics associated with the proposed standard and requested more robust quantitative standards for issuers to follow for the 2015 benefit year. For instance, several commenters requested further guidance on the cost-sharing characteristic.

Response: While we understand the reasoning for having more robust quantitative standards, we are not adding more robust quantitative standards to the characteristics because we believe that the characteristics are generally sufficiently detailed for issuers to be able to design QHPs that would be meaningfully different under this standard.

Comment: Some commenters expressed concern with the limited plan availability exception proposed at § 156.298(c). Commenters stated that they believed this exception may lead to cherry-picking of particular counties by issuers and anti-competitive practices to saturate the market.

Response: This policy helps to ensure that consumers have adequate plan choice in every county within the marketplace. We are finalizing this provision of the proposed policy as written.

Comment: Several commenters agreed with the approach of limiting an issuer's participation in the FFEs should there be significantly different rate increases for its QHPs and non-QHPs, based on the Exchange's authority under sections

1311(e)(1) and (e)(2) of the Affordable Care Act. Moreover, commenters thought that it is important for HHS to take sufficient action to ensure that a given plan in the FFE is in the interest of qualified individuals and qualified employees. Conversely, other commenters opposed the proposed policy as they noted that numerous components of the Affordable Care Act that mitigate adverse selection between QHP and non-QHPs already exist, so there is no need for HHS to impose a new protection for the FFEs.

Response: We appreciate all the feedback and comments regarding the proposed approach. We are not finalizing any new policy related to limiting participation in the FFEs on this basis and will take this feedback into consideration for future rulemaking.

7. Quality Standards: Establishment of Patient Safety Standards for QHP Issuers

In § 156.1110, we proposed that during phase one, a QHP issuer that contracts with hospitals that have more than 50 beds, must verify that they are Medicare-certified or have been issued a Medicaid-only CMS certification number (CCN), and are subject to Medicare Hospital Conditions of Participation (CoPs) requirements found in 42 CFR part 482 (specifically, standards regarding a quality assessment and performance improvement program and a discharge planning process). We proposed to direct QHP issuers to maintain documentation, including but not limited to the CCN for each hospital, to demonstrate compliance. We further proposed that a QHP issuer must make this documentation available to the Exchange, upon request by the Exchange, and in a time and manner specified by the Exchange. Lastly, we proposed that a QHP issuer must ensure that each of its QHPs meet these initial patient safety standards for plan or policy years beginning on or after January 1, 2015. Additional patient safety standards for QHP issuers would be implemented over time, under the Secretary's authority under section 1311(h)(2) of the Affordable Care Act. We noted that we anticipate establishing phase two implementation which would begin January 1, 2017 or when we issue further regulations based on a reassessment of the Exchange market, whichever is later, to include standards around hospitals and Patient Safety Organizations (PSO), health care providers, and health care quality improvement mechanisms. We noted that implementing all of the requirements described in section

1311(h) by January 1, 2015, could result in a shortage of qualified hospitals and providers available for contracting with QHPs.

We are finalizing this approach as proposed with one modification. We are modifying the documentation standard in § 156.1110(b) to remove “including, but not limited to, the CCN,” to indicate that only the CCN is required to be collected.

Comment: Many commenters agreed with the proposed provisions that we outlined in the proposed rule and supported the use of Medicare Hospital CoPs requirements in the initial phase of implementation of patient safety standards. Many commenters also expressed support for the phase-in approach to implementing the patient safety reporting standards for QHP issuers. They stated that the proposed approach was reasonable to ensure adequate numbers of hospitals in QHP networks and to safeguard patient access to health care services. Commenters agreed with HHS’s rationale that currently, there is insufficient capacity of Patient Safety Organizations (PSOs) and expressed concern that any more stringent standards than what was proposed would have negative effects on patient access and breadth of networks.

Response: We are finalizing the regulation as proposed with one minor change to the documentation standard, as discussed above. By finalizing as proposed, we believe that this approach to implementation of section 1311(h) would ensure that QHP issuers have sufficient hospitals and health care providers to contract with, while providing consumers with access to health care that meets adequate safety and quality standards.

Comment: Several commenters did not support the delay of the QHP issuer requirement of ensuring contracted hospitals have agreements with PSOs and disagreed with the proposed length of the phase-in period. These commenters disagreed regarding constraints for hospitals to enter into agreements with PSOs and for issuers to track such information. One commenter stated that Medicare Hospital CoPs requirements are not a proper substitute for hospital PSO relationships. Other commenters requested that CMS ensure that the phase-in lasts no more than one year as patient safety reporting is important to inform consumer choice and for health system improvement.

Response: We believe that the proposed phase-in for standards will ensure that QHP issuers and their contracted hospitals demonstrate the implementation of patient safety

activities while allowing time to develop more robust standards. We believe that establishing standards requiring hospital agreements with PSOs would be overly burdensome and an inefficient use of resources for the majority of hospitals and QHP issuers at this time. We believe it is important for hospitals to take adequate time to assess their unique patient safety data collection and analysis needs and to establish agreements with the appropriate PSOs. Further, we believe the proposed approach allows QHP issuers the opportunity to monitor patient safety of their network hospitals for meaningful compliance with patient safety standards. As the Exchange market evolves and as enrollment increases, we believe that patient safety reporting standards for QHP issuers should be enhanced. We do not intend phase one standards to be a substitute for hospital and PSO agreements. We believe that the first phase of implementation and aligning with Medicare Hospital CoPs requirements is appropriate at this time because the approach allows for effective alignment of hospital quality standards, clear standards for issuers and hospitals, and sufficient patient access to health care, in time to meet the statutory deadline of January 1, 2015.

Comment: A few commenters expressed concerns that the proposed rule fails to acknowledge successes of PSOs and participating providers and potentially has a negative impact on the progress in patient safety. Some commenters stated that those hospitals participating in PSO programs should be differentiated or rewarded using a preferred quality provider designation.

Response: We acknowledge that there are many successful, existing patient safety initiatives among health care providers across the country, including work by PSOs. In addition, we continue to encourage robust QHP provider networks that promote access to quality health care services. We believe the standards in the proposed rule support existing patient safety initiatives by providing a balanced approach to minimize potential duplication of hospital quality standards and ensure that individuals have the necessary access to health care. We recognize that many hospitals already have established agreements with PSOs but we do not believe it is necessary to require such agreements of hospitals at this time. We do not intend to restrict hospitals and QHP issuers from including such information in their marketing materials if they choose to.

Comment: One commenter supported the proposed approach as integrated

delivery systems are not able to follow the requirements of the Patient Safety Quality Improvement Act (PSQIA) which create barriers to the free flow of information between providers and the integrated health plan issuer of a QHP. One commenter was concerned with regard to the integrated system’s ability to participate in PSOs and encouraged the development of a reasonable alternative.

Response: We understand the commenter’s concern of the unique challenges of an integrated health care delivery system to participate in the Federal PSO program established under the PSQIA. As we state in the preamble to this final rule, we intend to issue future rulemaking regarding the establishment of reasonable exceptions pursuant to the Secretary’s authority in section 1311(h)(2) of the Affordable Care Act and will welcome additional comments at that time.

Comment: A few commenters were concerned that the proposed standards require QHP issuers to contract only with Medicare-certified hospitals and would therefore have a negative effect on patient access and breadth of networks. Specifically, commenters requested clarification that the standards only applied to Medicare-certified hospitals and would not restrict contracting with non-Medicare hospitals. They also asked for clarity that the standards did not apply to hospitals that may be temporarily without CCNs.

Response: We are clarifying that the standards do not require QHP issuers to only contract with Medicare-certified hospitals. As we stated in the proposed rule, the standards are designed to not significantly limit hospital participation in QHP networks and as proposed, would prevent a potential shortage of qualified hospitals and providers available for contracting with QHPs. The proposed standards in § 156.1110 establishes that a QHP issuer that contracts with a hospital with greater than 50 beds must verify that the hospital is Medicare-certified or has been issued a Medicaid-only CCN. However, QHP issuers are not prevented from contracting with other types of hospitals and providers.

Comment: One commenter cautioned CMS against implementing duplicative standards on hospitals and noted the hospital value-based purchasing programs and other quality reporting requirements included in the Affordable Care Act as potential areas for alignment. A few commenters made suggestions as to alignment of hospital standards across Medicare, Medicaid, and commercial markets.

Response: We believe the proposed standards to align with Medicare Hospital CoPs requirements for Quality Assurance and Performance Improvement programs and discharge planning in the initial years of implementation minimizes duplication and we intend to continue efforts to align with existing and effective Federal, State, and private health care quality reporting initiatives as well as other quality reporting requirements in the Affordable Care Act to minimize duplication. Comments regarding programs other than Exchanges and QHP issuers (such as hospital value-based purchasing programs) are outside the scope of this final rule.

Comment: One commenter urged CMS to establish standards, or at the least a framework, for 1311(g), related to quality improvement strategy reporting by QHP issuers, before implementing the second phase of section 1311(h) of the Affordable Care Act. The commenter stated that it is inappropriate to request issuers to comment on the future phase without providing standards for 1311(g) of the Affordable Care Act.

Response: We understand the commenter's concern of establishing standards regarding QHP quality improvement strategies in accordance with section 1311(g) of the Affordable Care Act prior to the future phase of implementation of patient safety standards. We intend to issue rulemaking in the future and will welcome comments to inform implementation of 1311(g) at that time. We agree with the commenter regarding the importance of harmonization of quality and patient safety reporting standards for QHP issuers.

Comment: One commenter suggested that phase one implementation of the standards should require hospitals to undergo an external evaluation by expert surveyors similar to the Medicare requirement for accredited hospitals.

Response: We believe that the proposed standards are adequate for phase one implementation of patient safety reporting for QHP issuers without placing undue burden on issuers or hospitals. We do not intend to duplicate standards for hospital survey and certification processes already in place and we also do not intend to interfere with hospital accreditation processes.

Comment: Many commenters supported the proposal to apply the patient safety reporting requirements to hospitals with more than 50 beds.

Response: We are finalizing the statutory distinction of number of hospital beds to be greater than 50 beds as proposed.

Comment: One commenter requested CMS to clarify what it considers to be a section 1861(e) hospital, including the types of hospitals. The commenter requested confirmation of their understanding that CMS intends for this provision to apply only to hospitals that are subject to the CoPs standards for Quality Assurance and Performance Improvement programs and discharge planning, which is broader than general acute care hospitals. Some commenters expressed concern that the proposed standards do not apply to hospitals with fewer beds, children's hospitals, critical access hospitals, inpatient psychiatric facilities or other hospitals that do not participate in Medicare or Medicaid.

Response: Section 1861(e) of the Social Security Act refers to the definition of the term, hospital. We clarify that the hospitals that are included in these proposed standards are those that are subject to the Medicare Hospital CoPs and that are Medicare-certified or are Medicaid-only hospitals that have CCNs. QHP issuers may continue to contract with other types of hospitals or providers that are not included in this reference; however, the issuer would not have to maintain the associated hospital CCNs based on these standards. For example, although we do not specifically identify psychiatric hospitals that are defined by 1861(f) of the Social Security Act, the proposed standards do not prevent QHP issuers from contracting with such hospitals. QHP issuers would not be required to collect and maintain CCNs for such hospitals in accordance with § 156.1110 but again, would be able to continue to contract with such hospitals. We encourage all hospitals and health care providers to engage in patient safety improvement activities with the goal of reducing harm and achieving better patient health outcomes. In the second phase of implementation, we will assess the feasibility of applying future patient safety reporting standards to other types of hospitals and will solicit comment at that time.

Comment: Several commenters did not support the proposed methodology for collecting and documenting a hospital's CCN as it could be burdensome to QHP issuers. Several other commenters offered suggestions for different methods that HHS could use, including having HHS collect the information from a hospital's accrediting entity or using publicly available data, such as Medicare's Provider of Services file. Another commenter asked that we specify what other documentation may be required in addition to a hospital's CCN.

Response: We acknowledge that there may be other sources for collecting a hospital's CCN; however, we believe that the QHP issuer should have the responsibility of tracking their contracted hospitals adherence to the standards we have proposed. In the final rule, we are modifying the documentation standard to direct QHP issuers to maintain only the CCNs for each hospital that these standards apply to. We maintain the collection and reporting of CCNs but we have removed reference to any other documentation.

Comment: One commenter seeks clarification that QHP issuers meet the documentation requirements for Medicare-certified or Medicaid-only CCN hospitals simply by providing Exchanges proof of those hospitals' certification or CCN, as provided to the QHP by the contracted hospital.

Response: We clarify that the QHP issuer would meet the documentation standard by providing the Exchange, upon request by the Exchange, the applicable hospitals' CCNs as provided by the contracted hospitals. We also clarify that it is the responsibility of the QHP issuer to ensure that accurate CCN information is maintained.

Comment: Several commenters disagreed with the proposed length of the phase-in period and requested that HHS ensure that the phase-in lasts no more than one year as patient safety reporting is important to inform consumer choice and for health system improvement. Another commenter requested that the phase-in period be shortened to one year.

Response: We maintain that the first phase of implementation would be for 2 years beginning January 1, 2015 or until we issue further regulations based on a reassessment of the Exchange market, whichever is later. We believe that this provides ample time for Exchange markets to develop, QHP provider networks to grow, PSOs to continue expanding, continued research regarding more robust patient safety standards for QHP issuers and examples of comparable activities to be included as reasonable exceptions.

Comment: Several commenters provided detailed suggestions for implementing the future phase of patient safety reporting standards including reasonable exceptions to the requirements and a number of comments regarding the core aspects of a hospital patient safety program, discharge planning program, health care quality improvement activities, and how QHPs can effectively track patient safety activities. Some commenters requested additional details regarding phase two

to be provided now so that stakeholders may have time to prepare.

Response: We intend to promulgate future rulemaking outlining a proposed approach and will seek additional public comment at that time.

8. Financial Programs

a. Netting of Payments and Charges

In the 2014 Payment Notice, HHS established a monthly payment and collections cycle for the advance payments of the premium tax credit, cost-sharing reductions, and FFE user fees, and an annual payment and collections cycle for the premium stabilization programs and reconciliation of cost-sharing reductions. For 2014, to streamline our payments and collections process, we provided in § 156.1215(a) that each month HHS will determine amounts owed to or by a QHP issuer by netting amounts owed by the QHP issuer to the Federal government against payments due to the QHP issuer for advance payments of the premium tax credit, advance payments of cost-sharing reductions, and payment of FFE user fees. In addition to this netting across these programs, as further described below, the monthly calculation of amounts due will reflect current information related to enrollment for past months, including information related to excess payments previously made. Finally, amounts owed to or by a QHP issuer will be netted across all entities operating under the same taxpayer identification number (TIN). This process will permit HHS to calculate amounts owed each month, and pay or collect those amounts from issuers more efficiently. When netting occurs, HHS will demand amounts due only when there is a net balance due to the Federal government.

Additionally, a number of annual payment flows will begin in 2015 for the risk adjustment program, the reinsurance program, the risk corridors program, and cost-sharing reduction reconciliation. To streamline payment and charge flows from all of these programs—advance payments of the premium tax credit, advance payments and reconciliation of cost-sharing reductions, FFE user fees, and the premium stabilization programs—we proposed in § 156.1215(b) that HHS may net amounts owed to the Federal government against payments due to an issuer (or an affiliated issuer under the same TIN) under these programs in 2015 and later years. We believe that this process will enable HHS to operate a monthly payment cycle that will be efficient for both issuers and HHS.

In § 156.1215(c), we proposed that any amount owed to the Federal government by an issuer and its affiliates for advance payments of the premium tax credit, advance payments of and reconciliation of cost-sharing reductions, FFE user fees, risk adjustment, reinsurance, and risk corridors after netting be the basis for calculating a debt owed to the Federal government. We proposed that payments and collections under all of these programs occur under an integrated monthly payment and collection cycle.

After considering the comments received, we are finalizing these provisions as proposed.

Comment: We received several comments supporting the proposed netting provisions in § 156.1215. However, one commenter asked HHS to net in a rolling fashion every month, and wait until the end of the calendar year to invoice issuers for any remaining balance.

Response: We believe that issuers should pay amounts owed on a monthly basis. Under our debt collection rules, these amounts owed could begin to accrue interest and penalties in subsequent months.

Comment: In response to our request for comment on payment timeframes, some commenters asked HHS to amend § 156.1210 in order to give issuers 15 business days, rather than 15 calendar days, to file discrepancy reports.

Response: The 15-calendar-day deadline established in § 156.1210 is necessary to permit HHS to resolve discrepancies by the next month's payment and collection process. Under § 156.1210(b), HHS will work with issuers that report discrepancies after 15 calendar days as long as the late reporting is not due to misconduct on the part of the issuer.

b. Confirmation of HHS Payment and Collections Reports

Under § 156.1210(a), an issuer must respond to the payment and collections report issued by HHS within 15 calendar days of receipt of the report by either confirming the report or notifying HHS if there is a discrepancy between the data provided in the payment and collections report and the data that the issuer has. Under § 156.1210(b), if an issuer reports a discrepancy in a payment and collections report later than 15 calendar days after receipt of the report, HHS will work with the issuer to resolve the discrepancy as long as the late reporting was not due to misconduct on the part of the issuer. Any resolution to such an identified discrepancy is reflected in a later

payment and collections report and the invoice generated under that later report does not affect the debt established by the invoice generated in connection with the earlier report.

We proposed that if an issuer notifies HHS of a discrepancy under § 156.1210(a) or (b), it would trigger an administrative discrepancy resolution process. Specifically, under § 156.1220(a), following the end of the benefit year, if the issuer remains dissatisfied with the results of that process, the issuer may make a request for reconsideration. To decrease the administrative burden on issuers, HHS, and the Exchanges, and in recognition of the number and timing of the data flows involved, we proposed not to retroactively adjust previous months' payment and collections reports and amounts previously due. The amount invoiced for a particular month, reflecting netted amounts as described above, constitutes an amount owed to the Federal government. As more accurate data become available to HHS, the Exchange, and the issuer, we proposed that this later information not reduce or increase the previous determination of an amount owed. Rather, the information is captured in subsequent months and reflected in subsequent payment cycles, and reflected in later invoices. Thus, an issuer would be required to pay the full amount of any invoice issued in connection with a payment and collection report for a month even if the issuer notes a discrepancy that may later be resolved as a credit in a later invoice. Therefore, we proposed to add paragraph (c) to § 156.1210 to provide that discrepancies in payment and collections reports identified to HHS under that section be addressed in subsequent payment and collections reports, and would not be used to change debts determined pursuant to invoices generated under previous payment and collections reports.

After considering comments on this approach, we are finalizing these provisions as proposed.

Comment: One commenter supported our proposal not to retroactively adjust HIX 820 payment and collections reports and amounts previously due. Another commenter asked HHS to amend proposed § 156.1215 to specify that HHS will delineate payments and charges by program and by issuer, so that issuers can track HHS netting, keep accurate track of payments by programs, and avoid penalties and fines for late payments.

Response: The HHS monthly payment and collections report will detail charges, payments, and netting by

program for each payee group. Each payee group consists of one or more issuers with the same TIN and is established and organized by a parent health insurer. In addition to this monthly statement, HHS anticipates providing issuers with more detailed reports relating to certain programs.

Comment: One commenter asked when HHS will make payments to issuers for reinsurance, risk adjustment, and cost-sharing reduction reconciliation.

Response: We will issue guidance on the timing of these payments in the future.

c. Administrative Appeals

In the proposed rule, we proposed an administrative appeals process designed to address unresolved discrepancies in advance payments of the premium tax credit, advance payments of cost-sharing reductions, FFE user fee payments, payments and charges for the premium stabilization programs, cost-sharing reduction reconciliation payments and charges, and assessments of default risk adjustment charges.

In § 156.1220(a), we proposed that an issuer be permitted to file a request for reconsideration of a processing error by HHS,⁵⁴ HHS's incorrect application of the relevant methodology, or HHS's mathematical error only with respect to: (1) Advance payments of the premium tax credit, advance payment of cost-sharing reductions and FFE user fee charges; (2) risk adjustment payments or charges for a benefit year, including an assessment of risk adjustment user fees; (3) reinsurance payments for a benefit year; (4) a risk adjustment default charge for a benefit year; (5) a reconciliation payment or charge for cost-sharing reductions for a benefit year; or (6) risk corridors payments or charges for a benefit year. For a dispute regarding advance payments of the premium tax credit, advance payments of cost-sharing reductions, or FFE user fee amounts for a benefit year, we proposed that a request for reconsideration be required to be filed within 30 calendar days after the issuer receives a final reconsideration notification specifying the aggregate amount of advance payments of the premium tax credit, advance payments of cost-sharing reductions, and FFE user fees for the

applicable benefit year. We sought comment on this proposal, including on the minimum materiality threshold that should be required for an issuer to seek reconsideration.

For a dispute regarding a risk adjustment payment or charge, including an assessment of risk adjustment user fees, a reinsurance payment, a default risk adjustment charge, a cost-sharing reduction reconciliation payment or charge, or a risk corridors payment or charge, we proposed that a request for reconsideration be filed within 30 calendar days of receipt of the applicable notification of payments and charges from HHS.

In proposed § 156.1220(a)(3)(i) (§ 156.1220(a)(4)(i) in this final rule), we proposed that the request for reconsideration specify the findings or issues that the issuer challenges, and the reasons for the challenge. In proposed § 156.1220(a)(3)(ii) (§ 156.1220(a)(4)(ii) in this final rule), we proposed that a reconsideration with respect to a processing error by HHS, HHS's incorrect application of the relevant methodology, or HHS's mathematical error be permitted to be requested only if, to the extent the issue could have been previously identified by the issuer to HHS under § 153.710(d)(2) or (e)(2), it was so identified and remains unresolved. Similarly, in proposed § 156.1220(a)(3)(iii) (§ 156.1220(a)(4)(iii) in this final rule), we proposed that a reconsideration with respect to advance payments of the premium tax credit, advance payments of cost-sharing reductions, and FFE user fees be permitted to be requested only if, to the extent the issue could have been previously identified by the issuer to HHS under § 156.1210, it was so identified and remains unresolved. We proposed that an issuer be permitted to request reconsideration if it previously identified an issue under § 156.1210 after the 15-calendar-day deadline, but that the issuer's late discovery of the issue was not due to misconduct on the part of the issuer.

In § 156.1220(a)(3)(iv) (§ 156.1220(a)(4)(iv) in this final rule), we proposed that the issuer be permitted to include in the request for reconsideration additional documentary evidence that HHS should consider. Such documents could not include data that was to have been filed by the applicable data submission deadline, but could include evidence of the timely submission of such documents.

In § 156.1220(a)(4) (§ 156.1220(a)(5) in this final rule), we proposed that in conducting the reconsideration, HHS would review the payment

determination, the evidence and findings upon which it was based, and any additional documentary evidence submitted by the issuer. HHS would also have the discretion to review any other evidence it believes is relevant in deciding the reconsideration (and would provide the issuer a reasonable opportunity to review and rebut the evidence), and would then inform the issuer of the final decision in writing. We proposed that an issuer would be required to prove its case by a preponderance of the evidence with respect to issues of fact.

In § 156.1220(a)(5) (§ 156.1220(a)(6) in this final rule), we proposed that a reconsideration decision would be final and binding for decisions regarding the advance payments of the premium tax credit, advance payments of cost-sharing reductions, and FFE user fees. A reconsideration with respect to other matters would be subject to the outcome of a request for informal hearing filed in accordance with proposed § 156.1220(b). We proposed in § 156.1220(b) that an issuer that elects to challenge the reconsideration decision for the final risk adjustment payment or charge, including an assessment of risk adjustment user fees; reinsurance payment; default risk adjustment charge; cost-sharing reduction reconciliation payment or charge; or risk corridors payment or charge for a benefit year provided under paragraph (a) of § 156.1220 would be entitled to an informal hearing before a CMS hearing officer. In § 156.1220(b)(1), we proposed that a request for an informal hearing be made in writing and filed with HHS within 15 calendar days of the date the issuer receives the reconsideration decision. In § 156.1220(b)(2), we proposed that the request for an informal hearing be required to include a copy of the reconsideration decision and specify the findings or issues in the decision that the issuer is challenging and its reasons for the challenge. We also proposed that HHS be permitted to submit for review by the CMS hearing officer a statement of the reasons supporting the reconsideration decision.

In § 156.1220(b)(3)(i), we proposed that the issuer would receive a written notice of the time and place of the informal hearing at least 15 calendar days before the scheduled date. In § 156.1220(b)(3)(ii), we proposed that the CMS hearing officer would neither receive testimony nor accept any new evidence that was not presented with the reconsideration request or in any statement provided by HHS. The scope of the CMS hearing officer's review would be limited to the statements provided by the issuer and HHS and the

⁵⁴ A processing error could result from HHS accessing the data submitted by the issuer on the dedicated distributed data environment in an incomplete or incorrect manner. We note that under proposed § 156.1220(a)(4)(i)–(ii), an issuer may not submit new data for consideration in an appeal if the data was not submitted prior to the applicable data submission deadline, but may submit documentary evidence to support a contention that data was timely submitted.

record that was before HHS in making the reconsideration determination. We would require that the issuer prove its case by clear and convincing evidence with respect to issues of fact and would permit the issuer to be represented by counsel in the informal hearing.

In § 156.1220(b)(4), we proposed that, following the informal hearing, the CMS hearing officer send the decision and the reasons for the decision to the issuer. We proposed that this decision be final and binding, but subject to any Administrator's review initiated in accordance with proposed § 156.1220(c).

We proposed in § 156.1220(c)(1) that if the CMS hearing officer upholds the reconsideration decision, the issuer be permitted to request a review by the Administrator of CMS within 15 calendar days of receipt of the CMS hearing officer's decision.⁵⁵ The request for a review by the Administrator of CMS would be required to specify the findings or issues in the decision that the issuer is challenging, and the reasons for the challenge. We proposed that HHS be permitted to submit for review by the Administrator of CMS a statement supporting the decision of the CMS hearing officer.

In § 156.1220(c)(2), we proposed that the Administrator of CMS or a delegate review the hearing officer's decision, any written documents submitted by HHS or the issuer, as well as any other information included in the record of the CMS hearing officer's decision, and determine whether to uphold, reverse, or modify the CMS hearing officer's decision. We proposed that the issuer be required to prove its case by clear and convincing evidence with respect to issues of fact. We proposed that the Administrator's determination be considered final and binding.

In response to comments, we are finalizing these provisions with the following modifications: We are extending the deadline to file a request for reconsideration to 60 calendar days instead of 30 calendar days, and the deadline for filing an informal hearing to 30 calendar days instead of 15 calendar days. We are also providing that these deadlines will run from the date of issuance of the notification and reconsideration decision, rather than the date an issuer receives the notification or reconsideration decision. Finally, we are providing that an issuer has 15 calendar days to request review by the

Administrator from the date of the CMS hearing officer decision, rather than from the date of receipt of the decision.

We are also providing for a minimum materiality threshold that an issuer must meet in order to request reconsideration for (1) advance payments of the premium tax credit, advance payments of cost-sharing reductions, or Federally-facilitated Exchange user fees (2) risk adjustment payment or charges (3) reinsurance payments (4) risk adjustment default charges (5) reconciliation payments or charges for cost-sharing reductions and (6) risk corridors payments or charges. That threshold is equal to the lesser of 1 percent of the applicable payment or charge listed in the prior enumerated categories payable to or due from the issuer for a benefit year, or \$10,000. For example, an issuer that received \$75,000 in advance payments of cost-sharing reductions would need to seek reconsideration of at least \$7,500 in those advance payments to meet the minimum materiality threshold, and an issuer that received \$800,000 in reinsurance payments would need to seek reconsideration of at least \$10,000 in reinsurance payments.

Comment: Several comments supported the proposed administrative appeals process. Some commenters asked that HHS allow issuers to appeal reconsideration decisions regarding advance payments of the premium tax credit, cost-sharing reductions, and FFE user fees.

Response: Issuers can dispute advance payments of the premium tax credit, advance payments of cost-sharing reductions, and FFE user fees amount on a monthly basis through the discrepancy report process set forth in § 153.1210, prior to receiving the final reconsideration notice in the summer of the year following the applicable benefit year. Furthermore, the methodology for calculating these payments provides few factors on which a request for reconsideration may be made. Given these considerations, we believe that providing one level of administrative appeal for advance payments of the premium tax credit, advance payments of cost-sharing reductions, and FFE user fees will provide issuers ample opportunity to resolve any discrepancies.

Comment: Several commenters sought extensions in the proposed timeframe for filing an appeal. Commenters asked that issuers have 60 calendar days to file a request for reconsideration, rather than 30 calendar days. The commenters also asked that issuers have 30 calendar days, rather than 15 calendar days to file a request for an informal hearing.

Response: We appreciate the need for additional time to analyze final notifications, and are amending § 156.1220(a)(2) to allow issuers 60 calendar days to file a request for reconsideration and § 156.1220(b)(1) to allow issuers 30 calendar days to request an informal hearing before a CMS hearing officer. In order to reduce the scope for disputes on when notifications are received, we are also amending our proposed policies to clarify that these timeframes will begin at the date of issuance of the notification and reconsideration decision rather than the date an issuer receives the notification or reconsideration decision.

Comment: Several commenters supported a minimum materiality threshold that should be required to seek reconsideration. One commenter suggested a minimum threshold of 1 percent of total payments made to or charges assessed on the issuer for a benefit year, while other commenters supported a materiality threshold equal to the lesser of 1 percent of total payments made to or charges assessed on the issuer for a benefit year, or \$10,000.

Response: We are amending our proposed rule to set a minimum materiality threshold for an issuer to request reconsideration under § 156.1220(a)(1) for (1) advance payments of the premium tax credit, advance payments of cost-sharing reductions, or FFE user fees; (2) risk adjustment payment or charges; (3) reinsurance payments; (4) risk adjustment default charges; (5) reconciliation payments or charges for cost-sharing reductions; and (6) risk corridors payments or charges only if the amount in dispute is equal to or exceeds 1 percent of the applicable payment or charge payable to or due from the issuer for the benefit year, or \$10,000, whichever is less. We are adopting a per-category calculation rather than an overall calculation because we do not believe the threshold should be artificially low if the issuer happens to have balancing payments and charges across the various programs.

Comment: Commenters asked that HHS provide detailed guidance on how to reflect amounts subject to reconsiderations and appeals in MLR filings.

Response: We are finalizing § 153.710(g), which provides details on how amounts subject to administrative appeals process should be reported for the purposes of MLR and risk corridors. Issuers must report, for the purposes of risk corridors and MLR, the risk adjustment or reinsurance payment to

⁵⁵ Consistent with the Medicare Advantage risk adjustment data validation audit dispute and appeal processes set forth in 42 CFR 422.311, we intend to propose in future rulemaking that CMS may also request review by the Administrator of a CMS hearing officer's decision.

be made by the Federal government, or the risk adjustment charge assessed by the Federal government, as reflected in the June 30th report, regardless of the amount in dispute. A QHP issuer would be required to report a cost-sharing reduction amount equal to the amount of the advance payments of cost-sharing reductions paid to the issuer by HHS for the benefit year, as reflected in the HHS report on cost-sharing reduction reconciliation payments and charges. Additionally, if a QHP issuer requests reconsideration of risk corridors payments or charges, then for purposes of MLR reporting, the QHP issuer would be required to report the risk corridors payment to be made to the Federal government or charge assessed by the Federal government as reflected in the notification provided under § 153.510(d). As stated in § 153.710(g)(2), an issuer must report any adjustment made following any discrepancy report made under paragraphs (d)(2) or (e)(2), or any request for reconsideration under § 156.1220(a) with respect to any risk adjustment payment or charge, including an assessment of risk adjustment user fees, reinsurance payment, cost-sharing reconciliation payment or charge, or risk corridors payment or charge, or following any audit, where the adjustment has not been accounted for in a prior risk corridors or MLR report, in the next following risk corridors and MLR report.

IV. Provisions of the Final Regulations

For the most part, this final rule incorporates the provisions of the proposed rule. Those provisions of this final rule that differ from the proposed rule are as follows:

1. Part 144—Requirements Relating to Health Insurance Coverage

We are finalizing the amendment to the definition of “policy year” for student health insurance coverage with a minor revision to remove the word “individual” from the reference to “individual health insurance coverage.”

2. Part 147—Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets

We are restructuring § 147.102(c)(3) as paragraphs (c)(3)(i) through (iii).

We are amending new § 147.102(c)(3)(ii) to provide that an issuer offering composite premiums is subject to the standards of new paragraph (c)(3)(iii), and to specify that the requirement that the total group premium must equal that the sum of per-member premiums is determined at

the time of applicable enrollment at the beginning of the plan year.

We are amending new § 147.102(c)(3)(iii) to provide that the standards in this paragraph apply in connection with a group health plan in the small group market.

We are amending new § 147.102(c)(3)(iii)(A) to clarify that composite premiums are calculated based on applicable enrollment of “participants and beneficiaries” at the beginning of the plan year, and deleting references to participants and beneficiaries elsewhere in this paragraph.

We are adding new § 147.102(c)(3)(iii)(B) to establish a two-tiered composite premium structure for small group market issuers that offer composite premiums. States may establish an alternate tiered-composite methodology with approval from HHS.

We are adding new § 147.102(c)(3)(iii)(C) to provide that an issuer cannot include any rating variation for tobacco use in a composite premium but instead must apply any applicable tobacco rating factor on a per-member basis, pursuant to applicable State law.

We are adding new § 147.102(c)(3)(iii)(D) to provide that issuers offering composite premiums with respect to a particular product offered in the small group market in a State must do so uniformly for all group health plans enrolling in that product, giving those group health plans the option to pay premiums based on a composite premium methodology, to the extent permitted by applicable State law and subject to § 156.285(c) of this final rule (prohibiting composite premiums in connection with employee choice in the FF-SHOPS).

3. Part 153—Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment Under the Affordable Care Act

a. Provisions and Parameters for the Permanent Risk Adjustment Program

We are amending § 153.630(b)(1) to provide that the issuer must attest that it has no conflicts of interest with the initial validation auditor to its knowledge, following reasonable investigation, and must attest that it has obtained an equivalent representation from the initial validation auditor.

We are amending § 153.630(b)(7)(i) to provide that an enrollee’s risk score must be validated by enrollment and demographic data review in a manner to be determined by HHS.

We are amending § 153.630(b)(7)(iv) to provide that, for the initial years of

risk adjustment data validation (the 2014 and 2015 benefit years), the senior reviewer may possess 3 or more years of experience.

We are amending § 153.630(b)(8) to provide that, for the initial years of risk adjustment data validation (the 2014 and 2015 benefit years), the initial validation auditor may meet an inter-rater reliability standard of 85 percent for validating review outcomes in accordance with the standards established by HHS.

b. Provisions and Parameters for the Transitional Reinsurance Program

We are amending the definition of “contributing entity” in § 153.20 to mean, for the 2015 and 2016 benefit years, a health insurance issuer and a self-insured group health plan (including a group health plan that is partially self-insured and partially insured, where the health insurance coverage does not constitute major medical coverage) that uses a TPA in connection with claims processing or adjudication (including the management of internal appeals) or plan enrollment for services other than for pharmacy benefits or excepted benefits within the meaning of section 2791(c) of the PHS Act. Notwithstanding the foregoing, a self-insured group health plan that uses an unrelated third party to obtain provider network and related claim repricing services, or uses an unrelated third party for up to 5 percent of claims processing or adjudication or plan enrollment for services other than for pharmacy or excepted benefits, will not be deemed to use a TPA, based on either the number of transactions processed by the third party, or the volume of the claims processing and adjudication and plan enrollment services provided by the third party.

We are amending the definition of “major medical coverage” in § 153.20 to include any catastrophic plan, or individual or small group market coverage subject to actuarial value requirements under § 156.140.

We are not finalizing our proposal to delete and reserve § 153.235(b).

c. Provisions for the Temporary Risk Corridors Program

We are adding a definition of “adjustment percentage” to § 153.500, and are amending the definitions of “profits” and “allowable administrative costs” in § 153.500 to account for the adjusted amount.

We are adding a definition of “transitional State” to § 153.500.

We are making a conforming change to § 153.530(d) to clarify that the July 31 submission deadline for risk corridors

data does not apply to the enrollment data specified in § 153.530(e).

We are adding paragraph (e) to § 153.530 to require health insurance issuers in the individual and small group markets to submit enrollment data for the risk corridors adjustment.

We are not finalizing our proposal in § 153.540 to establish our authority to assess CMPs for failure of an issuer to comply with applicable risk corridors rules.

4. Part 155—Exchange Establishment Standards and Other Related Standards Under the Affordable Care Act

a. Annual Open Enrollment Period for 2015

For consistency within this section, we are modifying § 155.410(f)(1) to refer to “QHPs” instead of “plans,” we are amending § 155.410(f)(1)(ii) to correct a typographical error referring to December 16, 2015 instead of 2014, we are amending § 155.410(e)(1) to change the close of the open enrollment period for 2015 to February 15, 2015, and we are amending § 155.410(f)(1)(iii) to provide for the applicable coverage effective dates for enrollments between January 16 and 31, 2015. We are not finalizing § 155.410(e)(2) or § 155.410(f)(2), as proposed.

b. Functions of a Small Business Health Options Program

We are modifying § 155.705(b)(3)(v)(B), which now allows an employer to choose to make available all stand-alone dental plans offered through an FF–SHOP at a level of coverage as described in § 156.150(b)(2).

We are finalizing amendments to § 155.705(b)(6) that were originally proposed in the Program Integrity proposed rule. We are finalizing language proposed at § 155.705(b)(6)(ii) at § 155.705(b)(6)(i)(A) instead of at (b)(6)(ii), to make clear that we never intended for this proposal to supersede the language at current § 155.705(b)(6)(ii), and are making a minor change to replace the word FF–SHOP with the term “Federally-facilitated SHOP.”

We added a heading to § 155.220(i).

We are not finalizing the proposed amendment to § 155.705(b)(11)(ii)(D).

5. Part 156—Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges

a. Provisions Related to Cost Sharing

We clarify in § 156.420(d) that the out-of-pocket spending required of enrollees in the zero cost sharing plan variation of a QHP for a benefit that is

not an essential health benefit from a provider (including a provider outside the plan’s network) may not exceed the corresponding out-of-pocket spending required in the limited cost sharing plan variation of the QHP and the corresponding out-of-pocket spending required in the silver plan variation of the QHP for individuals eligible for cost-sharing reductions under § 155.305(g)(2)(i), in the case of a silver QHP.

b. National Annual Limit on Cost Sharing for Stand-Alone Dental Plans in an Exchange

We are finalizing the annual limit on cost sharing with an increase compared to the proposed levels, to apply to SADPs certified by all Exchanges nationally.

We are not finalizing our proposal to delete the actuarial value requirement at § 156.150(b).

c. Additional Standards Specific to SHOP

We have modified § 156.285(a)(4)(i) to add the words “being sold through the SHOP” to provide clarity to the regulation text finalized at § 156.285(a)(4)(i).

We have modified § 156.285(a)(4)(ii) to provide that the policy expressed in that provision also applies to SADPs in the Federally-facilitated SHOP, if the employer elects to offer coverage to its employees under § 155.705(b)(3)(v)(B) as finalized in this rule.

d. Meaningful Difference Standard for Qualified Health Plans in the FFEs

We have modified § 156.298(b) to have the standard set at one material difference rather than two and have removed premiums as one of the characteristics among which plans must be different.

We are not finalizing the text proposed at § 156.298(b)(5) and are therefore renumbering the provisions proposed at § 156.298(b)(1) through (b)(7) as § 156.298(b)(1) through (b)(6) in this final rule.

e. Quality Standards: Establishment of Patient Safety Standards for QHPs Issuers

We are modifying the documentation standard in § 156.1110(b) to remove the reference to information other than the CCN to indicate that only the CCN is required to be collected.

f. Financial Programs

We are extending the deadline for an issuer to request reconsideration from 30 to 60 calendar days in § 156.1220(a)(3).

We are extending the deadline for an issuer to request an informal hearing before a CMS hearing officer from 15 calendar days to 30 calendar days in § 156.1220(b)(1).

We are modifying in § 156.1220(a)(3), § 156.1220(b)(1) and § 156.1220(c)(1) the date from which certain appeals-related deadlines will run so that the deadlines will run from the date of issuance of the notification, reconsideration decision, or CMS hearing officer decision, rather than the date an issuer receives the notification or decision.

We are establishing a minimum materiality threshold that an issuer must meet in order to request reconsideration for (1) advance payments of the premium tax credit, advance payments of cost-sharing reductions, or Federally-facilitated Exchange user fees (2) risk adjustment payment or charges (3) reinsurance payments (4) risk adjustment default charges (5) reconciliation payments or charges for cost-sharing reductions and (6) risk corridors payments or charges in § 156.1220(a)(2). That threshold is equal to the lesser of 1 percent of the applicable payment or charge listed in the prior enumerated categories payable to or due from the issuer for a benefit year, or \$10,000.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. This final rule contains information collection requirements (ICRs) that are subject to review by OMB. A description of these provisions is given in the following paragraphs with an estimate of the annual burden, summarized in Table 7. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We generally used data from the Bureau of Labor Statistics to derive average labor costs (including capital

costs, overhead, and fringe benefits) for estimating the burden associated with the ICRs.

A. ICRs Related to HHS Audits of State-Operated Reinsurance Programs (§ 153.270)

Under § 153.270, HHS or its designee may conduct a financial and programmatic audit of a State-operated reinsurance program to assess compliance with reinsurance program requirements. Under this provision, if an audit results in a finding of material weakness or significant deficiency, a State must ensure that the applicable reinsurance entity provides a written corrective action plan to HHS for approval within 60 calendar days of the issuance of the final audit report. The burden associated with meeting this third party disclosure requirement includes the burden for a State that establishes a reinsurance program to ensure that its applicable reinsurance entity and any relevant contractors, subcontractors, or agents cooperate with and take appropriate actions in connection with any audit, and the burden associated with preparing and submitting a corrective action plan to HHS for approval. Because only one State will operate reinsurance in the 2014 benefit year, this collection is exempt from the PRA under 44 U.S.C. 3502(3)(A)(i), and we will not seek approval from OMB for this information collection requirement. We discuss the impact associated with HHS audits of State-operated reinsurance programs in the Regulatory Impact Analysis section of this final rule.

B. ICRs Regarding Issuer and Entity Administrative Burden Related to Audits for the Premium Stabilization Programs (§ 153.405(i); § 153.540(a); § 153.410(d); § 153.620(c))

This final rule provides HHS or its designee with the authority to audit QHP issuers, contributing entities, and issuers of risk adjustment covered plans or reinsurance-eligible plans to assess compliance with the requirements of subparts E, F, G and H of part 153, as applicable. As mentioned earlier in this rule, where possible, we intend to align the risk corridors audit process with the audits conducted for the MLR program. Therefore, we believe that the issuer burden associated with the risk corridors audit is already accounted for as part of the Supporting Statement for the MLR program approved under OMB control number 0938–1164.

These provisions will require a third-party disclosure requirement of issuers of risk adjustment covered plans and issuers of reinsurance-eligible plans to

prepare and compile the financial and programmatic information necessary to comply with the audit. In the proposed rule, we estimated that it would take a total of approximately 60 hours of preparation time for each onsite review and an additional 30 hours of onsite time for each issuer, at an hourly labor cost of \$53.75 and a total cost of approximately \$4,838 for each issuer. Because we have not finalized our audit protocols, it is difficult to accurately estimate an audit rate. However, we believe that it is reasonable to assume that approximately 120 issuers, representing roughly 5 percent of issuers of risk adjustment covered plans or reinsurance-eligible plans, would be audited. Therefore, we estimated an aggregate burden of 10,800 hours and \$580,500 for issuers as a result of this requirement.

For contributing entities, we estimated that the disclosure burden would be substantially less because the audit would be simpler. We estimated the burden to be approximately one-quarter of that of an issuer of a risk adjustment covered plan or a reinsurance-eligible plan, or approximately 22.5 hours (at an hourly rate of \$53.75) at a cost of approximately \$1,209 for each contributing entity. We estimated that approximately 1 percent of contributing entities would be audited, representing 226 contributing entities. Therefore, we estimated an aggregate burden of 5,085 hours, or \$273,319, as a result of this requirement.

Comment: One commenter stated that HHS's burden estimates were unreasonable. In particular, the commenter believed that the initial meeting by issuers of risk adjustment covered plans and reinsurance-eligible plans with auditors would involve more personnel and labor hours.

Response: In response to this comment, we are revising our estimate for the onsite review portion of the audit to reflect the labor costs associated with additional personnel who would generally be expected to be involved in meetings and reviews. The new burden estimate includes 2 hours to schedule the onsite activities with the compliance reviewer (at an hourly labor cost of \$53.75), 32 hours for an introductory meeting involving 8 managers, 12 hours for three managers to tour with reviewers onsite, 15 hours of interview time with three managers, 8 hours to walk through processes with the reviewer, and 16 hours for concluding meetings, resulting in a total of 85 hours of onsite time for each issuer. Therefore, we estimate it will take 60 hours of preparation time and an additional 85 hours of onsite time for each issuer. We

now estimate it will require a total of 145 hours at a cost of approximately \$7,794 for each issuer to make information available to HHS for an onsite review. For approximately 120 issuers, representing roughly 5 percent of issuers of risk adjustment covered plans or reinsurance-eligible plans that might be audited in a year, we now estimate an aggregate burden of 17,400 hours and \$935,280 for issuers as a result of this requirement.

For contributing entities, we now estimate the burden to be approximately 37 hours at a cost of approximately \$1,989 for each contributing entity, or about one quarter of that of an issuer of a risk adjustment covered plan or a reinsurance-eligible plan. We estimate that approximately 1 percent of contributing entities will be audited, representing 226 contributing entities. Therefore, we now estimate an aggregate burden of 8,362 hours, or \$449,514 for contributing entities as a result of this requirement.

We will revise the information collection currently approved under OMB Control Number 0938–1155 with an October 31, 2015 expiration date to account for this additional burden.

C. ICRs Regarding Potential Adjustments for Transitional Plans (§ 153.500–§ 153.540)

We will make adjustments to the premium stabilization programs to help mitigate any unexpected losses for QHP issuers with plans that are affected by the transitional policy described in the preamble of this rule. To effectuate potential adjustments, we must estimate the State-specific effect on average claims costs. We thus will require all issuers participating in the individual and small group markets in a State to submit to HHS a member-month enrollment count for transitional plans and non-transitional plans in the individual and small group markets. This submission will occur in 2015 prior to the risk corridors July 31, 2015 data submission deadline. HHS will analyze that enrollment data, and publish the State-specific adjustments that issuers would use in the risk corridors calculations for the 2014 benefit year. To reduce the burden on issuers, we are considering coordinating this data collection with other data collections for the premium stabilization programs.

We estimate that there will be approximately 2,400 issuers in the individual and small group markets in the 2014 benefit year, and that it will take an insurance analyst approximately 30 minutes (at an hourly labor cost of \$38.49) to estimate enrollment in

transitional plans and non-transitional plans and submit this information to HHS. Therefore, we estimate a cost of approximately \$19.25 for each issuer, and an aggregate cost of \$46,200 for all individual and small group market issuers (though this cost may be lower depending upon the data collection method we adopt). Because we anticipate collecting this information in early 2015, and because we expect to issue additional clarifying guidance on this policy, we will seek OMB approval and solicit public comment on this data collection requirement at a future date.

D. ICRs Regarding Risk Corridors Data Validation (§ 153.530 and § 153.540)

For the 2014 benefit year, we will collect risk corridors data using the same form as is used for MLR data collection, at the same time (July 31st of the year following the applicable benefit year). We intend to modify the MLR collection form for benefit year 2015, approved under OMB control number 0938–1164, to add reporting elements (for example, QHP-specific premium amounts) that are required under the risk corridors data submission requirements at § 153.530. We intend to include these data elements in an amendment to the information collection approved under OMB control number 0938–1164 for MLR data submission that we will publish for public comment and advance for OMB approval in the future.

Because the MLR and risk corridors programs will require similar data, we estimate that submitting the data elements required for the risk corridors program will impose limited additional burden on issuers. We estimate that it will take each QHP issuer approximately 1.5 hours, representing 1 hour for an insurance analyst (at an hourly labor cost of \$38.49) and 30 minutes for a senior manager (at an hourly labor cost of \$77), to input and review data that is specific to the risk corridors program in the MLR and risk corridors reporting form for benefit year 2015. In the proposed ICR, we estimated that 1,200 QHP issuers would submit risk corridors data for the 2014 benefit year in the 2015 risk corridors and MLR reporting cycle. We are revising that estimate to reflect our most recent estimate of the number of QHP issuers that have registered in our Health Insurance Oversight System (HIOS) for the 2014 benefit year, and now estimate that approximately 475 QHP issuers will submit data. Therefore, we now estimate an aggregate burden of 712.5 hours (at a total cost of approximately \$36,573) for QHP issuers as a result of this requirement. We will revise the

information collection currently approved under OMB Control Number 0938–1155 with an October 31, 2015 expiration date to account for this additional burden.

E. ICRs Regarding Data Validation Requirements When HHS Operates Risk Adjustment (§ 153.630)

Pursuant to § 153.630(b)(1) of this final rule, an issuer of a risk adjustment covered plan must engage one or more independent auditors to perform an initial validation audit of a sample of its risk adjustment data selected by HHS. This provision also requires the issuer to provide HHS with the identity of the initial validation auditor, and attest to the absence of conflicts of interest between the initial validation auditor (or the members of its audit team, owners, directors, officers, or employees) and the issuer (or its owners, directors, officers, or employees), in a timeframe and manner to be specified by HHS. We previously estimated the cost to issuers to conduct an initial validation audit in the 2014 Payment Notice and the associated information collection request approved under OMB Control Number 0938–1155 with an October 1, 2015 expiration date. Therefore, the burden associated with this reporting requirement is the time and effort necessary to report the auditor's identity to HHS. We estimate it will take an insurance operations analyst (at an hourly labor cost of \$38.49) and a senior manager (at an hourly labor cost of \$77) each approximately 15 minutes to prepare and send an electronic report to HHS. Therefore, for 2,400 risk adjustment covered issuers in the individual and small group markets, the aggregate burden associated with this requirement is 1,200 hours, at an approximate cost of \$69,300.

In § 153.630(b)(8), we require the initial validation auditor to measure and report to the issuer and HHS, in a manner and timeframe specified by HHS, the inter-rater reliability rates among its reviewers. Also in this provision, we require that the initial validation auditor achieve a minimum consistency measure of 95 percent for demographic, enrollment, and health status review outcomes (85 percent for 2014 and 2015). We believe establishing standards for inter-rater reliability among reviewers is standard practice in the industry and will not result in extra cost for the initial validation auditor. Therefore, the burden associated with this reporting requirement is the time and effort for the initial validation auditor to report the inter-rater reliability rate to the issuer and to HHS.

We estimate it will take an insurance operations analyst (at an hourly labor cost of \$38.49) and a senior manager (at an hourly labor cost of \$77) each approximately 15 minutes to report the inter-rater reliability rate to the issuer and to HHS. Therefore, assuming that 2,400 issuers of risk adjustment covered plans each engage one independent auditor to perform the initial validation audit, the aggregate burden associated with this requirement is 1,200 hours, at an approximate cost of \$69,300. We will revise the information collection currently approved under OMB Control Number 0938–1155 with an October 31, 2015 expiration date to account for this additional burden.

F. ICRs Regarding Quarterly Data Submissions (§ 153.700(a))

Section 153.700 provides that issuers of a risk adjustment covered plan or a reinsurance-eligible plan must establish a dedicated distributed data environment and provide data access to HHS, in a manner and timeframe specified by HHS, for any HHS-operated risk adjustment and reinsurance program. In this final rule, we clarify this timeframe, requiring that an issuer must make good faith efforts to make complete, current enrollment and claims files accessible through its dedicated distributed data environments no less frequently than quarterly, once the issuer's dedicated distributed data environment is established.

Based on HHS's most recent estimate of fully insured issuers in the individual and small group markets, we estimate that 2,400 issuers will be subject to the requirement to establish a dedicated data environment to either receive reinsurance payments or make risk adjustment transfers. Although in this rule we clarify that issuers must make this data available to HHS on a quarterly basis, the information collection and the aggregate burden associated with this requirement is already accounted for under the Premium Stabilization Rule Supporting Statement that is approved under OMB control number 0938–1155 with an October 31, 2015 expiration date. We will revise that supporting statement to specify that issuers must comply with this information collection requirement on a quarterly basis.

G. ICRs Related to Confirmation of Dedicated Distributed Data Environment Reports (§ 153.700(d) and (e))

Under § 153.710(d) of this final rule, we require that within 30 calendar days of the date of an interim dedicated distributed data environment report from HHS, an issuer of a reinsurance-

eligible or risk adjustment covered plan must either confirm to HHS that the information in the interim reports for the risk adjustment and reinsurance programs accurately reflects the data to which the issuer has provided access to HHS through its dedicated distributed data environment in accordance with § 153.700(a) for the timeframe specified in the report, or describe to HHS any inaccuracy it identifies in the interim report. Similar to the interim report process, in § 153.710(e), we require that the issuer either confirm to HHS that the information in the final dedicated distributed data environment report accurately reflects the data to which the issuer has provided access to HHS through its dedicated distributed data environment in accordance with § 153.700(a) for the benefit year specified in the report, or describe to HHS any inaccuracy it identifies in the final dedicated distributed data environment report within 15 calendar days of the date of the report.

We estimate that 2,400 issuers of risk adjustment covered plans and reinsurance-eligible plans will be subject to this requirement, and that issuers will compare enrollee condition codes with risk scores and analyze claims costs to confirm information in the interim and final dedicated distributed data environment reports. On average, we estimate that it will take an insurance operations analyst (at an hourly labor cost of \$38.49) approximately 2 hours to respond to an interim report and 6 hours to respond to the final dedicated distributed data environment report. Therefore, we estimate an aggregate burden of 19,200 hours and \$739,008 for 2,400 issuers as a result of this requirement. We will revise the information collection currently approved under OMB Control Number 0938–1155 with an October 31, 2015 expiration date to account for this additional burden.

H. ICRs Regarding Privacy and Security of Personally Identifiable Information (§ 155.260(a))

In § 155.260(a), we state that an Exchange, at its option, may submit to the Secretary a request for approval of a proposed use or disclosure of eligibility and enrollment PII. The Exchange submitting such a request would describe the nature of the proposed use or disclosure and how it would ensure the efficient operation of the Exchange consistent with section 1411(g)(2)(A) of the Affordable Care Act, and describe the efficiency. The requesting Exchange also would describe how the information to be used or disclosed would be protected in

compliance with the privacy and security standards established by the Exchange and describe those protections. While this reporting requirement is subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.3(h)(1). This reporting is not intended as a substitute for a collection of information of, or to monitor, compliance with regulatory standards. Therefore, we are not seeking approval from OMB for these information collection requirements.

I. ICRs Regarding Advance Payments of Cost-Sharing Reductions (§§ 155.1030, 156.430, 156.470)

Based on our experience implementing the process for calculating advance payments of cost-sharing reductions for the 2014 benefit year, we are modifying §§ 155.1030, 156.430, and 156.470. However, because our previous methodology used data collected through vehicles that are used for other purposes, we expect these changes to only marginally reduce the reporting burden for issuers and Exchanges. Therefore, we will not be revising the burden estimates in the corresponding PRA packages at this time.

J. ICRs Regarding Quality Standards: Establishment of Patient Safety Standards for QHP Issuers (§ 156.1110)

In § 156.1110, we describe the information collection, recordkeeping, and disclosure requirements that a QHP issuer must meet to demonstrate compliance with the patient safety standards finalized in this rule. The burden estimate associated with these standards includes the time and effort required for QHPs to maintain and submit hospital CMS Certification Numbers to the Exchange, upon request, that demonstrates that each of its contracted hospitals with greater than 50 beds meets the patient safety standards required in § 156.1110(a). In the near future, HHS intends to publish a rule proposing more specific quality standards for Exchanges and QHPs and will solicit public comment. At that time and per requirements outlined in the PRA, we intend to estimate the burden on QHPs to comply with the patient safety provisions of § 156.1110.

K. ICRs Regarding Administrative Appeals (§ 156.1220)

In § 156.1220, we establish an administrative appeals process to address unresolved discrepancies for advance payment of the premium tax credit, advance payment and reconciliation of cost-sharing reductions, FFE user fees, and the

premium stabilization programs, as well as any assessment of a default risk adjustment charge under § 153.740(b).

In § 156.1220(a) as finalized in this rule, an issuer may file a request for reconsideration to contest a processing error by HHS, HHS's incorrect application of the relevant methodology, or HHS's mathematical error for the amount of: (1) Advance payment of the premium tax credit, advance payment of cost-sharing reductions or an FFE user fee charge for a particular month; (2) risk adjustment payments or charges for a benefit year, including an assessment of risk adjustment user fees; (3) reinsurance payments for a benefit year; (4) a risk adjustment default charge for a benefit year; (5) a reconciliation payment or charge for cost-sharing reductions for a benefit year; or (6) risk corridors payments or charges for a benefit year. While the hours involved in a request for reconsideration may vary, for purposes of this burden estimate we estimate that it will take an insurance operations analyst 1 hour (at an hourly labor cost of \$38.49) to make the comparison and submit a request for reconsideration to HHS. We estimate that 24 issuers, representing approximately 1 percent of all issuers that may be eligible for reinsurance payments, risk adjustment payments or charges (including any assessment of risk adjustment user fees or a default risk adjustment charge), advance payment and reconciliation of cost-sharing reductions, advance payment of the premium tax credit, and FFE user fees, will submit a request for reconsideration, resulting in a total aggregate burden of approximately \$924. We will revise the information collection currently approved OMB Control Number 0938–1155 with an October 31, 2015 expiration date to account for this additional burden.

In § 156.1220(b) of this final rule, an issuer that is dissatisfied with the reconsideration decision regarding: (1) Risk adjustment payments and charges, including an assessment of risk adjustment user fees; (2) reinsurance payments; (3) default risk adjustment charge; (4) reconciled cost-sharing reduction amounts; or (5) risk corridors payments or charges, provided under paragraph (a) of § 156.1220, is entitled to an informal hearing before a CMS hearing officer, if a request is made in writing within 30 calendar days of the date of the reconsideration decision. Further review is available from the Administrator of CMS. However, we believe these processes will occur extremely infrequently. Since collections from fewer than 10 entities are exempt from the PRA under 44

U.S.C. 3502(3)(A)(i), we will not seek

PRA approval for this information collection requirement.

TABLE 7—ANNUAL REPORTING, RECORDKEEPING AND DISCLOSURE BURDEN

Regulation section(s)	Number of respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting (\$)	Total labor cost of reporting (\$)	Total capital/maintenance costs (\$)	Total cost (\$)
§ 153.405	226	226	37.00	8,362	53.75	449,514	0	449,514
§ 153.410; § 153.620	120	120	145.00	17,400	53.75	935,280	0	935,280
§ 153.500 – § 153.540	2,400	2,400	0.50	1,200	38.49	46,200	0	46,200
§ 153.540	475	475	1.50	712.5	51.33	36,573	0	36,573
§ 153.630(b)(1)	2,400	2,400	0.50	1,200	57.75	69,300	0	69,300
§ 153.630(b)(8)	2,400	2,400	0.50	1,200	57.75	69,300	0	69,300
(§ 153.700(d) and (e))	2,400	2,400	8.00	19,200	38.49	739,008	0	739,008
§ 156.1220	24	24	1.00	24	38.49	924	0	924
Total	a 3,245					2,346,099	0	2,346,099

^a ICRs associated with § 153.500, § 153.630(b)(1), § 153.630(b)(8) and § 153.700(d) and (e) apply to the same respondents, so the total number of unique respondents is 3,970.

We have submitted an information collection request to OMB for review and approval of the ICRs contained in this final rule. The requirements are not effective until approved by OMB and assigned a valid OMB control number.

To obtain copies of the supporting statement and any related forms for the paperwork collections referenced above, access CMS's Web site at <http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html> or email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office at 410-786-1326.

If you comment on these information collection requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, CMS-9972-F. Fax: (202) 395-5806; or Email: OIRA_submission@omb.eop.gov.

VI. Regulatory Impact Analysis

A. Statement of Need

This final rule provides standards related to the premium stabilization programs (risk adjustment, reinsurance, and risk corridors) that will protect issuers from the potential effects of adverse selection and protect consumers from increases in premiums due to issuer uncertainty. The Premium Stabilization Rule and the 2014 Payment Notice provided detail on the implementation of these programs, including the specific parameters applicable to these programs. This final

rule provides additional standards with respect to composite premiums, privacy and security of personally identifiable information, the open enrollment period for 2015, the AV Calculator, the annual limitation on cost sharing for stand-alone dental plans, the meaningful difference standard for QHPs offered through an FFE, patient safety standards for issuers of QHPs, the Small Business Health Options Program, cost-sharing parameters, cost-sharing reductions, and FFE user fees.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects (\$100 million or more in any one year).

OMB has determined that this rule is “economically significant” within the meaning of section 3(f)(1) of Executive Order 12866, because it is likely to have an annual effect of \$100 million in any one year. Accordingly, we have prepared an RIA that presents the costs and benefits of this final rule.

Although it is difficult to discuss the wide-ranging effects of these provisions in isolation, the overarching goal of the premium stabilization programs and Exchange-related provisions and policies of the Affordable Care Act is to make affordable health insurance available to individuals who do not have access to affordable employer-sponsored coverage. The provisions within this final rule are integral to the goal of expanding access to affordable coverage. For example, the premium stabilization programs decrease the risk of financial loss that health insurance issuers might otherwise expect in 2015 and the advance payments of the premium tax credit and cost-sharing reduction programs assist low- and moderate-income consumers and Indians in purchasing health insurance. The combined impacts of these provisions affect the private sector, issuers, and consumers, through increased access to health care services, including preventive services, decreased uncompensated care, lower premiums, establishment of patient safety standards, and increased plan transparency. Through the reduction in financial uncertainty for issuers and increased affordability for consumers, these provisions are expected to increase access to health coverage.

In this RIA, we discuss the requirements in this final rule related to cost sharing and FFE user fees, as well as new oversight provisions for the premium stabilization programs. We also discuss the impact of the

transitional policy discussed earlier on the risk corridors and reinsurance programs, and the impact on reinsurance contributions of the change in the definition of contributing entities.

Comment: Several commenters stated that the proposed regulatory impact statement lacked an adequate economic analysis. In particular, the commenters criticized listing only \$2 million in annual costs and \$14 million in transfer payments for a rule determined by OMB to involve costs of \$100 million or more annually. One commenter said HHS should have included its internal analysis of the effect of regulation on enrollment and premium in this impact statement, and the omission of this analysis appeared to be a willful attempt to withhold information from the public. The commenter asked HHS to spell out how the rule affects premium costs, employer costs, and taxpayer subsidies.

Response: We previously estimated the annualized impact on issuers, contributing entities, and States of transfers and other programs in the Premium Stabilization Rule and in the 2014 Payment Notice. Therefore, to avoid double-counting, Table 8 contains only incremental changes incurred as a result of provisions in this rule. The results of HHS's internal analyses were used to set reinsurance rates discussed in the 2014 Payment Notice, and again in this rule, where we estimate that, in 2015, reinsurance payments from the Federal government to individual market issuers will result in premium decreases in the individual market of between 5 and 6 percent relative to expected premiums without reinsurance. As detailed below, for this analysis, we continue to believe that the best available estimates of the impact of the Affordable Care Act on the Federal budget, enrollment in health insurance programs, and revenue collection are by the Congressional Budget Office. The CBO's most recent updates are available

at <http://www.cbo.gov/sites/default/files/cbofiles/attachments/43900-2014-02-ACATables.pdf>.

In our proposed rule, we noted that we were preparing an RIA because, while we were uncertain of the exact magnitude of the effect of the proposed adjustments to the risk corridors and reinsurance programs as a result of the transitional policy, we believed that the impact of the proposed adjustments and the impact of the other provisions in the proposed rule would reach the level of economic significance defined by OMB. In this final rule, we are finalizing our adjustment to the risk corridors program as proposed, and are lowering the reinsurance attachment point. Although it is difficult to estimate the exact impact of these policies, we describe our preliminary analysis of their monetary effect on health insurance issuers and the Federal government below.

Comment: A commenter criticized the regulatory analysis for failing to analyze and directly address the impact of the proposed rule's provision to exclude certain self-administered, self-insured group health plans from payment of reinsurance contributions, and requested that HHS disclose the number of participants and types of plans excluded and the per participant charge. Another commenter estimated the change would affect 14 million covered lives and increase the per capita contribution from remaining entities by \$3.

Response: It is difficult to estimate the number of self-insured, self-administered group health plans that might be excluded from reinsurance contributions as a result of the provision in this rule. While we solicited information on the number of such organizations, we did not receive comments with quantitative detail. Therefore, we have not changed our proposed estimate.

C. Impact Estimates of the Payment Notice Provisions and Accounting Table

In accordance with OMB Circular A-4, Table 8 depicts an accounting statement summarizing HHS's assessment of the benefits, costs, and transfers associated with this regulatory action.

This final rule implements standards for programs that will have numerous effects, including providing consumers with affordable health insurance coverage, reducing the impact of adverse selection, and stabilizing premiums in the individual and small group health insurance markets and in an Exchange. We are unable to quantify certain benefits of this final rule—such as increased patient safety and improved health and longevity due to increased insurance enrollment, and certain costs—such as the cost of providing additional medical services to newly-enrolled individuals. The effects in Table 8 reflect qualitative impacts and estimated direct monetary costs and transfers resulting from the provisions of this final rule for contributing entities, States, Exchanges, and health insurance issuers. The annualized monetized costs described in Table 8 reflect direct administrative costs (including costs associated with labor, capital, overhead, and fringe benefits) to States and health insurance issuers as a result of the provisions in this rule, and include administrative costs estimated in the Collection of Information section. We note that the estimated transfers in Table 8 do not reflect any user fees paid by insurance issuers for FFEs because we cannot estimate those fee totals. We also note that, while the 2015 reinsurance contribution rate is lower than the 2014 reinsurance contribution rate, total reinsurance administrative expenses will increase from 2014 to 2015.

TABLE 8—ACCOUNTING TABLE

Benefits:

Qualitative:

- * Increased enrollment in the individual market leading to improved access to health care for the previously uninsured, especially individuals with medical conditions, which will result in improved health and protection from the risk of catastrophic medical expenditures.
- * A common marketing standard covering the entire insurance market, reducing adverse selection and increasing competition.
- * Robust oversight of programs that use Federal funds to ensure proper use of taxpayer dollars.
- * Access to higher quality health care through the establishment of patient safety standards.
- * Increasing coverage options for small employers and part-time employees while mitigating the effect of adverse selection.

Costs:

	Estimate	Year dollar	Discount rate	Period covered
Annualized Monetized (\$/year)	2.35 million	2014	7 percent	2014–2017
	2.35 million	2014	3 percent	2014–2017

Quantitative:

- * Costs incurred by issuers and contributing entities to comply with provisions in this rule.
- * Costs incurred by States for complying with audits of State-operated reinsurance programs.

Transfers:

	Estimate	Year dollar	Discount rate	Period covered
Annualized Monetized (\$/year)	– 17.25 million	2014	7 percent	2014–2017
	– 16.76 million	2014	3 percent	2014–2017

- * Transfers reflect incremental cost increases from 2014–2015 for reinsurance administrative expenses and the risk adjustment user fee, which are transfers from contributing entities and health insurance issuers to the Federal government.
- * Unquantified: Lower premium rates in the individual market due to the improved risk profile of the insured, competition, and pooling.

This RIA expands upon the impact analyses of previous rules and utilizes the CBO analysis of the Affordable Care Act's impact on Federal spending, revenue collection, and insurance enrollment. The CBO's estimates remain the most comprehensive for provisions pertaining to the Affordable Care Act, and include Federal budget impact estimates for provisions that HHS has not independently estimated. The CBO's February 2014 baseline projections estimated that 25 million enrollees will enroll in Exchange coverage by 2018, including approximately 20 million Exchange enrollees who will be receiving premium tax credits or cost-sharing reductions.⁵⁶ CBO forecasts that 92 percent of non-elderly Americans will receive coverage by 2017. Participation rates among potential enrollees are expected to be lower in the first few years of Exchange availability

as employers and individuals adjust to the features of the Exchanges. Table 9 summarizes the effects of the risk adjustment and reinsurance programs on the Federal budget for fiscal years 2014 through 2017, with the additional, societal effects of this final rule discussed in this RIA. We do not expect the provisions of this final rule to significantly alter CBO's estimates of the budget impact of the risk adjustment and reinsurance programs. CBO updated scoring for the Premium Stabilization programs and found all three programs will reduce the deficit by \$8 billion over the budget window. For risk corridors, CBO now estimates the Federal government will pay \$8 billion to issuers from FYs 2015–2017, but that collections for this program will total \$16 billion, for a net yield of \$8 billion to the Federal government. We note that transfers associated with the risk

adjustment and reinsurance programs were previously estimated in the Premium Stabilization Rule; therefore, to avoid double-counting, we do not include them in the accounting statement for this final rule (Table 8).

In addition to utilizing CBO projections, HHS conducted an internal analysis of the effects of its regulations on enrollment and premiums. Based on these internal analyses, we anticipate that the quantitative effects of the provisions in this rule are consistent with our previous estimates in the 2014 Payment Notice for the impacts associated with the cost-sharing reduction program, the advance payments of the premium tax credit program, the premium stabilization programs, and FFE user fee requirements for health insurance issuers.

⁵⁶ "Updated Estimates for the Insurance Coverage Provisions of the Affordable Care Act," Congressional Budget Office, February 2014.

TABLE 9—ESTIMATED FEDERAL GOVERNMENT OUTLAYS AND RECEIPTS FOR THE RISK ADJUSTMENT AND REINSURANCE PROGRAMS FROM FY 2013–2017

[In billions of dollars]

Year	2014	2015	2016	2017	2013–2017
Risk Adjustment, Reinsurance, and Risk Corridors Program Payments	0	20	19	23	62
Risk Adjustment, Reinsurance, and Risk Corridors Program Collections	0	21	21	27	69

Source: Congressional Budget Office. 2014. *Appendix B: Updated Estimates of the Insurance Coverage Provisions of the Affordable Care Act*. February 4, 2014.

Risk Adjustment

The risk adjustment program is a permanent program created by the Affordable Care Act that transfers funds from lower risk, non-grandfathered plans to higher risk, non-grandfathered plans in the individual and small group markets, inside and outside the Exchanges. In subparts D and G of the Premium Stabilization Rule (45 CFR part 153) and in the 2014 Payment Notice, we established standards for the administration of the risk adjustment program.

A State approved or conditionally approved by the Secretary to operate an Exchange may establish a risk adjustment program, or have HHS do so on its behalf. As described in the 2014 Payment Notice, if HHS operates risk adjustment on behalf of a State, it will fund its risk adjustment program operations by assessing a risk adjustment user fee on issuers of risk adjustment covered plans. For the 2015 benefit year, we estimate that the total cost for HHS to operate the risk adjustment program on behalf of States for 2015 will be approximately \$27.3 million, and that the risk adjustment user fee will be \$0.96 per enrollee per year for HHS to operate the risk adjustment program on behalf of States for 2015.

In § 153.620(c) of this final rule, we establish that HHS or its designee may audit an issuer of a risk adjustment covered plan, when HHS operates risk adjustment on behalf of a State, to assess the issuer's compliance with the requirements of subparts G and H of 45 CFR part 153. As discussed above, HHS intends to fund risk adjustment operations (not including Federal personnel costs), including risk adjustment program integrity and audit functions, by collecting a per capita user fee from issuers of risk adjustment covered plans. Therefore, we believe that the costs to the Federal government associated with the risk adjustment audit activities in this final rule will be covered through the risk adjustment user fee, and that there will be no

impact for the Federal government as a result of the audit provisions. The audit provision would result in additional costs for issuers of risk adjustment covered plans related to gathering information and preparing for an audit. We discuss the administrative costs associated with this requirement for issuers in the Collection of Information section of this final rule.

Although this final rule will result in some additional administrative burden for issuers of risk adjustment covered plans as a result of the requirements for risk adjustment data validation and submission of discrepancy reports in response to interim and final dedicated distributed data environment reports, we note that much of the impact associated with establishing a dedicated distributed data environment and a risk adjustment data validation process has previously been estimated in the Premium Stabilization Rule and the 2014 Payment Notice. We do not believe that provisions contained within this rule substantially alter the previous estimates. We describe these administrative costs in the Collection of Information Requirements section of this rule.

Reinsurance

The Affordable Care Act directs that a transitional reinsurance program be established in each State to help stabilize premiums for coverage in the individual market from 2014 through 2016. In the 2014 Payment Notice, we expanded upon the standards set forth in subparts C and E of the Premium Stabilization Rule (45 CFR part 153) and established the 2014 uniform reinsurance payment parameters and national contribution rate. In this final rule, we set forth the 2015 uniform reinsurance payment parameters and contribution rate, and certain oversight provisions related to the operation of the reinsurance program.

Section 153.220(c) provides that HHS will publish the uniform per capita reinsurance contribution rate for the upcoming benefit year in the annual HHS notice of benefit and payment

parameters. Section 1341(b)(3)(B)(iii) of the Affordable Care Act specifies that \$10 billion for reinsurance contributions is to be collected from contributing entities in 2014 (the reinsurance payment pool), \$6 billion in 2015, and \$4 billion in 2016. Additionally, sections 1341(b)(3)(B)(iv) and 1341(b)(4) of the Affordable Care Act direct that \$2 billion in funds is to be collected for contribution to the U.S. Treasury in 2014, \$2 billion in 2015, and \$1 billion in 2016. Finally, section 1341(b)(3)(B)(ii) of the Affordable Care Act allows for the collection of additional amounts for administrative expenses. Taken together, these three components make up the total dollar amount to be collected from contributing entities in each of the three years of the reinsurance program under the uniform per capita contribution rate.

For the 2015 benefit year, if HHS operates the reinsurance program on behalf of a State, HHS would retain \$0.14 as an annual per capita fee to fund HHS's performance of all reinsurance functions. If a State establishes its own reinsurance program, HHS would transfer \$0.07 of the per capita administrative fee to the State for purposes of administrative expenses incurred in making reinsurance payments, and retain the remaining \$0.07 to offset the costs of contribution collection.

To safeguard the use of Federal funds in the transitional reinsurance program, we provided in § 153.270(a) of this final rule that HHS or its designee may conduct a financial and programmatic audit of a State-operated reinsurance program to assess compliance with the requirements of subparts B and C of 45 CFR part 153. As discussed above, HHS intends to fund reinsurance operations (not including Federal personnel costs), including program integrity and audit functions, by collecting as part of the uniform contribution rate, administrative expenses associated with operating the reinsurance program from all reinsurance contributing entities. Therefore, we believe that the costs to the Federal government associated with

the reinsurance audit activities in this final rule would be covered through the reinsurance contribution rate, and that there would be no net budget impact for the Federal government as a result of the audit provision. Because this audit requirement would direct a State that establishes a reinsurance program to ensure that its applicable reinsurance entity and any relevant contractors, subcontractors, or agents cooperate with an audit, and would direct the State to provide to HHS for approval a written corrective action plan; implement the plan; and provide to HHS written documentation of the corrective actions once taken, if the audit resulted in a finding of material weakness or significant deficiency, the requirement does impose a cost on States operating reinsurance. However, we believe that State-operated reinsurance programs would already electronically maintain the information necessary for an audit as part of their normal business practices and as a result of the maintenance of records requirement set forth in § 153.240(c), no additional time or effort will be necessary to develop and maintain audit information. We estimate that it will take a compliance analyst (at an hourly labor cost of \$53.75) 40 hours to gather the necessary information required for an audit, 5 hours to prepare a corrective action plan based on the audit findings and 64 hours to implement and document, if necessary, the corrective actions taken. We also estimate a senior manager (at an hourly labor cost of \$77) will take 5 hours to oversee the transmission of audit information to HHS and to review the corrective action plan prior to submission to HHS, and 16 hours to oversee implementation of any corrective actions taken. Therefore, we estimate a total administrative cost of approximately \$7,476 for each State-operated reinsurance program as a result of this audit requirement. For the one State that will operate reinsurance for the 2014 benefit year, we estimate a burden of approximately \$7,476 as a result of this requirement. Although we have estimated the cost of a potential audit in this RIA, we note that we may not audit State-operated reinsurance programs.

In § 153.405(i) and § 153.410(d), we establish that HHS may audit contributing entities and issuers of reinsurance-eligible plans to assess compliance with reinsurance program requirements. We discuss the costs to contributing entities and issuers of reinsurance-eligible plans as a result of this requirement in the Collection of Information section of this proposed

rule. We intend to combine issuer audits for the premium stabilization programs whenever practicable to reduce the financial burden of these audits on issuers. Consequently, we anticipate that, because issuers of reinsurance-eligible plans may also be subject to risk adjustment requirements, we would conduct these audits in a manner that avoids overlapping review of information that is required for both programs.

In this final rule, we are finalizing with modifications the definition of a contributing entity for the purpose of reinsurance contributions. Specifically, we exempt self-insured, self-administered plans that do not use a TPA to perform claims processing, claims adjudication, and enrollment functions from the requirement to make reinsurance contributions for the 2015 and 2016 benefit years. As stated earlier in this regulatory impact analysis, it is difficult to estimate the number of self-insured, self-administered group health plans that might be affected by this modification. We did not receive quantitative estimates in comments, although as previously stated, we expect that few entities will qualify for this exemption. Therefore, we have not changed our proposed 2015 reinsurance contribution rate.

Risk Corridors

The Affordable Care Act created a temporary risk corridors program for the years 2014, 2015, and 2016 that applies to QHPs, as defined in § 153.500. The risk corridors program is a mechanism for sharing risk for allowable costs between the Federal government and QHP issuers. The Affordable Care Act established the risk corridors program as a Federal program; consequently, HHS will operate the risk corridors program under Federal rules with no State variation. The risk corridors program will help protect against inaccurate rate setting in the early years of the Exchanges by limiting the extent of issuer losses and gains. HHS intends to implement this program in a budget neutral manner.

As mentioned elsewhere in this rule, for the 2014 benefit year, we are making an adjustment to the risk corridors formula that would help mitigate potential QHP issuers' unexpected losses that are attributable to the effects of the transitional policy. We also estimate that this adjustment would result in direct administrative costs for individual and small group market issuers that are discussed in the Collection of Information section of this final rule. Because of the difficulty associated with predicting State

enforcement of the 2014 market rules and estimating the enrollment in transitional plans and in QHPs, it is difficult to estimate the precise magnitude of this impact on aggregate risk corridors payments and charges at this time.

Our initial modeling suggests that this adjustment for the transitional policy could increase the total risk corridors payment amount made by the Federal government and decrease risk corridors receipts, resulting in an increase in payments. However, we estimate that even with this change, the risk corridors program is likely to be budget neutral or, will result in net revenue to the Federal government. The magnitude of this effect seems likely to be substantially smaller than the magnitude of the effect of the transitional policy itself (because risk corridors applies only to the extent of an issuer's QHP business), and the magnitude of the effect of the reduction of the reinsurance attachment point and potential increased coinsurance payout. Because reinsurance receipts are a parameter in the risk corridors calculation, the increase in reinsurance payments that would result from lowering the attachment point and potentially increasing the coinsurance rate would exert downward pressure on an issuer's risk corridors ratio. Consequently, while the transitional risk corridors adjustment will result in higher risk corridors payments than would occur if no transitional adjustment were in place, we believe that the risk corridors program as a whole will be budget neutral or, will result in net revenue to the Federal government in FY 2015 for the 2014 benefit year. We note that even with an estimated increase in outlays, CBO still projects the Premium Stabilization programs to reduce the deficit by approximately \$8 billion over the budget window. HHS intends to implement this program in a budget neutral manner.

To ensure the integrity of risk corridors data reporting, we establish HHS authority in § 153.540(a) of this final rule to conduct post-payment audits of QHP issuers. We are contemplating several ways to reduce issuer burden, such as conducting the risk corridors audits using the existing MLR audit process or conducting risk corridors audits under an overall issuer audit program. Therefore, as described in the Collection of Information section of this rule, we believe that the cost for issuers that would result from this audit requirement is already accounted for as part of the MLR audit process.

Provisions Related to Cost Sharing

The Affordable Care Act provides for the reduction or elimination of cost sharing for certain eligible individuals enrolled in QHPs offered through the Exchanges. This assistance will help many low- and moderate-income individuals and families obtain health insurance—for many people, cost sharing is a barrier to obtaining needed health care.⁵⁷

To support the administration of the cost-sharing reduction program, we are finalizing reductions in the maximum annual limitation on cost sharing for silver plan variations for 2015 and minor modifications to the standards relating to the design of cost-sharing reduction plan variations. We are also finalizing certain modifications to the methodology for calculating advance payments for cost-sharing reductions. However, we do not believe these changes will result in a significant economic impact. Therefore, we do not believe the provisions related to cost-sharing reductions in this rule as finalized will have an impact on the program established by and described in the 2014 Payment Notice.

In this final rule, we also establish the methodology for calculating the premium adjustment percentage, and finalize the premium adjustment percentage for the 2015 benefit year. Section 156.130(e) provides that the premium adjustment percentage is the percentage (if any) by which the average per capita premium for health insurance coverage for the preceding calendar year exceeds such average per capita premium for health insurance for 2013, and that this percentage will be published annually in the HHS notice of benefit and payment parameters. The annual premium adjustment percentage that is issued sets the rate of increase for four parameters detailed in the Affordable Care Act: the annual limitation on cost sharing (defined at § 156.130(a)); the annual limitation on deductibles for plans in the small group (defined at § 156.130(b)); and the section 4980H(a) and section 4980H(b) assessable payment amounts (proposed at 26 CFR 54.4980H in the “Shared Responsibility for Employers Regarding Health Coverage,” published in the **Federal Register** January 2, 2013 (78 FR 218)). We believe that the 2015

premium adjustment percentage is well within the parameters used in the modeling of the Affordable Care Act, and do not expect that it will alter CBO’s February 2014 baseline estimates of the budget impact.

Annual Open Enrollment Period

We revised § 155.410(e) and (f) to amend the dates for the annual open enrollment period and related coverage effective dates. These amendments would benefit issuers at no additional cost, as Exchanges will delay their QHP certification dates by at least one month, giving issuers additional time. Because open enrollment dates will be moved forward, Exchanges will still have the same amount of time for the QHP certification process, and we do not anticipate that this comes at an additional cost to Exchanges. Consumers would have the benefit of a more beneficial open enrollment period, without any additional demand placed on them.

Calculation of Plan Actuarial Value

Issuers may incur minor administrative costs associated with altering cost-sharing parameters of their plan designs to ensure compliance with AV requirements when utilizing the AV Calculator from year-to-year. These requirements were established in the EHB Rule and are in accordance with the provisions in this final rule. Since issuers have extensive experience in offering products with various levels of cost sharing and since these modifications are expected to be relatively minor for most issuers, HHS expects that the process for computing AV with the AV Calculator will not demand many additional resources.

User Fees

To support the operation of FFEs, we require in § 156.50(c) that a participating issuer offering a plan through an FFE must remit a user fee to HHS each month equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year and the monthly premium charged by the issuer for each policy under the plan where enrollment is through an FFE. For the 2015 benefit year, we are establishing a monthly user fee rate equal to 3.5 percent of the monthly premium. We do not have an aggregate estimate of the collections from the user fee at this time because we do not yet have a count of the number of States in which HHS will run an FFE or FF-SHOP in 2015.

SHOP

The SHOPs facilitate the enrollment of eligible employees of small employers into small group health insurance plans. A qualitative analysis of the costs and benefits of establishing a SHOP was included in the RIA published in conjunction with the Exchange Establishment Rule.⁵⁸ This RIA addresses the additional costs and benefits of the modifications in this final rule to the SHOP sections of the Exchange Establishment Rule.

In this rule, we revise § 155.705(b)(1), which lists the rules regarding eligibility and enrollment to which the SHOPs must adhere, to include additional provisions regarding termination of coverage in SHOPs and SHOP employer and employee eligibility appeals that were finalized in the first final Program Integrity Rule. In § 155.705(b)(3), we establish that an employer in the FF-SHOPs has the option to offer its employees either a single SADP or a choice of all SADPs available at a single SADP actuarial value level for plan years beginning on or after January 1, 2015.

We are also amending § 155.705(b)(4) to allow SHOPs performing premium aggregation to establish a standard method for premium calculation, payment, and collection. We are establishing that in the FF-SHOPs, after premium aggregation becomes available in plan years beginning on or after January 1, 2015, employers will be required to remit premiums to the FF-SHOP in accordance with a payment timeline and process established by HHS through guidance, and that premiums for coverage of less than 1 month will be prorated by multiplying the number of days of coverage in the partial month by the premium for 1 month divided by the number of days in the month. We believe this approach to prorating to be the fairest for both consumers and issuers because an enrollee will pay for the portion of coverage provided for a partial month.

In this rule, we are finalizing amendments to § 155.705(b)(6) that were originally proposed in the Program Integrity proposed rule published in the June 19, 2013 **Federal Register** (78 FR 37032) to establish that SHOPs must require all issuers to make any changes to rates at a uniform time that is no more frequently than quarterly, as is the case small-group-market-wide. The finalized amendments would also provide that issuers participating in the FF-SHOPs with the maximum amount of flexibility permitted under the

⁵⁷ Brook, Robert H., John E. Ware, William H. Rogers, Emmett B. Keeler, Allyson Ross Davies, Cathy D. Sherbourne, George A. Goldberg, Kathleen N. Lohr, Patricia Camp and Joseph P. Newhouse. *The Effect of Coinsurance on the Health of Adults: Results from the RAND Health Insurance Experiment*. Santa Monica, CA: RAND Corporation, 1984. Available at: <http://www.rand.org/pubs/reports/R3055>.

⁵⁸ Available at: <http://ccio.cms.gov/resources/files/Files2/03162012/hie3r-ria-032012.pdf>.

market-wide rules and the amendment to § 155.705(b)(6)(i), standardize the effective dates for rate updates in the FF–SHOPs, and provide that FF–SHOP issuers must submit rates to HHS 60 days in advance of the effective date. Consistent with technical guidance provided to issuers through the Health Insurance Oversight System on April 8, 2013, issuers will be able to submit updated quarterly rates for the FF–SHOPs no sooner than for the third quarter of 2014, due to current system limitations. This provision is being finalized at § 155.705(b)(6)(i) and (i)(A), leaving current § 155.705(b)(6)(ii) in place, as we did not intend to replace it.

We also are amending § 155.705(b)(11) to provide additional flexibility with respect to an employer's ability to define a percentage contribution toward premiums under the employer selected reference plan in the FF–SHOPs. Although we proposed and rejected a similar approach in the 2014 Payment Notice because we concluded it was inconsistent with the uniformity provisions established in Internal Revenue Service Notice 2010–82, which require employers to contribute a uniform percentage to employee premiums in order to claim a small business tax credit, we believe small employers are best able to determine whether offering different contribution levels are in the best interest of the business and its employees. We believe that this additional flexibility will bring the FF–SHOPs more in line with current small group market practices and provide an additional incentive for small employers to participate in the FF–SHOPs. Additionally, we believe that providing a mechanism that allows different contribution levels based on full-time or non-full-time status may encourage some employers to offer coverage to non-full-time employees. While we are finalizing this provision as proposed, we note that this option is not expected to become available in the FF–SHOPs until sometime after January 1, 2015.

In this rule, we amend § 155.715 to provide SHOP eligibility adjustment periods for both employers and employees only when there is an inconsistency between information provided by an applicant and information collected through optional verification methods under § 155.715(c)(2), rather than when an employer submits information on the SHOP single employer application that is inconsistent with the eligibility standards described in § 155.710 or when the SHOP receives information on the employee's application that is

inconsistent with the information provided by the employer, as current paragraph § 155.715(d) provides. We also amend paragraph (c)(4) to replace a reference to sections 1411(b)(2) and (c) of the Affordable Care Act with a reference to Subpart D of 45 CFR part 155, and to add a reference to eligibility verifications as well as to eligibility determinations. The changes as finalized in this rule will prohibit a SHOP from performing any individual market Exchange eligibility determinations or verifications as described in Subpart D, which, for example, includes making eligibility determinations for advance payments of the premium tax credit and cost sharing reductions in the individual market Exchange.

In § 155.730 we provide that SHOPs are not permitted to collect information from applicants, employers, or employees that is not necessary to determine SHOP eligibility or effectuate enrollment through a SHOP. Limiting the information required of an applicant helps to protect consumer privacy and promote efficiency and streamlining of the SHOP application process.

In § 155.220, we establish that for plan years beginning on or after January 1, 2015 SHOPs, in States that permit this activity under State law, may permit enrollment in a SHOP QHP through the Internet Web site of an agent or broker under the standards set forth in § 155.220(c)(3). Permitting an employer to complete QHP selection through the Internet Web site of an agent or broker is an additional potential enrollment channel that would provide small employers with another avenue to the SHOPs. While we are finalizing this provision as proposed, we do not expect that FF–SHOPs will offer this option in 2015. For clarity, we are making the technical change to add a title to § 155.220(i) to say, “*Use of agents' and brokers' Internet Web sites for SHOP.*”

In § 156.285 of this rule as finalized, we establish that when premium aggregation becomes available in FF–SHOPs for plan years beginning on or after January 1, 2015, if an issuer does not receive an enrollment cancellation transaction from the FF–SHOP, it should effectuate coverage even if the issuer would not receive an employer's initial premium payment from the FF–SHOP prior to the coverage effective date. We also establish that a qualified employer in the SHOP that becomes a large employer, regardless of whether the QHP being sold through the SHOP is sold in the small group market or the large group market, will continue to be rated as a small employer and that

issuers cannot offer composite premiums in the FF–SHOPs when employee choice becomes available and an employer offers employees a level of coverage rather than a single plan. Furthermore, we establish that when employee choice is offered in the FF–SHOPs, composite premiums will not be allowed when the employer elects to offer its employees all plans in an actuarial value (or metal tier) selected by the employer, and we extend this limitation to SADP issuers when employers offer employees a choice of all SADPs at a dental AV level.

We do not expect the policies as finalized in this rule and related to the SHOP to create any new significant costs for small businesses, employees, or the FF–SHOPs.

Patient Safety

The patient safety requirements established in this final rule will be implemented in phases, to ensure that QHP issuers contract with hospitals that meet adequate safety and quality standards. The final rule requires QHP issuers to collect and maintain CCNs for each of its contracted hospitals that are certified for more than 50 beds. It also requires that this documentation, if requested by the Exchange, be submitted in a form and manner specified by the Exchange. QHP issuers already have established procedures and relationships to contract with hospitals including obtaining hospital identification information. Therefore, HHS believes that there will not be a significant additional cost for a QHP issuer to collect and maintain CCNs. QHP issuers will incur costs to submit this information, if requested, to the Exchange. We discuss the burden associated with submitting this information in the Collection of Information section of this final rule.

D. Regulatory Alternatives Considered

We considered a number of alternatives to our approach to program integrity for the premium stabilization programs. For example, although we finalized in previous rulemaking our framework for the risk adjustment data validation program to be used when we operate risk adjustment on behalf of a State, the preamble to this rule as proposed discussed and sought comment on a number of alternative approaches to the detailed methodology made final in this rule. For example, we suggested a number of options for confidence intervals and whether to use tests of statistical significance in determining plan average risk score adjustments. We also suggested an expedited second validation audit

approach to permit more time for inter-auditor discussions and appeals. We suggested a number of ways to calculate a default risk adjustment charge for an issuer that fails to provide initial validation audits.

In the preamble discussion of our proposed modifications to the risk adjustment methodology, we considered not providing for an induced demand adjustment for Medicaid expansion plan variations, but we believe that not doing so would underestimate the riskiness of those plans, potentially leading to higher premiums for those plans.

In § 153.270, we establish in this rule that HHS may audit State-operated reinsurance programs to ensure appropriate use of Federal funds. We also considered not proposing that HHS have such authority. However, we believe that because HHS will collect reinsurance contributions and because a State's issuers' reinsurance requests affect the availability of reinsurance funds for issuers in other States, we think it is critical for HHS to have the authority to perform these audits, so that issuers and States are confident that they will receive the correct allocation of the reinsurance payments. We also considered proposing that HHS have the authority to audit a State-operated risk adjustment program. However, we decided not to do so because those programs do not take in Federal funds and those programs have little impact on the health insurance markets in other States.

In the preamble discussion of the 2015 reinsurance payment parameters, we also considered, when setting forth the proposed 2015 reinsurance payment parameters, a set of different uniform reinsurance payment parameters, but believe those alternative uniform reinsurance payment parameters would have unduly raised the complexity of estimating the effects of reinsurance for issuers.

As detailed in the preamble discussion regarding our proposed approach to estimating cost-sharing reduction amounts in connection with reinsurance calculations, we considered a number of alternative approaches to this estimation. Finally, we considered a number of different approaches to the discrepancy and administrative appeals process proposed in § 153.710 and § 156.1220. Some of these approaches would have provided for lengthier and more formal administrative appeals processes, including for advance payments of the premium tax credit, advance payment for cost-sharing reductions, and FFE user fees in 2014. We did not adopt that approach for these 2014 programs, and instead rely

on operational discrepancy reports and one-level of administrative appeals—a request for reconsideration—because we believe that this approach will be simpler and less expensive, and will permit operations specialists, issuers and HHS to resolve most problems more quickly. We considered relying solely on a simpler operational discrepancy report process for the premium stabilization programs and cost-sharing reductions reconciliation in 2015, but decided that due to the complexity of the calculations involved in these programs and the potential magnitude of the payment flows, issuers would prefer that these calculations be subject to more formal administrative processes.

Multiple alternatives were considered to the proposed SHOP approaches, and these are discussed in detail above.

We considered requiring QHP issuers to only contract with hospitals that have agreements with one of the 79 listed PSOs; however, as we stated in preamble, this could result in a shortage of qualified hospitals and providers available for contracting with QHPs. We also considered establishing exceptions for hospitals and QHP issuers to these requirements. However, we believe that the phase in approach for implementing these requirements effectively balances the priorities for making quality health care accessible and safe in the Exchanges.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of the final rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The RFA generally defines a “small entity” as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of “small entity.” HHS uses a change in revenues of more than 3 to 5 percent as its measure of significant economic impact on a substantial number of small entities.

In this final rule, we provide provisions for the risk adjustment, reinsurance, and risk corridors programs, which are intended to stabilize premiums as insurance market reforms are implemented and Exchanges facilitate increased enrollment. Because we believe that insurance companies

offering comprehensive health insurance policies generally exceed the size thresholds for “small entities” established by the SBA, we do not believe that an initial regulatory flexibility analysis is required for such firms.

For purposes of the RFA, we expect the following types of entities to be affected by this proposed rule:

- Health insurance issuers.
- Group health plans.
- Reinsurance entities.

We believe that health insurance issuers and group health plans would be classified under the North American Industry Classification System (NAICS) code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of \$35.5 million or less would be considered small entities for these NAICS codes. Issuers could possibly be classified in 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard would be \$30 million or less.

In this final rule, we establish requirements for employers that choose to participate in a SHOP Exchange. Coverage through the SHOPs is limited by statute to small employers, which the statute defines as employers who employed on average at least one but not more than 100 employees in a given plan year. For plan years beginning before January 1, 2016, the statute also provides that states may elect to define a small employer as having at least one but not more than 50 employees, on average, in a given plan year. For this reason, we expect that many employers who would be affected by the rule would meet the SBA standard for small entities. We do not believe that the provisions in this final rule impose requirements on employers offering health insurance through the SHOP that are more restrictive than the current requirements on small employers offering employer-sponsored insurance. Additionally, as discussed in the RIA, we believe the policy will provide greater choice for both employees and employers. We believe the processes that we have established constitute the minimum requirements necessary to implement the SHOP program and accomplish our policy goals, and that no appropriate regulatory alternatives could be developed to further lessen the compliance burden.

We believe that a substantial number of sponsors of self-insured group health plans could qualify as “small entities.” This rule provides HHS with the authority to audit these entities. However, we do not believe that the burden of these audits is likely to reflect

more than 3 to 5 percent of such an entity's revenues.

F. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a State, local, or Tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. In 2014, that threshold is approximately \$141 million. Although we have not been able to quantify the user fees that will be associated with this final rule, the combined administrative cost and user fee impact on State, local, or Tribal governments and the private sector may be above the threshold. Earlier portions of this RIA constitute our UMRA analysis.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications. Because States have flexibility in designing their Exchange and Exchange-related programs, State decisions will ultimately influence both administrative expenses and overall premiums. States are not required to establish an Exchange or risk adjustment or reinsurance program. For States electing to operate an Exchange, risk adjustment, or reinsurance, much of the initial cost of creating these programs will be funded by Exchange Planning and Establishment Grants. After establishment, Exchanges will be financially self-sustaining, with revenue sources at the discretion of the State. Current State Exchanges charge user fees to issuers.

In HHS's view, while this final rule does not impose substantial direct requirement costs on State and local governments, this regulation has Federalism implications due to direct effects on the distribution of power and responsibilities among the State and Federal governments relating to determining standards relating to health insurance that is offered in the individual and small group markets. Each State electing to establish an Exchange must adopt the Federal standards contained in the Affordable Care Act and in this final rule, or have in effect a State law or regulation that implements these Federal standards.

However, HHS anticipates that the Federalism implications (if any) are substantially mitigated because under the statute, States have choices regarding the structure and governance of their Exchanges and risk adjustment and reinsurance programs. Additionally, the Affordable Care Act does not require States to establish these programs; if a State elects not to establish any of these programs or is not approved to do so, HHS must establish and operate the programs in that State.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have Federalism implications or limit the policy making discretion of the States, HHS has engaged in efforts to consult with and work cooperatively with affected States, including participating in conference calls with and attending conferences of the National Association of Insurance Commissioners, and consulting with State insurance officials on an individual basis.

Throughout the process of developing this final rule, HHS has attempted to balance the States' interests in regulating health insurance issuers, and Congress' intent to provide access to Affordable Insurance Exchanges for consumers in every State. By doing so, it is HHS's view that we have complied with the requirements of Executive Order 13132.

H. Congressional Review Act

This final rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.), which specifies that before a rule can take effect, the Federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report containing a copy of the rule along with other specified information, and has been transmitted to Congress and the Comptroller General for review.

List of Subjects

45 CFR Part 144

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, and State regulation of health insurance.

45 CFR Part 153

Administrative practice and procedure, Adverse selection, Health care, Health insurance, Health records,

Organization and functions (Government agencies), Premium stabilization, Reporting and recordkeeping requirements, Reinsurance, Risk adjustment, Risk corridors, Risk mitigation, State and local governments.

45 CFR Part 155

Administrative practice and procedure, Health care access, Health insurance, Reporting and recordkeeping requirements, State and local governments, Cost-sharing reductions, Advance payments of premium tax credit, Administration and calculation of advance payments of the premium tax credit, Plan variations, Actuarial value.

45 CFR Part 156

Administrative appeals, Administrative practice and procedure, Administration and calculation of advance payments of premium tax credit, Advertising, Advisory Committees, Brokers, Conflict of interest, Consumer protection, Cost-sharing reductions, Grant programs-health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, American Indian/Alaska Natives, Individuals with disabilities, Loan programs-health, Organization and functions (Government agencies), Medicaid, Payment and collections reports, Public assistance programs, Reporting and recordkeeping requirements, State and local governments, Sunshine Act, Technical assistance, Women, and Youth.

45 CFR Part 158

Administrative practice and procedure, Claims, Health care, Health insurance, Health plans, penalties, Reporting and recordkeeping requirements, Premium revenues, Medical loss ratio, Rebating.

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR parts 144, 147, 153, 155, 156, and 158 as set forth below:

PART 144—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

■ 1. The authority citation for part 144 continues to read as follows:

Authority: Secs. 2701 through 2763, 2791, and 2792 of the Public Health Service Act, 42 U.S.C. 300gg through 300gg-63, 300gg-91, and 300gg-92.

■ 2. Section 144.103 is amended by revising the first sentence in paragraph

(1) of the definition of “Policy year” to read as follows:

§ 144.103 Definitions.

* * * * *

Policy year * * *

(1) A grandfathered health plan offered in the individual health insurance market and student health insurance coverage, the 12-month period that is designated as the policy year in the policy documents of the health insurance coverage. * * *

* * * * *

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 3. The authority citation for part 147 continues to read as follows:

Authority: Secs. 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

■ 4. Section 147.102 is amended by revising paragraph (c)(3) to read as follows:

§ 147.102 Fair health insurance premiums.

* * * * *

(c) * * *

(3) *Application to small group market*—(i) In the case of the small group market, the total premium charged to a group health plan is determined by summing the premiums of covered participants and beneficiaries in accordance with paragraph (c)(1) or (2) of this section, as applicable.

(ii) Subject to paragraph (c)(3)(iii) of this section, nothing in this section prevents a state from requiring issuers to offer to a group health plan, or an issuer from voluntarily offering to a group health plan, premiums that are based on average enrollee premium amounts, provided that the total group premium established at the time of applicable enrollment at the beginning of the plan year is the same total amount derived in accordance with paragraph (c)(1) or (2) of this section, as applicable.

(iii) Effective for plan years beginning on or after January 1, 2015, an issuer that, in connection with a group health plan in the small group market, offers premiums that are based on average enrollee premium amounts under paragraph (c)(3)(ii) of this section must—

(A) Ensure an average enrollee premium amount calculated based on applicable enrollment of participants and beneficiaries at the beginning of the plan year does not vary during the plan year.

(B) Unless a state establishes and CMS approves an alternate rating

methodology, calculate an average enrollee premium amount for covered individuals age 21 and older, and calculate an average enrollee premium amount for covered individuals under age 21. The premium for a given family composition is determined by summing the average enrollee premium amount applicable to each family member covered under the plan, taking into account no more than three covered children under age 21.

(C) Pursuant to applicable state law, ensure that the average enrollee premium amount calculated for any individual covered under the plan does not include any rating variation for tobacco use permitted under paragraph (a)(1)(iv) of this section. The rating variation for tobacco use permitted under paragraph (a)(1)(iv) of this section is determined based on the premium rate that would be applied on a per-member basis with respect to an individual who uses tobacco and then included in the premium charged for that individual.

(D) To the extent permitted by applicable state law and, in the case of coverage offered through a Federally-facilitated SHOP, as permitted by § 156.285(a)(4) of this subchapter, apply this paragraph (c)(3)(iii) uniformly among group health plans enrolling in that product, giving those group health plans the option to pay premiums based on average enrollee premium amounts.

* * * * *

■ 5. Section 147.145 is amended by revising paragraph (b)(1)(ii) to read as follows:

§ 147.145 Student health insurance coverage.

* * * * *

(b) * * *

(1) * * *

(ii) For purposes of section 2702 of the Public Health Service Act, a health insurance issuer that offers student health insurance coverage is not required to accept individuals who are not students or dependents of students in such coverage, and, notwithstanding the requirements of § 147.104(b), is not required to establish open enrollment periods or coverage effective dates that are based on a calendar policy year or to offer policies on a calendar year basis.

* * * * *

PART 153—STANDARDS RELATED TO REINSURANCE, RISK CORRIDORS, AND RISK ADJUSTMENT UNDER THE AFFORDABLE CARE ACT

■ 6. The authority citation for part 153 continues to read as follows:

Authority: Secs. 1311, 1321, 1341–1343, Pub. L. 111–148, 24 Stat. 119.

■ 7. Section 153.20 is amended by revising the definition of “contributing entity” and adding in alphabetical order a definition of “major medical coverage” to read as follows:

§ 153.20 Definitions.

* * * * *

Contributing entity means—

(1) A health insurance issuer; or

(2) For the 2014 benefit year, a self-insured group health plan (including a group health plan that is partially self-insured and partially insured, where the health insurance coverage does not constitute major medical coverage), whether or not it uses a third party administrator; and for the 2015 and 2016 benefit years, a self-insured group health plan (including a group health plan that is partially self-insured and partially insured, where the health insurance coverage does not constitute major medical coverage) that uses a third party administrator in connection with claims processing or adjudication (including the management of internal appeals) or plan enrollment for services other than for pharmacy benefits or excepted benefits within the meaning of section 2791(c) of the PHS Act. Notwithstanding the foregoing, a self-insured group health plan that uses an unrelated third party to obtain provider network and related claim repricing services, or uses an unrelated third party for up to 5 percent of claims processing or adjudication or plan enrollment, will not be deemed to use a third party administrator, based on either the number of transactions processed by the third party, or the volume of the claims processing and adjudication and plan enrollment services provided by the third party. A self-insured group health plan that is a contributing entity is responsible for the reinsurance contributions, although it may elect to use a third party administrator or administrative services-only contractor for transfer of the reinsurance contributions.

* * * * *

Major medical coverage means, for purposes only of the requirements related to reinsurance contributions under section 1341 of the Affordable Care Act, a catastrophic plan, an individual or a small group market plan subject to the actuarial value requirements under § 156.140 of this subchapter, or health coverage for a broad range of services and treatments provided in various settings that

provides minimum value as defined in § 156.145 of this subchapter.

* * * * *

■ 8. Section 153.230 is amended by revising paragraph (d) to read as follows:

§ 153.230 Calculation of reinsurance payments made under the national contribution rate.

* * * * *

(d) *Uniform adjustment to national reinsurance payments.* If HHS determines that all reinsurance payments requested under the national payment parameters from all reinsurance-eligible plans in all States for a benefit year will not be equal to the amount of all reinsurance contributions collected for reinsurance payments under the national contribution rate in all States for an applicable benefit year, HHS will determine a uniform pro rata adjustment to be applied to all such requests for reinsurance payments for all States. Each applicable reinsurance entity, or HHS on behalf of a State, must reduce or increase the reinsurance payment amounts for the applicable benefit year by any adjustment required under this paragraph (d).

■ 9. Section 153.270 is added to subpart C to read as follows:

§ 153.270 HHS audits of State-operated reinsurance programs.

(a) *Audits.* HHS or its designee may conduct a financial and programmatic audit of a State-operated reinsurance program to assess compliance with the requirements of this subpart or subpart B of this part. A State that establishes a reinsurance program must ensure that its applicable reinsurance entity and any relevant contractors, subcontractors, or agents cooperate with any audit under this section.

(b) *Action on audit findings.* If an audit results in a finding of material weakness or significant deficiency with respect to compliance with any requirement of this subpart or subpart B, the State must ensure that the applicable reinsurance entity:

(1) Within 60 calendar days of the issuance of the final audit report, provides a written corrective action plan to HHS for approval;

(2) Implements that plan; and

(3) Provides to HHS written documentation of the corrective actions once taken.

■ 10. Section 153.400 is amended by revising paragraph (a)(1) introductory text and adding paragraphs (a)(1)(v) and (vi) to read as follows:

§ 153.400 Reinsurance contribution funds.

(a) * * *

(1) In general, reinsurance contributions are required for major medical coverage that is considered to be part of a commercial book of business, but are not required to be paid more than once with respect to the same covered life. In order to effectuate that principle, a contributing entity must make reinsurance contributions for lives covered by its self-insured group health plans and health insurance coverage except to the extent that:

* * * * *

(v) Such plan or coverage applies to individuals with primary residence in a territory that does not operate a reinsurance program.

(vi) In the case of employer-provided group health coverage:

(A) Such coverage applies to individuals with individual market health insurance coverage for which reinsurance contributions are required; or

(B) Such coverage is supplemental or secondary to group health coverage for which reinsurance contributions must be made for the same covered lives.

* * * * *

■ 11. Section 153.405 is amended by revising paragraphs (c) and (e)(3) and adding paragraph (i) to read as follows:

§ 153.405 Calculation of reinsurance contributions.

* * * * *

(c) *Notification and payment.* (1) Following submission of the annual enrollment count described in paragraph (b) of this section, HHS will notify the contributing entity of the reinsurance contribution amount allocated to reinsurance payments and administrative expenses to be paid for the applicable benefit year.

(2) In the fourth quarter of the calendar year following the applicable benefit year, HHS will notify the contributing entity of the portion of the reinsurance contribution amount allocated for payments to the U.S. Treasury for the applicable benefit year.

(3) A contributing entity must remit reinsurance contributions to HHS within 30 days after the date of a notification.

* * * * *

(e) * * *

(3) Using the number of lives covered for the most current plan year calculated based upon the “Annual Return/Report of Employee Benefit Plan” filed with the Department of Labor (Form 5500) for the last applicable time period. For purposes of this paragraph (e)(3), the number of lives covered for the plan year for a plan offering only self-only coverage equals the sum of the total

participants covered at the beginning and end of the plan year, as reported on the Form 5500, divided by 2, and the number of lives covered for the plan year for a plan offering self-only coverage and coverage other than self-only coverage equals the sum of the total participants covered at the beginning and the end of the plan year, as reported on the Form 5500.

* * * * *

(i) *Audits.* HHS or its designee may audit a contributing entity to assess its compliance with the requirements of this subpart.

■ 12. Section 153.410 is amended by adding paragraph (d) to read as follows:

§ 153.410 Requests for reinsurance payment.

* * * * *

(d) *Audits.* HHS or its designee may audit an issuer of a reinsurance-eligible plan to assess its compliance with the requirements of this subpart and subpart H of this part. The issuer must ensure that its relevant contractors, subcontractors, or agents cooperate with any audit under this section. If an audit results in a finding of material weakness or significant deficiency with respect to compliance with any requirement of this subpart or subpart H, the issuer must complete all of the following:

(1) Within 30 calendar days of the issuance of the final audit report, provide a written corrective action plan to HHS for approval.

(2) Implement that plan.

(3) Provide to HHS written documentation of the corrective actions once taken.

■ 13. Section 153.500 is amended by revising the definitions of “allowable administrative costs” and “profits” and adding in alphabetical order definitions for “adjustment percentage” and “transitional State” to read as follows:

§ 153.500 Definitions.

* * * * *

Adjustment percentage means, with respect to a QHP:

(1) For benefit year 2014, for a QHP offered by a health insurance issuer with allowable costs of at least 80 percent of after-tax premium in a transitional State, the percentage specified by HHS for such QHPs in the transitional State; and otherwise

(2) Zero percent.

* * * * *

Allowable administrative costs mean, with respect to a QHP, the sum of administrative costs of the QHP, other than taxes and regulatory fees, plus profits earned by the QHP, which sum is limited to the sum of 20 percent and

the adjustment percentage of after-tax premiums earned with respect to the QHP (including any premium tax credit under any governmental program), plus taxes and regulatory fees.

* * * * *

Profits mean, with respect to a QHP, the greater of:

(1) The sum of three percent and the adjustment percentage of after-tax premiums earned; and

(2) Premiums earned of the QHP minus the sum of allowable costs and administrative costs of the QHP.

* * * * *

Transitional State means a State that does not enforce compliance with §§ 147.102, 147.104, 147.106, 147.150, 156.80, or subpart B of part 156 of this subchapter for individual market and small group health plans that renew for a policy year starting between January 1, 2014, and October 1, 2014, in accordance with the transitional policy outlined in the CMS letter dated November 14, 2013.

■ 14. Section 153.510 is amended by adding paragraph (f) to read as follows:

§ 153.510 Risk corridors establishment and payment methodology.

* * * * *

(f) *Eligibility under health insurance market rules.* The provisions of this subpart apply only for plans offered by a QHP issuer in the SHOP or the individual or small group market, as determined according to the employee counting method applicable under State law, that are subject to the following provisions: §§ 147.102, 147.104, 147.106, 147.150, 156.80, and subpart B of part 156 of this subchapter.

■ 15. Section 153.530 is amended by revising paragraph (d) and adding paragraph (e) to read as follows:

§ 153.530 Risk corridors data requirements.

* * * * *

(d) *Timeframes.* For each benefit year, a QHP issuer must submit all information required under paragraphs (a) through (c) of this section by July 31 of the year following the benefit year.

(e) *Requirement to submit enrollment data for risk corridors adjustment.* A health insurance issuer in the individual or small group market of a transitional State must submit, in a manner and timeframe specified by HHS, the following:

(1) A count of its total enrollment in the individual market and small group market; and

(2) A count of its total enrollment in individual market and small group market policies that meet the criteria for

transitional policies outlined in the CMS letter dated November 14, 2013.

■ 16. Section 153.540 is added to subpart F to read as follows:

§ 153.540 Compliance with risk corridors standards.

HHS or its designee may audit a QHP issuer to assess its compliance with the requirements of this subpart. HHS will conduct an audit in accordance with the procedures set forth in § 158.402(a) through (e) of this subchapter.

■ 17. Section 153.620 is amended by adding paragraph (c) to read as follows:

§ 153.620 Compliance with risk adjustment standards.

* * * * *

(c) *Audits.* HHS or its designee may audit an issuer of a risk adjustment covered plan to assess its compliance with the requirements of this subpart and subpart H of this part. The issuer must ensure that its relevant contractors, subcontractors, or agents cooperate with any audit under this section. If an audit results in a finding of material weakness or significant deficiency with respect to compliance with any requirement of this subpart or subpart H of this part, the issuer must complete all of the following:

(1) Within 30 calendar days of the issuance of the final audit report, provide a written corrective action plan to HHS for approval.

(2) Implement that plan.

(3) Provide to HHS written documentation of the corrective actions once taken.

■ 18. Section 153.630 is amended by revising paragraph (b)(1) and adding paragraphs (b)(5) through (10) to read as follows:

§ 153.630 Data validation requirements when HHS operates risk adjustment.

* * * * *

(b) * * *

(1) An issuer of a risk adjustment covered plan must engage one or more independent auditors to perform an initial validation audit of a sample of its risk adjustment data selected by HHS. The issuer must provide HHS with the identity of the initial validation auditor, and must attest to the absence of conflicts of interest between the initial validation auditor (or the members of its audit team, owners, directors, officers, or employees) and the issuer (or its owners, directors, officers, or employees), to its knowledge, following reasonable investigation, and must attest that it has obtained an equivalent representation from the initial

validation auditor, in a timeframe and manner to be specified by HHS.

* * * * *

(5) An initial validation audit must be conducted by medical coders certified as such and in good standing by a nationally recognized accrediting agency.

(6) An issuer must provide the initial validation auditor and the second validation auditor with all relevant source enrollment documentation, all claims and encounter data, and medical record documentation from providers of services to each enrollee in the applicable sample without unreasonable delay and in a manner that reasonably assures confidentiality and security in transmission.

(7) The risk score of each enrollee in the sample must be validated by—

(i) Validating the enrollee's enrollment data and demographic data in a manner to be determined by HHS.

(ii) Validating enrollee health status through review of all relevant medical record documentation. Medical record documentation must originate from the provider of the services and align with dates of service for the medical diagnoses, and reflect permitted providers and services. For purposes of this section, “medical record documentation” means clinical documentation of hospital inpatient or outpatient treatment or professional medical treatment from which enrollee health status is documented and related to accepted risk adjustment services that occurred during a specified period of time. Medical record documentation must be generated under a face-to-face or telehealth visit documented and authenticated by a permitted provider of services;

(iii) Validating medical records according to industry standards for coding and reporting; and

(iv) Having a senior reviewer confirm any enrollee risk adjustment error discovered during the initial validation audit. For purposes of this section, a “senior reviewer” is a reviewer certified as a medical coder by a nationally recognized accrediting agency who possesses at least 5 years of experience in medical coding. However, for validation of risk adjustment data for the 2014 and 2015 benefit years, a senior reviewer may possess 3 or more years of experience.

(8) The initial validation auditor must measure and report to the issuer and HHS, in a manner and timeframe specified by HHS, its inter-rater reliability rates among its reviewers. The initial validation auditor must achieve a consistency measure of at

least 95 percent for his or her review outcomes. However, for validation of risk adjustment data for the 2014 and 2015 benefit years, the initial validation auditor may meet an inter-rater reliability standard of 85 percent for review outcomes.

(9) Enforcement actions. If an issuer of a risk adjustment covered plan fails to engage an initial validation auditor or to submit the results of an initial validation audit to HHS, HHS may impose civil money penalties in accordance with the procedures set forth in § 156.805 of this subchapter.

(10) Default data validation charge. If an issuer of a risk adjustment covered plan fails to engage an initial validation auditor or to submit the results of an initial validation audit to HHS, HHS will impose a default risk adjustment charge.

* * * * *

■ 19. Section 153.710 is amended by adding paragraphs (d), (e), (f), and (g) to read as follows:

§ 153.710 Data requirements.

* * * * *

(d) *Interim dedicated distributed data environment reports.* Within 30 calendar days of the date of an interim dedicated distributed data environment report from HHS, the issuer must, in a format specified by HHS, either:

(1) Confirm to HHS that the information in the interim report accurately reflects the data to which the issuer has provided access to HHS through its dedicated distributed data environment in accordance with § 153.700(a) for the timeframe specified in the report; or

(2) Describe to HHS any discrepancy it identifies in the interim dedicated distributed data environment report.

(e) *Final dedicated distributed data environment report.* Within 15 calendar days of the date of the final dedicated distributed data environment report from HHS, the issuer must, in a format specified by HHS, either:

(1) Confirm to HHS that the information in the final report accurately reflects the data to which the issuer has provided access to HHS through its dedicated distributed data environment in accordance with § 153.700(a) for the benefit year specified in the report; or

(2) Describe to HHS any discrepancy it identifies in the final dedicated distributed data environment report.

(f) *Unresolved discrepancies.* If a discrepancy first identified in an interim or final dedicated distributed data environment report in accordance with paragraphs (d)(2) or (e)(2) of this

section remains unresolved after the issuance of the notification of risk adjustment payments and charges or reinsurance payments under § 153.310(e) or § 153.240(b)(1)(ii), respectively, an issuer of a risk adjustment covered plan or reinsurance-eligible plan may make a request for reconsideration regarding such discrepancy under the process set forth in § 156.1220(a) of this subchapter.

(g) *Risk corridors and MLR reporting.*

(1) Notwithstanding any discrepancy report made under paragraph (d)(2) or (e)(2) of this section, or any request for reconsideration under § 156.1220(a) of this subchapter with respect to any risk adjustment payment or charge, including an assessment of risk adjustment user fees; reinsurance payment; cost-sharing reconciliation payment or charge; or risk corridors payment or charge, unless the dispute has been resolved, an issuer must report, for purposes of the risk corridors and MLR programs:

(i) The risk adjustment payment to be made or charge assessed, including an assessment of risk adjustment user fees, by HHS in the notification provided under § 153.310(e);

(ii) The reinsurance payment to be made by HHS in the notification provided under § 153.240(b)(1)(ii);

(iii) A cost-sharing reduction amount equal to the amount of the advance payments of cost-sharing reductions paid to the issuer by HHS for the benefit year; and

(iv) For medical loss ratio report only, the risk corridors payment to be made or charge assessed by HHS as reflected in the notification provided under § 153.510(d).

(2) An issuer must report any adjustment made following any discrepancy report made under paragraph (d)(2) or (e)(2) of this section, or any request for reconsideration under § 156.1220(a) of this subchapter with respect to any risk adjustment payment or charge, including an assessment of risk adjustment user fees; reinsurance payment; cost-sharing reconciliation payment or charge; or risk corridors payment or charge; or following any audit, where such adjustment has not been accounted for in a prior risk corridors or medical loss ratio report, in the next following risk corridors or medical loss ratio report.

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

■ 20. Authority citation for part 155 continues to read as follows:

Authority: Title I of the Affordable Care Act, sections 1301, 1302, 1303, 1304, 1311, 1312, 1313, 1321, 1322, 1331, 1332, 1334, 1402, 1411, 1412, 1413, Pub. L. 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18033, 18041–18042, 18051, 18054, 18071, and 18081–18083).

■ 21. Section 155.106 is amended by revising paragraph (a)(2) to read as follows:

§ 155.106 Election to operate an Exchange after 2014.

(a) * * *

(2) Have in effect an approved, or conditionally approved, Exchange Blueprint and operational readiness assessment at least 6.5 months prior to the Exchange's first effective date of coverage; and

* * * * *

■ 22. Section 155.220 is amended by adding paragraph (i) to read as follows:

§ 155.220 Ability of States to permit agents and brokers to assist qualified individuals, qualified employers, or qualified employees enrolling in QHPs.

* * * * *

(i) *Use of agents' and brokers' Internet Web sites for SHOP.* For plan years beginning on or after January 1, 2015, in States that permit this activity under State law, a SHOP may permit agents and brokers to use an Internet Web site to assist qualified employers and facilitate enrollment of qualified employees in a QHP through the Exchange, under paragraph (c)(3) of this section.

■ 23. Section 155.260 is amended by revising paragraphs (a)(1) and (2) and (b) to read as follows:

§ 155.260 Privacy and security of personally identifiable information.

(a) * * *

(1) Where the Exchange creates or collects personally identifiable information for the purposes of determining eligibility for enrollment in a qualified health plan; determining eligibility for other insurance affordability programs, as defined in § 155.20; or determining eligibility for exemptions from the individual responsibility provisions in section 5000A of the Code, the Exchange may only use or disclose such personally identifiable information to the extent such information is necessary:

(i) For the Exchange to carry out the functions described in § 155.200;

(ii) For the Exchange to carry out other functions not described in paragraph (a)(1)(i) of this section, which the Secretary determines to be in compliance with section 1411(g)(2)(A) of the Affordable Care Act and for

which an individual provides consent for his or her information to be used or disclosed; or

(iii) For the Exchange to carry out other functions not described in paragraphs (a)(1)(i) and (ii) of this section, for which an individual provides consent for his or her information to be used or disclosed, and which the Secretary determines are in compliance with section 1411(g)(2)(A) of the Affordable Care Act under the following substantive and procedural requirements:

(A) *Substantive requirements.* The Secretary may approve other uses and disclosures of personally identifiable information created or collected as described in paragraph (a)(1) of this section that are not described in paragraphs (a)(1)(i) or (ii) of this section, provided that HHS determines that the information will be used only for the purposes of and to the extent necessary in ensuring the efficient operation of the Exchange consistent with section 1411(g)(2)(A) of the Affordable Care Act, and that the uses and disclosures are also permissible under relevant law and policy.

(B) *Procedural requirements for approval of a use or disclosure of personally identifiable information.* To seek approval for a use or disclosure of personally identifiable information created or collected as described in paragraph (a)(1) of this section that is not described in paragraphs (a)(1)(i) or (ii) of this section, the Exchange must submit the following information to HHS:

(1) Identity of the Exchange and appropriate contact persons;

(2) Detailed description of the proposed use or disclosure, which must include, but not necessarily be limited to, a listing or description of the specific information to be used or disclosed and an identification of the persons or entities that may access or receive the information;

(3) Description of how the use or disclosure will ensure the efficient operation of the Exchange consistent with section 1411(g)(2)(A) of the Affordable Care Act; and

(4) Description of how the information to be used or disclosed will be protected in compliance with privacy and security standards that meet the requirements of this section or other relevant law, as applicable.

(2) The Exchange may not create, collect, use, or disclose personally identifiable information unless the creation, collection, use, or disclosure is consistent with this section.

* * * * *

(b) *Application to non-Exchange entities.* (1) *Non-Exchange entities.* A non-Exchange entity is any individual or entity that:

(i) Gains access to personally identifiable information submitted to an Exchange; or

(ii) Collects, uses, or discloses personally identifiable information gathered directly from applicants, qualified individuals, or enrollees while that individual or entity is performing functions agreed to with the Exchange.

(2) Prior to any person or entity becoming a non-Exchange entity, Exchanges must execute with the person or entity a contract or agreement that includes:

(i) A description of the functions to be performed by the non-Exchange entity;

(ii) A provision(s) binding the non-Exchange entity to comply with the privacy and security standards and obligations adopted in accordance with paragraph (b)(3) of this section, and specifically listing or incorporating those privacy and security standards and obligations;

(iii) A provision requiring the non-Exchange entity to monitor, periodically assess, and update its security controls and related system risks to ensure the continued effectiveness of those controls in accordance with paragraph (a)(5) of this section;

(iv) A provision requiring the non-Exchange entity to inform the Exchange of any change in its administrative, technical, or operational environments defined as material within the contract; and

(v) A provision that requires the non-Exchange entity to bind any downstream entities to the same privacy and security standards and obligations to which the non-Exchange entity has agreed in its contract or agreement with the Exchange.

(3) When collection, use or disclosure is not otherwise required by law, the privacy and security standards to which an Exchange binds non-Exchange entities must:

(i) Be consistent with the principles and requirements listed in paragraphs (a)(1) through (6) of this section, including being at least as protective as the standards the Exchange has established and implemented for itself in compliance with paragraph (a)(3) of this section;

(ii) Comply with the requirements of paragraphs (c), (d), (f), and (g) of this section; and

(iii) Take into specific consideration: (A) The environment in which the non-Exchange entity is operating;

(B) Whether the standards are relevant and applicable to the non-Exchange

entity's duties and activities in connection with the Exchange; and

(C) Any existing legal requirements to which the non-Exchange entity is bound in relation to its administrative, technical, and operational controls and practices, including but not limited to, its existing data handling and information technology processes and protocols.

* * * * *

■ 24. Section 155.410 is amended by revising paragraphs (e) and (f) to read as follows:

§ 155.410 Initial and annual open enrollment periods.

* * * * *

(e) *Annual open enrollment period.*

For the benefit year beginning on January 1, 2015, the annual open enrollment period begins on November 15, 2014, and extends through February 15, 2015.

(f) *Effective date for coverage after the annual open enrollment period.* For the benefit year beginning on January 1, 2015, the Exchange must ensure coverage is effective -

(1) January 1, 2015, for QHP selections received by the Exchange on or before December 15, 2014.

(2) February 1, 2015, for QHP selections received by the Exchange from December 16, 2014 through January 15, 2015.

(3) March 1, 2015, for QHP selections received by the Exchange from January 16, 2015 through February 15, 2015.

* * * * *

■ 25. Section 155.705 is amended by:

■ a. Revising paragraph (b)(1);

■ b. Adding paragraph (b)(3)(v);

■ c. Redesignating paragraph (b)(4)(ii) as (b)(4)(iii);

■ d. Adding new paragraph (b)(4)(ii);

■ e. Revising paragraph (b)(6)(i); and

■ f. Revising paragraph (b)(11)(ii)(C).

The additions and revisions read as follows:

§ 155.705 Functions of a SHOP.

* * * * *

(b) * * *

(1) Enrollment and eligibility functions. The SHOP must adhere to the requirements outlined in Subpart H.

* * * * *

(3) * * *

(v) For plan years beginning on or after January 1, 2015, a Federally-facilitated SHOP will provide a qualified employer a choice of two methods to make stand-alone dental plans available to qualified employees and their dependents:

(A) The employer may choose to make available a single stand-alone dental plan.

(B) The employer may choose to make available all stand-alone dental plans offered through a Federally-facilitated SHOP at a level of coverage as described in § 156.150(b)(2) of this subchapter.

(4) * * *

(ii) The SHOP may establish one or more standard processes for premium calculation, premium payment, and premium collection.

(A) Qualified employers in a Federally-facilitated SHOP must make premium payments according to a timeline and process established by HHS;

(B) For a Federally-facilitated SHOP, the premium for coverage lasting less than 1 month must equal the product of:

(1) The premium for 1 month of coverage divided by the number of days in the month; and

(2) The number of days for which coverage is being provided in the month described in paragraph (b)(4)(ii)(B)(1) of this section.

* * * * *

(6) * * *

(i) Require all QHP issuers to make any change to rates at a uniform time that is no more frequently than quarterly.

(A) In a Federally-facilitated SHOP, rates may be updated quarterly with effective dates of January 1, April 1, July 1, or October 1 of each calendar year, beginning with rates effective no sooner than July 1, 2014. The updated rates must be submitted to HHS at least 60 days in advance of the effective date of the rates.

(B) [Reserved]

* * * * *

(11) * * *

(ii) * * *

(C) The employer will define a percentage contribution toward premiums for employee-only coverage under the reference plan and, if dependent coverage is offered, a percentage contribution toward premiums for dependent coverage under the reference plan. To the extent permitted by other applicable law, for plan years beginning on or after January 1, 2015, a Federally-facilitated SHOP may permit an employer to define a different percentage contribution for full-time employees from the percentage contribution it defines for non-full-time employees, and it may permit an employer to define a different percentage contribution for dependent coverage for full-time employees from the percentage contribution it defines for dependent coverage for non-full-time employees.

* * * * *

■ 26. Section 155.715 is amended by revising paragraphs (c)(4), (d)(1)

introductory text, and (d)(2) introductory text to read as follows:

§ 155.715 Eligibility determination process for SHOP.

* * * * *

(c) * * *

(4) May not perform individual market Exchange eligibility determinations or verifications described in subpart D of this part.

(d) * * *

(1) When the information submitted on the SHOP single employer application is inconsistent with information collected from third-party data sources through the verification process described in § 155.715(c)(2), the SHOP must—

* * * * *

(2) When the information submitted on the SHOP single employee application is inconsistent with information collected from third-party data sources through the verification process described in § 155.715(c)(2), the SHOP must—

* * * * *

■ 27. Section 155.730 is amended by revising paragraph (g) to read as follows:

§ 155.730 Application standards for SHOP.

(g) *Additional safeguards.* (1) The SHOP may not provide to the employer any information collected on the employee application with respect to spouses or dependents other than the name, address, and birth date of the spouse or dependent.

(2) The SHOP is not permitted to collect information on the single employer or single employee application unless that information is necessary to determine SHOP eligibility or effectuate enrollment through the SHOP.

■ 28. Section 155.1030 is amended by revising paragraphs (b)(1), (3), and (4) to read as follows:

§ 155.1030 QHP certification standards related to advance payments of the premium tax credit and cost-sharing reductions.

* * * * *

(b) * * *

(1) The Exchange must collect and review annually the rate allocation and the actuarial memorandum that an issuer submits to the Exchange under § 156.470 of this subchapter, to ensure that the allocation meets the standards set forth in § 156.470(c) and (d) of this subchapter.

* * * * *

(3) The Exchange must use the methodology specified in the annual HHS notice of benefit and payment parameters to calculate advance

payment amounts for cost-sharing reductions, and must transmit the advance payment amounts to HHS, in accordance with § 156.340(a) of this subchapter.

(4) HHS may use the information provided to HHS by the Exchange under this section for oversight of advance payments of cost-sharing reductions and premium tax credits.

* * * * *

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 29. The authority citation for part 156 continues to read as follows:

Authority: Title I of the Affordable Care Act, sections 1301–1304, 1311–1312, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, and 1412, Pub. L. 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

■ 30. Section 156.135 is amended by revising paragraph (a) and adding paragraph (g) to read as follows:

§ 156.135 AV calculation for determining level of coverage.

(a) *Calculation of AV.* Subject to paragraphs (b) and (d) of this section, to calculate the AV of a health plan, the issuer must use the AV Calculator developed and made available by HHS for the given benefit year.

* * * * *

(g) *Updates to the AV Calculator.* HHS will update the AV Calculator as follows, HHS will:

(1) Update the annual limit on cost sharing and related functions based on a projected estimate to enable the AV Calculator to comply with § 156.130(a)(2);

(2) Update the continuance tables to reflect more current enrollment data when HHS has determined that the enrolled population has materially changed;

(3) Update the algorithms when HHS has determined the need to adapt the AV Calculator for use by additional plan designs or to allow the AV Calculator to accommodate potential new types of plan designs, where such adaptations can be based on actuarially sound principles and will not have a substantial effect on the AV calculations performed by the then current AV Calculator;

(4) Update the continuance tables to reflect more current claims data no more than every 3 and no less than every 5 years and to annually trend the claims data when the trending factor is more

than 5 percent different, calculated on a cumulative basis; and

(5) Update the AV Calculator user interface when a change would be useful to a broad group of users of the AV Calculator, would not affect the function of the AV Calculator, and would be technically feasible.

■ 31. Section 156.150 is amended by revising paragraph (a) to read as follows:

§ 156.150 Application to stand-alone dental plans inside the Exchange.

(a) *Annual limitation on cost-sharing.* For a stand-alone dental plan covering the pediatric dental EHB under § 155.1065 of this subchapter in any Exchange, cost sharing may not exceed \$350 for one covered child and \$700 for two or more covered children.

* * * * *

■ 32. Section 156.285 is amended by adding paragraph (a)(4) and revising paragraph (c)(7) to read as follows:

§ 156.285 Additional standards specific to SHOP.

(a) * * *

(4)(i) Adhere to the premium rating standards described in § 147.102 of this subchapter regardless of whether the QHP being sold through the SHOP is sold in the small group market or the large group market; and

(ii) Effective in plan years beginning on or after January 1, 2015, a QHP issuer in a Federally-facilitated SHOP may not offer to an employer premiums that are based on average enrollee premium amounts under § 147.102(c)(3) of this subchapter, if the employer elects to offer coverage to its employees under § 155.705(b)(3)(iv)(A) of this subchapter. This paragraph (a)(4)(ii) also applies to stand-alone dental plans in a Federally-facilitated SHOP, if the employer elects to offer coverage to its employees under § 155.705(b)(3)(v)(B) of this subchapter.

* * * * *

(c) * * *

(7) A QHP issuer must enroll a qualified employee only if the SHOP—

(i) Notifies the QHP issuer that the employee is a qualified employee;

(ii) Transmits information to the QHP issuer as provided in § 155.400(a) of this subchapter; and

(iii) Effective for QHPs offered through a Federally-facilitated SHOP in plan years beginning on or after January 1, 2015, does not send a cancellation notice to the QHP issuer prior to the effective date of coverage.

* * * * *

■ 33. Section 156.298 is added to subpart C to read as follows:

§ 156.298 Meaningful difference standard for Qualified Health Plans in the Federally-facilitated Exchanges.

(a) *General.* Subject to paragraph (b)(2) of this section, starting in the 2015 coverage year, in order to be certified as a QHP offered through a Federally-facilitated Exchange, a plan must be meaningfully different from all other QHPs offered by the same issuer of that plan within a service area and level of coverage in the Exchange, as defined in paragraph (b) of this section.

(b) *Meaningful difference standard.* A plan is considered meaningfully different from another plan in the same service area and metal tier (including catastrophic plans) if a reasonable consumer would be able to identify one or more material differences among the following characteristics between the plan and other plan offerings:

- (1) Cost sharing;
- (2) Provider networks;
- (3) Covered benefits;
- (4) Plan type;
- (5) Health Savings Account eligibility;

or

(6) Self-only, non-self-only, or child-only plan offerings.

(c) *Exception for limited plan availability.* If HHS determines that the plan offerings at a particular metal level (including catastrophic plans) within a county are limited, plans submitted for certification in that particular metal level (including catastrophic plans) within that county will not be subject to the meaningful difference requirement set forth in paragraph (b) of this section.

(d) *Two-year transition period for issuers with new acquisitions.* During the first 2 years after a merger or acquisition in which an acquiring issuer obtains or merges with another issuer, the FFEs may certify plans as QHPs that were previously offered by the acquired or merged issuer without those plans meeting the meaningful difference standard set forth in paragraph (b) of this section.

■ 34. Section 156.420 is amended by revising paragraphs (c), (d), and (e) to read as follows:

§ 156.420 Plan variations.

* * * * *

(c) *Benefit and network equivalence in silver plan variations.* A standard silver plan and each silver plan variation thereof must cover the same benefits and providers. Each silver plan variation is subject to all requirements applicable to the standard silver plan (except for the requirement that the plan have an AV as set forth in § 156.140(b)(2)).

(d) *Benefit and network equivalence in zero and limited cost sharing plan*

variations. A QHP and each zero cost sharing plan variation or limited cost sharing plan variation thereof must cover the same benefits and providers. The out-of-pocket spending required of enrollees in the zero cost sharing plan variation of a QHP for a benefit that is not an essential health benefit from a provider (including a provider outside the plan's network) may not exceed the corresponding out-of-pocket spending required in the limited cost sharing plan variation of the QHP and the corresponding out-of-pocket spending required in the silver plan variation of the QHP for individuals eligible for cost-sharing reductions under § 155.305(g)(2)(i) of this subchapter, in the case of a silver QHP. The out-of-pocket spending required of enrollees in the limited cost sharing plan variation of the QHP for a benefit that is not an essential health benefit from a provider (including a provider outside the plan's network) may not exceed the corresponding out-of-pocket spending required in the QHP with no cost-sharing reductions. A limited cost sharing plan variation must have the same cost sharing for essential health benefits not described in paragraph (b)(2) of this section as the QHP with no cost-sharing reductions. Each zero cost sharing plan variation or limited cost sharing plan variation is subject to all requirements applicable to the QHP (except for the requirement that the plan have an AV as set forth in § 156.140(b)).

(e) *Decreasing cost sharing and out-of-pocket spending in higher AV silver plan variations.* The cost sharing or out-of-pocket spending required of enrollees under any silver plan variation of a standard silver plan for a benefit from a provider (including a provider outside the plan's network) may not exceed the corresponding cost sharing or out-of-pocket spending required in the standard silver plan or any other silver plan variation thereof with a lower AV.

* * * * *

■ 35. Section 156.430 is amended by removing and reserving paragraph (a) and by revising paragraph (b)(1) to read as follows:

§ 156.430 Payment for cost-sharing reductions.

(b) * * *

(1) A QHP issuer will receive periodic advance payments based on the advance payment amounts calculated in accordance with § 155.1030(b)(3) of this subchapter.

* * * * *

■ 36. Section 156.470 is amended by revising paragraph (a) to read as follows:

§ 156.470 Allocation of rates for advance payments of the premium tax credit.

(a) *Allocation to additional health benefits for QHPs.* An issuer must provide to the Exchange annually for approval, in the manner and timeframe established by HHS, for each health plan at any level of coverage offered, or intended to be offered, in the individual market on an Exchange, an allocation of the rate for the plan to:

(1) EHB, other than services described in § 156.280(d)(1); and

(2) Any other services or benefits offered by the health plan not described in paragraph (a)(1) of this section.

* * * * *

■ 37. Section 156.1110 is added to Subpart L to read as follows:

§ 156.1110 Establishment of patient safety standards for QHP issuers.

(a) *Patient safety standards.* A QHP issuer that contracts with a hospital with greater than 50 beds must verify that the hospital, as defined in section 1861(e) of the Social Security Act, is Medicare-certified or has been issued a Medicaid-only CMS Certification Number (CCN) and is subject to the Medicare Hospital Conditions of Participation requirements for—

(1) A quality assessment and performance improvement program as specified in 42 CFR 482.21; and

(2) Discharge planning as specified in 42 CFR 482.43.

(b) *Documentation.* A QHP issuer must collect the CCN, from each of its contracted hospitals with greater than 50 beds, to demonstrate that those hospitals meet patient safety standards required in paragraph (a) of this section.

(c) *Reporting.* (1) A QHP issuer must make available to the Exchange the documentation referenced in paragraph (b) of this section, upon request by the Exchange, in a time and manner specified by the Exchange.

(2) Issuers of multi-State plans, as defined in § 155.1000(a) of this subchapter, must provide the documentation described in paragraph (b) of this section to the U.S. Office of Personnel Management, in the time and manner specified by the U.S. Office of Personnel Management.

(d) *Effective date.* A QHP issuer must ensure that each QHP meets patient safety standards in accordance with paragraph (a) of this section effective for plan years beginning on or after January 1, 2015.

■ 38. Section 156.1210 is amended by adding paragraph (c) to read as follows:

§ 156.1210 Confirmation of HHS payment and collections reports.

* * * * *

(c) *Discrepancies to be addressed in future reports.* Discrepancies in payment and collections reports identified to HHS under this section will be addressed in subsequent payment and collections reports, and will not be used to change debts determined pursuant to invoices generated under previous payment and collections reports.

■ 39. Section 156.1215 is added to Subpart M to read as follows:

§ 156.1215 Payment and collections processes.

(a) *Netting of payments and charges for 2014.* In 2014, as part of its monthly payment and collections process, HHS will net payments owed to QHP issuers and their affiliates under the same taxpayer identification number against amounts due to the Federal government from the QHP issuers and their affiliates under the same taxpayer identification number for advance payments of the premium tax credit, advance payments of cost-sharing reductions, and payment of Federally-facilitated Exchange user fees.

(b) *Netting of payments and charges for later years.* In 2015 and later years, as part of its payment and collections process, HHS may net payments owed to issuers and their affiliates operating under the same tax identification number against amounts due to the Federal government from the issuers and their affiliates under the same taxpayer identification number for advance payments of the premium tax credit, advance payments of and reconciliation of cost-sharing reductions, payment of Federally-facilitated Exchange user fees, and risk adjustment, reinsurance, and risk corridors payments and charges.

(c) *Determination of debt.* Any amount owed to the Federal government by an issuer and its affiliates for advance payments of the premium tax credit, advance payments of and reconciliation of cost-sharing reductions, Federally-facilitated Exchange user fees, risk adjustment, reinsurance, and risk corridors, after HHS nets amounts owed by the Federal government under these programs, is a determination of a debt.

■ 40. Section 156.1220 is added to subpart M to read as follows:

§ 156.1220 Administrative appeals.

(a) *Requests for reconsideration.* (1) *Matters for reconsideration.* An issuer may file a request for reconsideration under this section to contest a processing error by HHS, HHS's incorrect application of the relevant

methodology, or HHS's mathematical error only with respect to the following:

(i) The amount of advance payment of the premium tax credit, advance payment of cost-sharing reductions or Federally-facilitated Exchange user fees charge for a benefit year;

(ii) The amount of a risk adjustment payment or charge for a benefit year, including an assessment of risk adjustment user fees;

(iii) The amount of a reinsurance payment for a benefit year;

(iv) The amount of a risk adjustment default charge for a benefit year;

(v) The amount of a reconciliation payment or charge for cost-sharing reductions for a benefit year; or

(vi) The amount of a risk corridors payment or charge for a benefit year.

(2) *Materiality threshold.*

Notwithstanding paragraph (a)(1) of this section, an issuer may file a request for reconsideration under this section only if the amount in dispute under paragraph (a)(1)(i) through (vi) of this section, as applicable, is equal to or exceeds 1 percent of the applicable payment or charge listed in that subparagraph payable to or due from the issuer for the benefit year, or \$10,000, whichever is less.

(3) *Time for filing a request for reconsideration.* The request for reconsideration must be filed in accordance with the following timeframes:

(i) For advance payments of the premium tax credit, advance payments of cost-sharing reductions, or Federally-facilitated Exchange user fee charges, within 60 calendar days after the date of the final reconsideration notification specifying the aggregate amount of advance payments of the premium tax credit, advance payments of cost-sharing reductions, and Federally-facilitated Exchange user fees for the applicable benefit year;

(ii) For a risk adjustment payment or charge, including an assessment of risk adjustment user fees, within 60 calendar days of the date of the notification provided by HHS under § 153.310(e) of this subchapter;

(iii) For a reinsurance payment, within 60 calendar days of the date of the notification provided by HHS under § 153.240(b)(1)(ii) of this subchapter;

(iv) For a default risk adjustment charge, within 60 calendar days of the date of the notification of the default risk adjustment charge;

(v) For reconciliation of cost-sharing reductions, within 60 calendar days of the date of the notification provided by HHS of the cost-sharing reduction reconciliation payment or charge; and

(vi) For a risk corridors payment or charge, within 60 calendar days of the date of the notification provided by HHS under § 153.510(d) of this subchapter.

(4) *Content of request.* (i) The request for reconsideration must specify the findings or issues specified in paragraph (a)(1) of this section that the issuer challenges, and the reasons for the challenge.

(ii) Notwithstanding paragraph (a)(1) of this section, a reconsideration with respect to a processing error by HHS, HHS's incorrect application of the relevant methodology, or HHS's mathematical error may be requested only if, to the extent the issue could have been previously identified by the issuer to HHS under § 153.710(d)(2) or (e)(2) of this subchapter, it was so identified and remains unresolved.

(iii) Notwithstanding paragraph (a)(1) of this section, a reconsideration with respect to advance payments of the premium tax credit, advance payments of cost-sharing reductions, and Federally-facilitated Exchange user fees may be requested only if, to extent the issue could have been previously identified by the issuer to HHS under § 156.1210, it was so identified and remains unresolved. An issuer may request reconsideration if it previously identified an issue under § 156.1210 after the 15-calendar-day deadline, but late discovery of the issue was not due to misconduct on the part of the issuer.

(iv) The issuer may include in the request for reconsideration additional documentary evidence that HHS should consider. Such documents may not include data that was to have been filed by the applicable data submission deadline, but may include evidence of timely submission.

(5) *Scope of review for reconsideration.* In conducting the reconsideration, HHS will review the appropriate payment and charge determinations, the evidence and findings upon which the determination was based, and any additional documentary evidence submitted by the issuer. HHS may also review any other evidence it believes to be relevant in deciding the reconsideration, which will be provided to the issuer with a reasonable opportunity to review and rebut the evidence. The issuer must prove its case by a preponderance of the evidence with respect to issues of fact.

(6) *Reconsideration decision.* HHS will inform the issuer of the reconsideration decision in writing. A reconsideration decision is final and binding for decisions regarding the advance payments of the premium tax credit, advance payment of cost-sharing

reductions, or Federally-facilitated Exchange user fees. A reconsideration decision with respect to other matters is subject to the outcome of a request for informal hearing filed in accordance with paragraph (b) of this section.

(b) *Informal hearing.* An issuer may request an informal hearing before a CMS hearing officer to appeal HHS's reconsideration decision.

(1) *Manner and timing for request.* A request for an informal hearing must be made in writing and filed with HHS within 30 calendar days of the date of the reconsideration decision under paragraph (a)(5) of this section.

(2) *Content of request.* The request for informal hearing must include a copy of the reconsideration decision and must specify the findings or issues in the decision that the issuer challenges, and its reasons for the challenge. HHS may submit for review by the CMS hearing officer a statement of its reasons for the reconsideration decision.

(3) *Informal hearing procedures.* (i) The issuer will receive a written notice of the time and place of the informal hearing at least 15 calendar days before the scheduled date.

(ii) The CMS hearing officer will neither receive testimony nor accept any new evidence that was not presented with the reconsideration request and HHS statement under paragraph (b) of this section. The CMS hearing officer will review only the documentary evidence provided by the issuer and HHS, and the record that was before HHS when HHS made its reconsideration determination. The issuer may be represented by counsel in the informal hearing, and must prove its case by clear and convincing evidence with respect to issues of fact.

(4) *Decision of the CMS hearing officer.* The CMS hearing officer will send the informal hearing decision and the reasons for the decision to the issuer. The decision of the CMS hearing officer is final and binding, but is subject to the results of any Administrator's review initiated in accordance with paragraph (c) of this section.

(c) *Review by the Administrator.* (1) If the CMS hearing officer upholds the reconsideration decision, the issuer may request review by the Administrator of CMS within 15 calendar days of the date of the CMS hearing officer's decision. The request for review must specify the findings or issues that the issuer challenges. HHS may submit for review by the Administrator a statement supporting the decision of the CMS hearing officer.

(2) The Administrator will review the CMS hearing officer's decision, the

statements of the issuer and HHS, and any other information included in the record of the CMS hearing officer's decision, and will determine whether to uphold, reverse, or modify the CMS hearing officer's decision. The issuer must provide its case by clear and convincing evidence with respect to issues of fact. The Administrator will send the decision and the reasons for the decisions to the issuer.

(3) The Administrator's determination is final and binding.

PART 158—ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS

■ 41. The authority citation for part 158 continues to read as follows:

Authority: Section 2718 of the Public Health Service Act (42 U.S.C. 300gg–18), as amended.

■ 42. Section 158.130 is amended by revising paragraph (b)(5) to read as follows:

§ 158.130 Premium revenue.

* * * * *

(b) * * *

(5) Account for the net payments or receipts related to the risk adjustment, risk corridors (using an adjustment percentage, as described in § 153.500 of this subchapter, equal to zero percent), and reinsurance programs under sections 1341, 1342, and 1343 of the Patient Protection and Affordable Care Act, 42 U.S.C. 18061, 18062, 18063.

* * * * *

■ 43. Section 158.140 is amended by revising paragraph (b)(4)(ii) to read as follows:

§ 158.140 Reimbursement for clinical services provided to enrollees.

* * * * *

(b) * * *

(4) * * *

(ii) Receipts related to the transitional reinsurance program and net payments or receipts related to the risk adjustment and risk corridors programs (calculated using an adjustment percentage, as described in § 153.500 of this subchapter, equal to zero percent) under sections 1341, 1342, and 1343 of the Patient Protection and Affordable Care Act, 42 U.S.C. 18061, 18062, 18063.

* * * * *

■ 44. Section 158.240 is amended by revising paragraph (c)(2) to read as follows:

§ 158.240 Rebating premium if the applicable medical loss ratio standard is not met.

* * * * *

(c) * * *

(2) For example, an issuer must rebate a pro rata portion of premium revenue if it does not meet an 80 percent MLR for the individual market in a State that has not set a higher MLR. If an issuer has a 75 percent MLR for the coverage it offers in the individual market in a State that has not set a higher MLR, the issuer must rebate 5 percent of the premium paid by or on behalf of the enrollee for the MLR reporting year after subtracting a pro rata portion of taxes and fees and accounting for payments or receipts related to the reinsurance, risk adjustment and risk corridors programs (calculated using an adjustment percentage, as described in § 153.500 of this subchapter, equal to zero percent). If the issuer's total earned premium for the MLR reporting year in the individual market in the State is \$200,000, the issuer received transitional reinsurance payments of \$2,500, and made net payments related to risk adjustment and risk corridors of

\$20,000 (calculated using an adjustment percentage, as described in § 153.500 of this subchapter, equal to zero percent), the issuer's gross earned premium in the individual market in the State would be \$200,000 plus \$2,500 minus \$20,000, for a total of \$182,500. If the issuer's Federal and State taxes and licensing and regulatory fees, including reinsurance contributions, that may be excluded from premium revenue as described in §§ 158.161(a), 158.162(a)(1) and 158.162(b)(1), allocated to the individual market in the State are \$15,000, and the net payments related to risk adjustment and risk corridors, reduced by reinsurance receipts, that must be accounted for in premium revenue as described in §§ 158.130(b)(5), 158.221, and 158.240, are \$17,500 (\$20,000 reduced by \$2,500), then the issuer would subtract \$15,000 and add \$17,500 to gross premium revenue of \$182,500, for a base of \$185,000 in premium. The issuer

would owe rebates of 5 percent of \$185,000, or \$9,250 in the individual market in the State. In this example, if an enrollee of the issuer in the individual market in the State paid \$2,000 in premiums for the MLR reporting year, or 1/100 of the issuer's total premium in that State market, then the enrollee would be entitled to 1/100 of the total rebates owed by the issuer, or \$92.50.

* * * * *

Dated: February 26, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Approved: February 27, 2014.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2014-05052 Filed 3-5-14; 4:15 pm]

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EXHIBIT 11

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Consumer Information and Insurance Oversight
200 Independence Avenue SW
Washington, DC 20201



Date: April 11, 2014

Subject: Risk Corridors and Budget Neutrality

Q1: In the HHS Notice of Benefit and Payment Parameters for 2015 final rule (79 FR 13744) and the Exchange and Insurance Market Standards for 2015 and Beyond NPRM (79 FR 15808), HHS indicated that it intends to implement the risk corridors program in a budget neutral manner. What risk corridors payments will HHS make if risk corridors collections for a year are insufficient to fund risk corridors payments for the year, as calculated under the risk corridors formula?

A1: We anticipate that risk corridors collections will be sufficient to pay for all risk corridors payments. However, if risk corridors collections are insufficient to make risk corridors payments for a year, all risk corridors payments for that year will be reduced pro rata to the extent of any shortfall. Risk corridors collections received for the next year will first be used to pay off the payment reductions issuers experienced in the previous year in a proportional manner, up to the point where issuers are reimbursed in full for the previous year, and will then be used to fund current year payments. If, after obligations for the previous year have been met, the total amount of collections available in the current year is insufficient to make payments in that year, the current year payments will be reduced pro rata to the extent of any shortfall. If any risk corridors funds remain after prior and current year payment obligations have been met, they will be held to offset potential insufficiencies in risk corridors collections in the next year.

Example 1: For 2014, HHS collects \$800 million in risk corridors charges, and QHP issuers seek \$600 million risk corridors payments under the risk corridors formula. HHS would make the \$600 million in risk corridors payments for 2014 and would retain the remaining \$200 million for use in 2015 and potentially 2016 in case of a shortfall.

Example 2: For 2015, HHS collects \$700 million in risk corridors charges, but QHP issuers seek \$1 billion in risk corridors payments under the risk corridors formula. With the \$200 million in excess charges collected for 2014, HHS would have a total of \$900 million available to make risk corridors payments in 2015. Each QHP issuer would receive a risk corridors payment equal to 90 percent of the calculated amount of the risk corridors payment, leaving an aggregate risk corridors shortfall of \$100 million for benefit year 2015. This \$100 million shortfall would be paid for from risk corridors

charges collected for 2016 before any risk corridors payments are made for the 2016 benefit year.

Q2: What happens if risk corridors collections do not match risk corridors payments in the final year of risk corridors?

A2: We anticipate that risk corridors collections will be sufficient to pay for all risk corridors payments over the life of the three-year program. However, we will establish in future guidance or rulemaking how we will calculate risk corridors payments if risk corridors collections (plus any excess collections held over from previous years) do not match risk corridors payments as calculated under the risk corridors formula for the final year of the program.

Q3: If HHS reduces risk corridors payments for a particular year because risk corridors collections are insufficient to make those payments, how should an issuer's medical loss ratio (MLR) calculation account for that reduction?

A3: Under 45 CFR 153.710(g)(1)(iv), an issuer should reflect in its MLR report the risk corridors payment to be made by HHS as reflected in the notification provided under §153.510(d). Because issuers will submit their risk corridors and MLR data simultaneously, issuers will not know the extent of any reduction in risk corridors payments when submitting their MLR calculations. As detailed in 45 CFR 153.710(g)(2), that reduction should be reflected in the next following MLR report. Although it is possible that not accounting for the reduction could affect an issuer's rebate obligations, that effect will be mitigated in the initial year because the MLR ratio is calculated based on three years of data, and will be eliminated by the second year because the reduction will be reflected. We intend to provide more guidance on this reporting in the future.

Q4: In the 2015 Payment Notice, HHS stated that it might adjust risk corridors parameters up or down in order to ensure budget neutrality. Will there be further adjustments to risk corridors in addition to those indicated in this FAQ?

A4: HHS believes that the approach outlined in this FAQ is the most equitable and efficient approach to implement risk corridors in a budget neutral manner. However, we may also make adjustments to the program for benefit year 2016 as appropriate.

EXHIBIT 12

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Consumer Information & Insurance Oversight
200 Independence Avenue SW
Washington, DC 20201



Date: March 14, 2014

From: Center for Consumer Information and Insurance Oversight, Centers for Medicare & Medicaid Services

Title: 2015 Letter to Issuers in the Federally-facilitated Marketplaces

The Centers for Medicare & Medicaid Services (CMS) is releasing this Final 2015 Letter to Issuers in the Federally-facilitated Marketplaces (Letter). This Letter provides issuers seeking to offer Qualified Health Plans (QHPs), including stand-alone dental plans (SADPs), in a Federally-facilitated Marketplace (FFM) and/or Federally-facilitated Small Business Health Options Program (FF-SHOP), with operational and technical guidance to help them successfully participate in the Marketplaces. Except where noted, it finalizes the policies in the Draft 2015 Letter to Issuers in the Federally-facilitated Marketplaces (Draft 2015 Letter to Issuers)¹ published on February 4, 2014. Some policies with operational implications in the Draft 2015 Letter to Issuers are not being finalized in this Final 2015 Letter to Issuers, with the intent to continue work to accomplish them. Unless otherwise specified, references to the Marketplaces or FFM include the FF-SHOP.

As indicated in previous guidance,² states that are performing plan management functions in an FFM have some flexibility in assessing compliance with certification standards and adjusting processes. Throughout this Letter, we identify the areas in which states performing plan management functions in an FFM have flexibility to follow an approach different from that articulated in this guidance. We note that the policies articulated in this Letter apply to QHP issuers starting with the certification process for the 2015 benefit year and beyond, until or unless they are superseded by subsequent guidance or regulations. In the future, CMS intends to issue similar letters and other guidance to provide operational updates to QHP issuers, but we do not intend to issue these letters on more than an annual basis.

¹ Draft 2015 Letter to Issuers in the Federally-facilitated Marketplaces, available at: <http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/draft-issuer-letter-2-4-2014.pdf>.

² Guidance on the State Partnership Exchange, available at: <http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/partnership-guidance-01-03-2013.pdf>.

CMS has previously published regulations and guidance on market-wide and QHP certification standards, eligibility and enrollment procedures, and other Marketplace-related topics in several phases. Additional proposed requirements are included in a regulation titled “Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond,” CMS-9949-P, that is being released simultaneously with this letter.

These regulations are set out in 45 C.F.R. Subtitle A, Subchapter B as well as in Federal Register issuances. Issuers are advised to consult these materials in conjunction with the Letter to ensure full compliance with the requirements of the Patient Protection and Affordable Care Act and Health Care and Education Reconciliation Act of 2010 (together referred to as the Affordable Care Act), as implemented. These and other regulatory and guidance materials are available at <http://cciio.cms.gov/resources/regulations/index.html>. Unless otherwise indicated, regulatory references herein are to Title 45 of the Code of Federal Regulations. QHP issuers in FFMs may also be subject to other requirements for the 2015 certification year, as made in future rulemaking.

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CHAPTER 1: CERTIFICATION PROCESS AND STANDARDS FOR QUALIFIED HEALTH PLANS

The Affordable Care Act and the applicable Marketplace regulations establish that health plans must meet a number of standards to be certified as qualified health plans (QHPs). Several of these standards apply generally to plans offered in the individual and small group markets regardless of whether the plan is offered through or outside of the Marketplace; the remaining standards are specific to QHPs seeking certification from the Marketplace. CMS expects that states will enforce 2014 market reforms³; accordingly, CMS expects to rely on states' reviews of policy forms and rate filings for market reforms as part of its QHP certification process, provided that such states review for compliance with standards that are consistent with federal regulatory standards and complete such reviews in a manner consistent with operational timelines. Issuers should follow state guidance regarding compliance with the processes and criteria for reviews conducted by states.

The following sections describe CMS's approach to reviewing plans against standards that generally apply only to issuers seeking certification of QHPs from a Marketplace. The reviews described in these sections will be conducted either by a state that is performing plan management functions and making QHP certification recommendations to CMS, or by CMS as a part of the process of certifying a QHP in the applicable FFM. Each section describes CMS's planned approach to evaluating QHPs against a certification standard when the state is not performing plan management functions. As noted in previously released guidance, states that are performing QHP certification reviews have some flexibility in their application of QHP certification standards, provided that the state's application of each standard is consistent with CMS regulations and guidance. Issuers seeking QHP certification in states that are performing plan management functions should refer to state direction in addition to this guidance. State-based Marketplaces will conduct their own reviews for QHP-specific standards.

This Chapter provides an overview of the QHP certification process in FFMs, both when a state is performing plan management functions as well as when the FFM is performing plan management functions. The QHP certification process for the FFM for the 2015 benefit year maintains many aspects of the process carried out for 2014, including close coordination and

³ States are the primary regulators of health insurers and are responsible for enforcing the market reform provisions in title XXVII of the Public Health Service (PHS) Act both inside and outside the Marketplaces. Under §§ 2723 and 2761 of the PHS Act and existing regulations, codified at 45 C.F.R. part 150, CMS is responsible for enforcing the provisions of Parts A and B of title XXVII of the PHS Act in a state if a state notifies CMS that it has "not enacted legislation to enforce or that it is not otherwise enforcing" one or more of the provisions, or if CMS determines that the state is not substantially enforcing the requirements. As necessary, CMS will provide additional information on enforcement.

collaboration with states. The 2015 process also incorporates some adjusted review standards as well as operational changes.

Similar to the QHP certification process in 2014, in 2015, states may choose to conduct reviews of QHP Applications and provide recommendations to CMS on QHP certification determinations. These states will evaluate health plans against QHP certification standards as part of the state's traditional regulatory role for the insurance industry and/or enforcement of Title XXVII of the Public Health Service Act (PHS Act), or otherwise for state purposes. Based on the state's analysis and review, the state will recommend plans for QHP certification to CMS, and CMS will decide whether to certify the plans as QHPs. Similarly, in states not conducting all reviews or making QHP certification recommendations to CMS, CMS anticipates integrating state regulatory activities that the states conduct into its decision-making for QHP certification in the FFM, provided that states make these determinations and provide information to CMS consistent with federal standards and FFM timelines. These principles underlie the discussion in this Letter about the QHP certification process.

CMS will review the state's recommendations or findings to confirm that they are consistent with federal regulatory standards, and will communicate to the state any concerns that would preclude CMS's implementation of the state's recommendations or findings according to the process and timeline outlined below and in other guidance. CMS is responsible for the final QHP certification decisions in each FFM state.

Section 1. FFM QHP Application and Certification Process

This section describes how CMS, as administrator of the FFMs, will conduct QHP certification when CMS is performing the review and certification of QHPs, including stand-alone dental plans (SADPs).

In accordance with 45 C.F.R. part 155 subpart K, CMS will review and approve or deny QHP Applications from issuers that are applying to offer QHPs in an FFM. Table 1.1 presents a high-level overview of key dates in the FFM QHP certification process. Each major component of the process is described in greater detail in the subsections that follow.

For certification of a plan as a QHP for the 2015 benefit year, issuers will be required to submit a complete QHP Application, including for plans that were certified as QHPs for the 2014 benefit year. CMS will review QHP applications against all QHP certification standards for issuers that are currently offering QHPs in the FFM as well as issuers that are applying for QHP certification in the FFM for the first time. CMS also expects that states performing plan management functions in an FFM will review QHP Applications from all issuers applying for certification of a QHP for the 2015 benefit year.

For the 2014 certification cycle for the 2015 benefit year, CMS will allow issuers additional time to modify their plan data, in the following manner:

- *Ongoing data revision, with specified deadlines for review.* After the close of the initial application submission window, issuers will be able to upload revised data templates on an as-needed basis until the final data submission deadline. CMS reviews will occur at pre-defined times during this window and will be based on the QHP data in the system on certain dates.
- *Stand-alone dental plan QHP Application timeline synchronized with medical submissions.* Stand-alone and embedded dental plan data submission will follow the same timeline as that of medical plans.

We also intend to provide more specific guidance regarding the QHP certification timeline noted below before the beginning of the application submission window.

Table 1.1 Key Dates: QHP Certification in an FFM

Note: All dates are subject to change.

Activity		Dates (Approximate)
QHP Application Submission and Review Process	Initial FFM QHP Application Submission Window	5/27/2014 – 6/27/2014
	FFM Review of QHP Application Submissions as of Initial Submission Deadline	6/30/2014 – 7/25/2014
	1 st Correction Notice Sent	7/29/2014
	Deadline for Submission of Revised QHP Data for Re-review	8/7/2014
	FFM Reviews of Corrected QHP Application Submissions Received as of August 7	8/8/2014 – 8/25/2014
	2 nd Correction Notice Sent	8/26/2014
	Deadline for Final Submission of QHP Application data	9/4/2014
	FFM Completes Re-review of QHP Application Data; Data Locked Down	9/22/2014
	Limited Data Correction Window	9/24/2014 – 10/6/2014
QHP Agreement/ Final Certification	Certification Notices and QHP Agreements Sent to Issuers, Agreements Signed, QHP Data Finalized	10/14/2014 – 11/3/2014

Activity	Dates (Approximate)
Open Enrollment	11/15/2014

i. Registration and QHP Application

To offer QHPs in FFMs for the 2015 benefit year in states where CMS is performing both the primary review and certification of QHPs, health insurance issuers will complete QHP Applications electronically through the Health Insurance Oversight System (HIOS). Before submitting an application, issuers must gain access to HIOS and request user roles (such as QHP Issuer Submitter and QHP Issuer Validator), and obtain HIOS user IDs.

We expect that between May 27 and June 27, 2014, issuers will access the QHP Application in HIOS to submit all information necessary for certification of health plans and stand-alone dental plans as QHPs. The QHP Application will collect both issuer-level information and plan-level benefit and rate data, largely through standardized data templates. Applicants will also be required to attest to their adherence to the regulations set forth in 45 C.F.R. parts 155 and 156, and provide requested supporting documentation. Based on the requirement set forth in 45 C.F.R. 156.340 that QHP issuers maintain responsibility for the compliance of their delegated and downstream entities, these attestations will also reflect that vendors and contractors of the issuer will adhere to applicable requirements.

Issuers seeking to offer QHPs must also submit the Unified Rate Review Template (URRT) to CMS via HIOS according to the same timeline. Issuers not seeking to offer any QHPs should consult with state regulators and CMS regarding their rate review obligations. Consistent with the approach in 2014, issuers do not need to submit URRTs for SADPs.

ii. Issuer Data Collection and Coordination with States

CMS expects that states will review potential QHPs for compliance with all requirements under state law, as well as with market-wide standards established by the Affordable Care Act. Specifically, CMS expects states to review potential QHPs for compliance with essential health benefits (EHB) and actuarial value (AV) standards, among others.⁴ CMS expects that state regulators may request access to QHP data templates to facilitate review of potential QHPs. Issuers that wish to prevent CMS from sharing QHP Application and oversight information with

⁴ We note that, because SADP issuers are only required under federal law to adhere to pediatric dental essential health benefits requirements for SADPs offered through a Marketplace, CMS does not have the same expectation of state review for SADPs offered through the Marketplace if such standards are otherwise not applied under state law. Accordingly, CMS plans to review SADPs for compliance with applicable Affordable Care Act standards.

the relevant state department of insurance must do so by notifying CMS via email at CMS_QHP_Applications@cms.hhs.gov prior to the QHP Application submission deadline. In this case, the issuer may need to share this information directly with the state in addition to sharing it with CMS.

We expect that states will establish the timeline, communication process, and resubmission window for any reviews conducted under state authority. Issuers should comply with any state-specific guidelines for review and resubmission related to state-reviewed standards. CMS notes that issuers may be required to submit data to state regulators in addition to that required for QHP certification through the FFM, if required by a state, and must comply with any requests for resubmissions from the state or from CMS in order to be certified. CMS will coordinate with states to ensure that any state-specific review guidelines and procedures are consistent with applicable federal law and operational deadlines. In addition, CMS will conduct outreach to all state departments of insurance at the end of the QHP certification cycle to confirm that all potential QHPs meet applicable state and federal standards, and are approved for sale in the Marketplace.

iii. FFM review of QHP Applications

Issuers applying for QHP certification in the FFM will submit complete and accurate QHP Applications into HIOS by June 27, 2014. Plans for which QHP applications are received after this date and plans for which significant changes to the initial submission are submitted after this date without CMS approval may not be considered for certification.

CMS expects to review FFM QHP Applications in two rounds; one between June 30 and July 25, and a second between August 8 and August 25. Following each review period, CMS will send applicants notices summarizing any need for correction identified during CMS's review. Issuers will be able to upload revised QHP data templates and make other necessary changes to QHP Applications in response to CMS's feedback until September 4. Issuers will also be able to make changes based on state feedback and make other minor corrections to their applications, with state approval, on the same timeline. CMS also intends to implement a petition process to receive requests from issuers and review additional requested changes that are particularly significant during this time, such as changes to service area. Requests to make these more substantial changes must be reviewed and approved by CMS and the state prior to submission of an update to the QHP Application. CMS intends to release further guidance on this process.

As stated previously, all final QHP data must be submitted by September 4, 2014. After this date, issuers will conduct a limited data correction window, where issuers will not be allowed to make further changes to QHP data unless necessary to correct data display errors or align QHPs with products and plans as approved by the state. All such changes must be pre-approved by CMS and the state. CMS expects to review final QHP data, verify and confirm state approval, and inform issuers of its final certification determinations by October 14, 2014. CMS intends to provide a

process through which issuers will be able to review submitted plan data prior (timeline to be provided).

Section 2. QHP Certification Process in a State Performing Plan Management Functions in an FFM

This section describes how states performing plan management functions in an FFM will conduct QHP certification. Issuers applying in states where CMS is performing all QHP Application review and QHP certification should refer to Section 1 above.

In an FFM state where the state is performing plan management functions, issuers will work directly with the state to submit all QHP issuer application data in accordance with state guidance.⁵ FFM states performing review of QHP Applications will likely utilize the System for Electronic Rate and Form Filing (SERFF) system to collect QHP Applications from issuers. The state will review QHP Applications for compliance with the standards described in this guidance and will provide a certification recommendation for each proposed plan to CMS. CMS will review and confirm the state's QHP certification recommendations, make final QHP certification decisions, and load certified QHP plans on the Marketplace website. CMS will work closely with states that are performing plan management functions to coordinate this process.

As indicated in Table 1.2, the QHP certification process in FFM states where the state is performing plan management functions will align with the process for issuers for which CMS is performing the review. Each major component of the process is described in greater detail in the subsections that follow. We also intend to provide more specific guidance regarding the QHP certification timeline noted below as the application submission period approaches.

Table 1.2 Key Dates: QHP Certification in FFM States Where the State is Performing Plan Management Functions

Note: All dates are subject to change.

Activity		Dates (Approximate)
QHP Application Submission and	Issuers Submit Plan Data to States, States Review	Varied
	1 st SERFF Data Transfer Deadline	8/8/2014
	FFM Reviews Plan Data	8/11/2014-8/25/2014
	FFM Notifies States of any Needed Corrections to QHP Data	8/26/2014

⁵ CMS will work with states performing plan management functions in an FFM to ensure that such guidance is consistent with federal regulatory standards and operational timelines.

Activity		Dates (Approximate)
Review Process	Last date for Issuers to Resubmit Plan Data into SERFF	9/4/2014
	2 nd SERFF Data Transfer	9/5/2014-9/10/2014
	FFM Completes Re-review of Plan Data and State Recommendations	9/22/2014
	Limited Data Correction Window	9/24/2014 – 10/6/2014
QHP Agreement/Final Certification	Certification Notices and QHP Agreements Sent to Issuers, Agreements Signed, QHP Data Finalized	10/14/2014 – 11/3/2014
Open Enrollment		11/15/2014

i. *QHP Application and State Review Process*

An issuer's HIOS issuer ID will be used to link the state and federal records for a given issuer or QHP. Therefore, like an issuer applying in HIOS, an issuer applying to a state via SERFF must access HIOS and obtain the necessary identification numbers and user roles.

Issuers in states performing plan management functions in an FFM are to submit QHP Applications, typically in SERFF, according to the timeline set by each state. Each state will define the relevant submission window as well as dates and processes for corrections and resubmissions. Issuers seeking to offer QHPs must submit the URRT to the state, and to CMS via HIOS, on the same timeline as the submission of the QHP Application. Issuers that are applying for QHP certification in states performing plan management functions in an FFM should not submit QHP Applications into HIOS.

CMS will provide two defined SERFF transfer windows in order to better coordinate the flow of QHP data from states performing plan management functions in an FFM. The first SERFF transfer will take place by August 8, 2014 and will constitute an initial transfer by each state. QHP data in this transfer do not need to be final, and the plans included in the transfer do not need to be in final, approved status. CMS will review the plan data in the initial transfer, and will notify states of any needed corrections. States will work with issuers to revise their submissions according to CMS and state feedback.

The second SERFF transfer is planned to take place between September 5 and September 10, 2014. CMS will use the data transferred by September 10 to make final QHP certification decisions based on state recommendations. After this transfer, issuers will not be allowed to make any further changes to QHP data unless necessary to correct data display errors or align QHPs with products and plans approved by the state. All such changes must be pre-approved by

CMS and the state. CMS intends to provide a process through which issuers will be able to review submitted plan data (timeline to be provided).

Section 3. Recertification for 2015

Based on comments received to the Draft 2015 Letter to Issuers, we are including this section on our intended approach to recertification of 2014 QHPs for the 2015 plan year. For the 2015 plan year, CMS's process for recertifying a QHP or SADP that was certified for the 2014 benefit year will largely mirror the 2015 process for certification of a plan that was not a QHP or SADP in 2014. While there may be the opportunity for some streamlining for 2014 QHP issuers that submit applications for 2015 certification, issuers seeking recertification will generally resubmit the majority of information required under the 2015 QHP Application for plans that were not QHPs or SADPs in 2014. We anticipate moving to a more streamlined recertification process for future plan years.

A QHP that was certified in 2014 and that is recertified in 2015 can maintain the same plan and HIOS identification numbers that it used in 2014. Additionally, current enrollees in recertified plans will remain enrolled into the new benefit year, as long as those enrollees do not terminate their coverage.

If a plan being offered in 2015 is guaranteed renewable under the market-wide guaranteed renewability requirement,⁶ meaning that, outside the FFM, 2014 enrollees in the plan would be guaranteed the right to renew the plan for another plan year (subject to the exceptions to guaranteed renewability), and that plan was certified as a QHP in 2014, then the plan being offered in 2015 as a renewal of the 2014 QHP may be recertified if it continues to meet the certification criteria. For purposes of SADPs, we will apply the same standard, treating the SADP as if it were a QHP subject to guaranteed renewability.

In the regulation that is being released simultaneously with this letter, we are proposing to specify circumstances in which a plan is undergoing a uniform modification and, therefore, is guaranteed renewable, as opposed to being withdrawn and a new plan filed, in which case, the plan would not be guaranteed renewable. If that regulation is finalized as proposed, the criteria in that regulation regarding guaranteed renewability would apply in the context of recertification as well.

⁶ In the regulation that is being released simultaneously with this letter, we are proposing to specify circumstances in which a plan is undergoing a uniform modification and, therefore, is guaranteed renewable, as opposed to being withdrawn and a new plan filed, in which case, the plan would not be guaranteed renewable. If that regulation is finalized as proposed, the criteria in that regulation regarding guaranteed renewability would apply in the context of recertification as well.

Section 4. Review of Rates

This section addresses how CMS will work with states to review rate increases for QHPs when certifying plans as QHPs for participation in the FFM. States performing plan management functions in an FFM may use a similar approach. The approach for stand-alone dental plans is discussed in Section 8.

i. Consideration of Rate Increases

Regulations at 45 C.F.R. 155.1020 require a Marketplace to consider all rate increases when certifying plans as QHPs. For the 2015 benefit year, CMS will consider issuers' data and actuarial justifications provided in the Unified Rate Review Template (URRT), other information submitted as part of a filing under an Effective Rate Review program and any recommendations provided to CMS by the applicable state regulator about patterns or practices of excessive or unjustified rate increases and whether or not particular issuers should be excluded from participation in the Marketplace. In future years, CMS will also take into account other factors such as rate growth inside and outside the Marketplace as required by the Affordable Care Act.

CMS does not plan to duplicate reviews that a state is already conducting to enforce state law, and will take into consideration reviews the agency has conducted on behalf of a state for those states that do not have Effective Rate Review programs. CMS anticipates integrating state and other CMS rate reviews into its QHP certification processes, provided that states provide information to CMS consistent with federal standards and agreed-upon timelines.

For rate increases not being reviewed by a state under an Effective Rate Review program or CMS on behalf of a state (for those states that do not have Effective Rate Review programs):

- The QHP issuer's justification for all rate increases will be captured in the submission of Part I of the rate filing justification (URRT).
- To ensure consumer transparency, issuers must publish information from Part I of the rate filing justification by either: (1) posting a link on the issuer's website to the Marketplace's website (or HealthCare.gov), or (2) posting the information on the issuer's website.

ii. Review of QHP Rates

Rates that are too high or too low could have undesirable consequences for consumers. If rates are too high, consumers may be overpaying for coverage. If rates are too low, consumers may purchase a plan in which the pricing is not sustainable over time, potentially leading to significant rate increases in future years. Such increases could be disruptive to consumers who remain in the plan and to consumers who switch to more effectively priced plans but experience changes in prescription drug formularies or provider networks. In addition, QHP rates –

specifically, the rate for the second lowest cost silver plan – directly impact the value of premium tax credits as well as other federal outlays.

As detailed above, CMS does not plan to duplicate reviews that a state is already conducting as a matter of state law. CMS intends to implement a process that, in collaboration with existing state Effective Rate Review programs, will help ensure that QHP rates are reasonable and that, accordingly, offering the QHP through the FFM would be in the interest of consumers. Specifically, as it did in 2014, CMS will conduct an outlier analysis on QHP rates to identify rates that are relatively high or low compared to other QHP rates in the same rating area.

CMS recognizes that the identification of a QHP rate as an outlier does not necessarily indicate inappropriate rate development. CMS will notify the appropriate state entity of the results of its outlier identification process and will consider the state's assessment of the plan's rates when determining whether, based on its rates, certifying the QHP to be offered on the FFM would be in the interest of consumers.

Section 5. OPM Certification of Multi-State Plans

This section provides additional guidance for health insurance issuers seeking to offer multi-State plans in FFMs and State-based Marketplaces (SBMs).

The U.S. Office of Personnel Management (OPM) is responsible for implementing the Multi-State Plan (MSP) Program as required under section 1334 of the Affordable Care Act. In accordance with section 1334(d) of the Affordable Care Act, MSP options offered by MSP issuers under contract with OPM are deemed to be certified by a Marketplace.

OPM anticipates that the process for MSP issuers to participate in a Marketplace for the 2015 benefit year will largely mirror that used for 2014. Issuers seeking to offer MSP coverage must apply to participate via OPM's online application portal. OPM will evaluate issuer applications and determine which issuers are qualified to become MSP issuers. OPM works closely with states in reviewing benefits and rates to achieve its goals of offering more choice for consumers and maintaining a level playing field for all issuers within a state.

OPM's contract with each MSP issuer identifies each MSP option that the issuer will offer and in what state it will be offered. Each MSP option so identified is deemed to be certified by OPM to be offered through the Marketplace(s) operating in those states. In addition, the MSP Program contract sets forth performance requirements for MSP issuers.

For more information on requirements for MSP issuers, issuers should visit <http://www.opm.gov/healthcare-insurance/multi-state-plan-program/issuer/>. OPM will post specific instructions regarding the 2015 application timeline and process when available. The 2015 MSP Program Call Letter describes OPM program priorities and is available at http://www.opm.gov/media/4517978/2014-002_dms_.pdf.

Section 6. Certification of Consumer Operated and Oriented Plans (CO-OPs)

Consistent with the statute and the approach applied for 2014, CO-OPs are expected to apply for QHP certification using the same processes applied to other QHP issuers.

CHAPTER 2. QUALIFIED HEALTH PLAN AND STAND-ALONE DENTAL PLAN CERTIFICATION STANDARDS

Section 1. Licensure and Good Standing

This section describes how CMS will conduct QHP certification and recertification. States performing plan management functions in an FFM may use a similar approach.

Consistent with 45 C.F.R. 156.200(b)(4), each QHP issuer must be licensed and in good standing in each state in which it applies to offer QHPs for the applicable market, product type, and service area. CMS interprets the good standing requirement to mean that the issuer is in compliance with all applicable state solvency requirements and is in good standing in the state in relation to compliance with state laws and regulations. Applicable state licenses or certificates of authority will need to be provided with the QHP Application as supporting documentation. In addition, for the 2015 benefit year, CMS will require issuers to submit a State Certification Form. The issuer will need to indicate on this form that it is licensed and in good standing in each state in which it is applying to offer QHPs. The form must further include a certification from the applicable state insurance regulator that the issuer is licensed and in good standing in the state, including meeting state solvency requirements. Issuers applying for QHP certification must be able to demonstrate state licensure by no later than the first resubmission period during the QHP certification process, August 10, 2014.

In addition to requiring state certification of good standing, CMS will consider any complaints it receives and other QHP issuer oversight findings that occur during the 2014 benefit year, including state enforcement findings, in its determination of whether an issuer's offering of a plan is in the interest of consumers. CMS will consult with the applicable state on these findings.

Section 2. Service Area

This section describes how CMS will conduct QHP certification and recertification in an FFM. States performing plan management functions in an FFM may use a similar approach.

Consistent with regulations at 45 C.F.R. 155.1055(a), the Marketplace must ensure that each service area of a QHP covers a minimum geographic area that is at least the entire geographic area of a county, or a group of counties defined by the Marketplace, unless the Marketplace determines that serving a smaller geographic area is necessary, nondiscriminatory, and in the best interest of the qualified individuals and employers. The Marketplace must also ensure that

the service area of a QHP has been established without regard to racial, ethnic, language, or health status-related factors as specified under section 2705(a) of the PHS Act, or other factors that exclude specific high utilizing, high cost or medically-underserved populations.

For the 2015 benefit year, CMS will review requests for service areas that serve a geographic area smaller than a county to ensure that each service area meets the above regulatory standards, particularly with respect to ensuring that the establishment of this partial county service area is not discriminatory.

In the QHP Application process, CMS considers the service area of a plan to be the county or set of counties (or partial counties) that is covered by that particular plan. Any change to the list of counties associated with a particular plan is considered a change in the service area, even if the issuer offers other plans or products in the counties (or partial counties) in question. For the 2015 benefit year, QHP issuers will not be allowed to change their service area after their initial data submission except via petition to CMS. Petitions for service area changes must follow a CMS-prescribed format that will be detailed in future guidance and will only be allowed with state approval. Changes to service areas will only be approved under very limited circumstances, such as:

- To address limitations in provider contracting: issuers will need to provide substantial documentation of their contracting efforts in the geographic areas dropped, including lists of providers with whom the issuer attempted to contract and the contracts offered.
- Expansions at the request of the state and/or CMS to address an unmet consumer need.
- To address a data error in the issuer's initial Service Area Template submission: issuers will need to provide significant evidence documenting the error, including evidence in other parts of the QHP Application indicating an intent to cover a different area and/or a mismatch with the service area in the issuer's form filing.

Any additional circumstances would be severely limited and determined on a case by case basis and only based on state approval and significant evidence of necessity and the best interest of the consumer. CMS will not allow changes to service area after the final data submission date.

Section 3. Network Adequacy

This section describes how CMS will conduct QHP certification and recertification. States performing plan management functions in an FFM may use a similar approach. This section includes changes from the approach for network adequacy that were in the Draft 2015 Letter to Issuers.

Pursuant to 45 C.F.R. 156.230(a)(2), an issuer of a QHP that has a provider network must maintain a network that is sufficient in number and types of providers, including providers that specialize in mental health and substance use disorder services, to assure that all services will be

accessible to enrollees without unreasonable delay. All issuers applying for QHP certification will need to attest that they meet this standard as part of the certification/recertification process.

Unlike the certification process for benefit year 2014, CMS will no longer simply utilize issuer accreditation status, identify states with review processes at least as stringent as those identified in 45 C.F.R. 156.230(a), or collect network access plans as part of its evaluation of plans' network adequacy. Rather, CMS will assess provider networks using a "reasonable access" standard, and will identify networks that fail to provide access without unreasonable delay as required by 45 C.F.R. 156.230(a)(2). In order to determine whether an issuer meets the "reasonable access" standard, CMS will focus most closely on those areas which have historically raised network adequacy concerns. These areas may include the following:

- Hospital systems,
- Mental health providers,
- Oncology providers, and
- Primary care providers.

If CMS determines that an issuer's network is inadequate under the reasonable access review standard, CMS will notify the issuer of the identified problem area(s) and will consider the issuer's response in assessing whether the issuer has met the regulatory requirement and prior to making the certification or recertification determination. CMS will share information and analysis and coordinate with states which are conducting network adequacy reviews. Additional technical guidance regarding the collection method for a plan's provider list will be provided as part of the certification/recertification instructions.

CMS also intends to use information learned during the QHP Application process to assist in its articulation of time and distance or other standards for FFM QHP networks that CMS intends to reflect in future rulemaking. CMS will share its network adequacy findings with states and will incorporate state input into its network adequacy review process. CMS will also continue to monitor network adequacy, for example, via complaint tracking, to determine whether the QHP's network(s) continues to meet these certification standards. For future years, CMS is further considering appropriate formats for collection of provider network data, which would both enable CMS to review provider network adequacy and allow for the creation of a search engine function for consumers to find particular providers and provider types on HealthCare.gov.

Section 4. Essential Community Providers

This section describes how CMS plans to conduct QHP certification and recertification. States performing plan management functions in an FFM may use a similar approach. This section also discusses payment requirements for services provided by Federally Qualified Health Centers (FQHCs).

Essential community providers (ECPs) include providers that serve predominantly low-income and medically underserved individuals, and specifically include providers described in section 340B of the PHS Act and section 1927(c)(1)(D)(i)(IV) of the Social Security Act (SSA). At 45 C.F.R. 156.235, CMS establishes requirements for inclusion of ECPs in QHP provider networks and provides an alternate standard for issuers that provide a majority of covered services through physicians employed by the issuer or a single contracted medical group. Indian health providers are included among ECPs, as reflected in table 2.1.

i. Evaluation of Network Adequacy with respect to ECPs

Because the number and types of ECPs available vary significantly by location, CMS intends to evaluate QHP Applications for sufficient inclusion of ECPs for the 2015 benefit year against the ECP inclusion expectations described below. Specifically, CMS will consider a QHP issuer in compliance with the ECP guideline and will not pursue an enforcement action against an issuer with regards to meeting the ECP regulatory standard if it satisfies the ECP guidelines described below.

ECP Guideline: An application for QHP certification that adheres to the general ECP inclusion standard does not need to provide further documentation. For benefit year 2015, we will utilize a general ECP enforcement guideline whereby if an application demonstrates that at least 30 percent of available ECPs in each plan's service area participate in the provider network, we will consider the issuer to have satisfied the regulatory standard. In addition, and as required for the prior year, we expect that the issuer offer contracts in good faith to:

- All available Indian health providers in the service area, to include the Indian Health Service, Indian Tribes, Tribal organizations, and urban Indian organizations, using the recommended model QHP Addendum⁷ for Indian health providers developed by CMS; and
- At least one ECP in each ECP category (see Table 2.1) in each county in the service area, where an ECP in that category is available.

As part of the issuer's QHP application, we expect that the issuer list the contract offers that it has extended to all available Indian health providers and at least one ECP in each ECP category in each county in the service area. To be offered in good faith, a contract should offer terms that a willing, similarly-situated, non-ECP provider would accept or has accepted. We would expect issuers to be able to provide verification of such offers if CMS chooses to verify the offers.

⁷ The model QHP Addendum for Indian health providers is available at <http://www.cms.gov/ccio/programs-and-initiatives/health-insurance-marketplaces/qhp.html>.

If an issuer's application does not satisfy the 30 percent ECP guideline described above, the issuer would be required to include as part of its application a satisfactory narrative justification describing how the issuer's provider network(s), as currently designed, provides an adequate level of service for low-income and medically underserved enrollees and how the issuer plans to increase ECP participation in the issuer's provider network(s) in future years, as necessary.

An issuer that would have met only the 2014 minimum expectation standard option if the option had been extended for the 2015 benefit year will still be considered for QHP certification for the 2015 benefit year, contingent on the issuer's satisfactory narrative justification described above. As only one issuer submitted a justification for the 2014 benefit year as a means to satisfy the 20 percent ECP threshold, we anticipate that issuers will readily be able to contract with at least 30 percent of ECPs in a service area and that issuers will largely be able to satisfy this without having to submit written justification.

At a minimum, such narrative justification would include the following:

- Number of contracts offered to ECPs for the 2015 benefit year;
- Number of additional contracts issuer expects to offer for the 2015 benefit year and the timeframe of those planned negotiations;
- Names of the ECP hospitals and FQHCs to which the issuer has offered contracts, but an agreement with the providers has not yet been reached;
- Attestation that the issuer has satisfied the "good faith" contracting requirement with respect to offering contracts to all available Indian health providers, and one ECP in each major ECP category per county, where an ECP in that category is available; and
- Contingency plans for how, absent participation of the available ECP and Indian health providers, the plan will be able to provide adequate care to enrollees who might otherwise be cared for by relevant ECP providers. For example, if available Hemophilia Treatment Centers, Ryan White HIV/AIDS Program providers or Indian health providers are missing from the network(s), the Application must explain how its target populations will be served.

Examples:

- Issuer A proposes a service area in which 80 ECPs are available. Issuer A's network includes 35 ECPs, and Issuer A attests that it has offered "good faith" contracts to available Indian health providers and one ECP in each major ECP category per county, where an ECP in that category is available. Issuer A would meet the ECP standard; no additional documentation would be required.
- Issuer B also proposes a service area in which 80 ECPs (including 10 Indian health providers) are available. Issuer B's network includes 20 ECPs, which would not satisfy

the 30 percent ECP guideline. Issuer B provides a narrative justification that includes the following:

- o Explanation for why its network includes only 20 ECPs and how it will ensure service for low-income and medically underserved enrollees;
- o Attestation that the issuer has satisfied the “good faith” contracting requirement with respect to offering contracts to all available Indian health providers and one ECP in each major ECP category per county, where an ECP in that category is available;
- o Number of contracts offered to ECPs for the 2015 benefit year;
- o Number of additional contracts issuer expects to offer for the 2015 benefit year and the timeframe of those planned negotiations;
- o Names of the hospitals and FQHCs to which the issuer has offered contracts, but the providers have not yet accepted; and
- o A description of how care will be provided to specific populations (e.g., American Indians/Alaska Natives, persons with HIV, persons with hemophilia, etc.) that would otherwise be served by ECPs that are missing in the service area.

Under this general ECP standard, issuer B would be considered for QHP certification, despite not satisfying the 30 percent ECP guideline, based on the quantity of contracts being offered and the quality of the justification offered for not yet meeting this guideline. CMS would take into account factors and circumstances identified in the ECP Supplemental Response Form,⁸ along with an explanation of how the issuer will provide access to low-income and underserved populations. Additionally, justifications that include verification of contracts offered in good faith, that include terms that a willing, similarly-situated, non-ECP provider would accept or has accepted, would be considered toward satisfaction of the ECP guideline.

To assist issuers in identifying these providers, CMS published a non-exhaustive list of available ECPs based on data maintained by CMS and other federal agencies, which issuers may use to assess their satisfaction of the ECP guideline. This non-exhaustive list is available at: <http://cciio.cms.gov/programs/exchanges/qhp.html>. For providers on CMS’s non-exhaustive ECP list (including all Indian health providers), issuers would contract with the corporate entity named on the CMS list for that provider to be counted as an ECP. Individual practitioners having the same address as another ECP on the CMS list would not be counted as ECPs for purposes of meeting this standard.

Issuers will indicate which ECPs are included in their provider network(s) by populating a template as part of the QHP Application. CMS will provide detailed instructions to support

⁸ More information on the supplemental response can be found on the CCIIO website at: <http://www.cms.gov/cciio/programs-and-initiatives/health-insurance-marketplaces/qhp.html>.

issuers in completing the template. Issuers that submit a narrative justification will do so as part of the issuer application for QHP certification.

Issuers will be permitted to write in ECPs not on the CMS-developed list for consideration as part of CMS’s certification review, conditioned on the issuer satisfying the ECP write-in criteria provided below. Allowable write-ins will count toward the satisfaction of the 30 percent ECP guideline and will count toward the denominator of available ECPs for the issuer writing in the additional ECPs. CMS intends to credit the issuer with only one ECP write-in per street address. Examples of allowable write-ins include any providers that are currently eligible to participate in 340B programs but that are not included on the CMS-developed list, or not-for-profit or state-owned providers that would be entities described in section 340B but do not receive federal funding under the relevant section of law referred to in section 340B. Such providers include not-for-profit or governmental family planning service sites that do not receive a grant under Title X of the PHS Act.

Table 2.1: ECP Categories and Types in FFM

Major ECP Category	ECP Provider Types
Federally Qualified Health Centers (FQHC)	FQHC and FQHC “Look-Alike” Clinics, Outpatient health programs/facilities operated by Indian tribes, tribal organizations, programs operated by Urban Indian Organizations
Ryan White Providers	Ryan White HIV/AIDS Program Providers
Family Planning Provider	Title X Family Planning Clinics and Title X “Look-Alike” Family Planning Clinics
Indian Health Providers	Indian Health Service (IHS providers), Indian Tribes, Tribal organizations, and urban Indian Organizations
Hospitals	Disproportionate Share Hospital (DSH) and DSH-eligible Hospitals, Children’s Hospitals, Rural Referral Centers, Sole Community Hospitals, Free-standing Cancer Centers, Critical Access Hospitals
Other ECP Providers	STD Clinics, TB Clinics, Hemophilia Treatment Centers, Black Lung Clinics, and other entities that serve predominantly low-income, medically underserved individuals.

To write in a provider not on the CMS-developed ECP list, an issuer would maintain the following for each write-in to be considered an ECP:

- Provide National Provider Identifier (NPI) number, if provider has an NPI number;
- Indicate whether the provider is a not-for-profit provider entity;
- List the provider's zip code reflecting provider location within a Medically Underserved Area (MUA) and/or Health Professional Shortage Area (HPSA), or otherwise low-income, medically underserved area;
- Provide the provider's address (PO Box not sufficient, and only one ECP will be counted per address); and
- Attest that the provider is a not-for-profit entity operating in an MUA/HPSA and serves predominantly low-income, medically-underserved individuals; or provide a written justification describing how the provider serves predominantly low-income, medically-underserved individuals or otherwise meets the regulatory definition of an ECP.

Examples:

- Issuer C proposes a service area in which 80 ECPs are included on the CMS-developed ECP list. Issuer C's network includes 30 ECPs – 23 of which the issuer selects from the CMS-developed ECP list, and 7 of which the issuer writes in. Issuer C satisfactorily maintains all the required ECP write-in criteria for each ECP write-in. Issuer C's satisfaction of the 30 percent ECP guideline would be calculated by dividing 30 by 87, as the 7 approved ECP write-ins are counted toward the denominator of available ECPs in the issuer's service area (totaling 87). Issuer C would satisfy the 30 percent ECP guideline.
- Issuer D also proposes a service area in which 80 ECPs are included on the CMS-developed ECP list. Issuer D's network includes 25 ECPs – 5 of which the issuer selects from the CMS-developed ECP list, and 20 of which the issuer writes in. Issuer D satisfactorily maintains all the required ECP write-in criteria for each ECP write-in. Issuer D's satisfaction of the 30 percent ECP guideline is calculated by dividing 25 by 100 (as the 20 approved ECP write-ins are counted toward the denominator of available ECPs in the issuer's service area, totaling 100). Since issuer D's network demonstrates only 25 percent participation of available ECPs in the issuer's service area, Issuer D would not satisfy the 30 percent ECP guideline.

Note that CMS may conduct targeted audits of issuers that satisfy the ECP guideline by virtue of writing in a significant number of their ECPs.

Issuers that qualify for the alternate ECP standard articulated in 45 C.F.R. 156.235(a)(2) and (b)⁹ must demonstrate a sufficient number and geographic distribution of employed providers and

⁹ To qualify for the alternate standard, an issuer must provide a majority of covered professional services through physicians employed by the issuer or through a single contracted medical group.

hospital facilities, or providers of its contracted medical group and hospital facilities to ensure reasonable and timely access for low-income, medically underserved individuals in the QHP's service area, in accordance with the Marketplace's network adequacy standards. CMS interprets this standard as being met if the issuer complies with the ECP guideline described above, based on employed or contracted providers located in or contiguous to Health Professional Shortage Areas (HPSA)¹⁰ and 5-digit zip codes in which 30 percent or more of the population falls below 200 percent of the federal poverty level (FPL). For example, if an issuer's service area includes 50 available ECPs, the issuer would need 15 providers (30 percent of 50) in the service area that are also in or contiguous to a HPSA or low-income zip code to meet the 30 percent ECP guideline. CMS would not pursue an enforcement action against an issuer for failing to meet the regulatory ECP requirement if it meets this standard.

As with the general ECP guideline, an application that does not demonstrate compliance with the 30 percent ECP standard must include a narrative justification describing how the issuer's provider network(s) complies with the regulatory standard. In this context, an issuer's explanation in the ECP Supplemental Response Form would address how the issuer intends to ensure coverage in HPSAs or low-income zip codes in the service area(s). The explanation should describe the extent to which the issuer's provider sites are accessible to, and have services that meet the needs of, specific underserved populations, including:

- Individuals with HIV/AIDS (including those with co-morbid behavioral health conditions);
- American Indians and Alaska Natives (AI/AN); and
- Low-income and underserved individuals seeking women's health and reproductive health services.
- Other specific populations served by ECPs in the service area.

CMS is providing issuers with a database of zip codes listed as HPSAs or where more than 30 percent of the population falls below 200 percent of the FPL. The database is available at <http://www.cms.gov/ccio/programs-and-initiatives/health-insurance-marketplaces/qhp.html>. Issuers that qualify for the alternate standard would use the same data template as other issuers to complete this section of the application.

CMS will continue to assess QHP provider networks, including ECPs, and may revise its approach to reviewing for compliance with network adequacy and ECPs in later years.

¹⁰ More information on Health Professional Shortage Areas is available at: <http://bhpr.hrsa.gov/shortage/>.

ii. *Requirements for Payment of Federally Qualified Health Centers*

We reiterate the importance of issuers complying with 45 C.F.R. 156.235(e) regarding payment of FQHCs. For covered services provided by an FQHC, QHP issuers must pay an amount that is not less than the amount of payment that would have been paid to the center under section 1902(bb) of the SSA for such item or service, as specified in section 1302(g) of the Affordable Care Act. Section 156.235(e) does allow the QHP issuer and FQHC to mutually agree upon payment rates other than those that would have been paid to the center under section 1902(bb) of the SSA, as long as such mutually agreed upon rates are at least equal to the generally applicable payment rates of the issuer. We note that state law may define covered services for closed-panel HMO plans to be limited to those services provided by in-network providers. In such cases, this requirement would not apply to non-covered services, which would include non-emergent out-of-network services if provided by FQHCs if such services are not treated under state law as covered services. Otherwise, we would expect issuers to pay FQHCs for covered services in accordance with section 1902(bb) of the SSA. We encourage issuers and FQHCs, as well as other ECPs, to develop mutually beneficial business relationships that promote effective care for medically underserved and vulnerable populations. We intend to assess available data to understand the degree to which such patients are cared for effectively and to inform our future regulatory approach.

Section 5. Accreditation

This section describes how CMS will conduct QHP certification and recertification. States performing plan management functions in an FFM may use a similar approach.

Requirements at 45 C.F.R. 155.1045(b) establish the timeline by which QHP issuers offering coverage in an FFM must be accredited. CMS is continuing its phased approach to accreditation for QHP issuers in FFMs. Prior to a QHP issuer's second year of QHP certification, the QHP issuer must be accredited by a recognized accrediting entity on the policies and procedures that are applicable to its Marketplace products, or a QHP issuer must have commercial or Medicaid health plan accreditation granted by a recognized accrediting entity for the same state in which the issuer is offering Marketplace coverage and the administrative policies and procedures underlying that accreditation must be the same or similar to the administrative policies and procedures used in connection with the QHP. SADP issuers will not be reviewed for accreditation status.

To meet the 2015 benefit year requirement for QHP issuers entering their second year of Marketplace participation, QHP issuers will be required to attest that the administrative policies and procedures applicable to their Marketplace products have been reviewed and approved by a recognized accrediting entity in compliance with §155.1045(b)(2). The timeline in §155.1045(b) will be applied by looking at the issuer's accreditation status 90 days prior to open enrollment.

Issuers entering their initial year of QHP certification for the 2015 benefit year (i.e., issuers that did not offer a QHP the previous year) that do not have an existing commercial, Medicaid, or Marketplace health plan accreditation granted by a recognized accrediting entity for the same state in which the issuer is applying to offer coverage must schedule or plan to schedule with a recognized accrediting entity a review of its QHP policies and procedures. New QHP issuers may submit accreditation information for display if they have existing accreditation. The requirements for first-year accreditation are described in more detail in the 2014 Letter to Issuers.¹¹

In addition to the attestation noted above, issuers will be asked to provide some information about their accreditation status to determine if the standard in §155.1045(b) is met. This information will be verified with the indicated accrediting entity. For certification in 2014 for the 2015 benefit year, the National Committee for Quality Assurance (NCQA), URAC, and the Accreditation Association for Ambulatory Health Care (AAAHC) have been recognized by CMS as accrediting entities for the purpose of QHP certification. The issuer will be asked for information related to accreditation of their commercial, Medicaid, or Marketplace products.

Issuers will be considered accredited if the QHP issuer is accredited with the following status: by AAAHC with “Accredited,” status; by NCQA with “Excellent,” “Commendable,” “Accredited,” and /or “Interim” status; or by URAC with “Full,” “Provisional,” and/ or “Conditional,” status. An issuer will not be considered accredited if the accreditation review is scheduled or in process.

Section 6. Patient Safety Standards for QHP Issuers

This section describes how CMS will review issuer compliance with the patient safety standards for purposes of QHP certification and recertification. States performing plan management functions in an FFM may use a similar approach. SADP issuers will not be reviewed for patient safety standards compliance in 2015.

Section 1311(h) of the Affordable Care Act states that beginning on January 1, 2015, QHP issuers are required to comply with patient safety standards and may only contract with hospitals and health care providers that meet specified quality improvement criteria. Section 156.1110 in the 2015 Payment Notice¹² outlines how QHP issuers can demonstrate compliance with these standards, on a transitional basis, for 2 years beginning January 1, 2015 or until further regulations are issued, whichever is later. Specifically, the regulation requires QHP issuers that

¹¹ Letter to Issuers on Federally-facilitated and State Partnership Exchanges, April 5, 2013, http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2014_letter_to_issuers_04052013.pdf.

¹² Patient Protection and Affordable Care Act: Benefit and Payment Parameters for 2015, 79 FR 13744 (March 11, 2014) (to be codified at 45 CFR parts 144, 147, 153, 155, and 156).

contract with a hospital with greater than 50 beds to verify that the hospital, as defined in section 1861(e) of the SSA, is Medicare-certified or has been issued a Medicaid-only CMS Certification Number (CCN) and is subject to the Medicare Hospital Condition of Participation requirements for:

- (1) A quality assessment and performance improvement program as specified in 42 C.F.R. 482.21; and
- (2) Discharge planning as specified in 42 C.F.R. 482.43.

In addition, QHP issuers are required to collect and maintain documentation of the CCNs from their applicable network hospitals.

As part of the certification for the 2015 benefit year, QHP issuers will be required to demonstrate compliance with these patient safety standards as part of the QHP application with an attestation that they have collected and are maintaining the required documentation from their network hospitals.

Section 7. QHP and SADP Agreements

Issuers offering QHPs or SADPs in an FFM, including FFMs in states performing plan management functions, will be required to sign an agreement with CMS at the end of the certification or recertification process, as applicable. We anticipate that the QHP Issuer Agreement for the 2015 benefit year will be similar to the agreement signed by issuers for the 2014 benefit year. The agreement will cover all of the QHPs offered by a single issuer at the HIOS Issuer ID level, and must be signed by an officer of the legal entity who has legal authority to contractually bind the QHP or SADP legal entity. Of note, issuers should ensure that the legal entity information listed in HIOS (Issuer General Information section) is identical to the legal entity information that will be used when executing the agreement.

CHAPTER 3. QUALIFIED HEALTH PLAN AND STAND-ALONE DENTAL PLAN DESIGN

Section 1. Discriminatory Benefit Design: 2015 Approach

This section addresses how CMS will review health plans applying to be QHPs in an FFM for compliance with nondiscrimination standards. States performing plan management functions in an FFM are encouraged to use a similar approach to ensure issuer and plan compliance with nondiscrimination standards. In the future, CMS may require that states performing plan management functions provide details regarding their respective nondiscrimination review process.

i. *EHB Discriminatory Benefit Design*

Non-discrimination in benefit design with respect to EHB is a market-wide consumer protection that applies inside and outside of Marketplaces. Accordingly, the enforcement of this standard is largely conducted by states. CMS encourages states that are enforcing the Affordable Care Act to consider a number of strategies for assessing compliance with this standard including, but not limited to: analysis of information entered in the “explanations” and “exclusions” sections of the QHP Plans and Benefits Template.

For purposes of QHP certification, CMS will collect an attestation that issuers’ QHPs will not discriminate against individuals on the basis of health status, race, color, national origin disability, age, sex, gender identity or sexual orientation, consistent with 45 C.F.R. 156.200(e). CMS will continue to assess compliance through issuer monitoring and compliance reviews, including analysis of appeals and complaints, as set forth in Chapter 4 and Chapter 6.

ii. *QHP Discriminatory Benefit Design*

In addition to complying with EHB non-discrimination standards, QHPs must not employ market practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs (see 45 C.F.R. 156.225). To ensure non-discrimination in QHP benefit design, CMS will perform an outlier analysis on QHP cost sharing (e.g., co-payments and co-insurance) as part of the QHP certification application process. QHPs identified as outliers may be given the opportunity to modify cost sharing for certain benefits if CMS determines that the cost sharing structure of the plan that was submitted for certification could have the effect of discouraging the enrollment of individuals with significant health needs.

CMS’s outlier analysis will compare benefit packages with comparable cost-sharing structures to identify cost-sharing outliers with respect to specific benefits, including but not limited to those benefits listed below.

- Inpatient hospital stays,
- Inpatient mental/behavioral health stays,
- Specialist visits,
- Emergency room visits, and
- Prescription drugs.

With respect to prescription drugs, CMS intends to review plans that are outliers based on an unusually large number of drugs subject to prior authorization and/or step therapy requirements in a particular category and class. We encourage states performing plan management functions in an FFM to implement this type of review.

Section 156.122(c) requires issuers that provide EHB to have procedures in place that allow an enrollee to request and gain access to clinically appropriate drugs not covered by the plan. We are concerned that some enrollees, particularly those with certain complex medical conditions, are having trouble accessing in a timely fashion clinically appropriate prescription drugs, such as prescription drugs that are combination drugs not covered by their plans' formularies.

Accordingly, we are considering amending the formulary exceptions standards under 45 C.F.R. §156.122(c) to require that these processes can be expedited when necessary based on exigent circumstances, such as when an enrollee is suffering from a serious health condition or an enrollee is in a current course of treatment using a non-formulary drug. For example, we could specify that an issuer render decisions regarding formulary exceptions requests within 24 hours following the issuer's receipt of the exceptions request. This is currently suggested in the 2014 Letter to Issuers. As clarification, the prescription drug standard in §156.122(a)(1) was not intended to discourage issuers from offering clinically appropriate drugs to enrollees, including combination drugs.

Also in reviewing a plan's cost-sharing structure, CMS will analyze information contained in the Plans and Benefits Template, including, but not limited to, the "explanations" and "exclusions" sections, with the objective of identifying potentially discriminatory anomalies or wording. In the Draft 2015 Letter to Issuers, we stated that we would identify "clearly" discriminatory anomalies or wording but now change this to "potentially" as this is a nuanced analysis, and as noted below, CMS may offer issuers the opportunity to provide an explanation or revise the application based on any CMS follow-up. Discriminatory cost-sharing language would typically involve reduction in the generosity of a benefit in some manner for subsets of individuals other than based on clinically indicated common medical management practices. As in the case of cost-sharing outliers, where CMS identifies a potentially discriminatory practice, CMS may offer issuers the opportunity to revise the language in the "explanations" and "exclusions" portions of the Plans and Benefits Template (or other section(s) as applicable) to address the potentially discriminatory practices.

If CMS flags a potential QHP for follow-up based on this review, CMS may offer the issuer the opportunity to resolve the question identified and proceed in the certification process. Specifically, we anticipate that CMS may offer the issuer will be given the opportunity to submit a justification with supporting documentation to CMS explaining how the plan is not discriminatory or to make a change to its application to address the concern.

Section 2. Prescription Drugs

Regulations at 45 C.F.R. 156.122 establish that a health plan that provides EHB must cover at least the greater of (1) one drug in every United States Pharmacopeial Convention (USP) category and class or (2) the same number of prescription drugs in each USP category and class as the state's EHB -benchmark plan. All plans seeking QHP certification must cover EHB and comply with §156.122. With respect to prescription drugs, CMS uses data collected in the

Prescription Drug Template to review compliance with this standard. As part of the QHP Application, issuers must provide a URL to their formularies and must also provide information regarding formularies to consumers, pursuant to 45 C.F.R. 147.200(a)(2)(i)(K). CMS expects the URL link to direct consumers to an up-to-date formulary where they can view the covered drugs, including tiering, that are specific to a given QHP. The URL provided to the Marketplace as part of the QHP Application should link directly to the formulary, such that consumers do not have to log on, enter a policy number or otherwise navigate the issuer's website before locating it. If an issuer has multiple formularies, it should be clear to consumers which formulary applies to which QHP(s). CMS will make formulary links provided by issuers available to consumers on HealthCare.gov.

As stated in the interim final rule published on December 17, 2013 at 78 FR 76212, we encourage issuers to accommodate the needs of new enrollees by covering a transitional fill of non-formulary drugs to new enrollees. We encourage issuers to help with transitions for other types of care (e.g., continuity of access to specialists for individuals in the midst of a course of cancer treatment).

Section 3. Supporting Informed Consumer Choice

The content of this section applies to QHP issuers in the FFMs, including issuers participating in states that are performing plan management functions in FFMs. States with SBMs may consider following these same guidelines. We have updated this section to reflect the policy in the final 2015 Payment Notice.

Consistent with §156.298 as finalized in the 2015 Payment Notice, for 2015, CMS will use the following approach to assess whether all benefit packages proposed to be offered by potential QHP issuers are meaningfully different from other plans with the same plan characteristics that are proposed by the same issuer. CMS will use this review to target potential QHPs for additional review. The process for review described below is based on the CMS's interpretation as to what would be required for a reasonable consumer to identify differences in the characteristics of a plan. For example, CMS believes that a reasonable consumer is likely to identify a difference in deductibles of \$50 or more. The approach described below is consistent with the policies in the 2015 Payment Notice.

- First, an issuer's plans from a given state would be organized into subgroups based on plan type, metal level and overlapping counties/service areas.
- Second, CMS would review each subgroup to determine whether the potential QHPs in that subgroup differ from each other in at least one of the following criteria:
 - Different network;
 - Different formulary;
 - \$50 or more difference in both individual and family in-network deductibles;

- o \$100 or more difference in both individual and family in-network annual limit on cost sharing;
- o Difference in covered benefits;
- o Difference in Health Savings Account (HSA) eligibility; and
- o Difference in child-only, adult-only, or adult and child coverage offerings.
- If CMS finds that two or more plans within a subgroup do not differ based on at least one of the above criteria (that is, the two or more QHPs are of the same plan type and metal level; have overlapping service areas; have the same provider network, formulary, covered benefits; HSA eligibility, and child-only coverage; and have less than a \$50 difference in deductibles and less than a \$100 difference in annual limit on cost sharing), then those QHPs will be flagged for additional review and follow-up.
- Per §156.298(c) of the 2015 Payment Notice, if CMS determines that the plan offerings at a particular metal level (including catastrophic plans) within a county are limited, CMS could elect not to review plans for meaningful difference at the impacted metal level.

If CMS flags a potential QHP for follow-up based on this review, the plan(s) will not be removed from the certification process; rather, CMS may offer the issuer the opportunity to resolve the question identified and proceed in the certification process. Specifically, we anticipate that the issuer will be given the opportunity to amend or withdraw its submission for one or more of the identified health plans. Alternatively, the issuer will also be able to submit supporting documentation to CMS explaining how the potential QHP is substantially different from others offered by the issuer for QHP certification and, thus, is in the interest of consumers to certify as a QHP. For example, an issuer could highlight a feature of the plan(s) that they believe a reasonable consumer would consider a material difference that is not accounted for in the methods outlined above and at §156.298. This additional information will factor into the determination of whether it is in the interest of the qualified individuals and qualified employers to certify the plan as a QHP (*see* 45 C.F.R. 155.1000).

As stated in the 2015 Payment Notice, given the uniqueness of the stand-alone dental plan market, CMS will not review stand-alone dental plans for meaningful difference as part of the certification of those plans.

Section 4. Stand-alone Dental Plans: 2015 Approach

Issuers submitting applications for certification of SADPs will have several unique standards due to their excepted benefit status, as described in the 2014 Letter to Issuers, and their limited scope of benefits. The chart below (Table 3.1), which was not included in the Draft 2015 Letter to Issuers, is intended to assist issuers in understanding those standards that are applicable to SADPs seeking certification in the FFEs for the 2015 coverage year. We note that in addition to the certification standards outlined below, SADP issuers will need to comply with operational processes and standards. The application of QHP standards is addressed throughout the sections

of this Letter to Issuers. Therefore, this section only addresses those standards or evaluations that are unique to SADPs.

Table 3.1: Certification Standards Applicable to Stand-alone Dental Plans

Certification Standard Applies (* denotes modified standard)		Certification Standard Does Not Apply
Essential Health Benefits*	Actuarial Value*	Accreditation
Annual Limits on Cost Sharing*	Licensure	Cost-sharing Reduction Plan Variations
Network Adequacy	Inclusion of ECPs	Unified Rate Review Template
Marketing	Service Area	Meaningful Difference
Non-discrimination		

i. Stand-alone Dental Plan Rates

In the 2014 Letter to Issuers, CMS outlined a process for SADPs to complete the rating template portion of the QHP Application. SADP issuers were instructed to complete the rating templates in accordance with the associated rating and business rules and to indicate in the 2014 Plan and Benefits Template whether they were committing to charging that rate (“guaranteed” rates) or retaining flexibility to change the rate (“estimated” rates). As noted in the proposed 2015 QHP information collection request, CMS proposes to collect the average premium actually charged for those SADP issuers that indicated estimated rates in their template to determine the average difference using the 2015 Plan and Benefits Template.

ii. Intent to Apply

As described in the 2014 Letter to Issuers, QHP issuers are permitted to offer QHPs through a Marketplace that omit coverage of the pediatric dental EHB if a SADP exists in the same service area in which they intend to offer coverage. In 2014, CMS conducted a voluntary reporting process for SADP issuers to communicate their intent to apply and is following a similar approach for 2015.

Section 5. Cost Sharing Reduction Plan Variation Reviews

We have updated this section to reflect the policy in the 2015 Payment Notice. Regulations at 45 C.F.R. 156.420 generally require QHP issuers to submit three plan variations for each silver level QHP an issuer offers through the Marketplace, as well as zero and limited cost-sharing plan variations for all QHPs an issuer offers through the Marketplace.¹³ As part of the 2015 certification cycle, CMS will review QHP Applications for compliance with part 156, subpart E, including new standards for 2015 established in the 2015 Payment Notice under §156.420. The

¹³ This section does not apply to SADPs, which are not eligible for cost-sharing reductions.

certification review will include a review of each submitted Plans and Benefits Template to ensure that Silver plan variations:

- Meet AV requirements.
- Do not have an annual limitation on cost sharing that exceeds the permissible threshold for the specified plan variation, as finalized in the 2015 Payment Notice.

The cost sharing for enrollees under any silver plan variation for an EHB (or non-EHB, under the non-EHB out-of-pocket policy as modified in the 2015 Payment Notice) does not exceed the corresponding cost sharing in the standard silver plan or any other silver plan variation of the standard silver plan with a lower AV. For example, the cost sharing associated with a particular benefit must remain constant or decrease for a 94 percent AV plan variation compared to its associated 87 percent AV plan variation. Example:

Table 3.2

	Inpatient Hospital Services		Specialist Visit	
Enrollee Cost Sharing, 87% Plan Variation	25%	25%	\$40	\$40
Enrollee Cost Sharing, 94% Plan Variation	20%	30%	\$40	\$45
Review Outcome	Compliant	Not Compliant	Compliant	Not Compliant

- In accordance with 45 C.F.R. 156.420(b)(1), zero cost sharing plan variations do not have positive cost sharing for any EHB, whether in or out-of-network. (Under 45 C.F.R. 155.20, cost sharing means any expenditure required by or on behalf of an enrollee with respect to EHB, including deductibles, coinsurance, copayments, or similar charges, but excludes premiums, balance billing amounts for non-network providers, and spending for non-covered services.)¹⁴
- The out-of-pocket spending for a zero cost sharing plan variation of a QHP for a non-EHB may not exceed the corresponding out-of-pocket spending in the limited cost sharing plan variation of the QHP, and the corresponding out-of-pocket spending required in the 94 percent silver plan variation of the QHP, in the case of a silver metal level QHP.

¹⁴ If the QHP is a closed-panel HMO that does not cover services furnished by a provider outside of the network (i.e., cost sharing for services provided by an out-of-network provider is at 100 percent), the cost sharing, for these non-covered services would not need to be eliminated for the zero cost sharing plan variation, and should be entered as it would be for non-covered out-of-network services under the corresponding standard plan.

- The out-of-pocket spending for a limited cost sharing plan variation of the QHP for a non-EHB may not exceed the corresponding out-of-pocket spending required in the QHP with no cost-sharing reductions.

Section 6. Calculation of Cost-Sharing Reduction Advance Payments

As described in the 2014 Payment Notice, for the 2014 benefit year, cost-sharing reduction advance payment rates were calculated using actuarial data value data submitted by issuers under 45 C.F.R. 156.420 and data on claims costs allocable to EHB submitted by issuers under §156.470. In the FFMs, including FFMs in states performing plan management functions, these data were collected via the Plans and Benefits Template and the Unified Rate Review Template. QHP issuers were also given the option under 45 CFR 156.430(a)(2) to submit an estimate of the value of the cost-sharing reductions that they will provide under any limited cost sharing plan variations, via the Plans and Benefits Template, in order to receive advance payments for these cost-sharing reductions.

For the 2015 benefit year, we modified the methodology for calculating cost-sharing reduction advance payment rates. As described in the 2015 Payment Notice at §156.430(b)(1), Marketplaces will use a methodology for calculating the advance payment amounts that will not require QHP issuers to submit an estimate of the value of cost-sharing reductions to be provided or the EHB portion of expected allowed claims costs. Instead, Marketplaces will calculate the monthly advance payment amount for a specific policy as the product of (x) the total monthly premium for the specific policy, and (y) a cost-sharing reduction plan variation multiplier. HHS will make appropriate modifications to the templates and QHP certification instructions.

CHAPTER 4. QUALIFIED HEALTH PLAN PERFORMANCE AND OVERSIGHT

Section 1. Account Management: 2015 Issues

All issuers participating in FFMs, including issuers participating in states that are performing plan management functions, will continue to have an assigned federal Account Manager. Newly certified issuers will be assigned a federal Account Manager in September prior to the start of the benefit year. The Account Managers will serve as the QHP and SADP issuer's primary point of contact with the FFMs for non-technical QHP and SADP related issues and will provide QHP issuers with clarification and other assistance related to issuers' responsibilities and requirements for participating in the FFM. Additionally, the Account Manager will communicate updates to issuers, direct issuers to other resources as appropriate, and coordinate resolution of cross-cutting issues. CMS expects that states, regardless of Marketplace type, will continue to take the lead in addressing market-wide issues, such as complaints related to market conduct.

CMS has also assigned a CO-OP Program Account Manager to each CO-OP in addition to the federal Account Manager. The CO-OP Program Account Manager serves as the CO-OP's primary point of contact with the CO-OP Program Division for questions and issues regarding CO-OP responsibilities and requirements pursuant to section 1322 of the Affordable Care Act, 45 C.F.R. part 156 subpart F, and the CO-OP Program Funding Opportunity Announcement.

Section 2. QHP Issuer Compliance Monitoring Program

This section describes how CMS, as administrator of the FFMs, will monitor ongoing QHP compliance in 2015 in all FFMs, including in states that are performing plan management functions. The Final 2015 Letter to Issuers adds that we do not intend to extend the 2014 good faith enforcement safe harbor, though we intend to continue our existing approach to work with issuers to resolve compliance issues, as noted below.

In the Program Integrity: Exchange, SHOP, and Eligibility Appeals Final Rule,¹⁵ CMS acknowledged the transitional nature of the 2014 benefit year, and agreed not to impose civil money penalties or decertify QHPs for non-compliance with certain Marketplace requirements if the QHP issuer has made good faith efforts to comply with applicable requirements. CMS expects that by 2015, issuers will have gained more experience operating in the FFM environment and/or will be more familiar with the Marketplace requirements. We believe that our compliance approach provides issuers an adequate opportunity to resolve all but the most serious compliance issues. We encourage issuers to be proactive in monitoring their own compliance with applicable FFM standards and guidance, and to contact their CMS Account Managers if they have questions. CMS will also continue coordinating with states on federal monitoring, including compliance reviews (described in more detail below) and enforcement actions so as to minimize any unnecessary duplication of oversight activities.

Section 3. QHP Issuer Compliance Reviews

This section describes how CMS, as administrator of the FFMs, will monitor QHP issuers' compliance and evaluate QHP issuers' performance in the FFMs. States performing plan management functions in an FFM may take a similar approach to monitoring issuers' compliance with applicable FFM standards. CMS will also conduct routine monitoring of QHPs in FFMs, including, but not limited to, review of aggregate complaints data.

As required by 45 C.F.R. 155.1010, CMS will be monitoring QHP issuers for demonstration of ongoing compliance with the certification requirements outlined in 45 C.F.R. 155.1000(c). CMS will also evaluate issuers' compliance with general issuer standards and requirements in part 156,

¹⁵ Patient Protection and Affordable Care Act; Program Integrity: Exchange, SHOP, and Eligibility Appeals; Final Rule, 78 Federal Register 54070 (Aug. 30, 2013) (codified at 45 CFR Parts 147, 153, 155, and 156).

as well as issuers' performance with respect to its QHPs offered in the FFM as part of its determination that making the QHP available is in the interest of qualified individuals and qualified employers in accordance with 45 C.F.R. 155.1000(c)(2). CMS will monitor compliance and evaluate performance using information received from various sources, including states, which may include: aggregate complaint data, issuer self-reporting of problems, information related to customer service and satisfaction, health care quality and outcomes, QHP issuer operations, and network adequacy. We will examine trends in complaint data to assist us with evaluating the compliance of issuers and the performance of their QHPs.

Consistent with CMS's authority under 45 C.F.R. 156.715, CMS will perform a limited number of compliance reviews to address performance issues or non-compliance. These compliance reviews will focus on applicable FFM requirements, and CMS will review data at both the issuer and the QHP level. CMS will generally use a risk-based process, based in part on the compliance monitoring (e.g., aggregate complaint data) and performance data available, to select QHPs/issuers for compliance reviews. CMS intends to coordinate with the state regulatory entities, where appropriate, in conducting the compliance reviews.

Section 4. FFM Oversight of Agents/Brokers

Pursuant to 45 C.F.R. 156.340, a QHP issuer maintains responsibility for the compliance of its delegated and downstream entities, including affiliated agents, brokers, and web-brokers. Accordingly, CMS expects QHP issuers to check all affiliated agents' and brokers' licensure statuses and verify that they fulfilled the applicable FFM registration and training requirements, executed the FFM Privacy/Security Agreement, and (if applicable), signed the General FFM Marketplace Agreement before allowing them to access the issuer's tools and/or assist consumers with enrollment through the FFM. Agents, brokers and web-brokers should provide a copy of their FFM User ID and training completion certificate (if applicable) to each affiliated QHP issuer.

CMS strongly suggests that agents and brokers not use "Marketplace" or "Exchange" in the name of their businesses or websites. As required by 45 C.F.R. 155.220(c)(3)(vii), if an agent or broker assists a qualified individual with QHP selection through the agent, broker, or web-broker's non-FFM website, a standardized disclaimer must be prominently displayed to indicate that the site is not the Health Insurance Marketplace website, and a link to the FFM website must also be provided. Pursuant to 45 C.F.R. §155.220(i), as finalized in the 2015 Payment Notice, SHOPS may permit agents and brokers, in states that permit such activity under state law, to use an Internet website to provide assistance to qualified employers and facilitate enrollment of qualified employees in SHOP QHPs, subject to the requirements of §155.220(c)(3).

Section 5. Monitoring of Marketing Activities

This section describes how CMS will monitor QHP marketing during the 2015 benefit year in all FFMs and provides information that supplements what was discussed in the 2014 Letter to Issuers.

Regulations at 45 C.F.R. 156.200(e) provide that QHP issuers must not, with respect to their QHPs, discriminate on the basis of race, color, national origin, disability, age, sex, gender identity, or sexual orientation. Section 156.225(a) requires that in order to have a plan certified as a QHP, a QHP issuer must comply with all applicable state laws on health plan marketing by health insurance issuers. In addition, §156.225(b) states that a QHP issuer must not employ marketing practices that will have the effect of discouraging the enrollment of individuals with significant health needs in QHPs.

As we noted in the 2014 Letter to Issuers, states generally regulate health plan marketing materials and other related documents under state law, and CMS does not intend to review QHP marketing materials for compliance with state standards as described at §156.225(a). In FFM states where there is no or minimal review of QHP marketing materials for compliance with §156.200(e) and §156.225(b), CMS may review QHP marketing materials for compliance with these standards. CMS will work with states to determine where additional monitoring and review of marketing activities may be needed. For all QHP issuers in the FFMs, we recommend that agreements with agents and brokers, as well as marketing materials distributed to enrollees and to prospective enrollees, contain a clause such as the following: “[Insert plan’s legal or marketing name] does not discriminate on the basis of race, color, national origin, disability, age, sex, gender identity, sexual orientation, or health status in the administration of the plan, including enrollment and benefit determinations.” If CMS receives a consumer complaint about an issuer’s marketing activities or about an agent’s, broker’s, or Web-broker’s conduct which is generally overseen by the state, CMS will send the complaint to the state department of insurance, as appropriate, for investigation. Following the state’s investigation, CMS may take the necessary enforcement action against the issuer or agent, broker, or Web-broker.

CHAPTER 5. EMPLOYEE CHOICE AND PREMIUM AGGREGATION SERVICES IN FF-SHOPS

Section 1. Overview

This chapter applies to the FFM, including FFMs in states performing plan management functions. It provides policy, operational, and technical information to assist issuers as they prepare for employee choice and premium aggregation services in FF-SHOPS for plan years beginning in 2015.

Facilitation of employee choice at a single level of coverage selected by the employer – bronze, silver, gold, or platinum – is a required SHOP function for plan years beginning on or after January 1, 2015 under 45 C.F.R. 155.705(b)(2). In a Notice of Proposed Rulemaking being released today, we are proposing a one-year transition policy under which a SHOP would be permitted to limit employee choice in 2015 in a particular state, based on a recommendation from the state regulatory agency, under the following circumstances: (1) if employee choice would result in significant adverse selection in the state’s small group market that could not be fully remediated by the single risk pool or premium stabilization programs; or (2) if there is an insufficient number of issuers offering qualified health plans or qualified stand-alone dental plans at the selected level of coverage chosen by the employer to allow for meaningful choice in the state’s SHOP. Through this rulemaking, we have solicited comments on all aspects of this proposal. If this proposal is finalized, we would provide additional detail about the timing of such decisions in the final rule. This proposed policy would be an option for all SHOPs meeting the requisite criteria, including the FF-SHOP. If this proposal is finalized, CMS will also provide further guidance in the final rule regarding other policies that might also be affected.

Pending the finalization of this proposal, unless a state meets the criteria specified in the proposal, for plan years beginning on or after January 1, 2015, the FF-SHOP in that state will provide qualified employers with a choice of two methods to make QHPs available to qualified employees: they can offer employees a choice of all QHPs at a single level of coverage (as detailed in section 1302(d)(1) of the Affordable Care Act) or they can offer a single QHP. As outlined in 45 C.F.R. 155.705(b)(4), FF-SHOPs will also provide premium aggregation in plan years beginning on or after January 1, 2015. Premium aggregation services allow an employer to receive one bill and make one payment to the FF-SHOP instead of having to interact with multiple issuers for account set up and premium payment purposes.

Additionally, as finalized in the 2015 Payment Notice, for plan years beginning on or after January 1, 2015, qualified employers in FF-SHOPs may offer employees a choice of (1) all stand-alone dental plans offered through the FF-SHOP at a level of coverage as described in 45 CFR 156.150(b)(2); or (2) a single stand-alone dental plan.

Section 2. Single Bill, Single Payment under Premium Aggregation

Pursuant to §155.705(b)(4), for plan years beginning on or after January 1, 2015, the FF-SHOP will send each participating employer a single monthly bill covering all employees covered through the FF-SHOP and the employer will remit a single monthly payment to the FF-SHOP. For plan years beginning on or after January 1, 2015, CMS will provide these premium aggregation services for all issuers participating in the FF-SHOP, regardless of whether an employer chooses to offer a single plan or all plans at a single actuarial value level of coverage through employee choice. (Issuers will continue billing and receiving payments through the end of plan years that began in 2014.) Issuers need to be ready to accept initial enrollments and

payments as early as November 15, 2014 for groups enrolling in FF-SHOP coverage beginning as soon as January 1, 2015.

The FF-SHOP expects to generate invoices on or around the 10th of each month prior to the coverage month. CMS expects that the aggregated monthly bill will provide information about each employee's coverage and the employer and employee contributions toward that coverage. CMS anticipates that employers would be required to make an initial premium payment at least two days prior to the employer's desired coverage effectuation date.

Employers would be required to make their full monthly payment to the FF-SHOP before the end of the FF-SHOP's employer grace period as outlined at 45 C.F.R. 155.735(c)(2)(ii). CMS interprets §§155.705(b)(4)(i)(B) and 155.735(c) as requiring premium payment to be made to the FF-SHOP, not the issuer, by the end of the FF-SHOP grace period. Thus, an issuer should not terminate a group for non-payment of premiums unless it has been informed by the FF-SHOP that an employer has not paid its monthly premium amount by the end of the FF-SHOP's employer grace period, even if the FF-SHOP has not yet transmitted the employer's full monthly premium amount to the issuer by the end of the FF-SHOP's employer grace period. CMS will make every effort to remit payments promptly to issuers so any delay in transmitting payments to issuers at the end of the FF-SHOP's grace period should not inconvenience issuers.

The amount due each month would be the lesser of 1) the invoiced amount, or 2) the current account balance as outlined in the FF-SHOP payment portal (the current balance owed may be less than the invoiced amount because an enrollee may have dropped coverage after the invoice was generated). If a new person was added to a group's policy after an invoice was generated, CMS expects that an employer would be back-billed on the next monthly invoice or make an immediate payment to cover the new enrollment. CMS would use an EFT payment transaction to transmit payments and would not send partial payments to issuers. A partial payment not sent to issuers would be sent back to an employer if the employer is terminated for non-payment of premiums.

Section 3. FF-SHOP Enrollment and Payment Portals

CMS expects that the FF-SHOP website will maintain a payment system portal that can be accessed through an employer's MyAccount. Regardless of whether an employer selects a single QHP to offer to its employees or a single metal level, the employer would always be redirected to the FF-SHOP site and not any specific issuer's website for invoicing and payment purposes. CMS expects that employers may perform a variety of functions on this site, including: making a payment, verifying the status of payment, and downloading invoices. There is expected to be a seamless connection between the FF-SHOP's payment portal and the employer's MyAccount, where the employer may access enrollment matters impacting monthly invoices.

Section 4. Beginning Balances for Plan Years Beginning on and after January 1, 2015

For reconciliation purposes with the FF-SHOP, CMS expects issuers to have a zero balance on their accounts as they begin interacting with the FF-SHOP's premium aggregation services for plan years beginning on and after January 1, 2015. Issuers that have balances due from employers from FF-SHOP plan years that began in 2014 would be expected to collect that amount directly with the employer through their delinquency process, subject to 45 C.F.R. 156.270. If there is a credit on the employer's account at the end of a group's 2014 benefit year, the issuer would be expected to refund the balance on the account directly to the employer.

Section 5. Bank Accounts

The FF-SHOP expects that it will have the capability to make payments to one bank account for each issuer participating in the FF-SHOPs. CMS expects to request that issuers provide basic banking information, including the account and routing numbers and the type of account (savings/checking). If the FF-SHOP receives a payment rejection from a bank for payment to an issuer, CMS would notify the issuer to update its account information.

Section 6. Initial Payments for New Group Coverage and Frequency of Issuer Payments

For plan years beginning on or after January 1, 2015, employers will use the FF-SHOP's payment portal instead of an issuer's payment portal for purposes of finalizing an initial FF-SHOP enrollment. Employers may also make initial payments by calling the FF-SHOP's Employer Contact Center or by mailing in a check to the FF-SHOP. Issuers must effectuate coverage upon receipt of new group enrollment transactions unless CMS sends a termination transaction for non-payment of the initial payment.

CMS expects that the FF-SHOP will generally make payments to issuers on a weekly basis.

Section 7. Enrollment and HIX 820 Transactions

Employers will be expected to use the FF-SHOP enrollment portal to apply, enroll, and make changes to enrollments for plan years beginning on and after January 1, 2015. This online activity will generate group XML and 834 enrollment transactions that will be sent by the FF-SHOP to applicable issuers. An 820 transaction is expected to be generated each time CMS makes a payment to an issuer. The 820 transaction would inform issuers how to allocate funds received to active SHOP accounts.

Section 8. Terminations for and Reinstatements after Non-payment of Premiums

For plan years beginning in 2015, the FF-SHOP, will initiate termination of coverage for groups enrolled in the FF-SHOPs for non-payment of premiums. Pursuant to 45 C.F.R. 155.735(c)(2), employers wishing to be reinstated following non-payment of premium must contact the FF-

SHOP Employer Contact Center and arrange to bring their account up to date within 30 days of being terminated for non-payment of premium. After a group has paid its outstanding balance and pre-paid the next month's premium payment, the FF-SHOP will send a reinstatement transaction to the affected issuer (or issuers).

Section 9. Premium Payment Reconciliations

As part of its administration of premium aggregation, in plan years beginning on or after 2015, the FF-SHOP will reconcile issuer employee enrollment information submitted pursuant to 45 C.F.R. 156.285(c)(4) with FF-SHOP data about enrollment and paid premiums. The premium aggregation contractor will take corrective action to resolve any payment discrepancies discovered through the reconciliation process and will report payment reconciliation resolutions to issuers upon request. Issuers may contact the SHOP Employer Contact Center with any questions or concerns about premium payment reconciliations.

Section 10. Agent and Broker Commissions and User Fees

Issuers could continue to pay agent and broker commissions for FF-SHOP coverage in plan years beginning in 2015, just as they do today. In addition, the FF-SHOP would not take user fees out of FF-SHOP premiums owed issuers. CMS, as operator of the FFMs, would continue to calculate user fees each month based on current confirmed enrollments and would make adjustments for retroactive enrollments, terminations, changes, and cancellations. For issuers that also offer QHPs in the individual market FFM, the FF-SHOP would net user fee amounts against advance payments of the premium tax credit (APTC)/cost sharing reduction (CSR) payments during the monthly payment cycle, and invoice to the issuer any user fee totals that exceed APTC/CSR payments. CMS, as operator of the FFMs, would bill issuers not participating in the individual market FFM separately for user-fees.

Section 11. Customer Service for FF-SHOPs

Back-office functions for all FF-SHOPs, including premium aggregation, employer billing, receipt of payments, and disbursement of premium payments to issuers, will be facilitated by a single CMS contractor, which will also operate a call center that issuers and employers may contact for ongoing support and questions related to billing and payment. This call center will have dedicated customer service representatives for enrollment and premium payment reconciliations.

For billing inquiries, employers and agents/brokers and other authorized assisters calling on behalf of employers will be able to call the SHOP Employer Contact Center.

Section 12. Premium Aggregation Technical Assistance

CMS will continue to provide technical assistance to issuers through webinars and ongoing issuer calls. CMS expects that information specific to employee choice and premium aggregation will be available shortly.

Section 13. Minimum Participation Rates and Renewals during November 15-December 15

Due to consumer considerations, employers will not have to meet the FF-SHOP's minimum participation rate for renewals occurring between November 15 and December 15. The guaranteed availability regulation, at 45 C.F.R. 147.104(b)(1), requires that an employer be allowed to purchase coverage from November 15 through December 15, even if the employer cannot meet minimum participation requirements. We believe it would impose undue burden on employers, their employees, issuers, and the FF-SHOP to non-renew coverage under the exception to guaranteed renewability for failure to meet minimum participation rates and then re-enroll employers under guaranteed availability during this period. Therefore, the FF-SHOP will not impose (and QHP issuers offering coverage through the FF-SHOP may not enforce) minimum participation requirements for renewals occurring between November 15 and December 15.

CHAPTER 6. CONSUMER SUPPORT AND RELATED ISSUES

Section 1. Provider Directory

The content of this section applies to all QHP Issuers in the FFM, including FFM in states performing plan management functions in an FFM. States with SBMs may consider following these same guidelines.

Pursuant to 45 C.F.R. 156.230(b), CMS, as administrator of the FFM, will require QHPs to make their provider directories available to the Marketplace for publication online by providing the URL link to their network directory. CMS expects the URL link to direct consumers to an up-to-date provider directory where the consumer can view the provider network that is specific to a given QHP. The URL provided to the Marketplace as part of the QHP Application should link directly to the directory, such that consumers do not have to log on, enter a policy number, or otherwise navigate the issuer's website before locating the directory. If an issuer has multiple provider directories, it should be clear to consumers which directory applies to which QHP(s). Further, CMS expects the directory to include location, contact information, specialty, and medical group, any institutional affiliations for each provider, and whether the provider is accepting new patients. CMS encourages issuers to include languages spoken, provider credentials, and whether the provider is an Indian health provider. Directory information for Indian health providers should describe the service population served by each provider, as some

Indian health providers may limit services to Indian beneficiaries, while others may choose to serve the general public.

Section 2. Complaints Tracking and Resolution

The content of this section applies to QHP Issuers in the FFM, including FFM in states performing plan management functions. States with SBMs may consider following these same guidelines.

CMS encourages consumers to report complaints and concerns to the Marketplace Call Center as well as to the issuers of the QHPs in which they are enrolled. CMS expects QHP issuers to thoroughly investigate and resolve consumer complaints received directly from members or forwarded to the issuer by the state through the issuer's internal customer service process and as required by state law. Additionally, QHP issuers operating in an FFM must investigate and resolve consumer complaints forwarded by CMS in accordance with the requirements at §156.1010. Complaints may be forwarded through the Health Insurance Casework System (HICS) developed by CMS or by other means as determined by CMS. CMS expects issuers to resolve complaints in a timely and accurate manner to ensure consumers receive the highest level of service and to meet QHP issuer participation standards as outlined at 45 C.F.R. 156.200. Timeframes for resolving cases forwarded by CMS are specified in 45 C.F.R. 156.1010(d).

QHP issuers operating in an FFM, including FFM in states performing plan management functions, are expected to comply with all applicable state and federal laws related to consumer complaints, including any applicable requirement to advise consumers of their appeal rights. CMS intends to track complaints and use aggregated complaints information as a tool for directing oversight activities in FFM. To the greatest degree possible, CMS will collaborate with states in tracking complaints and sharing information suggestive of issuer performance problems.

Section 3. Coverage Appeals

The content of this section applies to all QHP Issuers in the FFM, including FFM in states performing plan management functions. States with SBMs may consider following these same guidelines.

QHPs are required to meet the standards for internal claims and appeals and external review established at 45 C.F.R. 147.136, which implements section 2719 of the PHS Act, as added by the Affordable Care Act. Section 2719 of the PHS Act requires that all non-grandfathered group health plans and non-grandfathered health insurance issuers offering group or individual health insurance coverage implement an effective process for internal claims and appeals and external review. QHPs must fully comply with the requirements of §147.136 as interpreted by any applicable guidance documents.

Section 4. Meaningful Access

This section describes how the measures that QHP issuers are encouraged to take to comply with the requirements that they ensure meaningful access by limited-English proficient (LEP) speakers and by individuals with disabilities. CMS is considering whether to develop model notices to assist issuers in meeting these standards.

QHP issuers are reminded that meaningful access requirements at 45 C.F.R. 155.205(c), 155.230(b), and 156.250, as well as discrimination prohibitions at 45 C.F.R. 156.200(e), are independent of other obligations QHPs may have. For example, QHP issuers that receive federal financial assistance are subject to Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, and section 1557 of the Affordable Care Act, and as a result, have separate responsibilities under the law not to discriminate on the basis of race, color, national origin, sex, age and disability, in providing access to their services. More information about language access can be found at www.lep.gov/interp_translation/trans_interpret.html. We also encourage QHP issuers to follow the Office of Minority Health's (OMH) National Standards on Culturally and Linguistically Appropriate Services (CLAS), available for review at www.ThinkCulturalHealth.HHS.gov.

In addition to ensuring meaningful access for individuals with LEP, QHP issuers must also ensure access for individuals with disabilities, including through the provision of auxiliary aids and services. CMS notes that all web content or communications materials produced by the FFM and its contractors – including text, audio or video, will conform to applicable standards related to section 508 of the Rehabilitation Act and, where applicable, the Americans with Disabilities Act and section 504 of the Rehabilitation Act.

CMS expects that QHP issuers will ensure meaningful access to at least the following essential documents:

- Applications (including the single streamlined application);
- Consent, grievance, and complaint forms, and any documents requiring a signature;
- Correspondence containing information about eligibility and participation criteria;
- Notices pertaining to the denial, reduction, modification, or termination of services, benefits, non-payment, and/or coverage;
- A plan's explanation of benefits or similar claim processing information;
- QHP ratings information;
- Rebate notices; and
- Any other document that contains information that is critical for obtaining health insurance coverage or access to care through the QHP.

Documents related to appeals and the Summary of Benefits and Coverage (SBC) would not be included in this list because they are subject to separate regulatory standards with which issuers must comply.

Section 5. Summary of Benefits and Coverage

The content of this section applies to all QHP issuers in the FFM, including states performing plan management functions in an FFM. States with SBMs may consider following these same guidelines.

QHPs are required to provide the Summary of Benefits and Coverage (SBC) in manner compliant with the standards set forth in 45 C.F.R. 147.200, which implements section 2715 of the PHS Act, as added by the Affordable Care Act. Section 2715 of the PHS Act requires that all group health plans and health insurance issuers offering group or individual health insurance coverage compile and provide an SBC that accurately describes the benefits and coverage under the applicable plan or coverage. QHPs must fully comply with the requirements of §147.200 and any applicable guidance.

While QHP issuers are not required to create separate SBCs to reflect different levels of cost-sharing reductions for each plan variation, QHP issuers should create an SBC that represents the base plan, consistent with the requirements set forth in §147.200. QHPs may not combine information about multiple plan variations in one SBC. However, QHP issuers are permitted, and encouraged, to create separate SBCs for each plan variation.

Section 6. Transparency

The content of this section applies to all QHP issuers in the FFMs, including FFMs in states that are performing plan management functions. States with SBMs may consider following these same guidelines.

QHPs in the FFMs are required to submit specified information to the Marketplace and other entities in a timely and accurate manner as required by 45 C.F.R. 156.220, implementing section 1311(e)(3) of the Affordable Care Act. Under these provisions, QHP issuers must provide the specified information to the Marketplace, CMS and the State insurance commissioner. As clarified in Affordable Care Act Implementation FAQs Set 15 Q4,¹⁶ QHP issuers will begin submitting information after they have been certified as QHPs for one benefit year. We intend to provide details on the implementation of the transparency in coverage reporting requirements, including what information must be provided and timing of submissions, through future guidance.

¹⁶ Affordable Care Act Implementation FAQs – Set 15, available at: http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs15.html.

CHAPTER 7: TRIBAL RELATIONS AND SUPPORT

Section 1. Model Contract Addendum for Issuers Working with Indian Health Providers

The federal government has a historic and unique relationship with Indian tribes. In adhering to QHP certification standards, CMS encourages QHPs to engage with Indian health care providers, through which a significant portion of American Indians and Alaska Natives (AI/AN) access care. To promote contracting between issuers and Indian health care providers, CMS expects issuers to offer contracts to Indian health care providers and use the recommended Model QHP Addendum (Addendum) as described in the 2014 Letter to Issuers. Issuers should refer to that document and the addendum itself, both of which are available on the CCIIO website, for further details.

We also note that Section 206 of the Indian Health Care Improvement Act (25 USC Section 1621e) provides that all Indian providers have the right to recover from third party payers, including QHPs, up to the reasonable charges billed for providing health services, or, if higher, the highest amount an insurer would pay to other providers to the extent that the patient or another provider would be eligible for such recoveries. Under Section 206 of IHCA, an Indian health provider can seek recovery from a QHP if it has a contract with the QHP or not. We encourage issuers and Indian health providers to set up payment terms and contracted relationships to which both parties agree.

Section 2. Tribal Sponsorship of Premiums

Regulations at 45 C.F.R. 155.240(b) provide Marketplaces with flexibility to permit Indian tribes, tribal organizations, and urban Indian organizations to pay QHP premiums—including aggregated payment—on behalf of members who are qualified individuals, subject to terms and conditions determined by the Marketplace. During consultations with tribal governments, tribal leaders indicated the importance of tribes having the ability to pay premiums on behalf of their members.

For the 2014 benefit year, CMS assessed its various systems to determine how the FFMs could establish a process to facilitate Tribal Premium Sponsorship or the ability of Indian tribes, tribal organizations, and urban Indian organizations to pay premiums on behalf of AI/ANs. Because the FFMs will not collect premiums directly from individuals, CMS concluded that the FFMs will not be able to establish a process that would facilitate premium sponsorship, including Tribal Premium Sponsorship, for October 1, 2013. This determination remains unchanged for the 2015 benefit year.

CMS recognizes that aggregating premium payments can be an effective mechanism for increasing the enrollment of AI/ANs in QHPs and will continue to work on this option for future years. It should be noted that tribes are able to work with issuers or tribal members directly to

pay premiums. Additionally, this determination does not preclude State-based Marketplaces from developing and implementing a process for Tribal Premium Sponsorship. CMS encourages tribes to continue to work closely with State-based Marketplaces, including the option to explore tribal premium sponsorship.

EXHIBIT 13

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Consumer Information & Insurance Oversight
200 Independence Avenue SW
Washington, DC 20201



July 21, 2015

Dear Commissioner,

Thank you for the work you and your teams did for the 2015 plan year to increase issuer competition and reduce premium rates, thus ensuring that coverage remained accessible and affordable for millions of Americans. In addition, thank you for the hard work you and your teams are investing to complete approval of final rates for the 2016 benefit year. With the availability of new Marketplace utilization experience data and the implementation of the reinsurance, risk adjustment, and risk corridor premium stabilization programs, we recognize that new information will need to be taken into account in reviewing rate proposals this year. We appreciate all that you and your staff do, and have the opportunity to do, to maintain affordability for consumers, while ensuring issuer solvency.

Based on preliminary filings for the coming year, we are confident that, overall, consumers will retain access to a wide range of affordable options in 2016. In addition, in the last few months, we have been meeting regularly with issuers and state officials from across the country to better understand key drivers of premium increases. These conversations have been encouraging and instructive, and we have distilled several findings that we would ask you to carefully consider as you make your final rate decisions:

1. **Recent claims data show healthier consumers.** Data show that consumers who signed up more recently are healthier than enrollees who were among the first to sign up during the first Open Enrollment Period. Further, recent experience may show an improved issuer medical loss ratio. For instance, Anthem CT announced on July 10 that it was proactively lowering its rates from its preliminary filings, which were based on claims from January 2014 through March 2015, because claims through May 2015 showed that their members' health care costs were lower than expected.

In addition, risk pools are expected to continue to get healthier. Many issuers are assuming consumers who enroll in Marketplaces during the remainder of 2015 and into 2016 will exhibit even lower rates of utilization than 2014 enrollees. Already, many issuers are reporting a decline in pent-up demand for services. Further, the increase in the individual shared responsibility fee in 2016 and increased consumer experience with individual shared responsibility should motivate a new segment of uninsured who may not have a high need for health care to enroll for coverage. This was the experience in Massachusetts in the first years of their Exchange before the Affordable Care Act became law, and we expect a similar trend.

2. **Recent data show a continued moderate medical cost trend.** Available data suggest that underlying trends in overall medical costs remained moderate through the end of 2014 and into early 2015, even accounting for rapid growth in pharmaceutical costs. Because recent trend experience can often provide a useful guide to the near future, these data may be relevant when evaluating the reasonableness of trend assumptions for 2016.
3. **CMS will use a one hundred percent coinsurance rate for the 2014 reinsurance program.** As you know, the Centers for Medicare & Medicaid Services (CMS) recently announced that, consistent with its regulations for the transitional reinsurance program, all eligible claim expenses for the 2014 benefit year would be paid at a 100 percent coinsurance rate, instead of 80 percent. Initial filing by issuers were due before this announcement was made in June.
4. **CMS remains committed to the risk corridor program.** As stated in our final payment notice for 2016, “We anticipate that risk corridors collections will be sufficient to pay for all risk corridors payments. HHS recognizes that the Affordable Care Act requires the Secretary to make full payments to issuers.” This spring, CMS announced that preliminary information about 2014 risk corridors payments and charges will be made available on August 14, 2015. We believe these payments should be taken into account before decisions are made on final rates.
5. **Public hearings are helpful.** Many states have found the use of public hearings helpful in rate evaluation. You and your staff undoubtedly have even more ideas to ensure that rates receive appropriate public scrutiny.

Like you, CMS is focused on both consumer affordability and issuer solvency. To that end, we ask that you consider these findings as you work to finalize rates for the 2016 plan year.

We appreciate all that you and your teams do to help us keep health insurance affordable and protect consumers. Please let us know of any ways we can be of further help.

Sincerely,

Kevin J. Counihan

Chief Executive Officer, Health Insurance Marketplace

Director, Center for Consumer Information & Insurance Oversight

EXHIBIT 14

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Consumer Information & Insurance Oversight
200 Independence Avenue SW
Washington, DC 20201



Date: February 20, 2015

From: Center for Consumer Information and Insurance Oversight (CCIIO),

Centers for Medicare & Medicaid Services (CMS)

Title: FINAL 2016 Letter to Issuers in the Federally-facilitated Marketplaces

The Centers for Medicare & Medicaid Services (CMS) is releasing this final 2016 Letter to Issuers in the Federally-facilitated Marketplaces (Letter). This Letter provides issuers seeking to offer qualified health plans (QHPs), including stand-alone dental plans (SADPs), in the Federally-facilitated Marketplaces (FFMs) or the Federally-facilitated Small Business Health Options Programs (FF-SHOPs) with operational and technical guidance to help them successfully participate in those Marketplaces in 2016. Unless otherwise specified, references to the FFMs include the FF-SHOPs.

Throughout this Letter, CMS identifies the areas in which States performing plan management functions in the FFMs have flexibility to follow an approach different from that articulated in this guidance. CMS notes that the policies articulated in this Letter apply to the certification process for plan years beginning in 2016.¹

Previously published rules concerning market-wide and QHP certification standards, eligibility and enrollment procedures, and other Health Insurance Marketplace-related topics are set out in 45 C.F.R. Subtitle A, Subchapter B. Additional requirements were included in a final rule titled, "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016" (2016 Payment Notice Final Rule), CMS-9944-F, which went on public display on February 20, 2015.² CMS expects issuers to consult all applicable regulations, in conjunction with the final version of this Letter, to ensure full compliance with the requirements of the Affordable Care Act. Throughout the plan year, QHPs may be required to correct deficiencies identified in CMS's post-certification activities, as a result of the investigation of consumer complaints or oversight by State regulators or by CMS, or as a result of an issuer's

¹ Plan years in the FF-SHOPs will not always align with calendar year 2016.

² Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016; CMS-9944-F.

own industry-standard internal compliance and risk management program. QHP issuers in the FFMs may also be subject to other requirements for plan years beginning in 2016, as indicated in future rulemaking.

Unless otherwise indicated, regulatory references in this Letter are to Title 45 of the Code of Federal Regulations (C.F.R.).

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CHAPTER 1: CERTIFICATION PROCESS FOR QUALIFIED HEALTH PLANS

The Affordable Care Act and the applicable regulations establish that health plans must meet a number of standards in order to be certified or recertified as QHPs. Several of these are market-wide standards that apply to plans offered in the individual and small group markets inside as well as outside of the Marketplaces. The remaining standards are specific to QHPs seeking certification or recertification from the Marketplaces.

As was the case for the 2015 benefit year, CMS expects to rely on States' reviews of policy forms and rate filings for market-wide standards as part of its QHP certification process, provided that such States review for compliance with standards that are consistent with Federal laws and regulations and complete such reviews in a manner consistent with operational timelines.³ In addition to ensuring compliance with ACA requirements, all QHP and SADP issuers must be licensed and in good standing to offer health insurance coverage in each State in which the issuer offers health insurance coverage, and in compliance with all applicable State laws that are conditions of offering health insurance in the State provided that the applicable laws are in accordance with Federal law. CMS further interprets this requirement to mean that, in order to have plans certified as QHPs in the FFMs, in addition to receiving final approval from CMS for their QHP Application submissions, issuers must receive any applicable form and rate filing approval from the appropriate State regulatory authority. Issuers should follow State guidance regarding compliance with the processes, criteria, and timeline for reviews conducted by States. States must provide CMS with State recommendations for QHP certification along the timeline specified by CMS in order for CMS to consider the recommendations and certify, or deny certification to QHPs, including SADPs. CMS will provide States with more detailed guidance regarding the process for submitting final plan approval recommendations to CMS as the final data lockdown date nears.

This chapter provides an overview of the QHP certification process in the FFMs, both when a State is performing plan management functions and making QHP certification recommendations to CMS, as well as when CMS is performing plan management functions and certifying QHPs. The QHP certification process that will take place in calendar year 2015 for plans effective

³ States are the primary regulators of health insurers and are responsible for enforcing the market reform provisions in title XXVII of the Public Health Service (PHS) Act both inside and outside the Marketplaces. Under sections 2723 and 2761 of the PHS Act and existing regulations, codified at 45 C.F.R. part 150, CMS is responsible for enforcing the provisions of Parts A and B of title XXVII of the PHS Act in a State if the State notifies CMS that it has "not enacted legislation to enforce or that it is not otherwise enforcing" one or more of the provisions, or if CMS determines that the State is not substantially enforcing the requirements. As necessary, CMS will provide additional information on enforcement. In direct enforcement States (currently, direct enforcement States are Alabama, Missouri, Oklahoma, Texas, and Wyoming), CMS enforces the market-wide provisions. Issuers in these States should work with CMS in instances in which this guidance references the "State."

beginning in 2016 maintains many aspects of the QHP certification process that CMS carried out in calendar year 2014 for plans effective beginning in 2015, including close coordination and collaboration with States. CMS is also incorporating some modified review standards as well as operational changes for the QHP certification process for plans effective beginning in 2016, as noted in this Letter.

Each section describes CMS's planned approach for evaluating QHPs against a certification standard when CMS is performing plan management functions for plan years beginning in 2016. States performing QHP certification reviews may exercise flexibility in their application of CMS's QHP certification standards, provided that the State's application of each standard is consistent with CMS regulations and guidance. Issuers seeking QHP certification in States that are performing plan management functions should continue to refer to State direction in addition to this guidance.

Similar to the QHP certification process for plan years beginning in 2015, States that choose to conduct reviews of QHP Applications and provide QHP certification recommendations to CMS for plan years beginning in 2016 will evaluate health plans against QHP certification standards. CMS will review the State's recommendations or findings to confirm that they are consistent with Federal regulatory standards and will communicate any concerns to the State. CMS is responsible for the final QHP certification decisions in each FFM, including FFMs in which CMS is not performing plan management functions.

In States not conducting reviews or making recommendations to CMS, CMS will continue to integrate State regulatory activities into its decision-making for QHP certification, provided that States make these determinations and provide information to CMS consistent with Federal standards and FFM timelines. These principles underlie the discussion in this Letter about the QHP certification process.

Section 1. QHP Application and Certification Process

This section describes how CMS, as administrator of the FFMs, will conduct QHP certification when CMS is performing the review and certification of QHPs, including SADPs.

In accordance with 45 C.F.R. part 155 subpart K, CMS will review, and approve or deny, QHP Applications from issuers that are applying to offer QHPs in the FFMs. Table 1.1 presents a high-level overview of key dates in the QHP certification process. Each major component of the process is described in greater detail in the subsections that follow.

For certification of a plan as a QHP effective beginning in 2016, issuers must submit a complete QHP Application for all plans they intend to offer on an FFM. Plans previously certified as QHPs must be recertified each calendar year that an issuer intends to continue to offer them on an FFM; or in the case of an FF-SHOP certification of a QHP, the QHP retains its certification

through the end of the employer's plan year, which may extend beyond the calendar year for which the FF-SHOP certified the QHP.

CMS will review QHP Applications against all QHP certification standards for issuers that are currently offering QHPs in an FFM, as well as issuers applying for QHP certification in an FFM for the first time. CMS expects States performing plan management functions in an FFM to review QHP Applications from all issuers applying for certification of a QHP for plan years beginning in 2016.

CMS intends to provide more specific guidance regarding the QHP certification timeline noted below before the beginning of the application submission window. Issuers are expected to adhere to the QHP certification timeline. Issuers that fail to meet deadlines or do not follow the process outlined below may have their QHP Application denied.

Issuers of SADPs will follow the same QHP Application timeline as that of medical plans. Issuers that wish to have SADPs certified by CMS for sale off the FFMs must also follow the same application timeline and requirements, with the exception of agreement signing.

Table 1.1. Key Dates for QHP Certification in the FFMs

Note: All dates are subject to change.

Activity		Dates (Approximate)
QHP Application Submission and Review Process	Initial FFM QHP Application Submission Window ⁴	4/15/2015 – 5/15/2015 ⁵
	FFM Review of Initial QHP Application Submissions Received as of May 15	5/18/2015 – 6/26/2015
	First Correction Notice Sent	6/29/2015 – 6/30/2015

⁴ URRT and Form Filing submissions to CMS in States in which CMS is either the Effective Rate Reviewer or direct enforcer of Federal law follow the same Initial Submission Window and Deadline as the QHP Initial FFM QHP Application Submission Window. This submission deadline applies to URRT and Form Filing submissions for QHPs and non-QHPs.

⁵ The deadline for a health insurance issuer to submit all QHP and non-QHP URR rate filing justifications to CMS and the applicable State is May 15th. The deadline for a State with an Effective Rate Review Program to post on the State's website at least the information contained in Parts I, II, and III of the Rate Filing Justification that CMS makes available on its website for proposed rate increases subject to review (or post a link to the information on the CMS website) is the 10th business day after receipt of all rate filings in the relevant market segment.

Activity		Dates (Approximate)
	Deadline for Submission of Revised QHP Data for Re-review	7/10/2015
	FFM Review of Corrected QHP Application Submissions Received as of July 10	7/13/2015 – 8/12/2015
	Second Correction Notice Sent	8/13/2015 – 8/14/2015
	Final Deadline for Submission of QHP Data; Final Deadline for State Plan Approval; Deadline for All Risk Pools with QHPs to be in “final” status in the URR System ^{6,7} ; Data Locked Down	8/25/2015
	Final FFM Review of Corrected QHP Application Submissions Received as of August 25	8/26/2015 – 9/16/2015
QHP Agreement/Final Certification	Certification Notices and QHP Agreements Sent to Issuers	9/17/2015 – 9/18/2015
	Agreements Signed by Issuers and Returned to CMS with Final Plan List	9/21/2015 – 9/25/2015
	Validation Notice Confirming Final Plan List and Countersigned Agreements Sent to Issuers	10/8/2015 – 10/9/2015
Open Enrollment		11/1/2015 – 1/31/2016

⁶ There are three final submission statuses in HIOS. All submissions in the single risk pool with QHPs that do not have any rate increases subject to review (rate increase less than 10%) must be in a status of “Rate Filing Accepted.” For submissions with rate increases that are subject to review (rate increase of 10% or greater), the submission must be in a status of “Review Complete” if the rate increase received a determination of “not unreasonable,” or in a status of “Final Justification Submitted” if the rate increase received a determination of “unreasonable” and the issuer has submitted the final justification.

⁷ All risk pools with no QHPs must be in final status in the URR system by October 9, 2015. *This footnote has been amended to reflect the correct date. All other content remains unchanged.*

i. *Registration and QHP Application*

To offer QHPs in the FFMs for plan years beginning in 2016 in States where CMS is performing both the primary review and certification of QHPs, health insurance issuers will complete QHP Applications electronically through the Health Insurance Oversight System (HIOS). Before submitting an application, issuers must register in the CMS Enterprise Identity Management System (EIDM) to gain access to HIOS where they request user roles (such as QHP Issuer Submitter and QHP Issuer Validator) and obtain HIOS user IDs. Issuers must obtain HIOS product and plan IDs. Once issuers have registered in the EIDM and HIOS systems, they are required to obtain a Health Plan Identifier (HPID) in the Health Plan and Other Entity System (HPOES) if they meet the definition of a controlling health plan at 45 C.F.R. § 162.103. In addition, each health plan that an issuer intends to offer on the Marketplace is required to obtain an HPID if it is a controlling health plan.⁸

CMS expects that between April 15, 2015 and May 15, 2015 issuers will access the QHP Application in HIOS to submit all information necessary for certification of health plans and SADPs as QHPs. CMS will use the QHP Application to collect both issuer-level information and plan-level benefit and rate data, largely through standardized data templates. Applicants will also be required to attest to their adherence to the regulations set forth in 45 C.F.R. parts 155 and 156, and provide requested supporting documentation. Based on the requirement set forth in 45 C.F.R. 156.340 that QHP issuers maintain responsibility for the compliance of their delegated and downstream entities, these attestations will also cover the adherence of the vendors and contractors of the issuer to applicable requirements.

Issuers seeking to offer QHPs must also submit the Unified Rate Review Template (URRT) to CMS via HIOS according to the same timeline referenced in Table 1.1 above. In the 2016 Payment Notice Final Rule, CMS requires issuers not seeking to offer QHPs to submit the URRT on this same timeline.

Under the Uniform Timeline for Submitting the URRT for on and off-Marketplace coverage, issuers will enter their submissions into the HIOS Rate Review Module for both their QHPs and their non-QHPs at the same time. In addition to the initial submission period, issuers will be able to make corrections to their URRT and upload supplemental materials needed to complete the review in direct enforcement States. In enforcing States when the State requires an issuer to make changes and the rate filing is altered, causing a change to the URRT, the issuer must revise its URRT in HIOS, ensuring that both the State and CCIIO have matching URRTs.

⁸ Additional information related to HPID requirements is available at: <http://www.cms.gov/ccio/Resources/forms-reports-and-other-resources/index.html#Health Insurance Market Reforms>.

Consistent with the approach for plan years beginning in 2015, issuers do not need to submit URRTs for SADPs.

ii. Issuer Data Collection and Coordination with States

CMS expects States to review plans seeking QHP certification for compliance with all applicable requirements under State law, as well as market-wide standards established by the Affordable Care Act. Specifically, CMS expects States to review these plans for compliance with essential health benefits (EHB) requirements and actuarial value (AV) standards, among others.⁹ State regulators may request access to QHP data templates to facilitate review of these plans.

Issuers in direct enforcement States will also be required to comply with any CMS requirements related to form filing, in addition to any applicable State requirements. Issuers may contact the CMS Form Filing Team at formfiling@cms.hhs.gov for details. Additionally, issuers in direct enforcement States will be required to submit rate filings for Federal rate compliance review. Issuers may contact the CMS Rate Review team at ratereview@cms.hhs.gov for details.¹⁰

CMS expects that States will establish the timeline, communication process, and resubmission window for any reviews conducted under State authority. As noted previously, issuers should comply with any State-specific guidelines for review and resubmission related to State-reviewed standards. CMS notes that issuers may be required to submit data to State regulators in addition to that required for QHP certification through the FFM, if required by a State, and must comply with any requests for resubmissions from the State or from CMS in order to be certified. CMS will coordinate with States to ensure that any State-specific review guidelines and procedures are consistent with applicable Federal law and operational deadlines. In addition, CMS will work with all State regulators near the end of the QHP certification cycle to confirm that all potential QHPs meet applicable State and Federal standards, and are approved for sale in the FFMs.

iii. FFM Review of QHP Applications

Issuers applying for QHP certification in the FFMs will submit complete and accurate QHP Applications through HIOS by May 15, 2015. CMS will not consider plans for which QHP Applications are received after this date. CMS will not conduct certification reviews of plans that

⁹ CMS notes that, because SADP issuers are only required under Federal law to adhere to pediatric dental EHB requirements for SADPs offered through a Marketplace, CMS does not have the same expectation of State review for SADPs offered through the Marketplace if such standards are otherwise not applicable under State law. Accordingly, CMS plans to review SADPs only for compliance with applicable Affordable Care Act standards.

¹⁰ Additional information on the CMS requirements for rate and form filings in direct enforcement States is available at: [http://www.cms.gov/ccio/Resources/forms-reports-and-other-resources/index.html#Health Insurance Market Reforms](http://www.cms.gov/ccio/Resources/forms-reports-and-other-resources/index.html#Health%20Insurance%20Market%20Reforms).

are submitted for offering only outside of the FFM. Additionally, if an issuer changes its application to indicate that plans will only be offered outside of the FFMs, such plans will no longer be eligible for certification. CMS reviews all prospective SADPs, whether offered on or off an FFM.

CMS expects to review FFM QHP Applications in two rounds: the first review period occurring between May 18 and June 26, 2015 and the second review period occurring between July 13 and August 12, 2015. Following each review period, CMS will send applicants notices summarizing any need for corrections identified during CMS's review. Issuers will be able to upload revised QHP data templates and make other necessary changes to QHP Applications in response to CMS's feedback until August 25, 2015. Issuers must submit all final QHP data by August 25, 2015.

Issuers may withdraw plans prior to August 25, 2015 by removing the plan from their QHP Application and submitting a plan withdrawal notification form.¹¹ Issuers will be given a final opportunity to withdraw plans during the agreement signing process.

After August 25, 2015, CMS will conduct a final round of review and make final certification decisions. CMS will notify issuers of its certification decisions between September 17 and September 18, 2015 followed by the QHP Agreement signing process. Issuers will not have an opportunity to make any further corrections to their QHP Application data after receiving CMS certification notices and prior to QHP Agreement signing.

iv. Data Changes

Issuers applying for QHP certification will be able to view plan data in the Plan Preview environment in order to identify and correct data submission errors before the final QHP Application data submission deadline.

During the certification process for plan years beginning in 2016, CMS will allow issuers to make changes to their QHP Application based on the guidelines below. These changes are in addition to any corrections that CMS has identified during its review of QHP Applications. Table 1.2 presents a high-level overview of key dates during the QHP data change process for FFMs. Each phase of the process is described in greater detail in the subsections that follow Table 1.2.

¹¹ The plan withdrawal notification form discussed here is not the same as HIPAA product discontinuation or market withdrawal. CMS intends to provide more details on the form for withdrawal from QHP certification in future guidance.

Table 1.2. Key Dates for QHP Data Changes in the FFMs

Note: All dates are subject to change.

Activity	Allowed Changes	Dates (Approximate)
Initial Application Submission	Issuers will submit QHP Applications including recertification for 2015 plans and new 2016 plans. Issuers may make any changes to their data without State or CMS authorization.	4/15/2015 – 5/15/2015
QHP Review and Modification	No new plans may be submitted. Petition to CMS required for changes to service area. Petitions must be submitted by 8/11/2015. For all other changes, issuers are not required to submit petitions or document State authorization to CMS. CMS will monitor all data changes and contact issuers if there are concerns about changes made.	5/16/2015 – 8/25/2015
After Final Data Submission	No further data changes allowed prior to Certification. CMS may allow issuers to make critical post-certification data corrections in order to: • Correct data display errors on HealthCare.gov, and • Align QHP plan display with products and plans approved by the State. Post-certification data corrections require data change petitions and State and CMS	8/26/2015 – onward

	approval. Allowed changes will occur during periodic, scheduled limited data correction windows.	

Initial Application Submission

As described in Section 1 of Chapter 1, issuers will submit their initial QHP Applications between April 15 and May 15, 2015, including applications for SADPs to be offered on and off the FFM. ¹² Issuers that intend to include new QHPs must submit their 2016 QHP Application data during this submission window. Issuers that are requesting recertification of 2015 QHPs must follow the guidelines in Chapter 1, Section 3 for recertification for 2016.

QHP Review and Modification

After the close of the initial QHP Application submission window, issuers will be able to upload revised data templates on an as-needed basis until the final data submission deadline of August 25, 2015. Issuers will be able to upload revised QHP data templates and make other necessary changes to QHP Applications in response to State or CMS feedback until the final data submission deadline. An issuer may also submit a petition to make service area changes during this period, as further described below. All changes must be authorized by the State, but issuers are only required to submit evidence of State approval for service area changes. For QHPs in direct enforcement States, the CMS Form Filing team, instead of the State, must authorize data changes. CMS reviews will be based on the issuer QHP data as of the specific due dates as listed in Table 1.1.

After the initial submission deadline of May 15, 2015, issuers cannot add new plans to a QHP Application or change an off-Marketplace plan to both on- and off-Marketplace.

CMS intends to implement a petition process to receive and review requests for service area changes after the initial application deadline of May 15, 2015, but before the final data submission deadline on August 25, 2015. The petition process will require a signed data change

¹² URRT and Form Filing submissions to CMS in States in which CMS is either the Effective Rate Reviewer or direct enforcer of federal law follow the same Initial Submission Window and Deadline as the QHP Initial FFM QHP Application Submission Window. This submission deadline applies to URRT and Form Filing submissions for QHPs and non-QHPs. The deadline for a State with an Effective Rate Review Program to post on the State's website (if the State elects to post on its website) at least the information contained in Parts I, II, and III of the Rate Filing Justification that CMS makes available on its website is the 10th business day after receipt of all rate filings in the relevant market segment.

request form, justification for the change, and evidence of State approval. Requests for service area changes must be submitted with evidence of State approval at least two weeks prior to the final data submission deadline in order to allow CMS sufficient time for review. Issuers must submit approved service area changes to QHP Applications prior to the final data submission deadline of August 25, 2015.

CMS will monitor all data changes made by issuers during this period. If there are concerns about changes made, CMS will contact the issuer to determine next steps.

Data changes to plans that are being recertified must follow the uniform modification guidelines, as outlined in Chapter 1, section 3, “Recertification for 2016.”

After Final Data Submission

After August 25, 2015, HIOS will close and no additional QHP data changes will be allowed until CMS completes its certification decisions and issuers sign the QHP Privacy and Security Agreement and Senior Official Acknowledgement. After this occurs, CMS may offer limited data correction windows, during which issuers will not be allowed to make further changes to QHP data unless changes are pre-approved by CMS and the State. For QHPs in direct enforcement States, the CMS Form Filing team instead of the State must authorize data changes, so, for issuers in direct enforcement States, references here to the “State” mean the CMS Form Filing team. During a data correction window, issuers may request to make changes necessary to correct data display errors or align QHP data with products and plans as approved by the State, or from a limited list of changes that do not impact certification, such as URLs and plan marketing names. Issuers will be required to provide a justification for any requested changes and submit a signed data change request form and evidence of State approval. Issuers are responsible for ensuring that requested changes are in compliance with Federal QHP certification standards set forth in the Affordable Care Act, Federal regulations, and all other guidelines discussed in this Letter. Discrepancies between the issuer’s QHP filings and approved State filings may result in a plan not being certified or a compliance action if CMS has already certified a plan as a QHP. Issuers that request to make changes that affect consumers may be suppressed until the data are refreshed for consumer display. Additional requirements may apply, and CMS intends to release further instructions about this process.

v. QHP/SADP Certification and Privacy and Security Agreement and Senior Officer Acknowledgements

As with the certification process for plan years beginning in 2015, issuers intending to offer QHPs or SADPs in the FFMs, including issuers in States performing plan management functions, will be required to sign and submit to CMS a QHP Privacy and Security Agreement and a Senior Officer Acknowledgement. Issuers will submit these signed agreements along with a final list of QHPs and SADPs they intend to offer on the FFMs. Among other things, the QHP Privacy and Security Agreement will include provisions for safeguarding the privacy of plan

applicant and participant data in the FFM and standards for issuer testing prior to the beginning of open enrollment. An officer of the legal entity who has legal authority to contractually bind the issuer must sign the agreement. The Senior Officer Acknowledgment includes provisions confirming that a senior officer of the issuer has knowledge of the content of the issuer's plans, as well as the content of the completed attestations and this Letter.

CMS will review these submissions and, if they are accurate and complete, sign and return the QHP Privacy and Security Agreement to issuers. The receipt of a signed QHP Privacy and Security Agreement completes the certification process for the following plan year. CMS will not sign the Senior Officer Acknowledgement.

The documents will apply to all of the QHPs offered by a single issuer in the FFM at the HIOS Issuer ID level or designee company.

Of note, issuers should ensure that the legal entity information listed in HIOS under the Issuer General Information section is identical to the legal entity information that will be used when executing the documents.

vi. *Sale of Ancillary Products on the FFMs*

Ancillary insurance products and health plans that are not QHPs (e.g., stand-alone vision plans, disability, or life insurance products) will not be offered on the FFMs. The FFMs will only offer QHPs and SADPs.

Section 2. QHP Certification Process in a State Performing Plan Management Functions in the FFMs

This section describes how States performing plan management functions in the FFMs will conduct QHP Application reviews. Issuers applying in States where CMS is performing all QHP Application review and QHP certification should refer to Section 1 of Chapter 1.

In FFMs where the State is performing plan management functions, issuers will work directly with the State to submit all QHP issuer application data in accordance with State guidance.¹³ States performing review of QHP Applications will generally utilize the System for Electronic Rate and Form Filing (SERFF) to collect QHP Applications from issuers. The State will review QHP Applications for compliance with the standards described in this guidance and will provide a certification recommendation for each proposed plan to CMS. CMS will review and confirm the State's QHP certification recommendations, make final QHP certification decisions, and load

¹³ CMS will work with States performing plan management functions in the FFM to ensure that such guidance is consistent with Federal regulatory standards and operational timelines.

certified QHP plans on the Marketplace website. CMS will work closely with States that are performing plan management functions to coordinate this process.

As indicated in Table 1.3, the QHP certification process in States where the State is performing plan management functions will align with the process for issuers for which CMS is performing the review. Issuers are expected to adhere to the QHP certification timeline. Issuers that fail to meet deadlines or do not follow the process outlined below may have their QHP Applications denied. Each phase of the process is described in greater detail in the subsections that follow. CMS also intends to provide more specific information regarding the QHP certification timeline as the application submission period for plan years beginning in 2016 approaches.

Table 1.3 Key Dates for QHP Certification in FFM States Where the State is Performing Plan Management Functions

Note: All dates are subject to change.

Activity		Dates (Approximate)
QHP Application Submission and Review Process	Issuers Submit Plan Data to States and States Review	Varied ¹⁴
	First SERFF Data Transfer Deadline for States ¹⁵	5/15/2015
QHP Application Submission and Review Process	FFMs Review Plan Data	5/18/2015 – 6/26/2015
	FFMs Notify States and Issuers of any Needed Corrections to QHP Data	6/29/2015 – 6/30/2015
	Issuers Resubmit Plan Data into SERFF	Varied ¹⁶
	Second SERFF Data Transfer Deadline for States	7/10/2015
	FFMs Conduct Re-review of Plan Data	7/13/2015 –

¹⁴ Date varies as determined by each respective State application submission deadline.

¹⁵ The deadline for a health insurance issuer to submit (and validate in HIOS) all QHP and non-QHP URR rate filing justifications to CMS and the applicable State is May 15th.

¹⁶ Date varies as determined by each respective State application submission deadline.

Activity		Dates (Approximate)
		8/12/2015
	FFMs Notify States and Issuers of any Needed Corrections to QHP Data	8/13/2015 – 8/14/2015
	Issuers Resubmit Plan Data into SERFF	Varied ¹⁷
	Final SERFF Transfer Deadline for Submission of QHP Data and Certification Recommendations; Deadline for All Risk Pools with QHPs to be in “Final” Status in the URR System; Data Locked Down	8/25/2015 ¹⁸
	FFMs Conduct Final Review of QHP Application Data	8/26/2015 - 9/16/2015
QHP Agreement/Final Certification	Certification Notices and QHP Agreements Sent to Issuers	9/17/2015 – 9/18/2015
	Agreements Signed by Issuers and Returned to CMS with Final Plan List	9/21/2015 – 9/25/2015
	Validation Notice Confirming Final Plan List and Countersigned Agreements Sent to Issuers	10/8/2015 – 10/9/2015
Open Enrollment		11/1/2015 – 1/31/2016

i. QHP Application and State Review Process

An issuer’s HIOS issuer ID will be used to link the State and Federal records for a given issuer or QHP. Therefore, like an issuer applying in HIOS, an issuer submitting an application to a State via SERFF must access HIOS and obtain the necessary identification numbers and user roles.

Issuers in States performing plan management functions in the FFMs are to submit QHP Applications, typically in SERFF, according to the timeline set by each State. Each State will

¹⁷ Date varies as determined by each respective State application submission deadline.

¹⁸ All risk pools with no QHPs must be in “final” status in the URR system by October 9, 2015.

define the relevant submission window as well as dates and processes for corrections and resubmissions. Issuers seeking to offer QHPs must submit the URRT to the State, and to CMS via HIOS, on the same timeline as the submission of the QHP Application. In the 2016 Payment Notice Final Rule, CMS requires issuers not seeking to offer QHPs to submit the URRT on the same timeline. Issuers that are applying for QHP certification in States performing plan management functions in the FFMs should not submit QHP Applications into HIOS.

CMS will provide three defined SERFF data transfer deadlines in order to better coordinate the flow of QHP data from States performing plan management functions in the FFMs. The first SERFF data transfer will take place by May 15, 2015 and will constitute an initial transfer by each State. This transfer should include all plans submitted to the State for certification including SADPs for off-Marketplace sale. CMS will treat all data transferred by May 15, 2015 as draft data. QHP data in this transfer do not need to be final, and the plans included in the transfer do not need to be in final, approved status. CMS will review the plan data in the initial transfer, and will notify States and issuers of any needed corrections. States will work with issuers to revise their submissions according to CMS and State feedback.

The second SERFF transfer deadline is July 10, 2015. CMS will review the data transferred by July 10, 2015 and will notify States and issuers of any needed corrections. States will again be able to work with issuers to revise their submissions according to CMS and State feedback.

A State must transfer all final plan data from SERFF to HIOS by August 25, 2015 and CMS will use the data transferred by August 25, 2015 to make final QHP certification decisions based on State recommendations. CMS will notify issuers of its certification decisions between September 17 and September 18, 2015 followed by the QHP Agreement signing process. Issuers will not have an opportunity to make any further corrections to their QHP Application data after receiving CMS certification notices and prior to QHP Agreement signing.

ii. Data Changes

Issuers in States performing plan management functions in the FFMs will be able to view their plan data once Plan Preview is available and after the State transfers QHP data from SERFF to HIOS. Issuers in these States will be able to review plan data and make any necessary corrections in SERFF according to the timeline established by the State. Changes will be reflected once the State retransfers plan data from SERFF to HIOS.

After August 25, 2015, SERFF data submissions will close, and no additional changes will be allowed until after CMS makes certification decisions and issuers sign the QHP Agreement. Issuers should work with their State to determine State specific data change deadlines prior to August 25, 2015. After QHP Agreement signing, CMS may offer the opportunity for a limited data correction window.

Any changes to QHP data transferred to HIOS must follow the data changes process described in Section 1, subsection iv of Chapter 1.

Section 3. Recertification for 2016

i. Policy and Process for Recertification

For plan years beginning in 2016, CMS's process for recertifying a QHP or SADP that was certified for the 2015 benefit year will largely mirror the 2014 process for certification of a plan. Issuers seeking recertification will submit all information required under the 2016 QHP Application for plans that were QHPs or SADPs in 2015. CMS anticipates moving to a more streamlined recertification process for future plan years.

To be eligible for recertification for plan years beginning in 2016, a QHP or SADP certified by an FFM must be the same "plan," as defined in 45 C.F.R. 144.103, as the plan that was certified for plan years beginning in 2015. CMS will use the amended definition of "plan" from §144.103 of the 2016 Payment Notice Final Rule. The same definition of "plan" also will apply to reenrollment of current enrollees into the same plan, pursuant to §155.335(j). CMS intends to use this standard (45 C.F.R. 144.104) to determine whether an SADP is eligible for recertification. A QHP or SADP recertified for plan years beginning in 2016 must use the same HIOS plan identification numbers that it used for its certification for plan years beginning in 2015.

If an issuer chooses to not recertify a plan in the Marketplace, it is subject to the standards outlined in 45 C.F.R. 156.290.

ii. Plan ID Crosswalk

For the individual market 2015 plan year, CMS developed and released a Plan ID Crosswalk Template for issuers to complete and submit to CMS. For the FFMs, this template cross-walked 2014 QHP plan ID and service area combinations (e.g., Plan ID and county combinations) to a 2015 QHP plan ID. This data facilitated enrollment transactions from CMS to the issuer in mid-December 2014 for those individual market enrollees who had not actively selected a different QHP during open enrollment at that time.

CMS expects to implement a similar approach for automatic re-enrollment from 2015 to 2016 QHPs in the FFMs. In addition, CMS expects that the FF-SHOPs will support automatic re-enrollment of employees and dependents for plan years beginning in 2016. As a result, issuers that offered plans on the individual market FFMs as well as the FF-SHOPs in plan years beginning in 2015, including QHPs and SADPs, should submit Plan ID Crosswalk data.

To note, SADPs, as excepted benefits, are not subject to the guaranteed renewability standards specified at 45 C.F.R. 147.106. However, as CMS has indicated in previous guidance, it again aims to apply the hierarchy set forth at 45 C.F.R. 155.335(j) and the business rules established

for the 2016 Plan ID Crosswalk Template to SADPs in order to support automatic re-enrollment for re-enrollment plan years beginning in 2016.

For a submission process, CMS expects that issuers will submit the template to a CMS email address, which is the same method that was used for plan years beginning in 2015.

CMS will conduct an overall data integrity review of submitted Plan ID Crosswalk data. This will include, but not be limited to, an evaluation for compliance with 45 C.F.R. 155.335(j).¹⁹ This will also include a review for consistency with submitted Service Area and Plans and Benefits Template data for both 2015 and 2016.

Section 4. OPM Certification of Multi-State Plan (MSP) Options

This section provides additional guidance for health insurance issuers seeking to offer Multi-State Plan (MSP) options in FFM and State-based Marketplaces (SBMs).

The U.S. Office of Personnel Management (OPM) is responsible for implementing the MSP Program as required under section 1334 of the Affordable Care Act. In accordance with section 1334(d) of the Affordable Care Act, MSP options offered by MSP issuers under contract with OPM are deemed to be certified by a Marketplace.

OPM anticipates that the process for MSP issuers to participate in a Marketplace for the 2016 benefit year will largely mirror that used for 2015, subject to finalization of a proposed rule for the program published on November 24, 2014.²⁰ Issuers seeking to offer MSP coverage must apply to participate via OPM's online application portal. OPM will evaluate issuer applications and determine which issuers are qualified to become MSP issuers. OPM works closely with States in reviewing benefits and rates to achieve its goals of offering more choice for consumers and maintaining a level playing field for all issuers within a State.

OPM's contract with each MSP issuer identifies each MSP option that the issuer will offer and in what State it will be offered. Each MSP option so identified is deemed to be certified by OPM to be offered through the Marketplace(s) operating in those States. In addition, the MSP Program contract sets forth performance requirements for MSP issuers.

¹⁹ Patient Protection and Affordable Care Act; Annual Eligibility Redeterminations for Exchange Participation and Insurance Affordability Programs; Final Rule, 79 Federal Register 52994 (September 5, 2014); codified at 45 C.F.R. parts 146, 147, 148, 155, and 156.

²⁰ Patient Protection and Affordable Care Act; Establishment of the Multi-State Plan Program for the Affordable Insurance Exchanges; Propose rule; 79 FR 69802; November 24, 2014.

For more information on requirements for MSP issuers, issuers should visit <http://www.opm.gov/healthcare-insurance/multi-state-plan-program/issuer/>. OPM will post specific instructions regarding the 2016 application timeline and process when available.

The 2016 MSP Program Call Letter was released on January 22, 2014 and is available at <http://www.opm.gov/healthcare-insurance/multi-state-plan-program/program-guidance/#url=2015>. This letter serves as OPM's annual call for applications and recertification submissions from prospective and current MSP issuers. It also highlights program priorities and re-emphasizes MSP issuers' obligations around the Program's External Review Process and coverage of abortion services.

CHAPTER 2: QUALIFIED HEALTH PLAN AND STAND-ALONE DENTAL PLAN CERTIFICATION STANDARDS

Section 1. Licensure and Good Standing

This section describes issuer requirements for licensure and good standing and how CMS will review prospective QHPs and SADPs for compliance with these standards in the FFM. States performing plan management functions may use a similar approach. This approach is largely the same approach used in 2015. However, the 2015 Letter to Issuers described a State Certification Form. CMS does not intend to use such a form for 2016 certification.

The following is a summary of key points:

- Each QHP issuer must be licensed and in good standing in each State in which it applies to offer QHPs for the applicable market, product type, and service area (see 45 C.F.R. 156.200(b)(4)).
- CMS interprets “good standing” to mean that an issuer faces no outstanding sanctions imposed by a State’s department of insurance. Therefore, the specific violations or infractions that would jeopardize standing may vary by State. Issuers must be in good standing to offer health insurance coverage in each State in which the issuer offers health insurance coverage, and in compliance with all applicable State laws that the State imposes as conditions of offering health insurance in the State provided that the applicable laws are in accordance with Federal law.
- Issuers must provide one of the following supporting documents as part of the QHP Application: State license, certificate of authority, certificate of compliance, or an equivalent form or document for the product(s) in the service area(s) in which the issuer intends to offer a QHP.
- Issuers applying for QHP certification must be able to demonstrate State licensure by no later than 90 days prior to open enrollment.

Section 2. Service Area

This section describes requirements for an issuer's service area(s) and how CMS will conduct its review for compliance with this standard in the FFMs. States performing plan management functions may use a similar approach. This approach is the same approach used in 2015 and applies to both QHPs and SADPs.

The Marketplace must ensure that each service area of a QHP covers a minimum geographic area that is at least the entire geographic area of a county, or a group of counties defined by the Marketplace, unless the Marketplace determines that serving a smaller geographic area is necessary, nondiscriminatory, and in the best interest of the qualified individuals and employers (see 45 C.F.R. 155.1055(a)). The Marketplace must also ensure that the service area of a QHP has been established without regard to racial, ethnic, language, or health status-related factors as specified under section 2705(a) of the Public Health Service (PHS) Act, or other factors that exclude specific high utilizing, high cost or medically-underserved populations (see 45 C.F.R. 155.1055(b)). CMS considers the service area of a plan to be the county or set of counties (or partial counties) that is covered by that particular plan. CMS will review requests for service areas that serve a geographic area smaller than a county (i.e., a partial county request) to ensure that each service area meets the above regulatory standards.

Any change to the list of counties associated with a particular plan is considered a change in the service area, even if the issuer offers other plans or products in the counties (or partial counties) in question.

QHP issuers will not be allowed to change their plans' service area after their initial data submission except via petition to CMS. Petitions for service area changes must follow a CMS-prescribed format that will be detailed in future guidance and will only be allowed with State approval. Changes to service areas will only be approved under very limited circumstances. CMS will not allow changes to service area after the final data submission date. For additional information on the data change process, please see Chapter 1, Section IV.

Section 3. Network Adequacy

This section includes information on network adequacy evaluation and network provider directory requirements. This section applies to QHPs and SADPs.

i. Network Adequacy Standard

This section describes how CMS will conduct its network adequacy review during 2016 QHP certification and recertification. States performing plan management functions may use a similar approach.

Pursuant to 45 C.F.R. 156.230(a)(2), an issuer of a QHP that uses a provider network must “maintain a network that is sufficient in number and types of providers, including providers that specialize in mental health and substance use disorder services, to assure that all services will be accessible to enrollees without unreasonable delay.” All issuers applying for QHP certification will need to attest that they meet this standard as part of the certification/recertification process.

As was done during the 2015 certification process, for 2016 certification CMS will assess provider networks using a “reasonable access” standard in order to identify networks that fail to provide access without unreasonable delay, consistent with requirements specified at 45 C.F.R. 156.230(a)(2). In order to determine whether an issuer meets the “reasonable access” standard, each issuer will submit detailed network provider data as part of its QHP certification application, including information on its physicians, facilities, and pharmacies as part of the certification process. CMS will analyze each issuer's network data and will focus most closely on those areas which have historically raised network adequacy concerns. CMS expects that these areas will include the following:

- Hospital systems,
- Mental health providers,
- Oncology providers,
- Primary care providers, and
- Dental providers, if applicable.

If CMS determines that an issuer's network may be inadequate under the reasonable access review standard, CMS will notify the issuer of the identified problem area(s) during the certification review process and will request that the issuer address the concern by adding providers to its network or submitting a justification explaining how it will provide reasonable access to enrollees in the area(s) identified. CMS will use the issuer's updated provider data, and any written justifications submitted as part of the certification process, in assessing whether the issuer has met the regulatory requirement prior to making the certification or recertification determination. CMS will share information about its analysis and coordinate with States that are conducting network adequacy reviews. CMS intends to provide additional technical detail regarding the collection method for the network data, and instructions explaining what should be included in any justification, as part of the 2016 certification/recertification application instructions. CMS also reminds issuers that they must meet network adequacy standards throughout the year, as providers enter and leave the network, and not just at certification. CMS will continue to monitor network adequacy, for example, via complaint tracking, to determine whether the QHP's network(s) continues to meet the current network adequacy standards.

CMS also intends to use information learned during the QHP certification process to assist in its articulation of future network adequacy standards in future rulemaking. Additionally, the National Association of Insurance Commissioners has formed a workgroup that is considering

revisions to its *Managed Care Network Adequacy Model Act*. CMS intends to evaluate the results of this workgroup in considering future additional rulemaking.

ii. *Provider Directory Links*

Pursuant to the 45 C.F.R. 156.230(b), CMS, as administrator of the FFM, will require QHPs to make their provider directories available to the FFM for publication online by providing the URL link to their network directory. As stated in the 2016 Payment Notice Final Rule, CMS is strengthening the provider directory requirement. Specifically, a QHP issuer must publish an up-to-date, accurate, and complete provider directory, including information on which providers are accepting new patients, the provider's location, contact information, specialty, medical group, and any institutional affiliations, in a manner that is easily accessible to plan enrollees, prospective enrollees, the State, the FFM, HHS, and OPM. A provider directory will be considered up-to-date if it is updated at least monthly and easily accessible when the general public is able to view all of the current providers for a plan in the provider directory on the issuer's public website through a clearly identifiable link or tab without having to create or access an account or enter a policy number. The general public should be able to easily discern which providers participate in which plan(s) and provider network(s). Further, if the health plan issuer maintains multiple provider networks, the plan(s) and provider network(s) associated with each provider, including the tier in which the provider is included, should be clearly identified on the website and in the provider directory.

CMS is also requiring issuers to make this information publicly available on their websites in a machine-readable file and format specified by HHS, to allow the creation of user-friendly aggregated information sources. The purpose of establishing machine-readable files with this data is to provide the opportunity for third parties to create resources that aggregate information on different plans. We believe this will increase transparency by allowing software developers to access this information and create innovative and informative tools to help enrollees better understand the availability of providers in a specific plan. CMS established these provider directory requirements to enhance the transparency of QHP provider directories and to help consumers make more informed decisions about their health care coverage.

The content of this section applies to all QHP issuers in the FFM, including in States performing plan management functions in the FFM.

Section 4. Essential Community Providers

This section describes how CMS plans to conduct reviews of the essential community provider (ECP) standard for QHP and SADP certification and recertification in 2016. States performing plan management functions in the FFM may use a similar approach.

ECPs include providers that serve predominantly low-income and medically underserved individuals, and specifically include providers described in section 340B of the PHS Act and

section 1927(c)(1)(D)(i)(IV) of the Social Security Act. In the 2016 Payment Notice Final Rule, we clarified that ECPs may also include not-for-profit or State-owned providers that are entities described in section 340B of the PHS Act but do not participate in the 340B Program, as these providers satisfy the same 340B eligibility requirements and therefore meet the definition of ECPs by virtue of the following description in section 1311(c)(1)(C) of the Affordable Care Act – “health care providers defined in section 340B(a)(4) of the PHS Act and providers in section 1927(c)(1)(D)(i)(IV) of the Act.” For the same reasons described above, not-for-profit or governmental family planning service sites that do not receive a grant under Title X of the PHS Act also qualify as ECPs. Furthermore, Indian health care providers are included among other ECPs, as reflected in Table 2.1. At 45 C.F.R. 156.235, CMS established requirements for inclusion of ECPs in QHP provider networks and provided an alternate standard for issuers that provide a majority of covered services through physicians employed by the issuer or a single contracted medical group.

i. Evaluation of Network Adequacy with respect to all ECPs

Because the number and types of ECPs available vary significantly by location, and consistent with the approach in prior years, CMS intends to evaluate QHP Applications for sufficient inclusion of ECPs for plan years beginning in 2016 against the ECP inclusion standard described below.

General ECP Standard

Similar to 2015, for plan years beginning in 2016, CMS will utilize a general ECP enforcement standard whereby it will consider the issuer to have satisfied the regulatory standard if an application demonstrates satisfaction of the following criteria:

- Contracts with at least 30 percent of available ECPs in each plan’s service area to participate in the plan’s provider network;
- Offers contracts in good faith to all available Indian health care providers in the service area, to include the Indian Health Service, Indian Tribes, Tribal organizations, and urban Indian organizations, applying the special terms and conditions necessitated by Federal law and regulations as referenced in the recommended model QHP Addendum²¹ for Indian health care providers developed by CMS; and

²¹ The model QHP Addendum for Indian health care providers is available at: <http://www.cms.gov/ccio/programs-and-initiatives/health-insurance-marketplaces/qhp.html>.

- Offers contracts in good faith to at least one ECP in each ECP category (see Table 2.1) in each county in the service area, where an ECP in that category is available and provides medical or dental services that are covered by the issuer plan type.

To be offered in good faith, a contract should offer terms that a willing, similarly-situated, non-ECP provider would accept or has accepted. CMS will expect issuers to be able to provide verification of such offers if CMS requests to verify compliance with the policy.

As in previous years, issuers will indicate which ECPs are included in their provider network(s) by populating a template as part of the QHP Application. CMS will provide application materials with detailed instructions to support issuers in completing the template.

To assist issuers in identifying these providers, CMS has published a non-exhaustive list of available ECPs based on data maintained by CMS and other Federal agencies, which issuers may use to assess their satisfaction of the ECP standard. This non-exhaustive list is updated annually near the beginning of the calendar year and is available at:

<http://cciio.cms.gov/programs/exchanges/qhp.html>.

In the 2016 Payment Notice Final Rule, we clarified that for purposes of inclusion on the non-exhaustive ECP list, those Medicare-certified rural health clinics (RHCs) that meet the following two requirements will be included: 1) based on attestation, the clinic accepts patients regardless of ability to pay and offers a sliding fee schedule; or is located in a primary care Health Professional Shortage Area (geographic, population, or automatic²²); and 2) Accepts patients regardless of coverage source (i.e., Medicare, Medicaid, CHIP, private health insurance, etc.). CMS has determined that all RHCs included on the non-exhaustive ECP list meet these standards.

Issuers will be permitted to write in ECPs not on the HHS non-exhaustive ECP list for consideration as part of CMS's certification review, conditioned on the issuer satisfying the ECP write-in criteria provided below. Examples of allowable write-ins include any providers that are currently eligible to participate in the 340B program but that are not included on the HHS non-exhaustive ECP list, or not-for-profit or State-owned providers that would be entities described

²² As of January 1, 2014, more than 1,000 Rural Health Clinics (RHCs) were designated as an automatic Health Professional Shortage Area (HPSA), the criteria for which include accepting patients regardless of ability to pay; offering a sliding fee schedule based on ability to pay (income); and accepting Medicare, Medicaid, CHIP, and private health insurance patients. To receive the automatic HPSA designation, each RHC is required to complete an attestation form, which is available at: <http://bhpr.hrsa.gov/shortage/hpsas/certofeligibility.pdf>. CMS intends to include RHCs that are not listed on the current non-exhaustive ECP list and complete the attestation form to receive an automatic HPSA designation through the Health Resources and Services Administration in future non-exhaustive ECP lists. More information about the HPSA designation requirements and process is also available at: <http://bhpr.hrsa.gov/shortage/hpsas/ruralhealthhpsa.html>.

in section 340B of the PHS Act, but do not participate in the Program. Such providers include not-for-profit or governmental family planning service sites that do not receive a grant under Title X of the PHS Act. Other providers that provide health care to populations residing in low-income zip codes or Health Professional Shortage Areas (HPSAs) could also be considered ECPs, on the condition that they do not limit their practice on the basis of a particular source of coverage (i.e., Medicare, Medicaid, CHIP, private health insurance, etc.).

To write in a provider not on the HHS non-exhaustive ECP list, an issuer must include the following information:

- The provider’s zip code reflecting provider location within a low-income zip code or HPSA included on the “Low-Income and Health Professional Shortage Area Zip Code Listing”²³;
- The provider’s street address (P.O. Box not sufficient, and only one ECP will be counted per address); and
- The National Provider Identifier (NPI) number, if the provider has an NPI number.

CMS will determine issuer satisfaction of the 30 percent ECP standard using the following calculation methodology:

- The denominator of available ECPs consists of any ECPs on the non-exhaustive HHS list of ECPs that are located within the plan’s service area and any allowable ECP write-ins that are located within the plan’s service area that the issuer has chosen to list on its template.
- The numerator of the issuer’s contracted ECPs consists of any ECPs that the issuer has listed from the non-exhaustive HHS list of ECPs that are located within the plan’s service area and any allowable ECP write-ins that are located within the plan’s service area that the issuer has chosen to list on its template.
- Applicable to both the numerator and denominator, multiple providers at a single street location will count as one ECP toward the available ECPs in the plan’s service area and toward the issuer’s satisfaction of the ECP participation standard to ensure a sufficient number and geographic distribution of ECPs as required under 45 C.F.R. 156.235(a).

If an issuer’s application does not satisfy the 30 percent ECP standard as well as the requirement to offer contracts in good faith to all available Indian health care providers in the service area,

²³ “Low-Income and Health Professional Shortage Area (HPSA) Zip Code Listing,” available at: <http://www.cms.gov/ccio/programs-and-initiatives/health-insurance-marketplaces/qhp.html>

and at least one ECP in each ECP category in each county in the service area, as described above, the issuer will be required to include as part of its application a satisfactory narrative justification describing how the issuer's provider network(s), as presently constituted, provides an adequate level of service for low-income and medically underserved individuals and how the issuer plans to increase ECP participation in the issuer's provider network(s) in future years. Issuers that submit a narrative justification will do so as part of the issuer application for QHP certification.

At a minimum, such narrative justification would include the following:

- The number of contracts offered to ECPs for plan years beginning in 2016;
- The number of additional contracts an issuer expects to offer for plan years beginning in 2016 and the timeframe of those planned negotiations;
- The names of the ECP hospitals, FQHCs, Indian health care providers, Ryan White providers, family planning providers, and providers in the other ECP categories listed in Table 2.1 to which the issuer has offered contracts in good faith, but an agreement with the providers has not yet been reached; and
- Contingency plans for how the issuer's provider network, as currently designed, will provide adequate care to enrollees who might otherwise be cared for by relevant ECPs. For example, if available FQHCs, Indian health care providers, Ryan White HIV/AIDS Program providers, or family planning providers are missing from the network(s), the Application must explain how its target populations will be served.

Table 2.1: 2016 ECP Categories and Provider Types in the FFM

Major ECP Category	ECP Provider Types
Family Planning Providers	Title X Family Planning Clinics and Title X "Look-Alike" Family Planning Clinics
Federally Qualified Health Centers (FQHC)	FQHC and FQHC "Look-Alike" Clinics, Outpatient health programs/facilities operated by Indian tribes, tribal organizations, programs operated by Urban Indian Organizations
Hospitals	Disproportionate Share Hospital (DSH) and DSH-eligible Hospitals, Children's Hospitals, Rural Referral Centers, Sole Community Hospitals, Free-standing Cancer Centers, Critical Access Hospitals

Major ECP Category	ECP Provider Types
Indian Health Care Providers	Indian Health Service (IHS providers), Indian Tribes, Tribal organizations, and urban Indian Organizations
Ryan White Providers	Ryan White HIV/AIDS Program Providers
Other ECP Providers	STD Clinics, TB Clinics, Hemophilia Treatment Centers, Black Lung Clinics, Community Mental Health Centers, Rural Health Clinics, and other entities that serve predominantly low-income, medically underserved individuals.

Alternate ECP Standard

Issuers that qualify for the alternate ECP standard articulated in 45 C.F.R. 156.235(a)(2) and (b)²⁴ must demonstrate a sufficient number and geographic distribution of employed providers and hospital facilities, or providers of its contracted medical group and hospital facilities to ensure reasonable and timely access for low-income, medically underserved individuals in the plan's service area, in accordance with the Marketplace's network adequacy standards. CMS interprets this standard as being met if the issuer complies with the ECP standard described above, based on employed or contracted providers located in HPSAs or 5-digit low-income zip codes in which 30 percent or more of the population falls below 200 percent of the Federal poverty line (FPL).

To ensure that consumers experience equal access to covered benefits, regardless of whether they are enrolled in plans offered by issuers that qualify for the general or the alternate ECP standard, issuers that qualify for the alternate ECP standard must provide access to the same categories of services provided by entities in each of the ECP categories in each county in the plan's service area as issuers that qualify for the general ECP standard. Therefore, in the 2016 Payment Notice Final Rule at §156.235(b)(2)(ii), issuers that qualify for the alternate ECP standard must provide within the issuer's integrated delivery system all of the categories of services provided by entities in each of the ECP categories in each county in the plan's service area as outlined in the general ECP standard; or otherwise offer a contract to at least one ECP outside of the issuer's integrated delivery system per ECP category in each county in the plan's service area that can provide those services to low-income, medically underserved individuals. Issuers that qualify for the alternate

²⁴ To qualify for the alternate standard, an issuer must provide a majority of covered professional services through physicians employed by the issuer or through a single contracted medical group.

ECP standard are not reviewed for compliance with the additional general ECP standard requirement of offering contracts in good faith to all available Indian health care providers.

As with the general ECP standard, an application that does not demonstrate compliance with the 30 percent ECP standard must include a narrative justification describing how the issuer's provider network(s) complies with the regulatory standard. In the context of issuers that qualify for the alternate ECP standard, an issuer's explanation in the ECP Supplemental Response Form would address how the issuer intends to ensure coverage to low-income populations residing in HPSAs or low-income zip codes in the service area(s). The explanation should describe the extent to which the issuer's provider sites are accessible to, and have services that meet the needs of, specific underserved populations, including:

- Individuals with HIV/AIDS (including those with co-morbid behavioral health conditions);
- American Indians and Alaska Natives (AI/AN);
- Low-income and underserved individuals seeking women's health and reproductive health services; and
- Other specific populations served by ECPs in the service area.

CMS is providing issuers with a database of zip codes listed as HPSAs or low-income areas where 30 percent or more of the population falls below 200 percent of the FPL. The database is available at <http://www.cms.gov/ccio/programs-and-initiatives/health-insurance-marketplaces/qhp.html>. Issuers that qualify for the general or alternate ECP standard would use this same HPSA and low-income zip code database as well as the same template to complete the ECP section of the application. As with the general ECP standard, issuers that qualify for the alternate ECP standard may write in additional providers not on the HHS non-exhaustive ECP list toward satisfaction of the 30 percent ECP standard if such providers are located within a low-income zip code or HPSA included on the "Low-Income and Health Professional Shortage Area Zip Code Listing" referenced above, on the condition that they do not limit their practice on the basis of a particular source of coverage (e.g., Medicare, Medicaid, CHIP, private health insurance, etc.).

CMS will continue to assess QHP provider networks, including ECPs, and may revise its approach to reviewing for compliance with network adequacy and ECP standards in later years.

ii. Evaluation of Network Adequacy with respect to dental ECPs

SADPs will be reviewed for satisfaction of the ECP standard described in subsection (i) of this same section, with the exception of the requirement to offer contracts in good faith to at least one ECP in each ECP category (see Table 2.1 above) in each county in the service area, where an

ECP in that category is available. Providers in several of the ECP categories listed in Table 2.1 do not generally provide dental services; therefore, CMS considers this ECP category requirement not applicable to SADPs.

CMS will consider issuers of SADPs to be compliant with the ECP standard if they demonstrate in their application satisfaction of the 30 percent ECP standard (described in more detail above) and the requirement to offer contracts in good faith to all available Indian health care providers in the plan's service area. Otherwise, an SADP issuer's application that does not satisfy the 30 percent ECP standard as well as the requirement to offer contracts in good faith to all available Indian health care providers in the service area will be required to include as part of its application a satisfactory narrative justification describing how the issuer's provider network(s), as currently designed, provides an adequate level of service for low-income and medically underserved individuals and how the issuer plans to increase ECP participation in the issuer's provider network(s) in future years, as necessary. An SADP issuer that submits a narrative justification would do so as part of the issuer application for QHP certification. See discussion in subsection (i) for additional guidance on the minimum level of detail expected to be included in a satisfactory narrative justification.

Section 5. Accreditation

This section describes how CMS will conduct a review of the accreditation standards necessary for QHP certification and recertification. States performing plan management functions in the FFM may use a similar approach. This section does not apply to SADPs.

Requirements at 45 C.F.R. 155.1045(b) establish the timeline by which QHP issuers offering coverage in the FFM must be accredited. In 2016, CMS is continuing its phased approach to accreditation for QHP issuers in the FFM. The accreditation requirements for QHP issuers entering their third year are the same as for QHP issuers entering their second year, as previously stated in the 2015 Letter to Issuers. Prior to a QHP issuer's third year of QHP certification, the QHP issuer must be accredited by a recognized accrediting entity based on the policies and procedures that are applicable to its Marketplace products, or a QHP issuer must have commercial or Medicaid health plan accreditation granted by a recognized accrediting entity for the same State in which the issuer is offering Marketplace coverage, and the administrative policies and procedures underlying that accreditation must be the same or similar to the administrative policies and procedures used in connection with the QHP. SADP issuers will not be reviewed for accreditation status.

As CMS required in 2015, QHP issuers entering their third year of Marketplace participation will be required to attest that the administrative policies and procedures applicable to their Marketplace products have been reviewed and approved by a recognized accrediting entity in compliance with 45 C.F.R. 155.1045(b)(2). The timeline in 45 C.F.R. 155.1045(b) will be

applied by looking at the issuer's accreditation status 90 days prior to open enrollment. An issuer will not be considered accredited if the accreditation review is scheduled or in process.

Issuers entering their initial year of QHP certification for plan years beginning in 2016 (i.e., issuers that did not offer a QHP the previous year) must meet the requirement at 45 C.F.R. 155.1045(b)(1). New QHP issuers may submit accreditation information for display if they have existing accreditation.

In addition to the attestation noted above related to the review and approval of administrative policies and procedures, issuers will be asked to provide some information about their accreditation status to determine if the standard in 45 C.F.R. 155.1045(b) is met, including information on their accrediting entity and status. This information will be verified with the indicated accrediting entity. The National Committee for Quality Assurance (NCQA), URAC, and the Accreditation Association for Ambulatory Health Care (AAAHC) have been recognized by CMS as accrediting entities for the purpose of QHP certification. The issuer will be asked for information related to accreditation of their commercial, Medicaid, or Marketplace products.

Issuers will be considered accredited if the QHP issuer is accredited with the following status: by AAAHC with "Accredited," status; by NCQA with "Excellent," "Commendable," "Accredited," "Provisional," and /or "Interim" status; or by URAC with "Full," "Provisional," and/ or "Conditional" status.

Section 6. Patient Safety Standards for QHP Issuers

This section describes how CMS will review issuer compliance with the patient safety standards for purposes of QHP certification and recertification. States performing plan management functions may use a similar approach. SADP issuers will not be reviewed for patient safety standards compliance in 2016.

Regulations at 45 C.F.R. 156.1110 outline how QHP issuers can demonstrate compliance with the patient safety standards. Specifically, the regulation requires QHP issuers that contract with a hospital with more than 50 beds to verify that the hospital, as defined in section 1861(e) of the SSA, is Medicare-certified or has been issued a Medicaid-only CMS Certification Number (CCN) and is subject to the Medicare Hospital Condition of Participation requirements for:

- (1) A quality assessment and performance improvement program as specified in 42 C.F.R. 482.21; and
- (2) Discharge planning as specified in 42 C.F.R. 482.43.

In addition, QHP issuers are required to collect and maintain documentation of the CCNs from their applicable network hospitals.

As part of the certification for plan years beginning in 2016, QHP issuers will be required to demonstrate compliance with these patient safety standards as part of the QHP Application with an attestation that they have collected and are maintaining the required documentation from their network hospitals.

Section 7. Quality Reporting

This section describes how CMS will review issuer compliance with the quality reporting standards related to the Quality Rating System (QRS) and the Enrollee Satisfaction Survey (QHP Enrollee Survey) for purposes of QHP certification and recertification. States performing plan management functions in an FFM may use a similar approach. Child-only plans and SADPs are not subject to the quality reporting standards at this time.

i. QHP Issuer Data Collection and Reporting Requirements

As established in the Final Rule, “Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond,”²⁵ QHP issuers are required to comply with standards and requirements related to data collection of quality rating information through implementation of the QRS pursuant to 45 C.F.R. 156.1120, and the QHP Enrollee Survey pursuant to 45 C.F.R. 156.1125. QHP issuers offering coverage through the Marketplaces must collect and report validated data annually, on a timeline and in a standardized form and manner specified by HHS, to support the calculation of the QRS scores and ratings for each QHP that has been offered in a Marketplace for at least one year.²⁶ QHP issuers are also required to contract with and authorize an HHS-approved vendor to annually collect and submit QHP Enrollee Survey data on their behalf for each QHP. QHPs required to submit this data are those with more than 500 enrollees in the previous year that have been offered in an FFM for at least one year.²⁷ The specific requirements related to data collection, validation and submission, as well as minimum enrollment criteria, for the QRS and QHP Enrollee Survey are detailed in technical guidance that CMS anticipates will be issued on an annual basis.²⁸

Using the QHP issuer’s validated data submissions, CMS will calculate QRS scores and ratings and QHP Enrollee Survey results for each QHP product using a standard methodology and will

²⁵ See Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond, 79 Federal Register 30240 (May 27, 2014); codified at 45 C.F.R. Parts 144, 146, 147, et al.

²⁶ 45 C.F.R. 156.1120

²⁷ 45 C.F.R. 156.1125

²⁸ Additional information on the Marketplace Quality Initiatives is available at: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Health-Insurance-Marketplace-Quality-Initiatives.html>.

assign each QHP a quality performance rating on a 1- to 5-star rating scale. QHP issuers may reference their respective QRS scores and ratings, as well as QHP Enrollee Survey results, in marketing materials in a manner specified by HHS.²⁹ An issuer that elects to include QRS and QHP Enrollee Survey information in its marketing materials must do so in a manner that does not mislead consumers. Guidance related to the use of QRS scores and ratings and QHP Enrollee Survey results in QHP issuer marketing materials is forthcoming.

CMS is continuing its phased approach to implementation of the Marketplace quality reporting standards. The QRS scores and ratings and QHP Enrollee Survey results calculated by CMS in 2016 will be publicly displayed on Marketplace websites in time for open enrollment for the 2017 coverage year. In preparation, CMS requires QHP issuers offering coverage through the Marketplaces in 2014 to report data for the QRS and QHP Enrollee Survey 2015 beta test. CMS published QRS and QHP Enrollee Survey technical guidance, specifying requirements for the 2015 beta test, in addition to accompanying QRS measure technical specifications, on the CMS Marketplace Quality Initiatives website in September 2014.³⁰ The beta test is a critical step for both CMS and QHP issuers to prepare for 2016 public reporting. Outcomes of the beta test will be used to refine QRS and QHP Enrollee Survey requirements for 2016. CMS anticipates that it will refine and publish updated technical guidance based on the beta test.

QHP issuers offering products that do not meet minimum enrollment criteria are not required to comply with QRS and QHP Enrollee Survey requirements, but are encouraged to submit survey and clinical quality measure data for products offered through the Marketplaces. Specific requirements related to data collection, validation, and submissions are detailed in the technical guidance.

Consistent with 45 C.F.R. 156.200(b)(5), in order to demonstrate compliance with the quality reporting standards as part of the certification process for the 2016 coverage year, QHP issuers will be required to attest that they comply with the specific quality reporting and implementation requirements related to the QRS and QHP Enrollee Survey.

ii. Marketplace Oversight & Display Requirements

Consistent with 45 C.F.R. 155.200(d), Marketplaces are required to oversee the implementation of the QRS and QHP Enrollee Survey (among other QHP Issuer Marketplace quality initiatives). In addition, beginning in 2016, Marketplaces must prominently display on their respective websites quality rating information assigned to each QHP under the QRS and QHP Enrollee

²⁹ 45 C.F.R.156.1120(c) and 156.1125(c)

³⁰ 2015 Beta Test of the Quality Rating System and Qualified Health Plan Enrollee Experience Survey: *Technical Guidance for 2015*, September 2014, available at: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Health-Insurance-Marketplace-Quality-Initiatives.html>.

Survey, as calculated by HHS and in a form and manner specified by HHS.³¹ Guidance related to the Marketplace display requirements is forthcoming.

The FFM will publicly display the QRS scores and ratings and QHP Enrollee Survey results on its website to help consumers compare QHPs beginning in 2016 to align with the start of open enrollment for the 2017 coverage year. State-based Marketplaces are also required to display the QRS scores and ratings and QHP Enrollee Survey results calculated by HHS on their respective websites in the 2016 calendar year to facilitate consumer shopping during open enrollment for the 2017 coverage year.

Section 8. Review of Rates

This section addresses how CMS will work with States to review rate increases for QHPs when certifying plans as QHPs for participation in the FFM. States performing plan management functions in an FFM may use a similar approach. The approach for SADPs is discussed in Chapter 3, Section 1: Stand-alone Dental Plan Rates.

Regulations at 45 C.F.R. 155.1020 require a Marketplace to consider all rate increases when certifying plans as QHPs. For the 2016 benefit year, CMS plans to complete the same reviews noted in Section 4 of the 2015 Letter to Issuers when considering rate increases for purposes of QHP certification in the FFM, including in States performing plan management functions in the FFM.

When considering rate increases, CMS will consider:

- Issuers' data and actuarial justification provided in the Unified Rate Review Template (URRT);
- Other information submitted as part of a filing under an Effective Rate Review program;
- Recommendations by applicable State regulators about patterns or practices of excessive or unjustified rate increases and whether or not particular issuers should be excluded from participation in the Marketplace; and
- Any excess of premium rate growth outside the Marketplace as compared to growth inside the Marketplace.

CMS does not plan to duplicate reviews by States to enforce State law, and will integrate State and other CMS rate reviews into its QHP certification process, provided that States provide information to CMS consistent with Federal standards and agreed-upon timelines. For all rate

³¹ 45 C.F.R. 155.1400 and 155.1405

increases subject to review, the issuer will enter justifications in Part II of the URR rate filing justification in the rate review module of HIOS.

CMS plans to continue review for rate outliers in order to identify possible market disruptions, as described in Section 4 of the 2015 Letter to Issuers. CMS recognizes that the identification of a QHP rate as an outlier does not necessarily indicate inappropriate rate development. CMS will notify the appropriate State entity of the results of its outlier identification process and will consider the State's assessment of the plan's rates when determining whether, based on its rates, certifying the QHP to be offered on the FFMs would be in the interest of consumers.

Section 9. Discriminatory Benefit Design

This section addresses how CMS will review health plans applying to be QHPs or SADPs in the FFMs for compliance with nondiscrimination standards. States performing plan management functions may use a similar approach.

As previously stated in guidance, EHB-benchmark plans may not reflect all requirements effective for plan years starting on or after January 1, 2014. Therefore, when designing plans that are substantially equal to the EHB-benchmark plan, issuers should design plan benefits, including coverage and limitations, to comply with requirements and limitations that apply to plans beginning in 2014. We also remind issuers that individuals under age 65 with end stage renal disease (ESRD) are not required to sign up for or enroll in Medicare. Further, individuals who do not have Medicare Part A or Part B are eligible to enroll in individual market coverage, including a QHP, if the individual meets the eligibility requirements for enrollment (i.e., criteria related to citizenship, lawful presence, incarceration, and residency).³²

i. EHB Discriminatory Benefit Design

Non-discrimination in benefit design with respect to EHB is a market-wide consumer protection that applies inside and outside of Marketplaces. As stated in 45 CFR 156.125(a), an issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions.

In the 2016 Payment Notice Final Rule, CMS addressed 45 CFR §156.125, which implements a prohibition on discrimination by issuers providing EHB. Also in the 2016 Payment notice Final Rule, CMS discussed three examples of potentially discriminatory practices. CMS cautions both

³² For more information, see Frequently Asked Questions Regarding Medicare and the Marketplace, August 1, 2014, available at: http://www.cms.gov/Medicare/Eligibility-and-Enrollment/Medicare-and-the-Marketplace/Downloads/Medicare-Marketplace_Master_FAQ_8-28-14_v2.pdf.

issuers and States that age limits may potentially be discriminatory when applied to services that have been found clinically effective at all ages. For example, it might be arbitrary to limit a hearing aid to enrollees who are 6 years of age and younger since there may be some older enrollees for whom a hearing aid is medically necessary. Although CMS does not enumerate which benefits fall into each statutory EHB category, issuers should not attempt to circumvent coverage of medically necessary benefits by labeling the benefit as a “pediatric service,” thereby excluding adults. CMS also cautions issuers to avoid discouraging enrollment of individuals with chronic health needs. For example, if an issuer refuses to cover a single-tablet drug regimen or extended-release product that is customarily prescribed and is just as effective as a multi-tablet regimen, absent an appropriate reason for such refusal, such a plan design might effectively discriminate against, or discourage enrollment by, individuals who would benefit from such innovative therapeutic options. As another example, if an issuer places most or all drugs that treat a specific condition on the highest cost tiers, that plan design might effectively discriminate against, or discourages enrollment by, individuals who have those chronic conditions.

The enforcement of this standard is largely conducted by States. CMS encourages States that are enforcing the Affordable Care Act to consider a number of strategies for assessing compliance with this standard including, but not limited to, analysis of information entered in the “explanations” and “exclusions” sections of the QHP Plans and Benefits Template.

Section 1302(b) of the Affordable Care requires that the definition of EHB be based on the scope of benefits provided under a typical employer plan, subject to requirements under the joint interpretive jurisdiction of the Departments of HHS, Labor, and the Treasury.³³ Because the nondiscrimination provisions are related to many other such requirements, HHS will consult with relevant Federal agencies, such as the Departments of Labor and the Treasury, as necessary in developing new guidance related to discriminatory benefit designs.

ii. *QHP Discriminatory Benefit Design*

For purposes of QHP certification, CMS will assess compliance with this standard by collecting an attestation that issuers’ QHPs will not discriminate against individuals on the basis of health status, race, color, national origin, disability, age, sex, gender identity or sexual orientation,

³³ To inform the determination as to the scope of a typical employer plan, section 1302(b)(2)(A) of the Affordable Care Act requires the Secretary of Labor to conduct a survey of employer sponsored coverage to determine the benefits typically covered by employers, and to provide a report to the Secretary of HHS. These provisions suggest that, while detailed requirements for EHB in the individual and small group health insurance markets were deemed necessary, the benefits covered by typical employer plans providing primary coverage at the time the Affordable Care Act was enacted were seen as sufficient to satisfy the Act’s objectives for the breadth of benefits needed for health plan coverage and, in fact, to serve as the basis for determining EHB.

consistent with 45 C.F.R. 156.200(e). CMS will continue to assess compliance through issuer monitoring and compliance reviews, including analysis of appeals and complaints.

In addition to complying with EHB non-discrimination standards identified above, QHPs must not employ market practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs pursuant to 45 C.F.R. 156.225. As in prior QHP certification review cycles, CMS will perform an outlier analysis on QHP cost sharing (e.g., co-payments and co-insurance). CMS's outlier analysis will compare benefit packages with comparable cost-sharing structures to identify cost-sharing outliers with respect to specific benefits.

Additionally, CMS is considering conducting a review of each QHP to identify outliers based upon estimated out-of-pocket costs associated with standard treatment protocols for specific medical conditions using nationally-recognized clinical guidelines. The conditions under consideration include: bipolar disorder, diabetes, HIV, rheumatoid arthritis, and schizophrenia.

Also in reviewing a plan's cost-sharing structure, CMS will analyze information contained in the Plans and Benefits Template, including, but not limited to the "explanations" and "exclusions" sections, with the objective of identifying discriminatory features or wording. Discriminatory cost sharing language would typically involve reduction in the generosity of a benefit in some manner for subsets of individuals for reasons not clearly based on common medical management practices.

CMS will notify an issuer when it sees an indication of a reduction in the generosity of a benefit in some manner for subsets of individuals that is not based on clinically indicated, reasonable medical management practices. CMS conducts this examination whenever a plan required to cover EHB reduces those benefits for a particular group. Issuers are expected to impose limitations and exclusions, if any, based on clinical guidelines and medical evidence, and are expected to use reasonable medical management. Issuers may be asked to submit justification with supporting documents to CMS explaining how the plan design is not discriminatory.

Section 10. Prescription Drugs

CMS seeks to ensure that all Marketplace consumers, regardless of medical condition, have appropriate access to prescription drugs. CMS will not review SADPs for adherence to prescription drug standards as part of the QHP certification process.

In 2015 for the FFM, CMS applied standards described in the 2015 Letter to Issuers to the formulary drug list URL that it collected as part of the QHP Application. Similar to 2015, CMS will collect QHPs' formulary drug list URLs as part of the QHP Application and will make formulary drug list links provided by issuers available to consumers on HealthCare.gov. This formulary drug list URL link should be the same direct formulary drug list link for obtaining

information on prescription drug coverage in the Summary of Benefits and Coverage, in accordance with 45 C.F.R. 147.200(a)(2)(i)(K).

In the 2016 Payment Notice Final Rule, CMS finalized a number of changes to the EHB prescription drug benefit. While some of these changes are not applicable until 2017, some of these changes apply starting with the 2016 plan year. These changes include a requirement that issuers' formulary drug lists be up-to-date, accurate, and include a complete list of all covered drugs. The formulary drug list must include any tiering structure that the plan has adopted and any restrictions on the manner in which a drug can be obtained. The Final Rule clarifies that for the purpose of 45 C.F.R. 156.122(d), for a formulary drug list to be considered complete, the formulary drug list must list all drugs that are EHB, and list all drug names that are currently covered by the plan at that time. The formulary drug list does not have to list every covered formulation for each covered drug, but the issuer should be prepared to provide information on the specific formulations upon request. Issuers must also include accurate information on any restrictions on the manner in which an enrollee can obtain the drug, including prior authorization, step therapy, quantity limits, and any access restrictions related to obtaining the drug from a brick and mortar retail pharmacy. The formulary drug list must be up-to-date, which means that the formulary drug list must accurately list all of the health plan's covered drugs at that time.

The formulary drug list must be published in a manner that is easily accessible to plan enrollees, prospective enrollees, the State, the Marketplace, HHS, OPM, and the general public. A formulary drug list is easily accessible when it can be viewed on the plan's public web site through a clearly identifiable link or tab without requiring an individual to create or access an account or enter a policy number; and if an issuer offers more than one plan, when an individual can easily discern which formulary drug list applies to which plan. CMS is also requiring issuers to make this information publicly available on their websites in a machine-readable file and format specified by HHS, to allow the creation of user-friendly aggregated information sources. The purpose of establishing machine-readable files with this data is to provide the opportunity for third parties to create resources that aggregate information on different plans. We believe this will increase transparency by allowing software developers to access this information and create innovative and informative tools to help enrollees better understand the drug coverage in a specific plan. CMS established these requirements to enhance the transparency of QHP formulary drug lists and to help consumers make more informed decisions about their health care coverage.

The 2016 Payment Notice Final Rule also includes new requirements for the prescription drug exception process, under which an enrollee can request and gain access to a drug not on the plan's formulary. These provisions include a requirement that starting with the 2016 plan year, an issuer must notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage decision no more than 72 hours following the receipt of a standard exception request, as well as a requirement that the issuer must have a process for the enrollee or the enrollee's designee or the prescribing physician (or other

prescriber) to request that the denied exception request be reviewed by an independent review organization. As part of these requirements, we also finalized in the 2016 Payment Notice Final Rule that in the event that an exception request is granted, the plan must treat the excepted drug(s) as an EHB, including by counting any cost-sharing towards the plan's annual limitation on cost-sharing under 45 C.F.R. 156.130, and that a health plan that grants a standard exception request must provide coverage of the excepted non-formulary drug for the duration of the prescription, including refills (or in the case of an expedited request, a health plan that grants an exception must provide coverage of the excepted non-formulary drug for the duration of the exigency). Issuers must update their policies and procedures to reflect the new requirements for plan years beginning in 2016. In addition to the above standards, CMS continues to encourage issuers to temporarily cover non-formulary drugs, as well as drugs that are on an issuer's formulary but require prior authorization or step therapy, as if they were on formulary or without imposing prior authorization or step therapy requirements, during the first 30 days of coverage when an enrollee is transitioning to a new plan.

Finally, as discussed in the 2016 Payment Notice Final Rule, CMS is concerned about issuers making mid-year formulary changes, and especially changes that negatively affect enrollees. In particular, for QHPs, we have concerns about these changes to the plan design when the plan design was certified under the assumption that it was going to cover specific benefits. For these reasons, we are monitoring this issue and whether further standards are needed on the updating of formulary drug lists. We note that under guaranteed renewability requirements and the definitions of "product" and "plan," issuers generally may not make plan design changes, including changes to drug formularies, other than at the time of plan renewal. However, we recognize that certain mid-year changes to drug formularies related to the availability of drugs in the market may be necessary and appropriate. Such changes generally would not affect a QHP's certification.

To help ensure that QHPs are in compliance with applicable regulations, CMS will conduct the following reviews as part of the 2016 QHP certification process. If CMS identifies a QHP for follow-up based on this review, CMS will offer the issuer the opportunity to resolve the identified issue as part of the certification process. CMS anticipates that it will offer the issuer the opportunity to submit a justification with supporting documentation explaining how the plan is not discriminatory or to make a change to its application to address the concern.

i. Formulary Outlier Review

Consistent with 45 C.F.R. 156.225 and 45 C.F.R. 156.125, CMS will review each QHP's formulary drug list to ensure non-discrimination in QHP prescription benefit design. CMS will perform an outlier analysis to identify QHPs that are outliers based on an unusually large number of drugs subject to prior authorization and/or step therapy requirements in a particular USP category and class. CMS encourages States performing plan management functions in the FFMs to implement this type of review.

ii. *Review of Prescription Drugs*

CMS will review each QHP's prescription drug coverage to ensure that it meets applicable standards in 45 C.F.R. 156.225 and 45 C.F.R. 156.125. Based on data submitted by issuers in the prescription drug template, this review will analyze the availability of covered drugs recommended by nationally-recognized clinical guidelines used in the treatment of the following four medical conditions: bipolar disorder, diabetes, rheumatoid arthritis, and schizophrenia. The purpose of the analysis is to ensure that issuers are offering a sufficient number and type of drugs needed to effectively treat these conditions, and on some first line drugs, are not restricting access through lack of coverage and inappropriate use of utilization management techniques. Other conditions, including HIV, may be considered as part of future reviews.

Section 11. Supporting Informed Consumer Choice/Meaningful Difference

The content of this section applies to QHP issuers in the FFM, including issuers participating in States that are performing plan management functions. This section does not apply to SADPs.

For 2016, CMS intends to use a similar approach as in previous years to assess whether all plans proposed to be offered by potential QHP issuers are meaningfully different from other plans the issuer has submitted for certification, in accordance with the requirements of 45 C.F.R.156.298.

CMS will organize an issuer's proposed QHPs from a given State into subgroups based on plan type, metal level, and overlapping counties/service areas. Second, CMS will review each subgroup to determine whether the potential QHPs in that subgroup differ from each other as detailed in the 2015 Letter to Issuers. If CMS finds that two or more plans within a subgroup do not differ based on at least one of the criteria, then those QHPs would be flagged for additional review and follow-up.

If CMS flags a potential QHP for follow-up, it anticipates that the issuer would be given the opportunity to amend its submission for one or more of the identified health plans. Alternatively, the issuer would be able to submit a justification to CMS explaining how the potential QHP is substantially different from others offered by the issuer for QHP certification and, thus, is in the interest of consumers to certify as a QHP.

CMS will not review SADPs for meaningful difference as part of the certification process.

Section 12. Third Party Payment of Premiums and Cost-sharing

Issuers of individual market QHPs, including SADPs, are required under 45 C.F.R. 156.1250 to accept third party premium and cost-sharing payments made on behalf of enrollees by the Ryan

White HIV/AIDS Program; Indian tribes, tribal organizations, and urban Indian organizations; and other Federal and State government programs.³⁴

HHS may impose civil money penalties against QHP issuers in the FFM for violations of 45 C.F.R. 156.1250, as set forth in 45 C.F.R. 156.805(a)(1) and 156.805(a)(4). Under 45 C.F.R. 156.805(c), an issuer offering a QHP or SADP through the FFM may be subject to a maximum penalty of \$100 per day, per each individual who is adversely affected by the QHP or SADP issuer's non-compliance.

Section 13. Cost-Sharing Reductions

QHP issuers are required under 45 C.F.R. 156.420 to submit three plan variations for each silver level QHP an issuer offers through the Marketplace, as well as zero and limited cost-sharing plan variations for all QHPs an issuer offers through the Marketplace. This section does not apply to SADPs, as cost-sharing reductions do not apply to SADPs. In the 2016 certification cycle, CMS will continue to review QHP Applications for compliance with Part 156, subpart E.

The certification review will include a review of each submitted Plans and Benefits Template to ensure that silver plan variations:

- Meet 2016 AV requirements.
- Do not have an annual limitation on cost-sharing that exceeds the permissible threshold for the specified plan variation, as finalized in the 2016 Payment Notice Final Rule.
- Are designed such that the cost-sharing for enrollees under any silver plan variation for an EHB (or non-EHB, under the non-EHB out-of-pocket policy at 45 C.F.R. 156.420(d)³⁵) does not exceed the corresponding cost-sharing in the standard silver plan or any other silver plan variation of the standard silver plan with a lower AV. For example, if an enrollee in a 87 percent plan variation pays a \$40 co-pay for a specialist visit, the specialist visit co-payment for an enrollee in the associated 94 percent plan variation must be less than or equal to \$40.

³⁴ This standard was effective on March 14, 2014; see Patient Protection and Affordable Care Act; Third Party Payment of Qualified Health Plan Premiums; Interim Final Rule; 79 Federal Register 15240 (March 19, 2014); codified at 45 C.F.R. part 156. The standard applies to all individual market QHPs and SADPs, regardless of whether they are offered through the FFM, an SBM, or outside of the Marketplace.

³⁵ To simplify benefit design, issuers may reduce out-of-pocket spending for non-EHB benefits for enrollees in plan variations, so that they no longer equal non-EHB out-of-pocket in the associated standard plan. However, such non-EHB cost-sharing reductions are not eligible for HHS reimbursement.

- Are designed such that zero cost-sharing plan variations may not have positive cost-sharing for any EHB, either in or out-of-network. This includes any copayment, coinsurance, deductible, or application of an annual limitation on cost-sharing.³⁶
- Are designed such that, for limited cost-sharing plan variations and zero cost-sharing plan variations, the cost-sharing values (for example, copayment and/or coinsurance) for a non-EHB are the same or less than the values for the non-EHB under the associated standard plan.

Section 14. Data Integrity Tool

This section describes the Data Integrity Tool and the data integrity reviews that CMS will conduct for 2016 QHP Applications.

The Data Integrity Tool is a publicly available Excel-based tool that allows issuers to check that the data contained in their QHP templates is in the correct format and conforms to validity checks that CMS will conduct upon submission. Running the QHP templates through the Data Integrity Tool provides issuers immediate feedback regarding the quality of their templates before uploading the final versions into HIOS or SERFF, potentially reducing the need for rework and resubmission. It should be noted that the tool does not replicate all HIOS and SERFF validations and that the tool contains many checks necessary for correct template submissions that are not performed by either HIOS or SERFF.

Based on a successful experience in 2014 for plan years beginning in 2015, CMS expects issuers to use the Data Integrity Tool in 2015 for plan years beginning in 2016 because it is in the best interest of both the issuers and CMS. Issuers that choose not to use the Data Integrity Tool should contact their CMS Account Manager in advance of the QHP submission and discuss why they are not using it. Issuers that do not use the Data Integrity Tool incur the risk that their plan information will not display properly on Plan Compare, including the risk that their plans will not be displayed at all due to display errors.

The Data Integrity Tool can be used by QHP and SADP issuers, and runs checks specific to individual and SHOP market plans. CMS will be releasing an updated version of the Data Integrity Tool that will incorporate validations specific to the 2016 QHP Application templates.

CMS will conduct data integrity reviews on all QHP and SADP applications for plan years beginning in 2016. During each review round, CMS will send issuers notices of data integrity

³⁶ If the QHP is a closed-panel HMO that does not cover services furnished by a provider outside of the network (i.e., cost-sharing for services provided by an out-of-network provider is at 100 percent), the cost-sharing, for these non-covered services would not need to be eliminated for the zero cost-sharing plan variation, and should be entered as it would be for non-covered out-of-network services under the corresponding standard plan.

errors that would result in either improper display of plan information to consumers or other irregularities. CMS will send summary data integrity review results to States during each review round. Data integrity notices are different from correction notices, which are generated during the separate process of QHP certification reviews.

CHAPTER 3: STAND-ALONE DENTAL PLANS: 2016 APPROACH

Issuers submitting applications for certification of SADPs will have several unique standards due to their excepted benefit status, as described in the 2014 Letter to Issuers on the Federally-facilitated and State Partnership Marketplaces (2014 Letter to Issuers),³⁷ and their limited scope of benefits. The charts below (Tables 3.1 and 3.2) are intended to assist issuers in understanding those standards that are applicable or not applicable to SADPs seeking certification in the FFM for plan years beginning in 2016, and are consistent with the approach in prior years. CMS notes that in addition to the certification standards outlined below, SADP issuers will need to comply with operational processes and standards. The application of QHP standards is addressed throughout the sections of this Letter. Therefore, this section only addresses those standards or evaluations that are unique to SADPs. As previously noted, States that are performing QHP certification reviews have flexibility in their application of QHP certification standards including SADPs, provided that the State's application of each standard is consistent with CMS regulations and guidance.

Table 3.1: Standards and Tools Applicable to Stand-alone Dental Plans

Standard or Tool Applies (* denotes modified standard)	
Essential Health Benefits*	Actuarial Value*
Annual Limits on Cost-sharing*	Licensure
Network Adequacy	Inclusion of ECPs
Marketing	Service Area
Non-discrimination	Acceptance of Third Party Premium and Cost-sharing Payments
Data Integrity Tool	

³⁷ Letter to Issuers on Federally-facilitated and State Partnership Exchanges; April 5, 2013; available at: http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2014_letter_to_issuers_04052013.pdf.

Table 3.2: Standards and Tools Not Applicable to Stand-alone to Dental Plans

Standard or Tool Does Not Apply	
Accreditation	Patient Safety
Cost-sharing Reduction Plan Variations	Quality Reporting
Unified Rate Review Template	Prescription Drugs
Meaningful Difference	Cost Sharing Reductions

Section 1. Stand-alone Dental Plan Rates

In the 2014 Letter to Issuers, CMS outlined a process for SADPs to complete the rating template portion of the QHP Application. As in previous years, for 2016 certification SADP issuers will complete the rating templates in accordance with the associated rating and business rules and indicate in the 2016 Plan and Benefits Template whether they were committing to charging that rate (“guaranteed” rates) or retaining flexibility to change the rate (“estimated” rates).

Section 2. Intent to Apply

As described in section 1302(b)(4)(F) of the Affordable Care Act, QHP issuers are permitted to offer QHPs that omit coverage of the pediatric dental EHB if a SADP is offered in the same service area in which they intend to offer coverage on the Marketplace. For the 2014 and 2015 plan years, CMS conducted a voluntary reporting process for SADP issuers to communicate their intent to apply. CMS will follow a similar approach for 2016.

CHAPTER 4: QUALIFIED HEALTH PLAN PERFORMANCE AND OVERSIGHT

Section 1. Account Management: 2016 Issues

All issuers participating in the FFM, including issuers in States that are performing plan management functions, will continue to have an assigned Account Manager. In addition, CMS will assign an Account Manager to issuers participating in SBMs that use CMS’s eligibility system and platform (i.e., HealthCare.gov and the FFMs Call Center). For issuers offering QHPs through the Marketplace for the first time, CMS will assign an Account Manager prior to the start of open enrollment for the 2016 plan year. The Account Managers will serve as issuers’ primary point of contact with the FFMs for non-technical QHP and SADP issues and will provide QHP issuers with clarification and other assistance related to issuers’ responsibilities and requirements for participating in the FFM. Additionally, the Account Manager will communicate updates to issuers, direct issuers to other resources as appropriate, and coordinate resolution of

cross-cutting issues. CMS expects that States, regardless of Marketplace type, will continue to take the lead in addressing market-wide issues, such as complaints related to market conduct.

CMS has also assigned a CO-OP Program Account Manager to each CO-OP in addition to the Federal Account Manager. The CO-OP Program Account Manager serves as the CO-OP's primary point of contact with the CO-OP Program Division for questions and issues regarding CO-OP responsibilities and requirements pursuant to section 1322 of the Affordable Care Act, 45 C.F.R. part 156, subpart F, and the CO-OP Program Funding Opportunity Announcement.

Section 2. QHP Issuer Compliance Monitoring Program

This section describes how CMS, in its role as operator of the FFM, will monitor issuer compliance with all applicable Marketplace standards on an ongoing basis throughout plan years beginning in 2016. CMS anticipates adopting the same approach in States that are performing plan management functions.

Pursuant to 45 C.F.R. 155.1010(a)(2), CMS will be monitoring QHP issuers participating in the FFMs for demonstration of ongoing compliance with the certification requirements of 45 C.F.R. 155.1000(c). CMS will evaluate an issuer's performance to determine if making the issuer's health plan(s) available is in the best interest of qualified individuals and employers enrolling in coverage through the Marketplace. Compliance monitoring will be based on several data sources, at the State and national level, including, but not limited to: complaints data; issuer self-reporting of problems; issuer policies, procedures, and operations; network adequacy analysis; and indicators of customer service and satisfaction.

The Program Integrity: Marketplace, SHOP and Eligibility Appeals Final Rule³⁸ established the good faith compliance policy at 45 C.F.R. 156.800(c) in acknowledgement of the operational and systemic changes that took place during the 2014 calendar year. The 2016 Payment Notice Final Rule extended that policy through the 2015 calendar year. Under that policy, for the 2015 calendar year, CMS will not impose civil monetary penalties on issuers or decertify QHPs that are not in compliance with applicable Marketplace requirements when the QHP issuer has made good faith efforts to comply with applicable requirements. Consistent with this good faith compliance policy, CMS expects issuers to develop effective internal monitoring programs to identify, report, and correct compliance violations in their operations. Furthermore, where compliance violations are identified by CMS, issuers are expected to have internal policies and procedures for coordinating with CMS to correct those violations when notified. When an issuer fails to develop a work plan to correct a compliance violation or fails to act on that work plan, CMS will consider such failure to be inconsistent with good faith compliance, as it did in 2014.

³⁸ Patient Protection and Affordable Care Act: Program Integrity: Exchange, SHOP and Eligibility Appeals; Final Rule, 78 Federal Register 54070 (August 30, 2013); codified at 45 C.F.R. Parts 147, 153, 155, and 156).

Regardless of the good faith compliance policy, issuers are expected to be in compliance with all applicable Marketplace standards at all times.

The good faith compliance policy will end after the 2015 calendar year. By plan years beginning in 2016, issuers will have gained more experience operating in the FFM environment and will be more familiar with the Marketplace requirements. As a general principle, CMS intends to continue providing technical assistance to issuers to assist with understanding applicable Marketplace standards and guidance. As in prior years, CMS will continue to work with States on oversight activities to prevent unnecessary duplication of effort and/or enforcement actions.

Section 3. QHP Issuer Compliance Reviews

This section describes how CMS, as administrator of the FFM, will assess QHP and SADP issuer compliance with applicable FFM standards and operational performance by performing a limited number of compliance reviews. States performing plan management functions in the FFMs may wish to take a similar approach to assessing issuer compliance with applicable FFM standards by choosing to perform selected compliance reviews on issuers in their respective States.

Consistent with CMS's authority under 45 C.F.R. 156.715, CMS will perform these compliance reviews to monitor issuer compliance with applicable FFM-specific requirements and operational standards. CMS will conduct compliance reviews throughout the year and issuer notification of selection for a review may occur at any time during the year.

CMS will generally use a risk-based process, based in part on compliance monitoring (e.g., complaint data) and available performance data, to select issuers for standard³⁹ compliance reviews. CMS may also select a QHP/SADP or issuer for a compliance review based on a specific issue of potential non-compliance. If CMS selects a QHP/SADP or issuer due to a specific issue of potential non-compliance, CMS may perform a targeted⁴⁰ review specific to the area(s) of potential non-compliance and/or conduct the compliance review on an expedited basis.⁴¹ In some cases, due to the potential magnitude of harm to consumers, CMS may conduct limited, expedited compliance reviews of issuers to ensure that potential operational problems can be identified and addressed early on.

CMS may conduct either a desk review or an on-site review⁴² and the type and location of the review will be included in the issuer selection notification. CMS will review data at both the

³⁹ Standard reviews include all review areas.

⁴⁰ Targeted reviews can include all review areas or just select review areas.

⁴¹ Issuers selected for expedited compliance reviews will be required to submit documentation with a shorter turnaround time.

⁴² On-site reviews will take place at the issuer's place of business.

issuer and the QHP/SADP level. CMS may request, as part of the compliance review process, policies, procedures, and any other applicable documentation⁴³ reasonably necessary to evaluate and verify compliance with the applicable FFM requirements.

CMS intends to coordinate with the State regulatory entities, when appropriate, in conducting the compliance reviews. At the conclusion of all compliance reviews for the year, CMS will share the results of the reviews conducted by the Agency with States and the lessons learned with issuers.

Section 4. FFM Oversight of Agents and Brokers

This section describes how CMS will approach oversight of agents and brokers participating in the FFMs. It also provides an overview of accompanying QHP and SADP issuer responsibilities regarding their relationships with and oversight obligations for their affiliated agents and brokers who will be assisting with enrollment in QHPs offered through the FFMs. Unless noted otherwise, references to agents and brokers include web-brokers.⁴⁴

i. QHP Issuer Responsibilities

Pursuant to 45 C.F.R. 156.340, a QHP issuer participating in the FFMs maintains responsibility for ensuring that its delegated and downstream entities, including affiliated agents and brokers, comply with applicable laws and regulations. Accordingly, CMS expects QHP issuers to confirm all affiliated agents' and brokers' licensure statuses, verify that they fulfilled the applicable FFM registration and training requirements before allowing access to the QHP issuer's tools to assist with enrollment through the FFMs and/or providing compensation for Marketplace transactions. QHP issuers may verify agents and brokers' FFM registration and training status according to the registration completion list on the CMS agent and broker resources page.⁴⁵ CMS intends to update the list of registered agents and brokers frequently, and QHP issuers will not have to collect training certificates and FFM user IDs from agents and brokers who complete plan year 2016 FFM registration. In addition to verifying registration and training status, QHP issuers are responsible for ensuring that activities related to the FFMs that are conducted on their behalf by affiliated agents and brokers (e.g., enrollment) comply with applicable Federal standards, including those related to privacy and security, conflict(s) of interest, marketing, and continuing education. CMS believes that these steps, at a minimum, would be required for a QHP issuer to

⁴³ Additional documentation could include sample sets of applicable data (i.e., notices, claims, complaints, etc.).

⁴⁴ CMS uses the term "web-broker" to refer to agents or brokers who use their own website, or that of another agent or broker, to facilitate enrollment in a QHP through the FFM in accordance with 45 C.F.R. 155.220(c)(3).

⁴⁵ This page is available at: <http://www.cms.gov/CCIIO/programs-and-initiatives/health-insurance-marketplaces/a-b-resources.html>. CMS intends to continue updating the list at least twice monthly.

demonstrate good faith efforts at complying with 45 CFR 156.340 as it relates to oversight of affiliated agents and brokers.

ii. *Agent and Broker Agreements*

Agents and brokers must comply with all applicable privacy and security requirements, including but not limited to the standards established by HHS pursuant to 45 C.F.R. 155.260, related to the use of handling of personally identifiable information (PII) by non-Marketplace entities.⁴⁶ Before assisting consumers in the FFMs, agents and brokers must execute the Individual Market and/or FF-SHOP Privacy/Security Agreement (depending on whether the agent or broker is participating in the FFMs for the Individual Market, the FF-SHOP, or both), which includes further details on the Marketplace privacy and security standards related to the use and disclosure of PII.

Every agent and broker must execute the applicable agreement(s) with CMS as part of the registration process with the FFMs. These agreements include:

- Agent Broker General Agreement for the FFMs Individual Market (General Agreement) — all agents and brokers who wish to assist consumers in the FFMs for the Individual Market must electronically execute this General Agreement.
- Agreement Between Agent or Broker and CMS for the FFMs Individual Market (IM Privacy and Security Agreement) — all agents and brokers who wish to assist individual market consumers in the FFMs must electronically execute this Privacy and Security Agreement.
- Agreement Between Agents and Brokers and CMS for the FF-SHOP (SHOP Privacy and Security Agreement) — all agents and brokers who wish to assist FF-SHOP consumers must electronically execute this Privacy and Security Agreement.
- Agreement Between Web-Broker Entity and CMS for the FFMs for the Individual Market (Web-Broker Agreement) — all web-brokers who wish to assist individual market consumers in the FFMs must electronically execute this Web-Broker Agreement.

By signing the applicable agreement(s), agents and brokers attest that they will:

- Comply with Marketplace privacy and security requirements, such as standards for use and disclosure of PII;
- Comply with all applicable State and Federal laws and regulations;

⁴⁶ These include the eight privacy principles listed at 45 C.F.R. 155.260(a)(3).

- Maintain valid licensure in all States where they wish to enroll qualified individuals and employers/employees into QHPs through the FFMs; and
- Complete the full FFM registration process in advance of assisting consumers, including taking all applicable training.

iii. *Monitoring and Oversight*

CMS works with States to coordinate oversight activities related to agents and brokers. CMS may investigate complaints pertaining to agents and brokers in the FFMs, and will monitor QHP issuer activities to confirm they are meeting their responsibilities for oversight of affiliated agents and brokers.

CMS may terminate an agent's or broker's Agreement(s) with the FFMs for cause if it determines that a specific finding of noncompliance or a pattern of noncompliance is sufficiently severe (based on what Federal standards have been violated, and factors such as financial impact and number of consumers affected), or if the agent or broker materially breaches any term of the General Agreement, IM Privacy and Security Agreement, SHOP Privacy and Security Agreement, and/or the Web-Broker Agreement, as applicable.⁴⁷ A termination would effectively bar the agent or broker from assisting with enrollment through the FFM. Termination can be temporary (e.g., subject to reinstatement upon correction of the noncompliance) or permanent. If an agent or broker's Agreement(s) with the FFMs is terminated (either by the agent or broker or by the FFMs), the agent or broker must continue to protect any PII that was accessed during the term of his or her relationship with the FFMs in accordance with the IM and/or SHOP Privacy/Security Agreement and the applicable requirements under 45 C.F.R. 155.260.

CMS will inform States, QHP issuers, and FFM consumers of agents and brokers who have had their registration terminated for cause pursuant to 45 C.F.R. 155.220(g) by posting a list of those agents' and brokers' NPNs on the CMS agent and broker resources webpage.⁴⁸ An agent's or broker's NPN would only be added to this revocation list after the conclusion of the reconsideration process, or the expiration of the time permitted for such activity.⁴⁹ Prior to posting the revocation list, CMS intends to adopt safeguards to ensure the accuracy of the NPN information. We note that termination for cause does not include a natural termination due to a lapse in completion of the annual registration requirements.

⁴⁷ 45 C.F.R. 155.220(g)

⁴⁸ This page is available at: <http://www.cms.gov/CCIIO/programs-and-initiatives/health-insurance-marketplaces/a-b-resources.html>.

⁴⁹ 45 C.F.R. 155.220(h)

Pursuant to 45 C.F.R. 155.285, HHS may impose a civil money penalty of up to \$25,000 for each application for failure to provide correct information to the Marketplaces, or for improper use or disclosure of consumer PII, where such failure is attributable to negligence or disregard of any HHS rules or regulations. HHS may impose a civil money penalty of up to \$250,000 for knowingly and willfully providing false or fraudulent information to the Marketplaces. Whether the agent or broker, or QHP issuer would be responsible for the civil money penalty will depend on an analysis of the particular facts and circumstances of the situation. The good faith compliance policy described in Section 2 above was extended only through the 2015 calendar year.

iv. Web-brokers

CMS regulations establish additional requirements that apply when an agent or broker uses their own website, or that of another agent or broker, to facilitate enrollment in a QHP through the FFMs.⁵⁰ CMS uses the term “web-broker” to refer to such agents or brokers who use a non-FFM website to assist consumers in the QHP selection and enrollment process as described in 45 C.F.R. 155.220(c)(3).

To the extent permitted by a State, CMS works with web-brokers that meet all applicable requirements to provide an alternate option to help consumers select and enroll in individual market QHPs⁵¹ through the FFMs online, alongside traditional agents and brokers who assist consumers with enrollment through the Marketplaces.

CMS has developed the capability to support Direct Enrollment integration between the web-broker’s website and HealthCare.gov using secure redirect and application programming interface (API) mechanisms. The Direct Enrollment pathway enables a consumer to initiate his or her shopping experience on the web-broker’s website, connect securely to HealthCare.gov to complete the eligibility application and determination process, and return securely to the web-broker’s site to compare plans and enroll in a QHP.

Regulations at 45 C.F.R. 155.220(c)(3)(i) generally require web-brokers to disclose and display all QHP information provided to them by the FFMs or directly by QHP issuers. To the extent that not all information required under 45 C.F.R. 155.205(b)(1) is displayed on the web-broker’s website, the web-broker must prominently display a standardized disclaimer provided by CMS

⁵⁰ 45 C.F.R. 155.220(c)(3),(4)

⁵¹ Pursuant to 45 C.F.R. 155.220(i), as amended by the 2016 Payment Notice Final Rule, beginning January 1, 2015, SHOPS may permit agents and brokers, in States that permit such activity under State law, to use a QHP issuer or web-broker website to provide assistance to employers and facilitate enrollment of enrollees in SHOP QHPs, subject to the requirements of 45 C.F.R. 155.220(c)(3). The FF-SHOPS may elect to implement this functionality for plan years beginning in 2016.

stating that information required under 45 C.F.R. 155.205(b)(1) for the QHP is available on HealthCare.gov, and provide an operational link to HealthCare.gov. This disclaimer is in addition to the requirement that web-brokers must prominently display a standardized disclaimer on its website to inform consumers that the website is not an official FFM website, and provide an operational link to HealthCare.gov.

In the 2016 Payment Notice Final Rule, CMS specified that a web-broker's existing obligation under 45 C.F.R. 155.205(c)(2)(i) to provide oral interpretation services includes making available telephonic interpreter services in at least 150 languages. This standard applies to web-brokers beginning November 1, 2015, or one year after a web-broker registers with the FFM, whichever date is later.

CMS also specified language access requirements for web-brokers pertaining to taglines and translation of website content which will become applicable beginning with the first day of the open enrollment period for the individual market for the 2017 benefit year, or one year after a web-broker registers with the FFM, whichever date is later. First, under 45 C.F.R. 155.205(c)(2)(iii)(B), we specified that a web-broker's existing obligation to include taglines in non-English languages specifically includes providing taglines on website content and any document that is critical for obtaining health insurance coverage or access to health care services through a QHP for qualified individuals, applicants, qualified employers, qualified employees, or enrollees. Such taglines must indicate the availability of language services in at least the top 15 languages spoken by individuals with limited English proficiency in the relevant State, as determined in HHS guidance. A document is deemed to be critical for obtaining health insurance coverage or access to health care services through a QHP if it is required to be provided by State or Federal law or regulation to a qualified individual, applicant, qualified employer, qualified employee, or enrollee. Second, under 45 C.F.R. 155.205(c)(2)(iv)(C), we specified that a web-broker must translate website content that is intended for a qualified individual, applicant, qualified employer, qualified employee, or enrollee on a website maintained by the web-broker into any non-English language that is spoken by an LEP population that reaches 10 percent or more of the population of the relevant State, as determined in HHS guidance.⁵² We intend to publish data identifying the non-English languages that are triggered by these standards for each State as well as sample taglines in future guidance.

v. *Compensation*

Agents and brokers are compensated directly by QHP issuers as per the terms of their QHP issuer contracts for assisting consumers to enroll in QHPs through the FFM. Compensation

⁵² We note that based on current data and subject to future changes, this threshold triggers the translation of website content into Spanish in California and Texas.

includes commissions, fees, or other incentives as established in the relevant contract between a QHP issuer and the agent or broker. An agent or broker must be affiliated or have a contractual relationship with the respective issuer, in accordance with applicable State law, and must complete the applicable FFM registration requirements in order to be paid by an issuer for a Marketplace transaction. The FFMs do not set compensation levels or pay commissions to agents or brokers. CMS does not require QHP issuers to offer contracts to agents and brokers, including offering compensation for enrollment in QHPs through the FFMs. QHP issuers should compensate only affiliated agents and brokers that are compliant with applicable Federal requirements, including those for registration with the FFMs.⁵³ CMS believes that withholding compensation from affiliated agents and brokers who fail to comply with FFM registration and other applicable Federal requirements would generally be required for an issuer to demonstrate good faith efforts at complying with 45 CFR 156.340 as it relates to oversight of affiliated agents and brokers.

The FFMs transmit the identifying information of agents and brokers (e.g., national producer number (NPN)) to QHP issuers on the 834s, but the FFMs do not play a role in setting compensation levels or ensuring that compensation is paid to agents and brokers because the FFMs are not a party to the contract between the QHP issuer and the agent or broker. However, Federal regulations require QHP issuers to provide the same compensation to agents and brokers for QHPs offered through the FFMs as they do for similar health plans offered in the State outside the Marketplaces.⁵⁴ This compensation approach is a required participation standard for QHP issuers offering coverage in the FFMs, including both the Individual Market and SHOP.

The specific location where the NPN can be captured is dependent on the Marketplace (i.e., Individual or SHOP Marketplace), re-enrollment type (i.e., passive or active), enrollment pathway (i.e., direct enrollment or Marketplace/Side-by-Side pathway), application form (i.e., new streamlined application or classic FFM application), and the timing of the NPN entry (i.e., during the eligibility application process or during the plan selection process). Please refer to the guidance document, “Operational Tips for Agents/Brokers Assisting Consumers with Plan years beginning in 2015 Enrollments in the FFM” for more details.⁵⁵

Agents and brokers who are acting as Navigators, certified application counselors, and/or (in FFMs and SPMs) non-Navigator assistance personnel may not receive any direct or indirect compensation from health insurance or stop loss insurance issuers in connection with the

⁵³ See “i. QHP Issuer Responsibilities” under this section, and 45 C.F.R. 156.340.

⁵⁴ 45 C.F.R. 156.200(f)

⁵⁵ Operational Tips for Agents/Brokers Assisting Consumers with Plan Year 2015 Enrollments in the FFM, November 12, 2014. Available at: <http://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Operational-Tips-Enrollment-11-12-2014-508.pdf>.

enrollment of any individuals or employees in a QHP or non-QHP. All agents and brokers should follow State standards with respect to charging consumers directly for services provided.

vi. *Registration Requirement for Re-enrollment Transactions*

Agents or brokers who are assisting consumers with enrollment in QHPs offered through the FFMs must have a current FFM registration at the time they are providing assistance. Because passive re-enrollments assume that agents or brokers are not directly assisting consumers to facilitate the re-enrollment in a QHP through the FFMs, agents or brokers would not need to have a current registration to be listed on the 2015 re-enrollment transaction. In contrast, for active re-enrollments that involve agent or broker assistance, agents or brokers must have a current registration with the FFMs at the time they are assisting consumers.

vii. *HHS-Approved Vendors of FFM Training and Information Verification*

In the 2016 Payment Notice Final Rule, HHS establishes standards at 45 C.F.R. 155.222 for approved vendors to provide training and information verification services by which State licensed agents and brokers could complete the training requirements necessary to assist consumers seeking coverage through the FFMs. This provides an additional avenue by which agents and brokers could satisfy the requirement to receive training in the range of QHP options and the insurance affordability programs; HHS will continue to offer training. An entity that is interested in becoming a vendor would be required to submit an application and, upon approval of the application, execute an agreement with HHS. Vendors will be approved for one-year terms and those seeking to continue their recognition the following year must be re-approved by HHS. Approved vendors are also required to adhere to HHS specifications for content, format, and delivery of training and information verification; and to collect, store, and share with HHS all data from agent and broker users of the vendor's training and information verification in a manner, format, and frequency specified by HHS. HHS will post the list of all approved vendors on its website. HHS also anticipates monitoring and auditing vendors' compliance after launching of their respective training and information verification programs, and HHS may revoke approval if the vendor does not comply with HHS standards. Entities whose applications are not approved or who have their approval revoked may request an appeal.

Section 5. Oversight of Marketing Activities

This section describes how CMS will monitor QHP marketing during plan years beginning in 2016 in the FFMs and provides information that supplements what was discussed in the 2015 Letter to Issuers. States performing plan management functions in the FFMs are encouraged to take a similar approach.

Regulations at 45 C.F.R. 156.200(e) provide that QHP issuers must not, with respect to their QHPs, discriminate on the basis of race, color, national origin, disability, age, sex, gender

identity, or sexual orientation. 45 C.F.R. 156.225(a) requires that in order to have a plan certified as a QHP, a QHP issuer must comply with all applicable State laws on health plan marketing by health insurance issuers. In addition, 45 C.F.R. 156.225(b) states that a QHP issuer must not employ marketing practices that will have the effect of discouraging the enrollment of individuals with significant health needs in QHPs.

As noted in the 2015 Letter to Issuers, States generally regulate health plan marketing practices and materials and related documents under State law, and CMS does not intend to review QHP marketing materials for compliance with State standards as described at 45 C.F.R. 156.225(a). In FFM States, CMS may review QHP marketing materials for compliance with 45 C.F.R. 156.200(e) and 45 C.F.R. 156.225(b). CMS will work with States to determine where additional monitoring and review of marketing activities may be needed. For all QHP issuers in the FFMs, CMS recommends that agreements with agents and brokers, as well as marketing materials distributed to enrollees and to prospective enrollees, contain a clause such as the following: “[Insert plan’s legal or marketing name] does not discriminate on the basis of race, color, national origin, disability, age, sex, gender identity, sexual orientation, or health status in the administration of the plan, including enrollment and benefit determinations.” If CMS receives a consumer complaint about an issuer’s marketing activities or about an agent’s, broker’s, or web-broker’s conduct which is generally overseen by the State, CMS will send the complaint to the State regulators, as appropriate, for investigation. Following the State’s investigation, CMS may take the necessary enforcement action against the issuer or agent, broker, or web-broker.

All marketing, whether paper, electronic, or other media, must reflect accurate information that complies with both Marketplace and market-wide standards. In addition, marketing materials that solicit PII must comply with the privacy and security standards described at 45 C.F.R. 155.260. CMS will refer cases of false advertising/false information, as well as privacy and/or security violations, to the appropriate State and Federal entities. Following the State’s or other entities’ investigation, CMS may take the necessary enforcement action against the QHP issuer or agent, broker, or web-broker.

CMS strongly suggests that QHP issuers, agents, brokers, and web-brokers not use “Marketplace” or “Exchange” in the name of their businesses or websites. We recommend that as a best practice, a non-FFM website should indicate if it does not offer all available Marketplace plans, and note that web-broker websites must provide consumers the ability to view all QHPs offered through the Exchange.⁵⁶ If an agent or broker assists a consumer with individual market FFM or FF-SHOP QHP selection through the agent’s, broker’s, or web-broker’s non-FFM website, a standardized disclaimer must be prominently displayed to indicate that the site is not a Health Insurance Marketplace website, and an active link to HealthCare.gov

⁵⁶ 45 C.F.R. 155.220(c)(3)(ii)

must also be provided.⁵⁷ Although CMS does not require disclosure of affiliations with QHP issuers, consistent with 45 C.F.R. 155.220(e), CMS expects agents, brokers, and web-brokers to comply with applicable State standards for disclosing financial information, including financial relationships with QHP issuers.

CHAPTER 5: FF-SHOPS

Section 1. Dental Changes

For plan years beginning as early as 2016, employers offering coverage through the FF-SHOPS will be able to offer dental coverage without also having to offer medical coverage. When only dental coverage is offered by an employer and dependent dental coverage is also made available by the employer, a qualified employee, as defined at 45 C.F.R. 155.20, would have to enroll in dental coverage before dependents of that qualified employee will be able to enroll in dental coverage, just as is the case for medical coverage.

We received comments about the availability of child-only plans in the FF-SHOP. Because qualified employees must first enroll in FF-SHOP coverage before any of their dependents can enroll in coverage, dependent child-only plans will generally not be available in the FF-SHOPS. If an employer participating in an FF-SHOP is offering qualified employees medical and dental coverage through the FF-SHOP, and a qualified employee under age 21 is eligible to enroll in that coverage consistent with Section 1302(f) of the Affordable Care Act, then the qualified employee may enroll in the dental coverage without also having to enroll in the medical coverage.

In addition, if an employer offers both medical and dental coverage to qualified employees and their dependents through an FF-SHOP, and a qualified employee enrolls in both medical and dental coverage, the qualified employee's dependents will be able to enroll in either the medical or dental coverage selected by the qualified employee, or in both. CMS notes that dependents of a qualified employee will be able to enroll only in the same medical and dental plans in which the qualified employee has enrolled.

For example, the following situations might be possible:

- A qualified employee and all dependents are enrolled in the same medical and dental coverage.

⁵⁷ See 45 C.F.R. 155.220(c)(3)(vii). Also see 45 C.F.R. 155.220(i), as amended by the 2016 Payment Notice Final Rule, which allows SHOPs to permit agents and brokers, in States that permit such activity under State law, to use an Internet website to provide assistance to qualified employers and facilitate enrollment of enrollees in SHOP QHPs, subject to the requirements of 45 C.F.R. 155.220(c)(3).

- A qualified employee and one dependent are enrolled in the same medical and dental coverage, but another dependent is enrolled only in the dental coverage in which the qualified employee is enrolled.
- A qualified employee and one dependent are enrolled in the same medical and dental coverage, while another dependent is enrolled only in the medical coverage in which the qualified employee is enrolled.
- A qualified employee is enrolled in both medical and dental coverage, and one dependent is enrolled only in the medical coverage in which the qualified employee is enrolled, while another dependent is enrolled only in the dental coverage in which the qualified employee is enrolled.

CMS notes that because of operational limitations, estimated premiums for SADPs will not be available in the FF-SHOP for plan years beginning on or after January 1, 2016. As is the case in 2015, consumers in 2016 will be able to obtain premium quotes for SADPs in the same way they do for QHPs, and premiums will always be guaranteed for the employer's plan year.

Section 2. Premiums Based on Average Enrollee Premium Amounts

45 C.F.R. 147.102(c)(3)(iii) and 156.285(a)(4)(ii) establish parameters for premiums based on average enrollee premium amounts in the FF-SHOPS. CMS anticipates that the capacity to calculate and display premiums based on an average enrollee premium amount will be available in the FF-SHOPS as early as plan years beginning on or after January 1, 2016.

45 C.F.R. 147.102(c)(3)(iii) does not require medical and dental issuers participating in the FF-SHOPS to make available premiums based on average enrollee premium amounts to small employers. 45 C.F.R. 156.285(a)(4)(ii) precludes a QHP or SADP issuer participating in an FF-SHOP from offering a qualified employer premiums based on average enrollee premium amounts if the employer elects to offer qualified employees a choice of plans at a specified level of coverage as described in 155.705(b)(3)(iv)(A) and 155.705(b)(3)(v)(B). Thus, in the FF-SHOPS, premiums based on average enrollee premium amounts will be available only to qualified employers that choose to offer their qualified employees a single plan instead of employee choice. In addition, because of operational limitations, premiums based on average enrollee amounts will only be allowed for groups that have at least one adult age 21 or older enrolled in coverage. Without an adult age 21 or older enrolling at the time of initial enrollment, CMS will not know how much to charge adults enrolling after initial enrollment because a 12-month average was not initially calculated.

When employers choose the single plan option, they will be able to decide whether to pay premiums using a per-member methodology or one based on average enrollee premium amounts. Employers will be able to search issuers by an indicator showing whether the issuer makes available premiums based on average enrollee premium amounts.⁵⁸ If an employer selects the option to select QHPs that make available premiums based on average enrollee amounts, then only those plans offered by issuers that have made this option available will be displayed.

To determine the total premium charged for a given family composition under a methodology based on average enrollee premium amounts, the FF-SHOPs will sum the average enrollee premium amount for each covered family member age 21 and older and the average enrollee premium amount for each covered family member under age 21, as applicable, taking into account no more than three covered children under age 21. Applicable tobacco rating factors will be excluded from these premium calculations and will be added separately to enrollee charges on monthly invoices, based on the applicable enrollee's per-member per-month premium.

For example, suppose the average enrollee premium for a group health plan is \$200 for each covered individual age 21 and older and \$100 for each covered individual under age 21. Also suppose that none of the enrollees use tobacco. In this example, the premium charged for a single qualified employee (over age 21) would be \$200; the premium charged for a qualified employee and spouse (both over age 21) would be \$400 ($\$200 + \$200$); and the premium charged for a family consisting of a qualified employee and spouse (both over age 21) and four children (all under age 21) would be \$700 ($\$200 + \$200 + \$100 + \$100 + \$100 + \$0$).

If an issuer offering premiums based on average enrollee premium amounts wishes to rate for tobacco use, consistent with applicable Federal and State law, the FF-SHOPs will calculate the tobacco rating factor based on the applicable enrollee's per-member per-month premium, not the average enrollee premium amount. The resulting tobacco rating factor is added to the average enrollee premium amount for the enrollee who uses tobacco to create a premium specific to each tobacco user.

For example, an employer chooses a plan offering premiums based on average enrollee premium amounts. The issuer imposes a 1.5:1 tobacco rating factor based on the enrollee's per-member per-month premium, not the average enrollee premium amount. Assume that the average enrollee premium for a group health plan is \$100 for each covered individual age 21 and older, that the premium for a 45-year old is \$100, and the premium for a 35-year old is \$80. In this example, the premium charged for the 45-year old who uses tobacco would be \$150 ($\$100 + (0.5 \times \$100)$), and the premium charged for the 35-year old who uses tobacco would be \$140 ($\$100 + (0.5 \times \$80)$),

⁵⁸ As part of the 2016 QHP Application process, medical and dental issuers will document their decision to accept or not accept premiums based on average enrollee premium amounts.

subject to the non-discrimination and wellness provisions under section 2705 of the PHS Act. A tobacco indicator and a wellness program indicator are present on member-level 834 transactions, which will inform FF-SHOP issuers whether a tobacco rating factor has been applied.

After an employer completes the enrollment process, the average enrollee premium amounts calculated will be locked in for the plan year and recalculated only at the time of renewal. Thus, regardless of how a group's composition changes during its plan year, premiums charged for children and adults will remain the same until the time of renewal. Any new hires or dependents added as a result of a special enrollment period will be charged the same average enrollee premium amount charged to initial enrollees.

The Group XML file transmitted to the issuer during initial enrollment will contain an indicator (either yes or no) indicating whether premiums based on average enrollee premium amounts apply to a group for the plan year as well as two average enrollee premium amounts—one for enrollees under age 21 and one for enrollees 21 and older. 834 enrollment transactions will also contain the average enrollee premium amount charged for each enrollee.

Issuers will communicate to CMS whether they will make available plans with premiums based on average enrollee premium amounts at the time of initial enrollment through the Plans and Benefits template. A new variable will be added to the Plans and Benefits template to identify whether the issuer is offering premiums based on average enrollee premium amounts.

Section 3. Online Renewals

An employer may decide to renew its FF-SHOP participation as well as the coverage it offered in the previous year through the FF-SHOPs. The employer may also decide that it will renew its FF-SHOP participation, but not renew the coverage it offered in the previous year through the FF-SHOPs. Both of these circumstances are considered renewals of FF-SHOP participation and must follow the FF-SHOP renewal process, even where they do not result in an issuer's renewing coverage, as defined for purposes of guaranteed renewability. For plan years beginning on or after January 1, 2016, CMS anticipates that renewals of FF-SHOP participation and renewals of health and dental coverage offered through the FF-SHOPs will continue to be handled by qualified employers and qualified employees online at HealthCare.gov. Employers and qualified employees working with an agent or broker will also need to handle renewals and changes to FF-SHOP participation and coverage at HealthCare.gov.

The FF-SHOP renewal process applies to employer groups that were determined eligible to buy coverage through the FF-SHOPs and had qualified employees enroll in a plan through the FF-SHOP in the previous plan year. The qualified employer renewing participation will have an annual election period during which he or she can renew or change his or her FF-SHOP coverage offer to qualified employees. This election period will begin when rate and plan information

becomes available for the quarter in which coverage would end, but not more than two months before the date an enrollment must be submitted to avoid a gap in coverage.⁵⁹ Qualified employers must provide their qualified employees with an annual open enrollment period of at least one week to decide whether to accept the coverage offer. All enrollments must be submitted by the 15th day of the month for coverage to start the first day of the next month. The employer's election period will therefore end at least one week prior to the deadline for completing an enrollment that would take effect at the end of the employer's prior plan year.

Pursuant to 45 C.F.R. 155.710(d), the FF-SHOPs must allow an employer to continue participating in an FF-SHOP for plan years beginning in 2016 if the following conditions are met: (1) the employer received a determination of eligibility from an FF-SHOP in a prior year and has continued participating in that FF-SHOP since that time, (2) the employer was a small employer when it began participating in the FF-SHOP but has ceased to be a small employer solely by reason of an increase in the number of employees, and (3) the employer continues to meet all other requirements for participating in an FF-SHOP. For plan years beginning in 2016, the FF-SHOPs will be sending notices to employer groups and qualified employees regarding the annual employer election period and the annual employee open enrollment period. Issuers are not responsible for distributing these notices, but are still subject to market-wide requirements regarding notices under 45 C.F.R.147.106.

Pursuant to 45 C.F.R. 155.725(i), a qualified employer's offer of coverage and a qualified employee's coverage may be automatically renewed if certain conditions are met. If no action is taken by the qualified employer or qualified employee, provided that the conditions in 155.725(i) are met, the qualified employee will remain in the QHP selected in the previous year. CMS expects that QHP and SADP renewals will be considered separately so that a qualified employee (and dependents, if applicable) may be automatically renewed in medical coverage alone, dental coverage alone, or both, provided that the qualified employer continues to offer both that medical and that dental coverage through the FF-SHOP. Pursuant to 45 C.F.R. 155.725(i), a qualified employee's coverage will not be automatically renewed if the qualified employee terminates coverage in accordance with 45 C.F.R. 155.430; the qualified employee enrolls in another QHP if such option exists; or the QHP is no longer available to the qualified employee.

Section 4. Employee Choice

Pursuant to 45 C.F.R. 155.705(b)(3)(vi), for plan years beginning in 2015, States could request that the FF-SHOPs provide employers only with the option to offer a single plan, rather than

⁵⁹ Employers renewing SHOP coverage as of the first quarter of calendar year 2016 will be able to view rates and begin the renewal process as early as October 1, 2015. Thus, they will have more than two months to complete the renewal process.

providing employers with the option to offer employee choice. This was a transitional policy that applied only to plan years beginning in 2015. For plan years beginning on or after January 1, 2016, employee choice will be available to all qualified employers in all States. Thus, in all FF-SHOPs for plan years beginning in 2016, employers will have a choice of two methods to make QHPs available to qualified employees: (1) they can offer qualified employees a choice of all QHPs at a single level of coverage -- bronze, silver, gold, or platinum, or (2) they can offer a single QHP. Employers will also have the option to make available either (1) all SADPs at a single level of coverage – high or low, or (2) a single SADP.

Section 5. Employer Group Size in the FF-SHOPs

Pursuant to 45 C.F.R. 155.20, in an FF-SHOP, small employer means, in connection with a group health plan, an employer who employed an average of at least 1 but not more than 100 full-time equivalent employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year. In the case of plan years beginning before January 1, 2016, a State was permitted to elect to define small employer by substituting “50 employees” for “100 employees.” For plan years beginning on or after January 1, 2016, this discretion no longer applies, and a small employer is defined as an employer who employed an average of at least one but not more than 100 full-time-equivalent employees on business days during the preceding calendar year and who employ at least 1 employee on the first day of the plan year. Thus, for plan years beginning on or after January 1, 2016, the statute and regulations provide that QHPs and SADPs are to be available through the FF-SHOPs to employers with 1 to 100 full-time-equivalent employees. Coverage through the FF-SHOPs will also be available to employers that were determined eligible to participate in the FF-SHOPs for plan years prior to 2016, that have participated in the FF-SHOPs continuously since first becoming eligible, and that grew to larger than 100 full-time-equivalent employees since first becoming eligible, so long as these employers continue to meet all other conditions of participation.

Under guidance CMS issued on March 5, 2014, CMS announced an exercise of enforcement discretion under which transition relief would apply to employers with between 51 and 100 employees that purchased large employer coverage while still defined as large employers in the State, under which these employers could renew such policies for plan years beginning before October 1, 2016 and be subject to Federal enforcement only of large employer requirements. As of January 1, 2016, however, employers with from 51 to 100 employees purchasing new coverage must comply with small employer requirements, including the rating restrictions and the single risk pool requirement. Similarly, except to the extent that 45 C.F.R. 155.710(d) applies, when an employer increases in size from a small employer to a large employer, the employer’s small group coverage generally is only guaranteed renewable if it meets all of the requirements applicable to the large group market.

CHAPTER 6: CONSUMER SUPPORT AND RELATED ISSUES

Section 1. Consumer Case Tracking and Resolution

The content of this section applies to QHP and SADP issuers in the FFM, including in States performing plan management functions.

CMS expects QHP issuers to thoroughly investigate and resolve consumer issues received directly from members or forwarded to the QHP issuer by the State through the issuer's internal customer service process and as required by State law. Additionally, QHP issuers operating in the FFMs must investigate and resolve consumer cases, including complaints, forwarded by CMS in accordance with the requirements at 45 C.F.R. 156.1010. Cases are forwarded through the Health Insurance Casework System (HICS). CMS expects issuers to resolve all cases in a timely and accurate manner to ensure consumers receive the highest level of service and to meet QHP issuer participation standards as outlined at 45 C.F.R. 156.200. Timeframes for resolving cases forwarded by CMS are specified in 45 C.F.R. 156.1010(d).

Cases that CMS may forward include, but are not limited to, issues related to cancellations/terminations, proper application of the advance payments of the premium tax credit, and adjustments of effective dates based on special enrollment periods (SEPs) or enrollment errors. In all cases, CMS expects QHP issuers operating in the FFMs to conduct appropriate research using all of the tools and systems available to them, including but not limited to 834 transactions and pre-audit files. Additionally, CMS expects QHP issuers operating in the FFMs to contact consumers as appropriate to conduct their investigations and research in order to ensure that issuers are using the most recent information available from the consumer. Issuers may often need to contact a consumer prior to the resolution of a case as a critical part of the investigation and research process. CMS expects that issuers will carry out the needed research for their cases in a comprehensive manner that assures consumers that issuers' case resolutions are based on all of the available and most current information. CMS Regional Office staff is available to assist QHP issuers by providing technical assistance on casework matters beyond QHP issuers' control to resolve.

QHP issuers operating in the FFM, including in States performing plan management functions, are expected to comply with all applicable State and Federal laws related to consumer complaints, including any applicable requirement to advise consumers of their appeal rights. CMS tracks cases and uses this information as a tool for directing oversight activities in the FFM. To the greatest degree possible, CMS collaborates with States, sharing information suggestive of issuer performance problems.

Section 2. Coverage Appeals

The content of this section applies to all QHP issuers in the FFM, including in States performing plan management functions.

As in plan years beginning in 2015, in 2016 QHPs are required to meet the same standards for internal claims and appeals and external review established at 45 C.F.R. 147.136, which implements section 2719 of the PHS Act, as added by the Affordable Care Act. Section 2719 of the PHS Act requires that all non-grandfathered group health plans and non-grandfathered health insurance issuers offering group or individual health insurance coverage implement an effective process for internal claims and appeals and external review. QHPs must fully comply with the requirements of 45 C.F.R. 147.136.

Section 3. Meaningful Access

This section summarizes the requirements and guidance that apply to QHP issuers (including SADP issuers) to ensure meaningful access by limited-English proficient (LEP) speakers and by individuals with disabilities.

In the 2016 Payment Notice Final Rule, CMS finalized amendments to 45 C.F.R. 155.205(c) pertaining to oral interpretation, the use of taglines indicating the availability of language services, and website translation. CMS also amended 45 C.F.R. 156.250, which extends the requirements in 45 C.F.R. 155.205(c) to QHP issuers, to require QHP issuers to provide all information that is critical for obtaining health insurance coverage or access to health care services through the QHP to qualified individuals, applicants, qualified employers, qualified employees, and enrollees in a manner consistent with 45 C.F.R. 155.205(c). A document is deemed to meet this standard if the issuer is required by State or Federal law or regulation to provide it to a qualified individual, applicant, qualified employer, qualified employee, or enrollee.

Under these amendments to 45 C.F.R. 156.250, QHP issuers must ensure meaningful access to at least the following essential documents:

- Applications;
- Consent, grievance, and complaint forms, and any documents requiring a signature;
- Correspondence containing information about eligibility and participation criteria;
- Notices pertaining to the denial, reduction, modification, or termination of services, benefits, non-payment, and/or coverage;
- A plan's explanation of benefits or similar claim processing information;

- Rebate notices;
- Summary of benefits and coverage disclosures;
- Formulary drug lists;
- Provider directories; and
- The policy, insurance contract, evidence of coverage, or similar legally-required document.

In the 2016 Payment Notice Final Rule, under 45 C.F.R. 155.205(c)(2)(i)(A), CMS specified that a QHP issuer's existing obligation to provide oral interpretation services includes making available telephonic interpretation services in at least 150 languages.

CMS also specified other language access requirements pertaining to taglines and translation of website content that apply to QHP issuers. These requirements will become applicable for issuers beginning with the first day of the open enrollment period for the individual market for the 2017 benefit year. First, under 45 C.F.R. 155.205(c)(2)(iii)(A), we specified that a QHP issuer's existing requirement to include taglines in non-English languages includes providing taglines on website content and any document that is critical for obtaining health insurance coverage or access to health care services through a QHP for qualified individuals, applicants, qualified employers, qualified employees, or enrollees. Such taglines must indicate the availability of language services in at least the top 15 languages spoken by individuals with limited English proficiency in the relevant State, as determined in HHS guidance. For this purpose, a document is deemed to be critical for obtaining health insurance coverage or access to health care services through the QHP if it is required to be provided by State or Federal law or regulation to the qualified individual, applicant, qualified employer, qualified employee, or enrollee.

Under 45 C.F.R. 155.205(c)(2)(iv)(B), we specified that a QHP issuer must translate certain website content that is "critical" within the meaning of 45 C.F.R. 156.250, into any non-English language that is spoken by an LEP population that reaches 10 percent or more of the population of the relevant State, as determined in HHS guidance.⁶⁰ We intend to publish data identifying the non-English languages that are triggered by these standards for each State as well as sample taglines in future guidance.

In order to achieve greater consistency among certain programs within HHS, CMS continues to work with other HHS components to further specify standards for ensuring meaningful access by LEP speakers and by people with disabilities.

⁶⁰ We note based on current data, this threshold only triggers the translation of website content into Spanish, and only with respect to California and Texas.

Finally, QHP issuers operating in the FFM are reminded that the meaningful access requirements at 45 C.F.R. 155.205(c), 155.230(b), and 156.250, as well as non-discrimination prohibitions at 45 C.F.R. 156.200(e), are independent of other obligations QHP issuers might have. For example, QHP issuers that receive Federal financial assistance are subject to Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973,⁶¹ and section 1557 of the Affordable Care Act, and as a result, have separate responsibilities under the law not to discriminate on the basis of race, color, national origin, sex, age and disability, in providing access to their services.

Section 4. Summary of Benefits and Coverage

The content of this section applies to all QHP issuers in the FFM, including States performing plan management functions. This does not apply to SADPs.

QHP issuers are required to provide the Summary of Benefits and Coverage (SBC) in a manner compliant with the standards set forth in 45 C.F.R. 147.200, which implements section 2715 of the PHS Act, as added by the Affordable Care Act. Specifically, issuers must fully comply with the requirements of 45 C.F.R. 147.200(a)(3), which requires issuers to “provide an SBC in the form, and in accordance with the instructions for completing the SBC, that are specified by the Secretary in guidance.”

In the 2016 Payment Notice Final Rule, CMS amended 45 C.F.R. 156.420 and 156.425 to require QHP issuers to provide SBCs that accurately represent plan variations in a manner consistent with the requirements set forth at 45 C.F.R. 147.200, and provide adequate notice, in the form of a new SBC, to enrollees after receiving notice from the Exchange of the enrollee’s assignment into a new plan variation (or standard QHP without cost-sharing reductions). In accordance with these new regulations, beginning no later than November 1, 2015, QHP issuers must provide separate SBCs for each plan variation and therefore may not combine information about multiple plan variations in one SBC. Issuers offering plan variations should include a separate URL linking to the SBC created for each plan variation as part of the QHP data submission to CMS.

⁶¹ Consistent with Section 504 of the Rehabilitation Act and HHS implementing regulations at 45 C.F.R. 84, covered entities, which include all recipients of federal financial assistance from HHS, are required to “provide auxiliary aids to persons with disabilities, at no additional cost, where necessary to afford an equal opportunity to participate in or benefit from a program or activity” (<http://www.hhs.gov/ocr/civilrights/understanding/disability/>). CMS encourages QHP issuers seeking to understand their legal obligations to provide auxiliary aids and services to people with disabilities to reference the U.S. Department of Justice’s Effective Communications guidance at <http://www.ada.gov/effective-comm.htm>.

Additional changes to 45 C.F.R. 147.200 and accompanying guidance, including the SBC template, Uniform Glossary, and instructions, were proposed by HHS, with the Departments of Labor and the Treasury, through a notice of proposed rulemaking published December 30, 2014.⁶² We note that these proposed changes, if finalized as proposed, would apply with respect to policy or plan years beginning on or after September 1, 2015.

We remind issuers that all URL links included on the SBC must be readily obtainable (that is, without requiring logging on to a website, entering a policy number, clicking through several web pages, or creating user accounts, memberships, or registrations) to consumers, including shoppers, and link directly to the information referenced on the SBC. For example, in accordance with 45 C.F.R. 147.200(a)(2)(i)(K), the link for obtaining information on prescription drug coverage in the SBC must directly link to the formulary for the benefit package reflected on the SBC, as noted previously. Similarly, pursuant to 45 C.F.R. 147.200(a)(2)(i)(J) (proposed to be recodified from 45 C.F.R. 147.200(a)(2)(i)(I)), the web address where a copy of the actual individual coverage policy or group certificate of coverage can be reviewed and obtained must also link directly from the appropriate space on the SBC and be readily obtainable to shoppers.

Section 5. Transparency in Coverage Reporting

The content of this section outlines transparency reporting requirements for all QHP including SADP issuers in the FFM, including the FFMs in States that are performing plan management functions. This section further outlines CMS's intent to implement the requirement for QHP issuers participating in the FFMs to comply with transparency requirements in 2016.

Under section 1311(e)(3) of the Affordable Care Act, as implemented by regulations at 45 C.F.R. 156.220, issuers seeking certification of a health plan as a QHP must make accurate and timely disclosures of certain information to the appropriate Marketplace, the Secretary of HHS, and the State insurance commissioner, and make it available to the public. As noted in the 2016 Payment Notice Final Rule, because a full year of claims data will be available, CMS anticipates the collection and public display of the required information listed in 45 C.F.R. 156.220 from QHP issuers offering coverage through Marketplaces will begin in 2016.

CMS intends to seek additional feedback on these transparency reporting requirements through a collection of information under the Paperwork Reduction Act.

⁶² Summary of Benefits and Coverage and Uniform Glossary; Notice of Proposed Rulemaking; 79 Federal Register 78578 (December 30, 2014).

CHAPTER 7: TRIBAL RELATIONS AND SUPPORT

CMS has a historic and unique relationship with Federally-recognized Indian tribes and Indian health care providers: health programs operated by the Indian Health Service (IHS), Tribes and Tribal organizations, and urban Indian organizations. In adhering to QHP certification standards, CMS encourages QHPs to contract with Indian health care providers, through which a significant number of American Indians and Alaska Natives (AI/AN) access health care. To promote contracting between issuers and Indian health care providers, CMS is continuing to require QHPs to offer contracts in good faith to all available Indian health care providers in the QHP's service area, applying the special terms and conditions necessitated by Federal law and regulations as referenced in the Model QHP Addendum⁶³ (Addendum), as described in the 2014 Letter to Issuers. Issuers should refer to that document and the addendum itself, both of which are available on the CCIIO website, for further details. A list of Indian health care providers and address/contact information may be found on the CCIIO website.

Section 206 of the Indian Health Care Improvement Act (IHCIA) (25 USC § 1621e) provides for a right of recovery from an insurance company and other third party entities, including QHP issuers, for reasonable charges billed by an Indian health care provider when providing services, or, if higher, the highest amount the third party would pay for services furnished by other providers. This right of recovery applies whether the Indian health care provider is in a plan network or not. Further details can be found at <http://www.ihs.gov/ihcia/>.

Even though Indian health care providers have a right of recovery under section 206 of the IHCIA, CMS encourages issuers and Indian health care providers to develop mutually beneficial business relationships that promote effective care for medically underserved and vulnerable populations.

⁶³ The model QHP Addendum for Indian health providers is available at <http://www.cms.gov/ccio/programs-and-initiatives/health-insurance-marketplaces/qhp.html>.

EXHIBIT 15

Department of Health & Human Services

Centers for Medicare & Medicaid Services
Center for Consumer Information & Insurance Oversight
200 Independence Avenue SW
Washington, DC 20201



Date: November 15, 2017

Subject: Risk Corridors Payment and Charge Amounts for the 2016 Benefit Year

Background:

Section 1342 of the Affordable Care Act directs the Secretary of the Department of Health and Human Services (HHS) to establish a temporary risk corridors program that provides issuers of qualified health plans (QHPs) in the individual and small group markets additional protection against uncertainty in claims costs during the first three years of Exchange operations.

HHS established a three-year payment framework for the risk corridors program and outlined the details of this payment framework in our April 11, 2014 guidance entitled *Risk Corridors and Budget Neutrality*.¹ As set forth in that guidance, if risk corridors collections for a particular benefit year are insufficient to make full risk corridors payments as calculated for that benefit year, risk corridors payments are reduced pro rata to the extent of any shortfall. HHS then uses risk corridors collections for the subsequent benefit year toward risk corridors payment balances for the previous benefit years, until issuers have been reimbursed in full for the previous benefit year, before making payments for the current benefit year. Consistent with this framework, HHS announced on November 18, 2016 that all 2015 benefit year risk corridors collections would be applied toward 2014 benefit year risk corridors payment balances.²

Today, HHS is announcing issuer-level risk corridors payments and charges for the 2016 benefit year. Because 2015 benefit year collections were insufficient to pay 2014 benefit year payment balances in full, HHS will use 2016 benefit year risk corridors collections to make additional payments toward 2014 benefit year payment balances. The table below shows risk corridors payments and charges calculated for the 2016 benefit year, by State and issuer, and the amount of anticipated 2016 risk corridors collections that HHS expects to pay for issuers that have 2014 benefit year payment balances.³

HHS intends to collect the full 2016 risk corridors charge amounts indicated in the tables below, however, the 2014 payment amounts listed in the tables below will be reduced pro rata based on

¹ *Risk Corridors and Budget Neutrality*, available at: <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/faq-risk-corridors-04-11-2014.pdf>

² *Risk Corridors Payment and Charge Amounts for the 2015 Benefit Year*, available at: <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2015-RC-Issuer-level-Report-11-18-16-FINAL-v2.pdf>

³ Risk corridor payment and charge amounts published in this bulletin reflect risk corridors data submitted to HHS by September 30, 2017 and do not account for amounts that may be held back for administrative appeals.

collections received. HHS is collecting 2016 risk corridor charges in November 2017 and will begin remitting risk corridors payments to issuers in January 2018, as collections are received.

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS 2016 RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET) ⁴	HHS 2016 RISK CORRIDOR AMOUNT (SMALL GROUP MARKET) ⁴	EXPECTED PAYMENT TOWARD 2014 AMOUNTS ^{4,5}
AK	38344	Premera Blue Cross Blue Shield of Alaska	\$0.00	\$0.00	\$71,752.90
AK	73836	Moda Health Plan, Inc.	\$2,331,107.54	\$2,535,475.85	\$14,666.28
AL	44580	Humana Insurance Company	\$5,347,297.70	\$0.00	\$8,238.76
AL	46944	Blue Cross and Blue Shield of Alabama	\$31,253,329.90	\$0.00	\$3,086.00
AL	59809	UnitedHealthcare Life Insurance Company	N/A	N/A	\$0.00
AL	68259	UnitedHealthcare of Alabama, Inc.	\$4,226,662.97	\$0.00	N/A
AR	37903	QualChoice Life & Health Insurance Company, Inc.	\$6,742,797.09	\$0.00	N/A
AR	62141	Celtic Insurance Company	-\$435,672.31	\$0.00	\$0.00
AR	65817	UnitedHealthcare of Arkansas, Inc.	-\$171,378.54	\$0.00	N/A
AR	70525	QCA Health Plan, Inc.	\$5,894,850.51	\$0.00	\$36,371.03
AR	75293	USABLE Mutual Insurance Company	\$19,022,135.87	-\$1,727.51	\$0.00
AZ	23307	Humana Health Plan, Inc.	\$3,030,258.28	\$0.00	\$16,107.78
AZ	51485	Health Net Life Insurance Company	\$6,406,342.85	\$0.00	\$390,038.18
AZ	53901	Blue Cross Blue Shield of Arizona, Inc.	\$10,845,468.60	\$0.00	\$101,672.21
AZ	60761	Meritus Health Partners	N/A	N/A	\$30,355.96
AZ	65441	Phoenix Health Plans, Inc.	\$14,356,552.64	\$0.00	N/A
AZ	70239	Health Choice Insurance Co.	\$12,591,097.47	\$0.00	\$10,944.97
AZ	78611	Aetna Health Inc. (a PA corp.)	\$2,200,505.68	\$0.00	N/A
AZ	84251	Aetna Life Insurance Company	N/A	N/A	\$522.54

⁴ N/A indicates that the issuer was not required to submit risk corridors data for the benefit year referenced.

⁵ \$0.00 indicates that the issuer submitted risk corridors data for the 2014 benefit year but does not have a 2014 benefit year risk corridors payment balance.

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS 2016 RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET) ⁴	HHS 2016 RISK CORRIDOR AMOUNT (SMALL GROUP MARKET) ⁴	EXPECTED PAYMENT TOWARD 2014 AMOUNTS ^{4,5}
AZ	86830	Cigna Health and Life Insurance Company	N/A	N/A	\$1,507.99
AZ	88925	University of Arizona Health Plans-University Healthcare, Inc.	N/A	N/A	\$5,611.56
AZ	91450	Health Net of Arizona, Inc.	\$10,827,593.54	\$1,688,379.12	\$398,961.79
AZ	92045	Meritus Mutual Health Partners	N/A	N/A	\$16,297.96
AZ	97667	Cigna HealthCare of Arizona, Inc	\$1,709,445.01	\$0.00	N/A
AZ	98971	All Savers Insurance Company	\$2,787,630.49	-\$49,087.07	N/A
CA	10544	Oscar Health Plan of California	\$4,167,289.22	\$0.00	N/A
CA	18126	MOLINA HEALTHCARE OF CALIFORNIA	\$0.00	\$0.00	\$0.00
CA	27603	Blue Cross of California(Anthem BC)	\$55,180,958.69	\$0.00	\$0.00
CA	37873	UnitedHealthcare Benefits Plan of California	\$510,269.44	\$0.00	N/A
CA	40513	Kaiser Foundation Health Plan, Inc.	\$22,533,814.62	\$133,003,881.28	\$321,273.85
CA	47579	Chinese Community Health Plan	\$523,908.24	\$763,358.71	\$6,200.40
CA	67138	Health Net of California, Inc	\$0.00	\$0.00	\$0.00
CA	70285	CA Physician's Service dba Blue Shield of CA	\$0.00	\$0.00	\$0.00
CA	84014	County of Santa Clara	\$233,230.49	\$0.00	\$0.00
CA	92499	Sharp Health Plan	\$652,496.53	\$630,358.81	\$67.63
CA	92815	Local Initiative Health Authority for Los Angeles County	\$3,948,187.97	\$0.00	\$117,969.86
CA	93689	Western Health Advantage	\$995,351.80	\$700,089.44	\$50.58
CA	99110	Health Net Life Insurance Company	\$8,099,981.20	\$0.00	\$44,005.99
CA	99483	CONTRA COSTA HEALTH PLAN	N/A	N/A	\$0.00
CO	11555	New Health Ventures Inc	N/A	N/A	\$926.60
CO	20472	Colorado Health Insurance Cooperative, Inc.	N/A	N/A	\$124,396.13

STATE	HIOS ID	HIOS INPUTTED INSURANCE COMPANY NAME	HHS 2016 RISK CORRIDOR AMOUNT (INDIVIDUAL MARKET) ⁴	HHS 2016 RISK CORRIDOR AMOUNT (SMALL GROUP MARKET) ⁴	EXPECTED PAYMENT TOWARD 2014 AMOUNTS ^{4,5}
CO	21032	Kaiser Foundation Health Plan of Colo.	\$76,429,472.92	\$0.00	\$123,181.64
CO	49375	Cigna Health and Life Insurance Company	\$3,811,568.48	\$0.00	\$0.00
CO	59036	UnitedHealthcare of Colorado, Inc.	\$719,427.07	\$0.00	N/A
CO	63312	Colorado Choice Health Plans	\$900,328.41	\$4,055,983.33	\$52,260.66
CO	66699	Denver Health Medical Plan, Inc	-\$688,815.34	\$0.00	\$2,501.26
CO	74320	Humana Health Plan	\$0.00	\$0.00	\$27,693.60
CO	76680	HMO Colorado, Inc., dba HMO Nevada	\$2,015,531.53	\$45,449.80	\$12,871.37
CO	80208	Rocky Mountain Health Care Options	\$0.00	\$4,463,039.51	\$3,832.28
CO	87269	Rocky Mountain Hospital and Medical Service, Inc., dba Anthem Blue Cross and Blue Shield	\$14,813,129.30	\$0.00	N/A
CO	92137	All Savers Insurance Company	-\$422,444.96	\$0.00	\$0.00
CO	97879	Rocky Mountain HMO	\$11,392,994.52	\$3,230,381.44	\$17,816.32
CT	49650	UnitedHealthcare Insurance Company	\$793,529.41	-\$34,355.06	\$98.29
CT	76962	ConnectiCare Benefits, Inc.	\$10,110,217.78	\$0.00	\$0.00
CT	86545	Anthem Health Plans Inc (Anthem BCBS)	\$6,673,451.37	\$0.00	\$0.00
CT	91069	HealthyCT, Inc.	\$22,557,147.20	\$3,025,676.93	\$15,952.57
DC	21066	UnitedHealthcare of the Mid-Atlantic Inc	\$0.00	\$53,160.65	N/A
DC	41842	UnitedHealthcare Insurance Company	\$0.00	\$0.00	\$0.00
DC	73987	Aetna Health Inc. (a PA corp.)	\$0.00	\$236,018.31	\$0.00
DC	75753	Optimum Choice, Inc.	\$0.00	-\$153,126.12	\$0.00
DC	77422	Aetna Life Insurance Company	\$0.00	\$1,348,005.01	\$0.00
DC	78079	GHMSI	\$54,354.10	\$379,836.03	\$0.00
DC	86052	CareFirst BlueChoice, Inc.	\$18,583.46	\$120,537.46	\$0.00

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DC	94506	Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc.	\$643,071.50	\$1,364,900.88	\$10,935.98
DE	13537	Coventry Health and Life	N/A	N/A	\$0.00
DE	29497	Aetna Life Insurance Company	\$474,963.04	\$0.00	N/A
DE	67190	Aetna Health Inc. (a PA corp.)	\$0.00	\$126,849.04	N/A
DE	76168	Highmark BCBSD Inc.	\$15,159,604.02	\$0.00	\$52,848.57
DE	81914	Coventry Health Care of Delaware, Inc.	N/A	N/A	\$0.00
FL	16842	Blue Cross and Blue Shield of Florida	\$0.00	\$0.00	\$125,572.05
FL	18628	Aetna Health Inc. (a FL corp.)	\$0.00	\$0.00	N/A
FL	21663	Celtic Insurance Company	\$0.00	\$0.00	N/A
FL	23841	Aetna Life Insurance Company	N/A	N/A	\$0.00
FL	27357	Health First Health Plans, Inc.	\$1,432,717.01	\$0.00	\$895.97
FL	30252	Health Options, Inc.	\$0.00	\$0.00	\$99,007.22
FL	35783	Humana Medical Plan, Inc.	\$32,890,544.08	\$173,712.62	\$358,660.25
FL	48121	Cigna Health and Life Insurance Company	N/A	N/A	\$35,388.79
FL	51398	Preferred Medical Plan, Inc.	N/A	N/A	\$302,522.11
FL	54172	Molina Healthcare of Florida, Inc	\$26,068,734.68	\$0.00	\$339.56
FL	56503	Florida Health Care Plan, Inc.	\$0.00	\$0.00	\$0.00
FL	57451	Coventry Health Care of Florida, Inc.	\$0.00	\$0.00	\$266,187.17
FL	68398	UnitedHealthcare of Florida, Inc.	\$9,330,450.46	\$0.00	N/A
FL	77150	Health First Insurance, Inc.	\$0.00	\$205,230.49	\$16,113.18
FL	83883	Florida Health Solution HMO Company	\$0.00	\$0.00	N/A
FL	86382	Sunshine State Health Plan	N/A	N/A	\$0.00
GA	43802	UnitedHealthcare of Georgia, Inc.	\$4,356,433.40	\$0.00	N/A
GA	45495	Peach State Health Plan	N/A	N/A	\$0.00
GA	49046	Blue Cross Blue Shield Healthcare Plan of Georgia, Inc.	\$212,623.53	\$0.00	\$0.00

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GA	50491	Cigna Health and Life Insurance Company	\$1,901,757.01	\$0.00	N/A
GA	70893	Ambetter of Peach State Inc.	\$0.00	\$0.00	N/A
GA	82824	Aetna Health Inc. (a GA corp.)	\$780,032.71	\$0.00	N/A
GA	83761	Alliant Health Plans	\$4,529,064.09	\$0.00	\$1.08
GA	89942	Kaiser Foundation Health Plan of Georgia	\$29,343,780.25	\$667,124.28	\$17,236.52
GA	93332	Humana Employers Health Plan of Georgia, Inc.	\$102,932,298.50	\$1,410,936.48	\$730,465.11
GA	95852	Harken Health Insurance Company	\$12,210,414.34	\$0.00	N/A
HI	18350	Hawaii Medical Service Association	\$14,609,115.03	\$1,514,974.14	\$0.00
HI	60612	Kaiser Foundation Health Plan, Inc.	\$15,458,919.49	\$714,193.48	\$161,886.27
IA	18973	Aetna Health Inc. (a IA corp.)	\$1,370,536.30	\$0.00	\$23,553.76
IA	27651	Gundersen Health Plan, Inc.	\$75,831.31	\$5,595.73	\$990.27
IA	51902	UnitedHealthcare of the Midlands, Inc.	\$1,351,512.14	\$0.00	N/A
IA	71268	CoOpportunity Health	N/A	N/A	\$487,173.70
IA	74980	Avera Health Plans, Inc.	\$155,933.71	\$207,564.57	\$877.81
IA	77638	Health Alliance Midwest, Inc.	N/A	N/A	\$0.00
IA	85930	Sanford Health Plan	\$0.00	\$163,552.53	\$1,123.32
IA	88678	UnitedHealthcare Insurance Company	\$0.00	\$0.00	N/A
IA	93078	Medica Insurance Company	\$1,748,293.69	\$0.00	N/A
ID	26002	SelectHealth	\$51,028,512.58	\$6,672,365.27	\$225,833.45
ID	38128	Montana Health Cooperative	\$13,010,336.93	\$179,300.09	N/A
ID	44648	Regence Blue Shield of Idaho	N/A	N/A	\$0.00
ID	59765	BridgeSpan Health Company	\$847,275.91	\$0.00	\$242.85
ID	60597	PacificSource Health Plans	\$1,205,143.84	\$0.00	\$19,508.86
ID	61589	Blue Cross of Idaho Health Service, Inc.	\$14,535,162.34	\$0.00	\$348,280.50
IL	16724	UnitedHealthcare of the Midwest, Inc.	\$157,038.37	\$0.00	N/A

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IL	20129	Health Alliance Medical Plans, Inc.	\$21,342,103.01	\$71,969.35	\$24,131.15
IL	27833	Celtic Insurance Company	\$1,846,059.24	\$0.00	N/A
IL	35670	Coventry Health & Life Co.	\$0.00	\$0.00	\$2,942.33
IL	36096	Blue Cross Blue Shield of Illinois	\$112,457,984.78	\$3,412,467.14	\$1,715,156.95
IL	58288	Humana Health Plan, Inc.	\$102,828.49	\$0.00	\$6,967.57
IL	68303	Humana Insurance Company	N/A	N/A	\$41,765.42
IL	72547	Aetna Life Insurance Company	N/A	N/A	\$1,361.64
IL	78463	Harken Health Insurance Company	\$28,285,818.16	\$0.00	N/A
IL	79763	Land of Lincoln Mutual Health Insurance Company	\$42,901,843.98	\$9,846,132.23	\$39,077.05
IL	96601	Coventry Health Care of Illinois, Inc.	\$0.00	\$0.00	\$27,641.33
IL	99129	Aetna Health Inc. (a PA corp.)	\$7,352,468.06	\$0.00	N/A
IN	17575	Anthem Ins Companies Inc(Anthem BCBS)	\$0.00	\$0.00	\$7,068.45
IN	20855	Advantage Health Solutions, Inc.	\$0.00	\$0.00	N/A
IN	33380	Indiana University Health Plans, Inc.	\$403,177.29	\$0.00	N/A
IN	35065	Coordinated Care Corporation Indiana	N/A	N/A	\$0.00
IN	36373	All Savers Insurance Company	\$6,211,732.83	\$0.00	N/A
IN	50816	Physicians Health Plan of Northern Indiana, Inc.	\$4,482,634.94	\$0.00	\$28,751.69
IN	54192	CareSource Indiana, Inc.	\$10,568,031.40	\$0.00	N/A
IN	62033	MDwise Marketplace, Inc.	\$9,751,130.86	\$0.00	N/A
IN	67920	Southeastern Indiana Health Organization	\$105,200.90	\$0.00	N/A
IN	76179	Celtic Insurance Company	-\$1,099,796.09	\$0.00	N/A
IN	85320	MDwise, Inc.	N/A	N/A	\$0.00
KS	18558	Blue Cross and Blue Shield of Kansas, Inc.	\$17,567,910.47	\$408,112.19	\$122,123.61

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KS	27811	BlueCross BlueShield Kansas Solutions, Inc.	\$28,453,460.78	\$142,714.94	N/A
KS	50274	UnitedHealthcare of the Midwest, Inc.	\$0.00	\$0.00	N/A
KS	61430	Coventry Health and Life	N/A	N/A	\$199,115.09
KS	65598	Coventry Health Care Of Kansas Inc	N/A	N/A	\$82,617.01
KS	94248	Blue Cross and Blue Shield of Kansas City	\$11,222,745.35	\$2,304,584.43	\$10,973.78
KS	94968	UnitedHealthcare Insurance Company	\$0.00	\$0.00	N/A
KY	15411	Humana Health Plan, Inc.	\$2,625,179.37	\$0.00	\$52,445.04
KY	23671	UnitedHealthcare of Kentucky, Ltd.	\$0.00	\$0.00	\$0.00
KY	34822	Aetna Health Inc. (a PA corp.)	\$0.00	\$0.00	N/A
KY	36239	Anthem Health Plans of KY(Anthem BCBS)	\$0.00	-\$37,294.97	\$0.00
KY	40586	Bluegrass Family Health, Inc.	\$9,865,154.55	\$2,898,208.49	\$12,805.35
KY	45636	CareSource Kentucky Co.	\$3,087,507.35	\$0.00	N/A
KY	47949	Golden Rule Insurance Company	N/A	N/A	\$0.00
KY	72001	WELLCARE HEALTH PLANS OF KENTUCKY, INC	-\$13,574.40	\$0.00	N/A
KY	77894	Kentucky Health Cooperative	N/A	N/A	\$670,458.18
LA	19636	HMO Louisiana, Inc.	\$4,490,022.42	\$687,627.16	\$27,646.68
LA	38499	UnitedHealthcare of Louisiana, Inc.	\$200,537.78	\$0.00	N/A
LA	44965	Humana Health Benefit Plan of Louisiana, Inc.	\$3,092,925.82	\$0.00	\$3,607.09
LA	67202	Louisiana Health Cooperative, Inc.	N/A	N/A	\$104,030.52
LA	67243	Vantage Health Plan, Inc.	\$8,130,698.29	-\$15,784.88	\$210.66
LA	97176	Louisiana Health Service & Indemnity Company	\$21,756,614.82	\$1,822,667.19	\$307,395.02
MA	29125	Tufts Associated Health Maintenance Org	\$0.00	\$0.00	\$0.00

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MA	31234	CeltiCare Health Plan of MA	\$0.00	\$0.00	\$1,746.54
MA	31779	UnitedHealthcare Insurance Company	\$492,333.25	\$0.00	N/A
MA	34484	Health New England, Inc.	\$591,143.39	\$1,823,346.74	\$0.00
MA	36046	Harvard Pilgrim Health Care Inc.	\$945,497.81	\$7,745,516.62	\$0.00
MA	41304	Neighborhood Health Plan	\$0.00	\$0.00	\$155,998.39
MA	42690	Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc.	\$0.00	\$0.00	\$0.00
MA	59763	Tufts Health Public Plans Inc.	\$0.00	\$0.00	\$0.00
MA	73331	Minuteman Health, Inc	\$2,916,284.01	\$311,545.12	\$9,904.80
MA	82569	Boston Medical Center Health Plan, Inc.	\$0.00	\$0.00	\$15,106.14
MA	88806	Fallon Community Health Plan, Inc.	\$1,606,849.24	\$328,544.25	\$4,875.12
MA	95878	HPHC Insurance Company Inc.	\$8,976,329.97	\$9,268,445.40	\$10,565.74
MD	14468	Coventry Health Care of Delaware, Inc.	N/A	N/A	\$0.00
MD	23620	UnitedHealthcare Insurance Company	\$0.00	\$0.00	\$0.00
MD	28137	CareFirst BlueChoice, Inc.	\$41,057,486.62	-\$46,498.46	\$155,946.37
MD	31112	UnitedHealthcare of the Mid-Atlantic Inc	\$0.00	-\$27,309.80	\$0.00
MD	32812	Cigna Health and Life Insurance Company	\$743,128.94	\$0.00	N/A
MD	36677	All Savers Insurance Company	\$0.00	\$0.00	\$1,205.34
MD	45532	CareFirst of Maryland, Inc.	\$11,539,940.12	\$62,844.74	\$47,341.07
MD	65635	MAMSI Life and Health Insurance Company	\$0.00	-\$117,035.51	\$0.00
MD	66516	Aetna Health Inc. (a PA corp.)	\$0.00	\$0.00	N/A
MD	68541	Coventry Health and Life	\$0.00	\$0.00	\$0.00
MD	70767	Aetna Life Insurance Company	\$0.00	\$34,442.90	N/A
MD	72375	Optimum Choice, Inc.	\$0.00	\$0.00	\$0.00
MD	72564	Evergreen Health Cooperative, Inc.	\$5,446,190.67	\$15,614,288.59	\$35,975.13

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MD	90296	Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc.	\$31,064,359.51	\$77,950.89	\$4,896.36
MD	94084	GHMSI	\$9,019,881.61	\$0.00	\$8,886.20
ME	33653	Maine Community Health Options	\$21,050,424.64	\$4,317,337.28	\$2,102.64
ME	48396	Anthem Health Plans of ME(Anthem BCBS)	\$0.00	\$0.00	\$0.00
ME	96667	Harvard Pilgrim Health Care Inc.	\$747,510.63	\$444,527.55	N/A
MI	15560	Blue Cross Blue Shield of Michigan Mutual Insurance Company	\$5,296,176.54	\$0.00	\$0.00
MI	20393	McLaren Health Plan	\$0.00	\$781,057.65	\$4,634.82
MI	29241	Priority Health Insurance Company (PHIC)	\$7,075,598.39	\$0.00	\$9,411.44
MI	29698	Priority Health	\$26,339,617.56	\$0.00	\$3,580.16
MI	37651	Health Alliance Plan (HAP)	\$0.00	\$0.00	\$0.00
MI	40047	Molina Healthcare of Michigan, Inc.	-\$39,105.84	\$0.00	\$0.00
MI	41895	Consumers Mutual Insurance of Michigan	N/A	N/A	\$15,920.95
MI	45002	UnitedHealthcare Life Insurance Company	\$0.00	-\$906.46	\$0.28
MI	46275	Humana Medical Plan of Michigan, Inc.	\$9,529,350.76	\$0.00	\$70,478.35
MI	58594	Meridian Health Plan of Michigan, Inc.	\$0.00	\$0.00	\$0.00
MI	60829	Physicians Health Plan	\$277,579.39	\$0.00	N/A
MI	63631	UnitedHealthcare Insurance Company	\$0.00	\$0.00	N/A
MI	67183	Total Health Care USA, Inc.	\$0.00	-\$2,047,580.25	\$0.00
MI	67577	Alliance Health and Life Insurance Company	\$846,068.00	\$0.00	\$562.17

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MI	71667	UnitedHealthcare Community Plan, Inc.	\$0.00	\$0.00	N/A
MI	74917	McLaren Health Plan Community	\$0.00	\$0.00	N/A
MI	98185	Blue Care Network of Michigan	\$20,617,731.68	\$0.00	\$149,563.12
MN	31616	Medica Insurance Company	\$0.00	\$0.00	\$2,757.22
MN	34102	Group Health Plan, Inc.	\$14,052,643.55	\$0.00	\$22,722.12
MN	49316	BCBSM, INC.	\$61,016,505.39	\$7,923,542.86	\$60,505.56
MN	57129	HMO Minnesota	\$5,336,936.71	\$504,528.26	N/A
MN	65847	Medica Health Plans of Wisconsin	\$35,597,185.27	\$0.00	\$0.00
MN	85736	UCare Minnesota	\$10,114,026.06	\$0.00	\$0.00
MN	88102	PreferredOne Insurance Company	N/A	N/A	\$461,585.23
MO	16049	All Savers Insurance Company	\$0.00	\$0.00	N/A
MO	30613	Humana Insurance Company	\$373,172.66	\$0.00	N/A
MO	32753	Healthy Alliance Life Co(Anthem BCBS)	\$0.00	\$0.00	\$196.52
MO	34762	Blue Cross and Blue Shield of Kansas City	\$21,589,143.65	\$49,355.14	\$24,424.21
MO	44240	Coventry Health and Life	\$0.00	\$0.00	\$252,932.81
MO	74483	Cigna Health and Life Insurance Company	\$1,404,505.78	\$0.00	N/A
MS	48963	Humana Insurance Company	\$9,041,890.00	\$0.00	\$0.00
MS	61794	UnitedHealthcare Life Insurance Company	\$0.00	\$0.00	\$0.00
MS	90714	Ambetter of Magnolia Inc.	\$0.00	\$0.00	N/A

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MS	94237	Magnolia Health Plan	N/A	N/A	\$0.00
MS	97560	UnitedHealthcare of Mississippi, Inc.	\$3,906,592.67	\$0.00	N/A
MT	23603	PacificSource Health Plans	\$9,717,931.78	\$135,770.45	\$16,858.72
MT	30751	Blue Cross and Blue Shield of Montana	\$31,380,006.00	\$3,027,515.02	\$208,874.79
MT	32225	Montana Health Cooperative	\$290,347.23	\$355,758.03	\$54,200.16
NC	11512	Blue Cross and Blue Shield of NC	\$18,159,126.49	\$0.00	\$1,282,852.75
NC	54332	UnitedHealthcare of North Carolina, Inc	\$0.00	\$0.00	N/A
NC	56346	Coventry Health Care of the Carolinas, Inc.	N/A	N/A	\$88,629.95
NC	61671	Aetna Health Inc. (a PA corp.)	\$15,884,547.64	\$0.00	N/A
ND	37160	Blue Cross Blue Shield of North Dakota	\$0.00	\$0.00	\$3,987.33
ND	39364	Medica Insurance Company	\$0.00	\$19,371.92	N/A
ND	73751	Medica Health Plans	\$0.00	\$62,294.31	\$2,090.31
ND	89364	Sanford Health Plan	\$1,765,053.70	\$108,586.34	\$0.00
NE	15438	Coventry Health Care of Nebraska Inc.	\$14,918,861.69	\$0.00	\$0.00
NE	20305	Medica Insurance Company	\$7,670,841.68	\$0.00	N/A
NE	29678	Blue Cross and Blue Shield of Nebraska	\$25,923,663.23	\$520,261.48	\$123,027.09
NE	43198	CoOpportunity Health	N/A	N/A	\$643,281.99
NE	44751	UnitedHealthcare of the Midlands, Inc.	\$6,406,781.24	\$0.00	N/A
NE	68389	UnitedHealthcare Life Insurance Company	\$0.00	\$0.00	N/A
NE	73102	UnitedHealthcare Insurance Company	\$0.00	\$0.00	N/A
NE	77931	Health Alliance Midwest Inc.	N/A	N/A	\$63.65
NH	19304	Maine Community Health Options	\$5,826,502.09	\$4,804,390.97	N/A
NH	59025	Harvard Pilgrim Health Care of NE	\$291,440.74	\$0.00	N/A

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NH	61163	Minuteman Health, Inc	\$10,710,229.92	\$9,045.97	N/A
NH	75841	Celtic Insurance Company	-\$10,549,229.99	\$0.00	N/A
NH	96751	Matthew Thornton Hlth Plan(Anthem BCBS)	\$0.00	\$0.00	\$0.00
NJ	10191	Freelancers CO-OP of New Jersey, Inc.	\$36,610,266.63	\$7,789,387.27	\$1,306.25
NJ	48834	Oxford Health Plans (NJ), Inc.	\$4,561,830.04	\$0.00	N/A
NJ	50221	Oscar Insurance Corporation of New Jersey	\$3,064,840.14	\$0.00	N/A
NJ	77606	AmeriHealth HMO, Inc.	\$3,974,893.09	\$105,954.94	\$30,437.40
NJ	91661	Horizon Healthcare Services, Inc.	\$16,478,389.42	\$0.00	\$27,709.38
NJ	91762	AmeriHealth Ins Company of New Jersey	\$73,160,117.68	\$344,230.91	\$10,070.13
NM	19722	Molina Health Care of New Mexico, Inc.	\$0.00	\$0.00	\$0.00
NM	52744	Presbyterian Insurance Company, Inc.	\$0.00	\$8,019,908.13	\$0.00
NM	57173	Presbyterian Health Plan, Inc.	\$2,450,553.68	\$350,630.79	\$21,562.43
NM	72034	CHRISTUS Health Plan	\$2,352,154.70	\$0.00	N/A
NM	75605	Blue Cross Blue Shield of New Mexico	\$2,231,211.41	\$653,200.67	\$57,124.04
NM	93091	New Mexico Health Connections	\$13,116,504.33	\$10,319,090.60	\$36,636.23
NV	16698	Prominence HealthFirst	\$0.00	\$0.00	\$0.00
NV	33670	Rocky Mountain Hospital and Medical Service, Inc., dba Anthem Blue Cross and Blue Shield	\$4,030,060.93	\$0.00	N/A
NV	34996	Nevada Health CO-OP	N/A	N/A	\$93,079.06
NV	60156	HMO Colorado, Inc., dba HMO Nevada	\$0.00	-\$7,237.91	\$23.62
NV	95865	Health Plan of Nevada, Inc.	\$3,326,339.65	\$0.00	\$0.00
NY	11177	MetroPlus Health Plan	\$14,216,773.89	\$820,311.63	\$76,155.52
NY	18029	Independent Health Benefits Corporation	\$2,527,441.24	\$12,491,216.10	\$0.00

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NY	25303	New York State Catholic Health Plan, Inc.	\$3,996,255.02	\$0.00	\$0.00
NY	31808	American Progressive Life & Health Insurance Company of New York	N/A	N/A	\$0.00
NY	39595	WellCare of New York	\$442,366.09	\$0.00	N/A
NY	40064	HealthNow New York	\$5,597,212.16	\$23,522,343.21	\$0.00
NY	54235	UnitedHealthcare of New York, Inc.	\$4,509,245.86	\$0.00	\$0.00
NY	56184	MVP Health Plan, Inc.	\$5,120,950.13	\$1,162,229.18	\$13,489.22
NY	57165	Affinity Health Plan, Inc.	\$20,735,006.33	\$0.00	\$10,259.07
NY	71644	Freelancers Health Service Corporation d/b/a Health Republic Insurance of New York	N/A	N/A	\$1,299,031.53
NY	74289	Oscar Insurance Corporation	\$107,138,699.40	\$0.00	\$81,270.32
NY	78124	Excellus Health Plan, Inc.	\$0.00	\$23,595,031.50	\$65,471.29
NY	80519	Empire HealthChoice HMO, Inc.	\$8,305,584.61	\$0.00	\$0.00
NY	82483	North Shore-LIJ Insurance Company Inc	\$50,880,224.71	\$62,252,325.98	\$30,592.89
NY	85629	Oxford Health Insurance, Inc.	N/A	N/A	\$0.00
NY	88582	Health Insurance Plan of Greater New York	\$8,669,878.30	\$1,686,044.58	\$0.00
NY	91237	Healthfirst PHSP, Inc.	\$6,891,430.55	\$0.00	\$656.96
NY	92551	CDPHP Universal Benefits Inc.	\$0.00	\$10,440,924.71	\$127,063.72
NY	94788	CDPHP	\$1,128,625.43	\$0.00	\$0.00
NY	95456	Atlantis Health Plan	N/A	N/A	\$0.00
OH	16204	Coordinated Health Mutual, Inc.	\$20,218,260.47	\$310,347.28	N/A
OH	20126	HealthSpan Integrated Care	\$1,619,850.19	\$2,851,843.52	\$97,447.70
OH	23340	Consumers Life Insurance Company	-\$160,706.30	\$0.00	N/A
OH	26734	Premier Health Plan, Inc.	\$5,682,287.55	\$0.00	N/A
OH	28162	AultCare Insurance Company	\$0.00	\$0.00	\$5,685.81
OH	29276	Community Insurance Company(Anthem BCBS)	\$0.00	\$0.00	\$139.50

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OH	33931	UnitedHealthcare of Ohio, Inc.	\$3,833,592.57	\$0.00	N/A
OH	41047	Buckeye Community Health Plan	\$0.00	\$0.00	\$0.00
OH	52664	Summa Insurance Company, Inc.	\$2,037,988.17	-\$146,496.91	\$18,755.19
OH	64353	MOLINA HEALTHCARE OF OHIO	\$0.00	\$0.00	\$0.00
OH	66083	Humana Health Plan of Ohio, Inc.	\$0.00	\$0.00	\$80,623.79
OH	67129	Aetna Life Insurance Company	\$0.00	\$0.00	N/A
OH	74313	Paramount Insurance Company	\$267,351.46	\$0.00	\$0.00
OH	77552	CareSource	\$32,086,445.80	\$0.00	\$0.00
OH	78726	All Savers Insurance Company	\$446,164.50	\$0.00	N/A
OH	92036	HealthSpan	\$1,335,788.24	\$211,049.76	\$44,083.11
OH	98894	Coventry Health and Life	N/A	N/A	\$4,981.15
OH	99969	Medical Health Insuring Corp. of Ohio	\$13,342,648.57	-\$8,758.40	\$43,298.40
OK	45480	UnitedHealthcare of Oklahoma, Inc.	\$3,012,668.48	\$0.00	N/A
OK	53524	Coventry Health and Life	N/A	N/A	\$1,394.42
OK	66946	Aetna Life Insurance Company	N/A	N/A	\$3,740.86
OK	76668	Coventry Health Care of Kansas, Inc.	N/A	N/A	\$10,986.77
OK	85408	GlobalHealth, Inc.	N/A	N/A	\$24,404.54
OK	87571	Blue Cross Blue Shield of Oklahoma	\$57,436,784.47	\$787,973.67	\$468,796.42
OK	87698	CommunityCare Life & Health Insurance Co	\$0.00	\$1,522,505.85	\$1,332.98
OK	98905	CommunityCare HMO Inc.	\$0.00	\$677,742.83	\$2,826.00
OR	10091	PacificSource Health Plans	\$5,543,447.37	\$1,501,673.38	\$26,164.27
OR	10940	Health Net Health Plan of Oregon, Inc.	N/A	N/A	\$20,486.10
OR	30969	ZOOM+Care Health Insurance	\$1,045,273.45	\$21,956.61	N/A
OR	32536	ATRIO Health Plans	\$3,823,044.78	\$0.00	\$1,030.23
OR	39424	Moda Health Plan, Inc.	\$33,246,324.18	\$2,164,823.82	\$763,234.82
OR	56707	Providence Health Plan	\$66,897,686.23	\$68,882.34	\$16,551.00
OR	63474	BridgeSpan Health Company	\$154,767.68	\$0.00	\$0.00

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OR	71287	Kaiser Foundation Healthplan of the NW	\$15,251,167.48	\$0.00	\$0.00
OR	85804	LifeWise Health Plan of Oregon	\$11,093,351.11	\$0.00	\$41,979.64
OR	95417	Trillium Community Health Plan	-\$152,773.99	-\$1,237.14	\$0.00
OR	96383	Health Republic Insurance Company	N/A	N/A	\$68,588.91
OR	99389	Community Care of Oregon, Inc.	\$6,321,118.60	\$4,270,863.90	\$13,297.97
PA	16322	UPMC Health Options, Inc.	\$59,842,450.12	\$872,510.61	N/A
PA	16481	UPMC Health Network, Inc.	N/A	N/A	\$1,933.41
PA	22444	Geisinger Health Plan	\$13,244,631.61	\$0.00	\$199,187.89
PA	23489	UnitedHealthcare Insurance Company	\$0.00	\$2,903.41	N/A
PA	24872	UnitedHealthcare of Pennsylvania, Inc.	\$2,254,922.55	\$0.00	N/A
PA	31609	Independence Blue Cross (QCC Ins. Co.)	\$9,763,812.15	\$0.00	\$93,682.09
PA	33709	Highmark Inc.	\$13,432,627.24	\$1,567,070.49	\$1,390,214.34
PA	33871	Keystone Health Plan East, Inc	\$8,955,428.25	\$0.00	\$254,626.90
PA	33906	Aetna Life Insurance Company	N/A	N/A	\$2,655.77
PA	36247	Highmark Select Resources Inc.	\$7,665,319.69	\$0.00	N/A
PA	45127	Capital Advantage Assurance Company	\$12,578,353.88	\$6,463.00	N/A
PA	52899	UPMC Health Plan, Inc.	N/A	N/A	\$118.37
PA	53789	Keystone Health Plan Central	\$14,440,418.45	\$60,166.33	\$1,013.51
PA	55957	First Priority Life Insurance Company, Inc.	\$15,373,532.92	\$0.00	\$95,110.60
PA	62560	UPMC Health Coverage, Inc.	\$0.00	\$281,136.83	N/A
PA	64844	Aetna Health Inc. (a PA corp.)	\$7,165,507.59	\$0.00	\$0.00
PA	70194	Highmark Health Insurance Company	\$13,156,877.36	-\$406,467.62	\$275,664.50
PA	75729	Geisinger Quality Options	\$5,955,066.10	\$0.00	\$66,969.88

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PA	82795	Capital Advantage Insurance Company CAIC	N/A	N/A	\$2,523.63
PA	91303	HealthAmerica Pennsylvania, Inc.	N/A	N/A	\$17,765.54
RI	15287	Blue Cross & Blue Shield of Rhode Island	\$6,723,928.86	\$0.00	\$0.00
RI	77514	Neighborhood Health Plan of Rhode Island	-\$2,475,751.37	-\$38,745.91	\$0.00
RI	79881	UnitedHealthcare of New England, Inc.	\$0.00	\$0.00	\$6.63
SC	26065	Blue Cross and Blue Shield of South Carolina	\$21,882,021.95	\$0.00	\$0.00
SC	38408	Aetna Health Inc. (a PA corp.)	-\$4,047,046.75	\$0.00	N/A
SC	41614	Coventry Health Care of the Carolinas, Inc.	N/A	N/A	\$44,328.35
SC	49532	BlueChoice HealthPlan of South Carolina, Inc.	\$29,862,056.07	\$1,524,317.55	\$0.00
SC	57860	UnitedHealthcare Insurance Company	\$486,864.50	\$0.00	N/A
SC	65122	Consumers' Choice Health Insurance Company	N/A	N/A	\$108,084.37
SD	31195	Sanford Health Plan	\$11,217,457.61	\$0.00	\$30,763.76
SD	60536	Avera Health Plans, Inc.	\$13,756,105.86	\$311,636.34	\$69,300.60
SD	62210	South Dakota State Medical Holding Company, Inc.	N/A	N/A	\$688.23
TN	14002	BlueCross BlueShield of Tennessee	\$64,972,431.35	\$0.00	\$684,777.34
TN	66842	Community Health Alliance Mutual Insurance Company	N/A	N/A	\$3,196.92
TN	69443	UnitedHealthcare Insurance Company	\$2,134,105.98	\$0.00	N/A
TN	82120	Humana Insurance Company	\$2,795,659.26	\$0.00	\$63,434.93
TN	99248	Cigna Health and Life Insurance Company	\$6,667,000.07	\$0.00	\$0.00
TX	20069	Oscar Insurance Company of Texas	\$35,085,745.70	\$0.00	N/A

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TX	26539	SHA, LLC DBA FirstCare Health Plans	\$7,590,347.71	\$118,270.44	\$18,539.02
TX	27248	Community Health Choice, Inc.	\$3,212,369.47	\$0.00	\$0.00
TX	29418	Celtic Insurance Company	\$0.00	\$0.00	N/A
TX	32673	Humana Health Plan of Texas, Inc.	\$15,164,712.65	\$0.00	\$532,622.61
TX	33602	Blue Cross Blue Shield of Texas	\$157,277,306.72	\$10,601,287.65	\$2,560,124.49
TX	37392	Prominence HealthFirst of Texas, Inc.	\$1,572,951.33	\$0.00	N/A
TX	37755	Insurance Company of Scott & White	\$75,429,033.03	\$0.00	N/A
TX	40788	Scott and White Health Plan	\$25,086,485.39	\$0.00	\$6,701.62
TX	45786	Molina Healthcare of Texas	\$0.00	\$0.00	\$0.00
TX	46224	Community First Health Plans, Inc.	\$0.00	\$0.00	\$85.01
TX	55409	Cigna Health and Life Insurance Company	\$12,607,716.28	\$0.00	\$112,051.45
TX	63141	Humana Insurance Company	\$1,157,247.50	\$0.00	\$44,137.59
TX	63509	Allegian Insurance Company	\$6,758,866.06	\$0.00	N/A
TX	66252	CHRISTUS Health Plan	\$9,529,090.47	\$0.00	N/A
TX	71837	Sendero Health Plans, inc.	\$9,085,117.80	\$0.00	\$5,957.77
TX	76589	Cigna HealthCare of Texas, Inc.	\$4,891,396.84	\$0.00	N/A
TX	85947	All Savers Insurance Company	\$37,545,522.88	\$83,872.87	N/A
TX	87226	Superior Health Plan	N/A	N/A	\$0.00
TX	91716	Aetna Life Insurance Company	\$5,142,859.96	\$0.00	\$9,581.33
TX	98809	UnitedHealthcare Insurance Company	\$0.00	\$0.00	N/A
UT	18167	Molina Healthcare of Utah	\$19,606,971.43	\$0.00	\$0.00
UT	27619	Arches Mutual Insurance Company	N/A	N/A	\$104,531.54
UT	34541	BridgeSpan Health Company	\$0.00	\$0.00	\$17,545.89
UT	38927	Aetna Health of Utah Inc.	N/A	N/A	\$17,466.91
UT	42261	University of Utah Health Insurance Plans	\$182,764.40	\$0.00	N/A

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UT	56764	Humana Medical Plan of Utah, Inc.	\$1,711,863.52	\$0.00	\$84,119.08
UT	66413	UnitedHealthcare of Utah, Inc.	\$0.00	\$53,669.11	\$0.00
UT	68781	SelectHealth	\$129,565,046.28	\$14,423,772.02	\$726,669.04
VA	10207	CareFirst BlueChoice, Inc.	\$8,737,341.69	\$0.00	\$6,356.82
VA	12028	Innovation Health Insurance Company	\$32,520,623.08	\$0.00	\$3,713.14
VA	15668	Piedmont Community HealthCare, Inc.	\$636,028.99	\$579,061.87	N/A
VA	20507	Optima Health Plan	\$8,636,390.10	\$0.00	\$0.00
VA	37204	Piedmont Community HealthCare HMO, Inc.	\$737,160.77	\$0.00	N/A
VA	38234	Aetna Life Insurance Company	\$0.00	\$0.00	\$0.00
VA	38599	UnitedHealthcare of the Mid-Atlantic Inc	\$1,646,134.28	\$0.00	N/A
VA	40308	Group Hospitalization and Medical Services Inc.	\$4,073,508.25	-\$602,890.46	\$0.00
VA	86443	Innovation Health Plan, Inc.	\$0.00	\$75,765.11	N/A
VA	88380	HealthKeepers, Inc.	\$0.00	\$0.00	\$0.00
VA	95185	Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc.	\$35,656,640.04	\$1,309,812.93	\$1,485.37
VA	99663	Coventry Health Care of Virginia, Inc	\$3,614,943.00	\$0.00	\$0.00
VT	13627	Blue Cross Blue Shield of Vermont	\$2,552,850.56	\$3,784,868.82	\$0.00
VT	77566	MVP Health Plan, Inc.	\$257,849.50	\$226,463.69	\$13,596.16
WA	18581	Community Health Plan of Washington	\$492,042.87	\$0.00	\$0.00
WA	23371	Kaiser Foundation Healthplan of the NW	\$6,553,058.03	\$0.00	\$0.00
WA	38229	Health Alliance Northwest Health Plan Inc.	\$16,154.71	\$0.00	N/A
WA	38498	LifeWise Health Plan of WA	\$2,511,858.16	\$0.00	\$0.00
WA	43861	UnitedHealthcare of Washington, Inc.	\$917,117.57	\$457,090.26	N/A

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WA	49831	Premera Blue Cross	\$27,211,442.78	\$0.00	\$0.00
WA	53732	BridgeSpan Health Company	\$0.00	\$0.00	\$0.00
WA	61836	Coordinated Care Corporation	\$0.00	\$0.00	\$0.00
WA	65907	Moda Health Plan, Inc.	\$0.00	\$264,613.60	N/A
WA	80473	Group Health Cooperative	\$21,043,260.92	\$0.00	\$0.00
WA	84481	Molina Healthcare of Washington, Inc.	\$2,547,925.84	\$0.00	\$0.00
WA	87718	Regence BlueShield	\$0.00	\$0.00	N/A
WI	32754	Managed Health Services Insurance Corporation	-\$834,199.47	\$0.00	N/A
WI	35334	MercyCare Insurance Company	\$0.00	\$690,228.89	\$3,093.35
WI	37833	Unity Health Plans Insurance Corporation	\$0.00	\$0.00	\$0.00
WI	38166	Security Health Plan of Wisconsin, Inc.	\$24,508,429.21	\$2,534,857.63	\$7,617.14
WI	38345	Dean Health Plan	\$5,406,793.42	\$0.00	\$122,558.13
WI	39924	All Savers Insurance Company	\$925,020.38	\$201,371.29	N/A
WI	47342	Health Tradition Health Plan	\$733,565.54	\$1,958,359.42	\$5,048.00
WI	52697	Molina Healthcare of Wisconsin, Inc.	\$27,554,627.62	\$0.00	\$0.00
WI	57637	Medica Insurance Company	\$0.00	\$573,305.09	\$4,186.53
WI	57845	Medica Health Plans of Wisconsin	\$0.00	\$0.00	\$0.00
WI	58326	MercyCare HMO, Inc.	\$0.00	\$1,966,338.04	\$10,291.91
WI	58564	Physicians Plus Insurance Corporation	\$464,542.33	\$0.00	\$0.00
WI	79475	Compicare Health Serv Ins Co(Anthem BCBS)	\$0.00	\$0.00	\$42,897.95
WI	81413	Network Health Plan	\$2,307,460.56	\$0.00	N/A
WI	84670	WPS Health Plan, Inc.	\$8,723,207.17	\$663,495.55	\$55,803.86
WI	87416	Common Ground Healthcare Cooperative	\$26,987,917.60	\$669,339.38	\$393,547.93
WI	91058	Gundersen Health Plan, Inc.	\$3,596,244.55	\$53,602.89	\$18,047.13
WI	94529	Group Health Cooperative-SCW	\$385,820.36	-\$126,846.57	\$0.00

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WV	31274	Highmark Blue Cross Blue Shield West Virginia	\$23,939,268.98	\$0.00	\$125,468.50
WV	50328	CareSource West Virginia Co.	\$1,239,716.45	\$0.00	N/A
WY	11269	Blue Cross Blue Shield of Wyoming	\$6,400,796.86	\$83,778.46	\$5,283.77
WY	53189	WINhealth Partners	N/A	N/A	\$44,073.60