NO. 20-35521

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

STATE OF WASHINGTON,
Plaintiff-Appellee,

v.

ALEX M. AZAR II, in his official capacity as Secretary of Health and Human Services, et al.,
Defendants-Appellants.

ON APPEAL FROM THE
UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON
AT SPOKANE

No. 20-cv-00047
The Honorable Stanley A. Bastian
United States District Court Judge

ANSWERING BRIEF

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I. INTRODUCTION

Under a funding restriction known as the Hyde Amendment, federal law generally prohibits the use of federal monies to pay for abortion care. When it enacted the Patient Protection and Affordable Care Act (ACA), Congress specifically preserved traditional state regulatory authority over the health insurance industry, as evidenced by the ACA's multiple express anti-preemption provisions. In order to reconcile state authority with the prohibition on the use of federal funds for abortion care, Section 1303 of the ACA requires issuers to "collect . . . a separate payment" for the portion of an enrollee's health plan premium that covers abortion care, and to segregate such payments into a separate account to which federal tax credits and cost-sharing reductions may not be applied. Neither the ACA nor (until recently) its implementing regulations require a specific billing method for collecting such payments. To the contrary, Section 1303 expressly disclaims preemption of such traditional state insurance regulation. Similarly, in Section 1321 of the ACA, Congress commanded that "nothing" in the ACA will preempt "any State law" unless that law "prevent[s] the application of the provisions of this title."

A Washington statute requires insurers to bill enrollees for their premium through a single invoice, collecting the separate payments for abortion coverage

and maintaining those payments in separate accounts as federal law requires. Washington's Single-Invoice Statute does not conflict with Section 1303; indeed, the U.S. Department of Health and Human Services (HHS) took the position for years that single-invoice billing was one of several ways for insurers to satisfy Section 1303.

In December 2019, HHS promulgated a new federal rule. Reversing its prior interpretation of Section 1303, which reflected state flexibility to regulate insurance billing practices in their markets, HHS's new rule requires insurers providing coverage for non-federally-fundable abortion care to send their enrollees two separate bills for their insurance premium each month and instruct enrollees to pay via two separate transactions. HHS does not contend that double-billing is *required* by Section 1303, only that separate bills "better align" with purported Congressional intent. HHS's new Double-Billing Rule, however, cannot be reconciled with either the Single-Invoice Statute or the anti-preemption provisions of Section 1303 and Section 1321 of the ACA.

The district court granted summary judgment to the State of Washington on two of its claims, ruling that HHS could not preempt the Single-Invoice Statute via rulemaking because Congress had already determined that such state laws would *not* be preempted by the ACA. Its judgment should be affirmed.

II. STATEMENT OF JURISDICTION

The Court has jurisdiction to hear this appeal under 28 U.S.C. § 1291.

III. STATEMENT OF THE ISSUE

Congress included multiple express anti-preemption provisions in the ACA, specifically preserving traditional state regulatory authority over the health insurance industry in the absence of a direct conflict with the ACA. Section 1303 of the ACA requires insurers to "collect . . . a separate payment" for the portion of a health plan premium that covers abortion care, and to segregate such payments into separate accounts. Washington's Single-Invoice Statute requires insurers to bill enrollees for both components of their premium through a single invoice. No party argues that Washington's procedure fails to satisfy Section 1303's funding-segregation requirements or that it otherwise conflicts with the ACA.

The issue presented is whether the district court correctly found that the Washington law was not preempted by an HHS rule requiring insurers to send policyholders two separate bills and directing them to pay their insurance premium via two separate transactions every month.

IV. PERTINENT STATUTES AND REGULATIONS

Pertinent statutes and regulations not included in the opening brief's addendum appear in the supplemental addendum hereto.

V. STATEMENT OF THE CASE

A. The ACA and State Health Benefit Exchanges

In 2010, Congress enacted the Patient Protection and Affordable Care Act (ACA). Title 1 of the ACA requires states to establish health benefit exchanges on which issuers can offer qualified health plans (QHPs). 42 U.S.C. § 18031(b). Section 1301 specifically requires each QHP to offer health care coverage for "essential health benefits" as defined in the Act, *id.* § 18021(a), but QHP coverage requirements are not limited to those identified by federal law. Indeed, Section 1302 reserves to the issuer the choice to cover additional benefits, as "[n]othing in this title shall be construed to prohibit a health plan from providing benefits in excess of the essential health benefits described in this subsection." *Id.* § 18022(b)(5). Further, Section 1311 expressly preserves state authority in this area, providing that individual states may require QHPs to offer benefits in addition to the "essential health benefits" required by federal law. *Id.* § 18031(d)(3)(B).

Under a funding restriction known as the Hyde Amendment, federal law generally prohibits the use of federal monies to pay for abortion care. To address this prohibition, Section 1303 of the ACA prohibits QHP issuers who offer coverage for abortion care from applying federal tax credits or federal cost-sharing reductions to pay for "abortions for which public funding is prohibited[.]" 42 U.S.C. § 18023(b)(1)(B)(i). Section 1303 of the ACA implements this restriction by establishing specific funding-segregation obligations on any issuer offering a QHP that includes abortion coverage. *Id.* § 18023(b)(2); *accord* 45 C.F.R. § 156.280 (HHS regulations). The statute makes clear, however, that federal law does not otherwise affect QHP issuers' "voluntary choice of coverage of abortion services," *id.* § 18023(b)(1), further reinforcing the congressional policy choice enshrined in Section 1302. *Id.* § 18022(b)(5).

The ACA reconciles federal abortion-funding prohibitions with state requirements and issuer choice by providing that an issuer of a QHP covering abortion care must "collect" from each enrollee "separate payment[s]" for the portions of the premium that pay for abortion and non-abortion coverage, respectively. *Id.* § 18023(b)(2)(B)(i). These separate payments must be deposited into "separate allocation accounts," thereby segregating funds collected and used

to cover abortion services from funds collected and used to cover all other health services. *Id.* § 18023(b)(2)(B)(ii).

Neither Section 1303 nor any other provision of the ACA specifies any particular billing practice an issuer must use to "collect . . . [the] separate payment" for abortion coverage.

B. The ACA's Anti-Preemption Provisions

The ACA contains multiple provisions that expressly disclaim federal preemption and preserve state insurance-regulation laws. Section 1303 of the ACA—the same section that establishes the funding segregation requirements—contains an express anti-preemption provision, which provides:

> (1) *No preemption of state laws regarding abortion.* Nothing in this Act shall be construed to preempt or otherwise have any effect on State laws regarding the prohibition of (or requirement of) coverage, funding, or procedural requirements on abortions, including parental notification or consent for the performance of abortion on a minor.

42 U.S.C. § 18023(c)(1).

Section 1321 of the ACA, entitled "State flexibility in operation and enforcement of Exchanges and related requirements," contains a second anti-preemption provision. That subsection, entitled "No interference with State regulatory authority," provides in full: "Nothing in this title shall be construed to preempt any State law that does not prevent the application of the provisions of

this title." 42 U.S.C. § 18041(d). Thus, state law is not preempted unless it directly conflicts with Title 1 of the ACA.[1]

C. Washington's State Exchange and HHS Regulations

In compliance with the ACA's mandate, in 2011 Washington created the State's Health Benefit Exchange (the "State Exchange") as a public–private partnership. *See* Wash. Rev. Code Ch. 43.71. Private insurance carriers offer QHPs on the State Exchange, subject to oversight by Washington's Insurance Commissioner and the requirements of both federal and state law. Washington's Reproductive Parity Act requires QHPs offered on the State Exchange that cover maternity care or services to also include substantially equivalent coverage for abortion care or services. Wash. Rev. Code § 48.43.073.[2]

As early as 2012, Washington's Insurance Commissioner reviewed the federal statutory scheme and determined that Section 1303 of the ACA does not

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[1] This principle is reflected in other ACA anti-preemption provisions, too. *E.g.*, 42 U.S.C. § 300gg-23(a)(1) ("[T]his part shall not be construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with individual or group health insurance coverage . . . .").

[2] Issuers are exempt from the Reproductive Parity Act to the extent required by federal law (e.g., laws requiring accommodations for religious organizations). *See* Wash. Rev. Code § 48.43.073(5); *cf.* Opening Br. at 13 n.4; *contra id.* at 14.

require QHPs to issue separate *bills* for a plan's coverage of abortion services. *See* Wash. Admin. Code § 284-07-540 (state regulations for Section 1303 compliance). HHS agreed: its 2012 regulations did not include any such requirement. *See* 45 C.F.R. § 156.280(e). This was not an oversight; in 2015, HHS promulgated a final rule confirming that Section 1303 "do[es] not specify the method an issuer must use to comply with the separate payment requirement." *Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016*, 80 Fed. Reg. 10,750, 10,840 (Feb. 27, 2015) (2015 Rule).

Rather, the 2015 Rule notified health plan issuers and state regulators that the "separate payment" requirement "may be satisfied in a number of ways," including but not limited to (i) sending the enrollee a single monthly invoice that separately itemizes the premium amount for abortion services, (ii) sending a separate monthly bill for abortion coverage, or (iii) sending the enrollee a notice upon enrollment that the monthly invoice will include a separate, specified charge for abortion coverage. *Id.* Further, the 2015 Rule confirmed that QHP enrollees could make the separate payments for abortion coverage and other coverage through a "single transaction." *Id.* As HHS explained, these standards offered QHP issuers "several ways to comply with [Section 1303's] requirements, while minimizing burden on QHP issuers and consumers." *Id.* at 10,841.

In October 2017, the Centers for Medicare and Medicaid Services (CMS) issued its own guidance, listing the same options for complying with Section 1303's funding segregation requirements. *CMS Bulletin Addressing Enforcement of Section 1303 of the Patient Protection and Affordable Care Act* (Oct. 6, 2017) at 3, *available at* https://tinyurl.com/y6xyqr93 (2017 Guidance).

D. Washington's Single-Invoice Statute

By law, non-exempt QHP issuers must comply with Washington's Reproductive Parity Act. Wash. Rev. Code § 48.43.073. Additionally, a Washington statute—the Single-Invoice Statute[3]—codifies the State's longstanding policy of requiring health insurance carriers to bill enrollees with a single monthly invoice in a manner consistent with Section 1303. Wash. Rev. Code § 48.43.074; *see also* Wash. Admin. Code § 284-07-540.

The Single-Invoice Statute provides in full:

> (1) The legislature intends to codify the state's current practice of requiring health carriers to bill enrollees with a single invoice and to segregate into a separate account the premium attributable to abortion services for which federal funding is prohibited.

[3] While formally enacted in May 2019, after HHS released its proposed rule, the Single-Invoice Statute reflects Washington's prior legislative determinations that the "business of insurance is one affected by the public interest," that participants must "practice honesty and equity in all insurance matters," Wash. Rev. Code § 48.01.030, and that the inevitable confusion engendered by sending two separate monthly bills is not required by either the ACA or Washington law. *See* Wash. Admin. Code § 284-07-540.

> Washington has achieved full compliance with section 1303 of the federal patient protection and affordable care act by requiring health carriers to submit a single invoice to enrollees and to segregate into a separate account the premium amounts attributable to coverage of abortion services for which federal funding is prohibited. Further, section 1303 states that the act does not preempt or otherwise have any effect on state laws regarding the prohibition of, or requirement of, coverage, funding, or procedural requirements on abortions.
>
> (2) In accordance with RCW 48.43.073 related to requirements for coverage and funding of abortion services, an issuer offering a qualified health plan must:
>
> (a) Bill enrollees and collect payment through a single invoice that includes all benefits and services covered by the qualified health plan; and
>
> (b) Include in the segregation plan required under applicable federal and state law a certification that the issuer's billing and payment processes meet the requirements of this section.

Wash. Rev. Code § 48.43.074.

E. The Double-Billing Rule

On November 9, 2018, HHS and CMS published a Notice of Proposed Rulemaking (NPRM) proposing to curtail the flexibility enshrined in the ACA and reverse the positions reflected in HHS's 2015 Rule and CMS's 2017 Guidance. The new rule would require any QHP issuer providing coverage for non-federally-fundable abortion care to send enrollees two separate bills for their monthly insurance premium. *Patient Protection and Affordable Care Act; Exchange Program Integrity*, 83 Fed. Reg. 56,015 (Nov. 9, 2018). As detailed in the NPRM,

after years of taking a different position, the agencies would now read Section 1303's requirement that QHP issuers "collect . . . a separate payment" for such coverage to mean that the "separate payment" must be both separately *billed* by the issuer and separately *submitted* by the enrollee. Specifically, the proposed rule would require QHP issuers to (1) "send an entirely separate monthly bill" to each enrollee "for only the portion of the premium attributable to" non-federally-fundable abortion coverage and (2) "instruct the policy subscriber" to pay each bill in a "separate transaction." *Id.* at 56,022 (proposed 45 C.F.R. § 156.280).

Despite opposition from "most commenters"—many of whom pointed out that a double-billing rule would depart from standard industry practice, confuse consumers, increase the risk of inadvertent nonpayment and coverage loss, and penalize insurance carriers for complying with state coverage-parity requirements—HHS and CMS promulgated the final Double-Billing Rule without material change. *Patient Protection and Affordable Care Act; Exchange Program Integrity*, 84 Fed. Reg. 71,684 (Dec. 27, 2019). The stated rationale for the Double-Billing Rule is that "HHS now believes" the Rule will "better align with congressional intent regarding the separate payments provision of section 1303 of the PPACA." *Id.* at 71,699. HHS did not offer any evidence for this rationale, nor did it take the position that separate billing and separate payment transactions are

required by Section 1303 of the ACA. *See id.* HHS asserted only that separate billing and separate payment transactions "better align" with purported congressional intent. *Id.*; *see also* Opening Br. at 12.

In promulgating the Double-Billing Rule, however, HHS disclaimed any intent to preempt state law in the area. The Rule's preamble contains a section entitled "Federalism," in which HHS noted "Federalism implications" arising from other provisions of the Rule not at issue here. *Id.* at 71,709. In contrast, HHS disavowed any federalism implications of the Rule's double-billing requirements, declaring that "*[t]his final rule does not* impose substantial direct costs on state and local governments *or preempt state law*." *Id.* (emphasis added).

Prior to litigation, the relevant provisions of the Double-Billing Rule were scheduled to go into effect on June 27, 2020. 84 Fed. Reg. 71,684, 71,710; *see also id.* at 71,686, 71,689–690.

F. The Lower Court Rulings

On March 6, 2020, the State of Washington moved for summary judgment on its two claims addressing the narrow issue of preemption.[4] The district court

[4] The district court determined it would be "more efficient" to bifurcate the case and decide Washington's anti-preemption claims at the first stage, as a ruling in Washington's favor would obviate the need to consider the State's additional claims. *See* Case No. 2:20-cv-00047-SAB (E.D. Wash.), ECF No. 5 at 2. Appellants take no issue with that ruling. *Cf.* Opening Br. at 16.

determined that the Double-Billing Rule directly conflicted with Washington's existing Single-Invoice Statute mandating that QHP issuers must send enrollees a single invoice for each billing period, and therefore violated the ACA's express anti-preemption provisions.

As the district court acknowledged, the ACA "does not specify the method an issuer must use to comply with the segregation of funds requirement." ER7–8. At the same time, the court found it was obligated to "give meaning to Congress' intent to not preempt state law," as expressed in the ACA's anti-preemption provisions. ER12. The district court applied the principle that when a statute contains an "express disclaimer of preemption, the Court must focus on the plain wording of the clause," which "'necessarily contains the best evidence of Congress' preemptive intent.'" ER14 (quoting *Chamber of Commerce of U.S. v. Whiting*, 563 U.S. 582, 594 (2011)). While acknowledging that courts confronting an ambiguous statute "have a duty to accept the reading that disfavors preemption," the district court rejected HHS's argument that Section 1303 was ambiguous. The district court instead found that Washington's Single-Invoice Statute is a law "regarding" abortion coverage and funding that "falls squarely within the scope of" Section 1303's anti-preemption provision and "does not conflict with the ACA or frustrate its purposes and objectives[.]" ER15.

Accordingly, the district court declared the Rule "invalid and without force in the State of Washington." ER16. HHS filed a notice of appeal on June 8, 2020. ER1.

Meanwhile, two other district courts in Maryland and California both rejected the Double-Billing Rule on the grounds that it violated the Administrative Procedure Act (APA), and both courts vacated the Rule in full. Unlike the instant case, the Maryland and California cases did not involve conflicting state statutes and so did not address the ACA's anti-preemption provisions. Rather, the Maryland district court determined that the Double-Billing Rule was contrary to Section 1554 of the ACA (which forbids HHS from promulgating any regulation that creates unreasonable barriers to access to care) and was arbitrary and capricious because HHS:

> provided virtually no explanation for finding that the 'separate billing' rule is more consistent with Congressional intent when it appears to acknowledge that the plain language of the statute does not require it, when Congressional intent is the only justification for a rule that HHS acknowledges will impose massive costs, and when HHS failed to consider any other factors that traditionally have been used in determining Congressional intent.

Planned Parenthood of Md., Inc. v. Azar, No. CV CCB-20-00361, 2020 WL 3893241, at *12 (D. Md. Jul. 10, 2020), *appeal docketed*, No. 20-2006 (4th Cir. Sept. 18, 2020).

The California district court likewise determined that the Double-Billing Rule was arbitrary and capricious because HHS's "belief" that requiring two separate bills aligned with Congressional intent "is not an explanation:" HHS concluded "that the prior rule did not adequately reflect Congress's intent (without explaining why)" and provided "no context" for why its "belief advances Congress's intent." *California v. U.S. Dep't of Health & Human Servs.*, --- F. Supp. 3d ----, 2020 WL 4051705, at *6 (N.D. Cal. Jul. 20, 2020), *appeal docketed*, No. 20-16802 (9th Cir. Sept. 17, 2020). Further, the California court ruled that HHS's interpretation of Section 1303 was not entitled to *Chevron* deference, noting that HHS failed to "identify some problem that it is solving or benefit that it is achieving" with the policy change, and that a different desired interpretation was not, on its own, "reason enough to change course." *Id.* at *7.

VI. SUMMARY OF ARGUMENT

When it passed the ACA, Congress decided not to preempt insurance laws such as Washington's Single-Invoice Statute in the absence of a direct conflict with the federal statute. The district court, following decades of Supreme Court jurisprudence on anti-preemption clauses, correctly found that this congressional intent was clear from the plain language of the ACA's express anti-preemption provisions. As they did below, Appellants here press a new and extremely

narrow reading of the anti-preemption clause in Section 1303 that would only preserve state laws prohibiting or requiring abortion coverage, or those prohibiting state funding for abortion care. As the district court correctly found, however, Section 1303 is not ambiguous, and Appellants' new interpretation—offered for the first time in litigation—is entitled to no deference. The Supreme Court subsequently reiterated this principle in *Department of Homeland Security v. Regents of the University of California*.

Appellants' conflict preemption arguments are grounded in the conflict between Washington's statute and the Double-Billing Rule. That is not the relevant inquiry. Instead, because the governing statute expressly disclaims preemption, Appellants must show a conflict between the Single-Invoice Statute and the ACA itself. They cannot do so, and the Single-Invoice Statute falls squarely within Section 1303's anti-preemption clause. Moreover, the Single-Invoice Statute does not conflict with any other provision of the ACA and therefore *cannot* be preempted under Section 1321—a second, equally important anti-preemption provision that Appellants largely ignore.

It is black-letter law that agencies cannot accomplish by rulemaking what the statute itself forbids, and indeed Appellants here disclaimed any preemptive intent in the Double-Billing Rule itself. Not until this litigation did Appellants

assert that the Rule *was* preemptive. But Appellants had no authority under the ACA to promulgate a rule that would preempt the Single-Invoice Statute in the guise of reinterpreting Section 1303. On this point, Appellants ignore the teaching of this Court's prior ruling in *Oregon v. Ashcroft*, relying instead on a recent Second Circuit opinion that has no bearing on the issues presented. The district court's ruling should be affirmed.

VII. STANDARD OF REVIEW

This Court reviews legal challenges to agency action decided on summary judgment de novo, *Turtle Island Restoration Network v. U.S. Dep't of Commerce*, 878 F.3d 725, 732 (9th Cir. 2017), and may affirm on any basis supported by the record. *Stimpson v. Midland Credit Mgmt., Inc.*, 944 F.3d 1190, 1195 (9th Cir. 2019).

VIII. ARGUMENT

A. Congress Clearly Disclaimed Any Intent to Preempt State Laws That Do Not Conflict with the ACA

Congress's power to preempt state law derives from the Supremacy Clause of the United States Constitution. *See English v. Gen. Elec. Co.*, 496 U.S. 72, 78 (1990); U.S. Const. art. VI, cl. 2. There are three types of preemption: "(1) *express preemption*—where Congress explicitly defines the extent to which its enactments preempt state law; (2) *field preemption*—where state law attempts to regulate

conduct in a field that Congress intended the federal law exclusively to occupy; and (3) *conflict preemption*—where it is impossible to comply with both state and federal requirements, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Williamson v. Gen. Dynamics Corp.*, 208 F.3d 1144, 1149 (9th Cir. 2000) (internal quotation marks omitted); ER11.

As they must, Appellants concede that that express and field preemption do not apply here, and they rely exclusively on conflict preemption arguments. *See* Opening Br. at 9 ("the ACA does not occupy the field with respect to the regulation of abortion-related requirements . . . "); *id.* at 10–15 (limiting analysis to conflict preemption). Yet, where Congress specifically intends *not* to supersede state law in a given area and the state law does not conflict with the federal statute, there is no conflict preemption.

1. The presumption against preemption can only be overcome by a finding of clear Congressional intent to supersede state law.

"[T]he purpose of Congress is the ultimate touchstone of pre-emption analysis." *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) (internal quotation marks omitted); *accord* ER11 (citing *Wyeth v. Levine*, 555 U.S. 555, 566 (2009)). "Consideration of the issues arising under the Supremacy Clause start[s] with the assumption that the historic police powers of the states [are] not

to be superseded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress." *Williamson*, 208 F.3d at 1149 (internal quotation marks omitted). Agencies "seeking to invalidate a state law based on preemption 'bear the considerable burden of overcoming the starting presumption that Congress does not intend to supplant state law.'" *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1227–28 (9th Cir. 2013) (en banc) (quoting *De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 814 (1997)). Courts confronted with two plausible interpretations of a statute "have a duty to accept the reading that disfavors preemption." ER12 (quoting *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005) and citing *City of Columbus v. Ours Garage & Wrecker Serv., Inc.*, 536 U.S. 424, 439–40 (2002)).

Because preemption is not presumed, courts must determine whether Congress intended to preempt state law "from the language of the [relevant] statute and the 'statutory framework' surrounding it." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 486 (1996). In so doing, courts must consider the "structure and purpose of the statute as a whole, . . . as revealed not only in the text, but through the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law." *Id.* (internal quotation marks and citation omitted). As the Supreme

Court instructs: "The case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there is between them." *CTS Corp. v. Waldburger*, 573 U.S. 1, 18 (2014) (internal quotation marks and brackets omitted).

2. Where Congress expressly decides not to preempt state law, the anti-preemption provisions' plain language controls.

Here, there is no relevant "preemption" clause that needs interpretation. To the contrary, the ACA's express *anti-preemption* provisions govern this case. The Supreme Court has repeatedly and consistently rejected conflict preemption arguments where the relevant federal statute contains an *anti*-preemption provision. *See Va. Uranium, Inc. v. Warren*, 139 S. Ct. 1894, 1902–03 (2019) (statute's "non-preemption clause" preserved states' traditional regulatory authority over mining); *Chamber of Commerce of U.S.*, 563 U.S. at 600 (under federal immigration statute that "expressly preserves" some state powers, Arizona licensing law was "well within the confines of the authority Congress chose to leave to the States"); *Brown v. Hotel & Rest. Emps. & Bartenders Int'l Union Local 54*, 468 U.S. 491, 505–06 (1984) (statute's "express disclaimer of pre-emption" "preserving the operation of state laws" showed that Congress did not "seek to impose a uniform federal standard"); *Askew v. Am. Waterways Operators,*

Inc., 411 U.S. 325, 328–29 (1973) (declining to "allow federal admiralty jurisdiction to swallow most of the police power of the States over oil spillage" where the statute "does not preclude, but in fact allows, state regulation") (emphasis added); *see also* ER13–15 (district court below citing and discussing same). Appellants make no effort to distinguish these cases.

As the district court found, two of the ACA's express anti-preemption provisions reveal—by their plain language—that Congress intended *not* to preempt state laws like the Single-Invoice Statute unless the law directly conflicts with the ACA. ER16. First, Section 1303 states that "[n]othing in this Act shall be construed to preempt or otherwise have any effect on State laws regarding the prohibition of (or requirement of) coverage, funding, or procedural requirements on abortions . . . ." 42 U.S.C. § 18023(c)(1). Second, Section 1321 reinforces this deference to state regulatory authority: "Nothing in this title shall be construed to preempt any State law that does not prevent the application of the provisions of this title." 42 U.S.C. § 18041(d). The district court found that the Single-Invoice Statute "falls squarely within the scope of § 1303(c)." ER15. The district court further found that Section 1321 "provides that state laws are not preempted unless they directly conflict with Title 1 of the ACA," which the Single-Invoice Statute does not. ER12.

A plain reading of the ACA demonstrates that Congress intended *not* to preempt state laws regulating the insurance industry absent a direct conflict with Title 1 of the ACA. This is not surprising; the ACA's anti-preemption provisions appropriately reflect longstanding principles of federalism respecting the states' historical prerogative to regulate matters of health, safety, and consumer protection. *See Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 536 (2012) ("[T]he facets of governing that touch on citizens' daily lives are normally administered by smaller governments closer to the governed."); *Medtronic*, 518 U.S. 485 (noting the "historic primacy of state regulation of matters of health and safety"); *Oregon v. Ashcroft*, 368 F.3d 1118, 1125 (9th Cir. 2004), *aff'd sub nom. Gonzales v. Oregon*, 546 U.S. 243 (2006) (federal preemption is improper in "an area of law traditionally reserved for state authority" absent Congress's "unmistakably clear" authorization); ER11, ER16. In particular, "state laws enacted for the purpose of regulating the business of insurance do not yield to conflicting federal statutes unless a federal statute specifically requires otherwise." *U.S. Dep't of Treasury v. Fabe*, 508 U.S. 491, 507 (1993) (internal quotation marks omitted). Indeed, Appellants have conceded elsewhere that "[s]tates are the primary regulators of their insurance markets." *Patient Protection and Affordable*

Care Act; HHS Notice of Benefit and Payment Parameters for 2019, 83 Fed. Reg. 16,956 (Apr. 17, 2018).

In their brief, Appellants do not address the presumptions against preemption, or the myriad Supreme Court decisions rejecting conflict preemption in cases addressing a federal anti-preemption statute. Nor do they assert that Congress intended to preempt Washington law regulating the procedures for billing insurance premiums to consumers. Instead, Appellants exclusively rely on a narrow, *post hoc* reading of Section 1303—which was offered for the first time in litigation, and not advanced by HHS in the Double-Billing Rule—to contend that Washington's Single-Invoice Statute falls outside the ACA's reservation of powers to the State. This argument is unavailing.

B. Washington's Single-Invoice Statute Falls Squarely within the ACA's Anti-Preemption Provisions

Conflict preemption occurs when state law "'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,' or when it 'interferes with the methods by which the federal statute was designed to reach [its] goal.'" *Arellano v. Clark Cty. Collection Serv., LLC*, 875 F.3d 1213, 1216 (9th Cir. 2017) (internal citations omitted). Where, as here, "Congress has made its intent known through explicit statutory language, the courts' task is 'an easy one' and largely a matter of statutory interpretation." *Palmer v. Sprint Nextel*

Corp., 674 F. Supp. 2d 1224, 1230 (W.D. Wash. 2009) (citing *English*, 496 U.S. at 79).

There is no reasonable argument that Congress intended to preempt Washington's Single-Invoice Statute via the ACA, as there is no conflict between the federal and state statutes. To the contrary, the Single-Invoice Statute is well within the anti-preemption clauses of both Section 1303 and Section 1321, and Appellants' new "interpretation" of Section 1303 is not entitled to any deference.

1. The Single-Invoice Statute falls squarely within Section 1303(c)(1).

As relevant here, Section 1303's subsection (c)(1), entitled "No preemption of State laws regarding abortion," unambiguously provides that the ACA is not to be "construed to preempt or otherwise have any effect on State laws regarding [abortion] coverage, funding, or procedural requirements . . . ." 42 U.S.C. § 18023(c)(1). As one court recently put it, "Congress recognized the potential conflict between section 1303 and . . . state statutes," but directed that "nothing in the ACA shall be construed to preempt or effect state laws on abortion . . . ." *New York v. U.S. Dep't of Health & Human Servs.*, 414 F. Supp. 3d 475, 502 (S.D.N.Y. 2019).

Appellants assert that Washington's Single-Invoice Statute is not within the purview of Section 1303(c)(1) because the Single-Invoice Statute does not directly

prohibit or require coverage for abortion care. Opening Br. at 15. In so doing, Appellants would have the Court read "regarding" out of the statute altogether. This is improper. *See Lamar, Archer & Cofrin, LLP v. Appling*, 138 S. Ct. 1752, 1759–60 (2018) (the word "regarding," like "respecting" and "relating to," has a "broadening effect"); *Coventry Health Care of Mo., Inc. v. Nevils*, 137 S. Ct. 1190, 1197 (2017) (the phrase "relate to" in a preemption clause should be read broadly "to reach any subject that has 'a connection with, or reference to,' the topics the statute enumerates"). The subjects of the Single-Invoice Statute—billing plan enrollees and receiving premium payments for coverage—obviously relate to coverage and funding for health care services. Indeed, this relationship is inherent in Section 1303's own text and structure: the statute establishes "special rules relating to *coverage* of abortion services"—i.e., *funding*-segregation requirements that implement restrictions on the use of federal funds. 42 U.S.C. § 18023(b) (emphasis added). Moreover, HHS itself addressed the obvious relationship between billing, funding, and coverage by acknowledging in the Double-Billing Rule's preamble that policyholders who fail to pay both monthly premium bills required by the Rule may suffer "loss of coverage." 84 Fed. Reg. 71,684, 71,706.

Further, Appellants *concede* that Section 1303 "preserves state laws such as" Washington's Reproductive Parity Act, *see* Opening Br. at 13 (referring to

Wash. Rev. Code § 48.43.073), but ignore that the Single-Invoice Statute is closely related to and furthers the purpose of the Parity Act. The Parity Act *does* directly require coverage for abortion care and prohibits health plans from "limit[ing] in any way a person's access to [abortion] services . . . ." Wash. Rev. Code § 48.43.073. Requiring issuers to send a single monthly premium bill, which is consistent with longstanding industry practice, furthers this purpose by ensuring that enrollees will not inadvertently fail to make a separately-billed payment for covered services. Indeed, the Single-Invoice Statute cites the Parity Act directly. *See* Wash. Rev. Code § 48.43.074 ("In accordance with RCW 48.43.073 related to requirements for coverage and funding of abortion services, an issuer . . . must . . . [b]ill enrollees and collect payment through a single invoice . . .").

The Single-Invoice Statute reflects Washington's legislative determination that access to and coverage of abortion care is a priority for the State, and that sending two separate monthly premium bills will inevitably engender consumer confusion[5] that is not required by the ACA. *See* Wash. Admin. Code § 284-07-

[5] Indeed, commenters on the proposed rule identified this as a serious concern, pointing out that receiving two separate bills and being asked to make two separate payments each month would confuse consumers, increase the risk of inadvertent nonpayment and coverage loss, and effectively penalize insurance carriers for complying with state coverage-parity requirements. ER32, ¶ 43; *see also Planned Parenthood of Md.*, 2020 WL 3893241, at *2, 9–10; *California*, 2020 WL 4051705, at *2–3; ER16 ("The Double-Billing Rule attempts to

540. The Single-Invoice Statute is part and parcel of Washington's coverage mandate, and is thus a law "regarding" abortion coverage that is well within Section 1303's anti-preemptive scope.

2. Appellants' reading of Section 1303 is not entitled to any deference.

The district court correctly found that the Single-Invoice Statute "falls squarely within the scope of § 1303(c)" and that Appellants' contrary, *post hoc* interpretation was not entitled to deference. ER15–16; *see Price v. Stevedoring Servs. of Am., Inc.*, 697 F.3d 820, 830 (9th Cir. 2012) (agency's expedient litigation position is not entitled to deference); *Alaska v. Fed. Subsistence Bd.*, 544 F.3d 1089, 1095 (9th Cir. 2008) ("We do not afford *Chevron* or *Skidmore* deference to litigation positions unmoored from any official agency interpretation"); *U.S. v. Mead Corp.*, 533 U.S. 218, 228 (2001) (interpretations "advanced for the first time in a litigation brief" are treated with "near indifference"); *accord Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016) (*Chevron* deference does not apply to "procedurally defective" agency

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intrude on the State's right to [legislate in the area of abortion care] . . . by imposing onerous, arbitrary, and unnecessary billing practices that have . . . everything to do with trying to prevent Washington's State recognition of a women's right to assess safe and legal abortions."). A statute that prevents such harms by requiring a single invoice for monthly insurance premiums is plainly related to abortion coverage and funding.

actions). After the district court's ruling, the Supreme Court forcefully reiterated the "foundational principle of administrative law" that "*post hoc* rationalizations" for agency action are not a proper subject of judicial review and should be disregarded altogether. *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1909 (2020). "An agency must defend its actions based on the reasons it gave when it acted." *Id.*

In this litigation, Appellants offered for the first time an interpretation of Section 1303(c)(1)'s anti-preemption provision that would exclude Washington's Single-Invoice Statute. *See* Opening Br. at 12–13. This directly contradicts the Double-Billing Rule itself, which plainly states that it "does not . . . preempt state law." 84 Fed. Reg. at 71,709. Not surprisingly, then, the Double-Billing Rule does not purport to interpret the anti-preemption provisions of Section 1303(c)(1) or Section 1321(d). The Court should not consider Appellants' litigation-driven departure from their stated position in the Rule under review. *See Regents*, 140 S. Ct. at 1909.

Even if the Court were to consider it, Appellants do not seriously argue that their new, litigation-driven reading of Section 1303 is entitled to *Chevron* deference, referring to deference only once in a footnote without citation. *See* Opening Br. at 12 n.3. For good reason. *Chevron* deference is grounded in the

general proposition that "a statute's ambiguity constitutes an implicit delegation from Congress to the agency to fill in the statutory gaps." *Smith v. Berryhill*, 139 S. Ct. 1765, 1778 (2019). But here, Appellants fail to identify any ambiguity in Section 1303, and they do not substantively address Section 1321(d)'s *explicit* anti-preemption language. The district court correctly found that where, as here, Congress has included express anti-preemption provisions in the statute, there is no ambiguity to interpret. ER16 ("Given the plain language of the ACA, this Court is under no obligation to defer to HHS's interpretation . . ."); *see King v. Burwell*, 576 U.S. 473, 486 (2015) ("If the statutory language is plain, [the court] must enforce it according to its terms."); *Util. Air Regulatory Grp. v. EPA*, 573 U.S. 302, 328 (2014) ("an agency may not rewrite clear statutory terms . . .").

Even if some ambiguity did exist, *Chevron* deference is particularly inappropriate where, as here, "Congress has not authorized" HHS to preempt state law. *Wyeth*, 555 U.S. at 576–77 (no deference to claim of preemption in FDA rule's preamble where Congress did not authorize preemption by regulation, proposed rule had disclaimed preemption, and preemption was at odds with Congress's purposes and "FDA's own longstanding position"); *see also Gonzales*, 546 U.S. at 258 (*Chevron* deference "is not accorded merely because the statute is ambiguous and an administrative official is involved"; "the rule must be

promulgated pursuant to authority Congress has delegated to the official"). Here, Congress authorized HHS to enforce Section 1303's provisions, not to promulgate preemptive rules—rather, Congress expressly forbade this in Section 1303(c)(1) and Section 1321(d). *See also* Section VII.C, *infra*.

Appellants' purported "interpretation" of Section 1303(b)(2) in the Double-Billing Rule—i.e., that separate billing and separate payment transactions "better align" with purported congressional intent—should likewise be disregarded. *See Solberg v. Victim Servs., Inc.*, 415 F. Supp. 3d 935, 955 (N.D. Cal. 2019) (arguments based on purported legislative intent "cannot override an 'anti-preemption provision' . . . that embodies express legislative intent"); *Conway v. United States*, 145 Fed. Cl. 514, 522–23 (2019) (preemptive HHS rule was not "authorize[d]" given ACA Section 1321's anti-preemption provision). Appellants had no authority to "interpret" Section 1303(b)(2), via rulemaking, to override the Single-Invoice Statute.[6]

[6] Because the ACA's anti-preemption provisions dictate the outcome here, the Court need not reach the issue of whether HHS's "interpretation" of Section 1303(b)(2) was rational or supported by the record. These issues were not briefed below, but a ruling that the Rule was arbitrary and capricious is the subject of a pending appeal in this Circuit. *See* Case No. 20-16802 (appeal of *California v. U.S. Dep't of Health & Human Servs.*, discussed *supra* at 15).

Finally, even if the Double-Billing Rule's "interpretation" were one *possible* reading of Section 1303(b)(2), "[w]ell-established preemption principles favor upholding state law if it can plausibly coexist with the federal statute." *Cal. Ins. Guar. Ass'n v. Azar*, 940 F.3d 1061, 1071 (9th Cir. 2019) (citing *Altria Grp., Inc. v. Good*, 555 U.S. 70, 77 (2008)); *accord* ER11–12 (citing *Bates*, 544 U.S. at 449; *City of Columbus*, 536 U.S. at 439–40). Appellants' 2015 Rule and CMS's 2017 Guidance demonstrate that Section 1303 can—and should—be read in perfect harmony with the Single-Invoice Statute. *See supra* at 8–9.

3. The Single-Invoice Statute presents no conflict with the ACA and thus falls within Section 1321(d)'s broad anti-preemption provision.

The district court further found that Section 1321(d) "provides that state laws are not preempted unless they directly conflict with Title 1 of the ACA," which the Single-Invoice Statute does not. ER12. Tellingly, Appellants do not address Section 1321(d)'s application to this case. *See* Opening Br. at 7–8 n.2 (referencing Section 1321 but failing to offer any analysis). Their silence is fatal, as Section 1321(d) provides an independent basis to affirm. *See Stimpson*, 944 F.3d at 1195.

Appellants do not dispute that the plain language of Section 1321(d) preserves state law in the absence of a direct conflict with the ACA. In Section

1321(d), Congress expressly refused to preempt *any* state laws that do not directly conflict with the text of the ACA itself. *See Conway*, 145 Fed. Cl. at 522 (Section 1321(d) prohibits preemption by agency rule); *Deanco Healthcare, LLC v. Becerra*, 806 F. App'x 581, 584 (9th Cir. 2020) (rejecting argument that ACA preempted state-law requirement, in light of Section 1321(d)); *Unum Life Ins. Co. of Am. v. D.C.*, --- A.3d ----, 2020 WL 5666899, at *3 (D.C. App. Sept. 24, 2020) (same; describing Section 1321(d) as "an express *non*preemption provision").

Further, in the Double-Billing Rule, HHS tacitly conceded that separate bills and separate payment transactions are not *required* by Section 1303(b)(2). *See* 84 Fed. Reg. at 71,683, 71,699 ("Section 1303 of the PPACA . . . *do[es] not specify the method* a QHP issuer must use to comply with the separate payment requirement"; asserting only that double-billing "better align[s]" with purported Congressional intent) (emphasis added); Opening Br. at 6 (quoting same); *see also Planned Parenthood of Md.*, 2020 WL 3893241, at *12 (HHS "appears to acknowledge that the plain language of the statute" does not require separate billing and separate payment transactions). Nor could HHS have credibly interpreted Section 1303 to mandate double-billing, in light of HHS's own 2015 Rule and CMS's 2017 Guidance (*supra* at 8–9) and the statute's plain text, which—unlike other ACA provisions—does not directly address issuer billing or

invoicing. *Compare, e.g.*, 42 U.S.C. § 18082 (issuer responsibilities for billing statement disclosures) *with* 42 U.S.C. § 18023(b)(2) (funding segregation); *see Bond v. United States*, 872 F.2d 898, 900 (9th Cir. 1989) (if Congress had intended to require a particular method, it "would have employed apt language to clearly state this intent"). This is dispositive: Appellants' concession that Section 1303(b)(2) does not *require* two monthly bills and two monthly payment transactions leads inevitably to the conclusion that the Single-Invoice Statute does not conflict with the ACA, and is therefore within the anti-preemption provision of Section 1321(d).

With Section 1303, Congress reconciled the states' authority to regulate their insurance markets with the funding prohibitions of federal law by requiring collection of a separate payment for premiums that cover abortion care. The undisputed purpose of the separate payment requirement is to ensure that insurance companies calculate the premium amount attributable to coverage for non-federally-fundable abortion care and segregate that amount into a separate account, so that abortion care can be funded from those segregated accounts rather than through federal funding. *See* 2015 Final Rule; CMS 2017 Guidance (characterizing funding-segregation as the substantive effect of the separate payment provision). Congress's purpose is fully accomplished without requiring

separate *billing* to the insured, in much the same way that a doctor's office can send a single bill to a patient for multiple office visits that are reimbursed as separate transactions by the insurance company or Medicaid. Appellants never explain how Washington's Single-Invoice Statute compromises the purpose of Section 1303, or how double-billing would better further this purpose in any way. They simply rely on a new, myopic interpretation of "separate payment," divorced from the statutory context and purpose. Because Appellants cannot identify any conflict between the Single-Invoice Statute and Section 1303, the state law falls squarely within Section 1321(d).

Appellants' contention that the district court failed to address the anti-preemption provision in Section 1321(d), Opening Br. at 7 n.2, cannot be squared with the district court's order. *See* ER9 (State moved for summary judgment on two preemption counts); ER12 (identifying Section 1321 as second basis of opinion and finding that it "provides that state laws are not preempted unless they directly conflict with Title 1 of the ACA."); ER16 ("because the Double-Billing Rule clearly conflicts with Washington's Single-Invoice State and cannot be squared with the ACA's multiple non-preemption provisions, the Court declares the Double-Billing Rule invalid and without force in the State of Washington.").

In any event, the contention is irrelevant, as this Court may affirm on any basis in the record. *Stimpson*, 944 F.3d at 1195.

In the event the Court does not affirm the ruling below on the basis of Section 1303's anti-preemption clause, it should affirm under Section 1321's clear provision.

C. HHS Lacks Authority to Preempt Washington's Single-Invoice Statute via Its Double-Billing Rule

Federal agencies may preempt state law by regulation, but only where authorized by statute. *See, e.g.*, Exec. Order 13132 § 4 ("Agencies, in taking action that preempts State law, shall act in strict accordance with governing law."). Where the governing federal statute includes an anti-preemption provision, agency rules that conflict with state law are contrary to that statute, are invalid, and cannot be applied in the affected state. *Oregon v. Ashcroft*, 368 F.3d 1118 (9th Cir. 2004), *aff'd sub nom. Gonzales v. Oregon*, 546 U.S. 243 (2006), is directly on point.

In *Oregon v. Ashcroft*, this Court found that the U.S. Attorney General's interpretive rule declaring that physician-assisted suicide violates the federal Controlled Substances Act (CSA) could not be enforced in a state with contrary existing law, based on the CSA's anti-preemption provision. *Oregon*, 368 F.3d at 1131 (upholding district court injunction). In 1994, Oregon enacted its Death With Dignity Act, which authorized the use of controlled substances for physician-

assisted suicide. *Id.* at 1122. The CSA generally permits the Attorney General to revoke a medical practitioner's federal registration upon a finding that the practitioner improperly prescribed a controlled substance or acted inconsistent with the public interest, but includes an anti-preemption provision that preserves state law absent a "positive conflict" with the CSA. 21 U.S.C. § 903. In 2001, Attorney General Ashcroft issued a rule interpreting the CSA to permit him to revoke Oregon practitioners' licenses if they participated in physician-assisted suicide using controlled substances, even though this was permitted by state law. *Id.* at 1123. The Ninth Circuit held that "the Attorney General's expansive interpretation of the CSA clearly conflicts with the Oregon law and therefore cannot be squared with the CSA's non-preemption clause." *Oregon*, 368 F.3d at 1126.

Here, just as in *Oregon v. Ashcroft*, the Double-Billing Rule "clearly conflicts" with Washington's Single-Invoice Statute and "cannot be squared" with the ACA's multiple anti-preemption provisions. *See supra* at 20–23; *New York*, 414 F. Supp. 3d at 502 ("Congress recognized the potential conflict between section 1303 and . . . state statutes," but directed that "nothing in the ACA shall

be construed to preempt or effect state laws on abortion . . . ."); *Conway*, 145 Fed. Cl. at 522; *Deanco*, 806 F. App'x at 584; *Unum*, 2020 WL 5666899, at *3.[7]

Despite its central importance to the analysis, Appellants did not include *Oregon v. Ashcroft* among the eight cases they cited. Instead of addressing the prior decision of this Court, Appellants instead cite a recent Second Circuit case as persuasive contrary authority. *See* Opening Br. at 10 (citing *UnitedHealthCare of N.Y., Inc. v. Lacewell*, 967 F.3d 82 (2d Cir. 2020)). But *Lacewell* just highlights why the district court's ruling should be affirmed.

The *Lacewell* court analyzed Section 1321(b) of the ACA, in which Congress specifically directed HHS "to issue regulations that establish standards and a federal methodology for a risk adjustment program" under Part E of the statute. *Lacewell*, 967 F.3d at 84–86 (discussing 42 U.S.C. § 18041(a)(1)(C) (Section 1321(b)) and 42 U.S.C. § 18063(b) (Part E's Risk Adjustment subsection)). In the same section, Congress further specified that each participating state must either (1) adopt the federal standards promulgated by

[7] Relatedly, other courts have rejected ACA preemption as a defense to state-law claims on the grounds that the ACA "was not enacted to preempt state law." *Tex. Med. Res., LLP v. Molina Healthcare of Tex., Inc.*, 356 F. Supp. 3d 612, 617 (N.D. Tex. 2019) (preemption not "applicable"); *Desai v. CareSource, Inc.*, No. 3:18-CV-118, 2019 WL 1109568, at *4 (S.D. Ohio Mar. 11, 2019) (same).

HHS, or (2) obtain HHS approval of their alternative risk adjustment calculation. 42 U.S.C. § 18041(b)(1)–(2).

In *Lacewell*, health care insurers on New York's state exchange challenged an emergency state regulation that directly conflicted with HHS's promulgated standards for the ACA's risk adjustment provisions, without HHS approval. In considering the regulation, the *Lacewell* court acknowledged that a court should find conflict preemption only where the "conflict between state and federal law is so direct and positive that the two acts cannot be reconciled or consistently stand together." *Id.* at 92.The Second Circuit found that the state regulation could not be reconciled with the express statutory language, noting that "the 'unavoidable implication' of the ACA's risk adjustment framework is 'that a State may not enforce its own' risk adjustment methodology 'without obtaining [HHS's] approval.'" *Id.* (quoting *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 99 (1992) (plurality op.)). The *Lacewell* court held that, having initially opted into the federal system, New York was not free to change to an alternative risk adjustment calculation unless and until it obtained HHS approval in the manner set out in agency regulations. *Lacewell*, 967 F.3d at 92.

Here, in contrast, Washington's Single-Invoice Statute is readily reconcilable with Section 1303, as HHS itself acknowledged for years before

issuing the Double-Billing Rule. And HHS's expansive preemption position is at odds with both preemption law and the ACA's express language. *Lacewell* does not support Appellants: the *Lacewell* court had no need to analyze the ACA's anti-preemption clauses; Congressional intent was not disputed; and HHS's regulatory position on the statutory requirements was consistent over time. *See generally id.* By contrast, here HHS essentially contends that the general rulemaking authority in Section 1321 allows it to preempt state law on any abortion-related issue except for laws requiring or prohibiting abortion coverage, or those that prohibit use of state funds for abortion care. Opening Br. at 13. But this reading of Section 1321 acknowledges no meaningful limit to HHS's authority to interfere with states' regulation of their insurance markets, and directly conflicts with the multiple express disclaimers of preemption in the ACA. 42 U.S.C. § 18023(c)(1) ("No preemption of State laws regarding abortion"); 42 U.S.C. § 18041(d) ("No interference with State regulatory authority").

Finally, while the *Lacewell* court applied some measure of deference to HHS's interpretation of what would constitute approval under its regulations, 967 F.3d at 94–95, that deference was grounded in the fact that the agency's views were directly solicited by the Court; not driven by a litigation position; and consistent with the agency's prior statements. "Far from pressing a 'post hoc

rationalization,' HHS has, 'in response to the Court's request,' offered its views in a case in which it has no direct interest." *Id.* at 94 (quoting *Kisor v. Wilkie,* 139 S. Ct. 2400, 2417 & n.6 (2019)). The opposite circumstances are presented here.

IX. CONCLUSION

The district court's declaration that the Double-Billing Rule is invalid and without force in the State of Washington should be affirmed.

RESPECTFULLY SUBMITTED this 14th day of October 2020.

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ADDENDUM

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	Washington Reproductive Parity Act, RCW 48.43.073	Add.003
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12/27/2019	Double-Billing Rule, 84 Fed. Reg. 71,684	Add.133

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such plans, and the manner in which Exchanges meet their goals;

(2) any significant observations regarding the utilization and adoption of Exchanges;

(3) where appropriate, recommendations for improvements in the operations or policies of Exchanges;

(4) a survey of the cost and affordability of health care insurance provided under the Exchanges for owners and employees of small business concerns (as defined under section 632 of title 15), including data on enrollees in Exchanges and individuals purchasing health insurance coverage outside of Exchanges; and

(5) how many physicians, by area and specialty, are not taking or accepting new patients enrolled in Federal Government health care programs, and the adequacy of provider networks of Federal Government health care programs.

(Pub. L. 111–148, title I, § 1313, title X, § 10104(k), Mar. 23, 2010, 124 Stat. 184, 902.)

REFERENCES IN TEXT

This title, referred to in subsecs. (a)(4), (5) and (b), is title I of Pub. L. 111–148, Mar. 23, 2010, 124 Stat. 130, which enacted this chapter and enacted, amended, and transferred numerous other sections and notes in the Code. For complete classification of title I to the Code, see Tables.

This Act, referred to in subsec. (a)(4), (6)(A), is Pub. L. 111–148, Mar. 23, 2010, 124 Stat. 119, known as the Patient Protection and Affordable Care Act. For complete classification of this Act to the Code, see Short Title note set out under section 18001 of this title and Tables.

The False Claims Act, referred to in subsec. (a)(6), was the popular name for sections 231, 232, 233, and 235 of former Title 31, Money and Finance. Sections 231, 232, 233, and 235 were repealed by Pub. L. 97–258, § 5(b), Sept. 13, 1982, 96 Stat. 1084, and reenacted by the first section thereof as sections 3729 to 3731 of Title 31, Money and Finance.

AMENDMENTS

2010—Subsec. (b)(4), (5). Pub. L. 111–148, § 10104(k), added par. (4) and redesignated former par. (4) as (5).

TERMINATION OF PROVISION

Pub. L. 111–148, title X, § 10104(j)(1), Mar. 23, 2010, 124 Stat. 901, provided that: ''Subparagraph (B) of section 1313(a)(6) of this Act [42 U.S.C. 18033(a)(6)(B)] is hereby deemed null, void, and of no effect.''

PART C—STATE FLEXIBILITY RELATING TO EXCHANGES

§ 18041. State flexibility in operation and enforcement of Exchanges and related requirements

(a) Establishment of standards

(1) In general

The Secretary shall, as soon as practicable after March 23, 2010, issue regulations setting standards for meeting the requirements under this title,[1] and the amendments made by this title,[1] with respect to—

(A) the establishment and operation of Exchanges (including SHOP Exchanges);

(B) the offering of qualified health plans through such Exchanges;

(C) the establishment of the reinsurance and risk adjustment programs under part E; and

(D) such other requirements as the Secretary determines appropriate.

The preceding sentence shall not apply to standards for requirements under subtitles A and C (and the amendments made by such subtitles) for which the Secretary issues regulations under the Public Health Service Act [42 U.S.C. 201 et seq.].

(2) Consultation

In issuing the regulations under paragraph (1), the Secretary shall consult with the National Association of Insurance Commissioners and its members and with health insurance issuers, consumer organizations, and such other individuals as the Secretary selects in a manner designed to ensure balanced representation among interested parties.

(b) State action

Each State that elects, at such time and in such manner as the Secretary may prescribe, to apply the requirements described in subsection (a) shall, not later than January 1, 2014, adopt and have in effect—

(1) the Federal standards established under subsection (a); or

(2) a State law or regulation that the Secretary determines implements the standards within the State.

(c) Failure to establish Exchange or implement requirements

(1) In general

If—

(A) a State is not an electing State under subsection (b); or

(B) the Secretary determines, on or before January 1, 2013, that an electing State—

(i) will not have any required Exchange operational by January 1, 2014; or

(ii) has not taken the actions the Secretary determines necessary to implement—

(I) the other requirements set forth in the standards under subsection (a); or

(II) the requirements set forth in subtitles A and C and the amendments made by such subtitles;

the Secretary shall (directly or through agreement with a not-for-profit entity) establish and operate such Exchange within the State and the Secretary shall take such actions as are necessary to implement such other requirements.

(2) Enforcement authority

The provisions of section 2736(b)[1] of the Public Health Services[2] Act [42 U.S.C. 300gg–22(b)] shall apply to the enforcement under paragraph (1) of requirements of subsection (a)(1) (without regard to any limitation on the application of those provisions to group health plans).

[1] See References in Text note below.

[2] So in original. Probably should be ''Service''.

(d) No interference with State regulatory authority

Nothing in this title[1] shall be construed to preempt any State law that does not prevent the application of the provisions of this title.[1]

(e) Presumption for certain State-operated Exchanges

(1) In general

In the case of a State operating an Exchange before January 1, 2010, and which has insured a percentage of its population not less than the percentage of the population projected to be covered nationally after the implementation of this Act, that seeks to operate an Exchange under this section, the Secretary shall presume that such Exchange meets the standards under this section unless the Secretary determines, after completion of the process established under paragraph (2), that the Exchange does not comply with such standards.

(2) Process

The Secretary shall establish a process to work with a State described in paragraph (1) to provide assistance necessary to assist the State's Exchange in coming into compliance with the standards for approval under this section.

(Pub. L. 111–148, title I, § 1321, Mar. 23, 2010, 124 Stat. 186.)

REFERENCES IN TEXT

This title, referred to in subsecs. (a)(1) and (d), is title I of Pub. L. 111–148, Mar. 23, 2010, 124 Stat. 130, which enacted this chapter and enacted, amended, and transferred numerous other sections and notes in the Code. For complete classification of title I to the Code, see Tables.

Subtitles A and C, referred to in subsecs. (a)(1) and (c)(1)(B)(ii)(II), are subtitles A (§§ 1001–1004) and C (§§ 1201–1255), respectively, of title I of Pub. L. 111–148, Mar. 23, 2010, 124 Stat. 130, 154. Subtitle A enacted sections 300gg–11 to 300gg–19, 300gg–93, and 300gg–94 of this title, transferred sections 300gg–4 to 300gg–7 and 300gg–13 of this title to sections 300gg–25 to 300gg–28 and 300gg–9 of this title, respectively, amended sections 300gg–11, 300gg–12, and 300gg–21 to 300gg–23 of this title, and enacted provisions set out as a note under section 300gg–11 of this title. Subtitle C enacted subchapter II of this chapter and sections 300gg to 300gg–2 and 300gg–4 to 300gg–7 of this title, transferred section 300gg of this title to section 300gg–3 of this title, amended sections 300gg–1 and 300gg–4 of this title, and enacted provisions set out as a note under section 300gg of this title. For complete classification of subtitles A and C to the Code, see Tables.

The Public Health Service Act, referred to in subsec. (a)(1), is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to chapter 6A (§ 201 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 201 of this title and Tables.

Section 2736 of the Public Health Service Act, referred to in subsec. (c)(2), was renumbered section 2723 of that Act by Pub. L. 111–148, § 1563(c)(13)(C) (formerly § 1562(c)(13)(C)), Mar. 23, 2010, 124 Stat. 269, and is classified to section 300gg–22 of this title.

This Act, referred to in subsec. (e)(1), is Pub. L. 111–148, Mar. 23, 2010, 124 Stat. 119, known as the Patient Protection and Affordable Care Act. For complete classification of this Act to the Code, see Short Title note set out under section 18001 of this title and Tables.

§ 18042. Federal program to assist establishment and operation of nonprofit, member-run health insurance issuers

(a) Establishment of program

(1) In general

The Secretary shall establish a program to carry out the purposes of this section to be known as the Consumer Operated and Oriented Plan (CO–OP) program.

(2) Purpose

It is the purpose of the CO–OP program to foster the creation of qualified nonprofit health insurance issuers to offer qualified health plans in the individual and small group markets in the States in which the issuers are licensed to offer such plans.

(b) Loans and grants under the CO–OP program

(1) In general

The Secretary shall provide through the CO–OP program for the awarding to persons applying to become qualified nonprofit health insurance issuers of—

(A) loans to provide assistance to such person in meeting its start-up costs; and

(B) grants to provide assistance to such person in meeting any solvency requirements of States in which the person seeks to be licensed to issue qualified health plans.

(2) Requirements for awarding loans and grants

(A) In general

In awarding loans and grants under the CO–OP program, the Secretary shall—

(i) take into account the recommendations of the advisory board established under paragraph (3);

(ii) give priority to applicants that will offer qualified health plans on a Statewide basis, will utilize integrated care models, and have significant private support; and

(iii) ensure that there is sufficient funding to establish at least 1 qualified nonprofit health insurance issuer in each State, except that nothing in this clause shall prohibit the Secretary from funding the establishment of multiple qualified nonprofit health insurance issuers in any State if the funding is sufficient to do so.

(B) States without issuers in program

If no health insurance issuer applies to be a qualified nonprofit health insurance issuer within a State, the Secretary may use amounts appropriated under this section for the awarding of grants to encourage the establishment of a qualified nonprofit health insurance issuer within the State or the expansion of a qualified nonprofit health insurance issuer from another State to the State.

(C) Agreement

(i) In general

The Secretary shall require any person receiving a loan or grant under the CO–OP program to enter into an agreement with the Secretary which requires such person to meet (and to continue to meet)—

RCW 48.43.073

Required abortion coverage—Limitations.

(1) Except as provided in subsection (5) of this section, if a health plan issued or renewed on or after January 1, 2019, provides coverage for maternity care or services, the health plan must also provide a covered person with substantially equivalent coverage to permit the abortion of a pregnancy.

(2)(a) Except as provided in (b) of this subsection, a health plan subject to subsection (1) of this section may not limit in any way a person's access to services related to the abortion of a pregnancy.

(b)(i) Coverage for the abortion of a pregnancy may be subject to terms and conditions generally applicable to the health plan's coverage of maternity care or services, including applicable cost sharing.

(ii) A health plan is not required to cover abortions that would be unlawful under RCW 9.02.120.

(3) Nothing in this section may be interpreted to limit in any way an individual's constitutionally or statutorily protected right to voluntarily terminate a pregnancy.

(4) This section does not, pursuant to 42 U.S.C. Sec. 18054(a)(6), apply to a multistate plan that does not provide coverage for the abortion of a pregnancy.

(5) If the application of this section to a health plan results in noncompliance with federal requirements that are a prescribed condition to the allocation of federal funds to the state, this section is inapplicable to the plan to the minimum extent necessary for the state to be in compliance. The inapplicability of this section to a specific health plan under this subsection does not affect the operation of this section in other circumstances.

[2018 c 119 § 3.]

NOTES:

Findings—Declarations—2018 c 119: See note following RCW 48.43.072.



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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: Adrianne 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 habilitative 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

[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.*

[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).

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).

[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).

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

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 Brain Tumors, and Other Cancers and Tumors	3.447	3.235	3.117	3.051	3.043
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 musculoskeletal 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	4.078	3.830	3.661	3.498	3.479
Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors	3.274	3.044	2.901	2.749	2.731
Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors	1.832	1.650	1.520	1.360	1.342
Pancreas Transplant Status/Complications	35.005	34.817	34.724	34.753	34.755
Diabetes with Acute Complications	2.695	2.350	2.169	1.832	1.794
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	15.577	15.458	15.387	15.437	15.442
Mucopolysaccharidosis	6.759	6.440	6.245	6.182	6.176
Lipidoses and Glycogenosis	6.759	6.440	6.245	6.182	6.176
Congenital Metabolic Disorders, Not Elsewhere Classified	6.759	6.440	6.245	6.182	6.176
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	35.005	34.817	34.724	34.753	34.755
End-Stage Liver Disease	15.326	15.150	15.059	15.061	15.063
Cirrhosis of Liver	10.171	9.978	9.868	9.837	9.836
Chronic Hepatitis	1.316	1.149	1.025	0.917	0.908
Acute Liver Failure/Disease, Including Neonatal Hepatitis	10.916	10.745	10.640	10.615	10.614
Intestine Transplant Status/Complications	35.005	34.817	34.724	34.753	34.755
Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	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 guidance [11] 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 years[16] 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:

$$Uniform\ Reinsurance\ Contribution\ Rate = \frac{Reinsurance\ payment\ pool + Treasury\ contribution + Administrative\ costs}{Estimate\ of\ enrollees\ in\ plans\ required\ to\ make\ reinsurance\ contributions}$$

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.

[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.

[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.

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*IDF*GCF* (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.regtap.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/CCIIO/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 assistance [40] 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 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 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).

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 the 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).

[44] See Exchange Establishment Rule, 77 FR 18310 at 18399.

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.

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 Terms [45]: 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).

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

[45] *http://www.cms.gov/CCIIO/Resources/Files/Downloads/uniform-glossary-final.pdf.*

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 though 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 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 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 (⅔ reduction in the maximum annual limitation on cost sharing), and 150 and 200 percent of the FPL (⅔ 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 (½ 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 ⅕, rather than ½. 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 ⅔, 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

[61] Affordable Care Act Implementation Set 15, available at: *http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs15.html.*

[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.

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 Marketplaces [63] 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 polices 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/cciio/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 year [67] 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/cciio/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 automatic [68]);

[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

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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.

[70] In 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 assisters 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)(ii)) 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] 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.

[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 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://cciio.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 habilitative 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 habilitative 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 violation within the multi-State plan, or

(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]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 155 and 156

[CMS–9922–F]

RIN 0938–AT53

Patient Protection and Affordable Care Act; Exchange Program Integrity

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule revises standards relating to oversight of Exchanges established by states and periodic data matching frequency. This final rule also includes new requirements for certain issuers related to the collection of a separate payment for the portion of a plan's premium attributable to coverage for certain abortion services.

DATES: This final rule is effective on February 25, 2020.

FOR FURTHER INFORMATION CONTACT: Emily Ames, (301) 492–4246 or Marisa Beatley, (301) 492–4307.

SUPPLEMENTARY INFORMATION:

I. Background

A. Legislative and Regulatory Overview

Sections 1311(b) and 1321(b) of the Patient Protection and Affordable Care Act (PPACA) provide that each state has the opportunity to establish an Exchange. Section 1311(b)(1) of the PPACA gives each state the opportunity to establish an Exchange that facilitates the purchase of qualified health programs (QHPs) by individuals and families, and provides for the establishment of a Small Business Health Options Program (SHOP) that is designed to assist qualified small employers in the state in facilitating the enrollment of their employees in QHPs offered in the small group market in the state.

Section 1313 of the PPACA describes the steps the Secretary of Health and Human Services (the Secretary) may take to oversee Exchanges' compliance with HHS standards related to title I of the PPACA and ensure their financial integrity, including conducting investigations and annual audits.

Section 1321(a) of the PPACA provides broad authority for the Secretary to establish standards and regulations to implement the statutory standards related to Exchanges, QHPs, and other identified standards of title I of the PPACA.

Section 1321(c)(2) of the PPACA 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 Public Health Service Act (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 with respect to health insurance issuers.

Section 1303 of the PPACA, as implemented in 45 CFR 156.280, specifies standards for issuers of qualified health plans (QHPs) through the Exchanges that cover abortion services for which public funding is prohibited (also referred to as non-Hyde abortion services). The statute and regulation establish that, unless otherwise prohibited by state law, a QHP issuer may elect to cover such non-Hyde abortion services. If an issuer elects to cover such services under a QHP sold through an individual market Exchange, the issuer must take certain steps to ensure that no premium tax credit (PTC) or cost-sharing reduction (CSR) funds are used to pay for abortion services for which public funding is prohibited.

As specified in section 1303(b)(2), one such step is that individual market Exchange issuers must determine the amount of, and collect, from each enrollee, a separate payment for an amount equal to the actuarial value of the coverage for abortions for which public funding is prohibited, which must be no less than $1 per enrollee, per month. QHP issuers must also segregate funds for non-Hyde abortion services collected through this payment into a separate allocation account used to pay for non-Hyde abortion services.

Section 1411(c) of the PPACA requires the Secretary to submit certain information provided by applicants under section 1411(b) of the PPACA to other federal officials for verification, including income and family size information to the Secretary of the Treasury.

Section 1411(d) of the PPACA provides that the Secretary must verify the accuracy of information provided by applicants under section 1411(b) of the PPACA for which section 1411(c) does not prescribe a specific verification procedure, in such manner as the Secretary determines appropriate.

Section 1411(f)(1)(B) of the PPACA requires the Secretary to establish procedures to redetermine eligibility on a periodic basis, in appropriate circumstances, including for eligibility to purchase a QHP through the Exchange and for advance payments of the premium tax credit (APTC) and CSRs.

Section 1411(g) of the PPACA allows the exchange of applicant information only for the limited purposes of, and to the extent necessary to, ensure the efficient operation of the Exchange, including by verifying eligibility to enroll through the Exchange and for APTC and CSRs.

On October 30, 2013, we published a final rule entitled, ''Patient Protection and Affordable Care Act; Program Integrity: Exchange, Premium Stabilization Programs, and Market Standards; Amendments to the HHS Notice of Benefit and Payment Parameters for 2014,'' (78 FR 65046), to implement certain program integrity standards and oversight requirements for State Exchanges.

On March 27, 2012, we published a final rule entitled ''Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers,'' (Exchange Establishment Rule (77 FR 18309), in which we codified the statutory provisions of section 1303 of the PPACA in regulation at 45 CFR 156.280, and established many standards related to Exchanges. On February 27, 2015, we published the Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016, final rule (80 FR 10750) (hereinafter referred to as the 2016 Payment Notice) providing guidance regarding acceptable billing and premium collection methods for the portion of the policy holder's total premium attributable to non-Hyde abortion coverage for purposes of satisfying the statutory separate payment requirement.

On March 8, 2016, we published the Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017, final rule (81 FR 12204), in which we provided issuers the option to adopt a premium payment threshold policy to avoid situations in which an enrollee who owes only a de minimis amount of premium has his or her enrollment terminated for non-payment of premiums.

On November 9, 2018, we published a proposed rule entitled ''Patient Protection and Affordable Care Act; Exchange Program Integrity'' (83 FR 56015), which proposed to revise standards relating to oversight of Exchanges established by states and periodic data matching frequency and authority. It also proposed new requirements for certain issuers related to the billing and collection of the separate payment for the premium portion attributable to coverage for certain abortion services.

B. Stakeholder Consultation and Input

HHS has consulted with stakeholders on policies related to the operation of Exchanges. We have held a number of listening sessions with consumers, providers, employers, health plans, the actuarial community, and state representatives to gather public input, with a particular focus on risks to the individual and small group markets, and how we can alleviate burdens facing patients and issuers. We consulted with stakeholders through regular meetings with the National Association of Insurance Commissioners, regular contact with State Exchanges through the Exchange Blueprint process and ongoing oversight and technical assistance engagements, and meetings with Tribal leaders and representatives, health insurance issuers, trade groups, consumer advocates, employers, and other interested parties.

II. Provisions of the Proposed Rule and Analysis of and Responses to Public Comments

A. Exchange Establishment Standards and Other Related Standards Under the Affordable Care Act

1. Functions of an Exchange (§ 155.200)

We proposed to revise § 155.200 to clarify that the Exchanges must perform oversight functions generally, and cooperate with oversight activities, in accordance with section 1313 of the PPACA and as required under 45 CFR part 155. Section 155.200 describes the functions that an Exchange must perform. Section 155.200(c) specifies that the Exchange must perform functions related to oversight and financial integrity in accordance with section 1313 of the PPACA. HHS interprets this requirement broadly to include program integrity functions related to protecting against fraud, waste, and abuse, including functions not explicitly identified in section 1313 of the PPACA. We believe State Exchanges, including State Exchanges on the Federal Platform (SBE–FPs), have also generally interpreted this requirement broadly, as evidenced by their engagement in activities designed to combat fraud and abuse.

However, questions about the breadth of this function have arisen when Exchanges have sought to understand what uses and disclosures of personally identifiable information (PII) are permitted under § 155.260.[1] Specifically, we received questions about whether Exchanges are permitted under § 155.260 to disclose applicant PII to government oversight entities, such as state departments of insurance, when investigating fraudulent behavior related to Exchange enrollments on the part of agents and brokers. As noted in the proposed rule, we believe that use and disclosure of PII related to Exchange program integrity efforts, such as combatting fraud, currently fall under § 155.200(c), but seek to make that position more clear. Therefore, we proposed to revise § 155.200(c) to clarify that the Exchanges must perform oversight functions generally, and cooperate with oversight activities, in accordance with section 1313 of the PPACA and as required under 45 CFR part 155, including overseeing its Exchange programs, Navigators, agents, brokers, and other non-Exchange entities as defined in § 155.260(b). We further explained that because this is a clarification and not a new function, we did not believe it would impose additional burdens on Exchanges, but instead would help resolve questions about the available tools and authority to enable Exchanges to effectively oversee and combat potentially fraudulent behavior.

After consideration of comments received, we are finalizing this provision as proposed, with one technical modification to remove a redundant term included in the proposed regulation text. The comments we received on this topic are summarized below, along with our responses.

Comment: All commenters on this topic supported the proposed amendment to § 155.200(c) as it clarifies that oversight and transparency for all Exchanges is required with respect to determining eligibility for APTC and combatting fraud. Two commenters encouraged HHS to work closely with states once the proposal is finalized to ensure that individuals who are assisting consumers receive proper notice and training on the applicable compliance requirements and standards in their states. One commenter suggested that HHS solicit stakeholder feedback on the possibility of incorporating an additional level of collaborative issuer-Exchange oversight and verification prior to enrollment when the applicant's coverage has been previously terminated for fraud.

Response: We remain committed to improving Exchange program integrity, including efforts related to combatting fraud, and appreciate commenters' support for our clarification that Exchanges are permitted to use and disclose applicant PII to certain entities for these efforts. We agree that it is important for agents, brokers, Navigators, and other assisters to understand the applicable standards in their state, and plan to work closely with states to ensure compliance. We continue to explore other pathways for combatting fraud in Exchanges and appreciate commenters' recommendations.

We are finalizing the amendment to § 155.200(c) as proposed, with one modification. We are removing the reference to assisters because it is redundant of the reference to non-Exchange entities. Non-Exchange entities are defined in § 155.260(b) and include Navigators, non-Navigator assistance personnel, certified application counselors, agents, brokers, web-brokers and other individuals or entities who gain access to PII submitted to an Exchange or collect, use or disclose PII gathered directly from Exchange applicants or enrollees.

2. Verification Process Related to Eligibility for Insurance Affordability Programs (§ 155.320)

We requested comment on our proposed plans to expand the current scope of Medicare periodic data matching (PDM), which only identifies and notifies those dual enrollees receiving financial assistance, to also include the Exchange population not receiving financial assistance. Specifically, we proposed to add a new authorization compliant with Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191) standards to the single streamlined application to permit Exchanges using the federal platform to collect PHI in order to determine enrollees' Medicare enrollment status. We also proposed to leverage the current attestation question on the single, streamlined application, for applicants to provide written consent permitting the Exchange to terminate their coverage if they are found later to be dually enrolled in Medicare and a QHP to expand the scope of Medicare PDM to the population not receiving financial assistance. We will not finalize these proposed actions, but will continue to identify and notify dual enrollees receiving financial assistance

[1] Section 155.260 limits an Exchange's use and disclosure of PII when an 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 § 155.300; or determining eligibility for exemptions from the individual shared responsibility provisions in section 5000A of the Internal Revenue Code. One of the permitted uses and disclosures is for the Exchange to carry out the functions described in § 155.200.

as part of current Medicare PDM operations.

Under § 155.330, Exchanges are required to periodically examine available data sources to identify whether enrollees on whose behalf APTC or CSRs are being paid have been found eligible for or are enrolled in Medicare, Medicaid, Children's Health Insurance Program (CHIP), or the Basic Health Program (BHP), if a BHP is operating in the service area of the Exchange. Individuals identified as enrolled both in Exchange coverage (with or without APTC or CSRs) and one of these other forms of coverage are referred to as dually enrolled consumers. Generally, if an individual is eligible for or enrolled in such other forms of coverage that qualify as minimum essential coverage (MEC) under section 5000A of the Code, the individual is not eligible to receive APTC or CSRs. For instance, if an individual is eligible for premium-free Medicare Part A or enrolled in Medicare Part A or Part C (also known as Medicare Advantage), all of which qualify as MEC, he or she is not eligible to receive APTC or CSRs to help pay for an Exchange plan or covered services.

The Secretary has broad authority under section 1321(a) of the PPACA to establish regulations setting standards to implement certain statutory requirements under title I of the PPACA, including with respect to the establishment and operation of Exchanges, the offering of QHPs through the Exchanges, the establishment of the risk adjustment and reinsurance programs, and such other requirements as the Secretary determines appropriate. Additionally, section 1411(g) of the PPACA allows the exchange of certain applicant information as necessary to ensure the efficient operation of the Exchange, including verifying eligibility to enroll in coverage through the Exchange and to receive APTC or CSRs.

Furthermore, 45 CFR 155.430(b)(1)(ii) requires an Exchange to provide an opportunity at the time of plan selection for enrollees receiving and not receiving financial assistance to choose to remain enrolled in a QHP if he or she becomes eligible for other MEC, or to terminate QHP coverage if the enrollee does not choose to remain enrolled in the QHP upon completion of the redetermination process. As such, for plan year 2018 and thereafter, we added language to the existing single, streamlined application to support compliance with this requirement by all Exchanges using the federal platform. This new language allows all consumers, regardless of whether they are seeking financial assistance, to authorize the Exchange to obtain eligibility and enrollment data and, if so desired by the consumer, to end their QHP coverage if the Exchange finds during its periodic eligibility checks that the consumer has become eligible for or enrolled in other MEC, such as Medicare, Medicaid/CHIP, or BHP.

In addition, for plan years beginning with the 2020 plan year, we stated in the proposed rule our intention to add a new HIPAA authorization to the single, streamlined application used by Exchanges using the federal platform, which would meet HIPAA standards regarding how one's protected health information (PHI) is collected and used. In the preamble to the proposed rule, we discussed using this proposed new HIPAA authorization to expand the current scope of Medicare PDM to individuals in the Exchange population who are not receiving financial assistance and who authorize the Exchanges using the federal platform to conduct certain PDM by requesting PHI from HHS such as their name, Social Security Number, Medicare eligibility or enrollment status, and other data elements the Exchange may determine necessary, to allow the Exchange to determine whether the consumer is dually enrolled in Medicare and Exchange coverage. This HIPAA authorization would allow HHS to check Medicare enrollment databases for applicants regardless of whether they seek or receive financial assistance.

As we discussed in the preamble to the proposed rule, for consumers who request voluntary termination upon a finding of dual enrollment, the Exchange would terminate coverage after following the current PDM process outlined in § 155.330(e)(2)(i), which requires Exchanges to provide notice of the updated information the Exchange found, as well as a 30-day period for the enrollee to respond to the notice. We emphasize again, because the Exchange cannot identify through this process those consumers who are eligible for, but not enrolled in premium-free Part A, we encourage all consumers who are 65 and older to apply with the Social Security Administration (SSA) to receive an eligibility determination with respect to Medicare.

We received multiple comments on this discussion regarding expanding the scope of Medicare PDM to the Exchange population not receiving financial assistance. After further consideration of the technical complexity of implementing a HIPAA authorization on the single, streamlined application and the potential burden on consumers to read, decipher, and agree to legal agreements many may find confusing, we will not pursue the addition of a new authorization to the single streamlined application. Instead, we will explore other means through which the Exchanges can expand the scope of Medicare PDM to the Exchange population that is not receiving financial assistance. A summary of these comments and our responses to those comments follow:

Comment: Most commenters generally supported HHS's goal to reduce dual enrollment in Medicare and Exchange coverage, but cautioned HHS about the consequences of terminating QHP coverage for this population. Commenters noted that terminating Exchange coverage could: (1) Interfere with the continuity of care, (2) create gaps in coverage, especially for those dual enrollees who have not yet enrolled in Medicare Part B, (3) cause other family members on the Medicare beneficiary's policy to lose coverage, and (4) cause increased consumer confusion over their coverage options. Rather than terminating QHP coverage, commenters recommended targeted outreach and education to the Medicare eligible population to ensure this population fully understands the consequences of dual enrollment, the appropriate time to enroll in Medicare Part B to avoid financial penalties for delayed enrollment, and how access to their Medicare eligibility information intersects with QHP termination via Medicare PDM. One commenter recommended that we prevent all individuals with Medicare from enrolling in QHP coverage through screening at initial application.

Response: Given the technical complexity of implementing a HIPAA authorization on the single streamlined application and the potential burden it would place on consumers as consumers would be required to read, decipher, and agree to complex legal agreements that may be confusing for consumers, we are reconsidering our approach to expanding Medicare PDM to the Exchange population not receiving financial assistance. We are exploring other options to identify and notify this population of their dual enrollment in Medicare and Exchange coverage to ensure that this population is able to enroll in Medicare Part B at the appropriate time and without financial penalty.

For enrollees in Exchanges using the federal platform who are receiving financial assistance, the Exchanges will continue to end subsidies or QHP coverage for those consumers who permit the Exchange to do so in accordance with § 155.330. For the Exchange population receiving financial

assistance, terminating QHP coverage as part of Medicare PDM ensures that consumers are not enrolled in unnecessary duplicative coverage, reduces the potential for taxpayer financial liability related to possibly having to repay APTC at the time of federal income tax reconciliation, and also protects the integrity of the Exchange by ensuring enrollees no longer eligible for financial assistance do not receive these subsidies inappropriately.

HHS is also aware of concerns from stakeholders that consumers often do not know when they should contact the Exchange to end their QHP coverage after enrolling in Medicare. We believe this voluntary option to provide written consent for the Exchange to end a Medicare dual enrollee's QHP coverage will alleviate some of the confusion consumers currently face when transitioning from Exchange coverage to Medicare as the Exchange provides information in the intial warning notice on how to end QHP coverage after enrolling in Medicare. Furthermore, in instances where the dual enrollee does not take action, the Exchange will automatically end coverage for the dual enrollee; thus, saving the enrollee time and reducing the risk of the consumer having to pay back some or all of the APTC received when they file their federal income taxes.

In addition, in response to commenter concerns about the consequences of termination of dually enrolled consumers' coverage, we note that enrollees receiving financial assistance have 30 days to respond to their Medicare PDM notice before the Exchange takes action as specified in § 155.330(e)(2)(i)(D). As we noted in the preamble to the proposed rule, upon receiving the required notice, the enrollee could (1) return to the Exchange and terminate his or her QHP coverage, (2) revoke the prior authorization for the Exchange to terminate his or her QHP coverage in the event dual enrollment is found, so that he or she would remain enrolled both in the QHP and in Medicare, or (3) notify the Exchange that he or she is not eligible for, or enrolled in, Medicare. For enrollees who revoke their prior authorization for the Exchange to terminate their QHP enrollment where the Exchange finds the enrollee is eligible for or enrolled in Medicare, or who disagree that they are eligible for or enrolled in Medicare, the Exchange would only proceed to terminate the enrollee's APTC and CSRs, and not his or her enrollment in QHP coverage through the Exchange, using the process specified in § 155.330(e)(2)(i). Therefore, we believe this operational change mitigates adverse impacts on the continuity of care and the risk of coverage gaps because enrollees can choose to opt out and remain in QHP coverage without APTC, pursuant to the current regulation.

We also appreciate the concerns raised that non-Medicare family members could potentially lose coverage. We note that a special enrollment period will be available for family members of dual enrollees when such family members lose their coverage or their financial subsidies as a result of the PDM process described here.

Additionally, we continue to prioritize consumer and stakeholder education regarding dual enrollment and transitioning between coverage, and to engage in various outreach activities including distributing webinar, newsletter, and fact sheet content for assisters, agents, brokers, and issuers, as well as direct consumer notification and application help text. We also are working to develop educational materials to ensure that all Medicare beneficiaries understand the consequences of dual enrollment and associated penalties for not enrolling in Medicare Part B when first eligible. We believe this will help reduce consumer confusion over their coverage options and the appropriate time to sign up for Medicare. We appreciate the comments and ideas for future education efforts for this population and will consider these suggestions as part of our Medicare PDM stakeholder outreach moving forward.

3. Eligibility Redetermination During a Benefit Year (§ 155.330)

We proposed to add a new paragraph (d)(3) to § 155.330, under which Exchanges would be required to conduct PDM at least twice each calendar year beginning with calendar year 2020. We are finalizing this proposal. However, we have changed the implementation date to the 2021 calendar year, and added clarifying language regarding State Exchanges that have fully integrated eligibility systems with their respective Medicaid agencies.

In accordance with § 155.330(d), Exchanges must periodically examine available data sources to determine whether enrollees in a QHP through an Exchange with APTC or CSRs have been determined eligible for or enrolled in other qualifying coverage through Medicare, Medicaid, CHIP, or the BHP, if applicable. HHS has not previously defined ''periodically.'' Currently, Exchanges using the federal platform conduct Medicare PDM and Medicaid/CHIP PDM twice a year. To ensure that all Exchanges are taking adequate steps to identify enrollees who have become eligible for or enrolled in these other forms of MEC, and to terminate APTC and CSRs for those identified, we proposed to add paragraph (d)(3) to specify that Exchanges would be required to conduct Medicare, Medicaid/CHIP, and, if applicable, BHP PDM at least twice a calendar year, beginning with the 2020 calendar year. We indicated that this timeframe would likely give Exchanges that are not already performing these PDM checks twice a year sufficient time to implement any business, operational, and information technology changes needed to comply with the proposed new requirement.

We explained our belief that this policy would reduce QHP premiums, since Medicare and Medicaid/CHIP beneficiaries tend to have a higher risk profile than a typical Exchange enrollee and, therefore, may have negative impacts on the risk pool. Because this population includes significant numbers of older and disabled beneficiaries, or persons that may have poorer health outcomes generally associated with lower income statuses, we expect that these populations typically will utilize health care services at a greater rate as compared to other populations.[2] So that the Exchanges could prioritize the implementation of the proposed requirement to conduct PDM for Medicare, Medicaid, CHIP, and, if applicable, BHP eligibility or enrollment at least twice yearly, we did not also propose requiring Exchanges to perform PDM for death at least twice in a calendar year, and will consider this as part of future rulemaking.

Since most State Exchanges that operate their own eligibility and enrollment platform have a single shared, integrated eligibility system with their respective Medicaid programs, the Medicaid/CHIP PDM requirements may be met differently by State Exchanges. State Exchanges that have fully integrated eligibility systems generally have controls in place to prevent concurrent or dual enrollment of an individual in both a QHP through the Exchange with APTC/CSRs, and Modified Adjusted Gross Income (MAGI)-based Medicaid/CHIP coverage, at any given time. We proposed at paragraph (d)(3) that we will deem these State Exchanges to be in compliance with the requirement to perform

[2] For example, see Urban Institute and Center on Society and Health, How Are Income and Wealth Linked to Health and Longevity? (April 2015), available at *https://www.urban.org/sites/default/files/publication/49116/2000178-How-are-Income-and-Wealth-Linked-to-Health-and-Longevity.pdf.*

Medicaid/CHIP PDM or, if applicable, BHP PDM. Thus, these State Exchanges would not need to perform additional Medicaid/CHIP PDM outside of the controls that are currently in place to prevent dual enrollment in their integrated eligibility system. State Exchanges that operate their own eligibility and enrollment platform and do not have fully integrated eligibility systems for APTC/CSRs and Medicaid/CHIP or BHP, if applicable, would be required to perform Medicaid/CHIP PDM at least twice a year.

We anticipate many State Exchanges will meet or exceed the proposed requirements for Medicare PDM, Medicaid/CHIP PDM and, if applicable, BHP PDM, based on operations reported to us through the State-based Marketplace Annual Reporting Tool (SMART). This view is also supported by information we have learned through technical assistance engagements. Furthermore, the new Medicaid/CHIP PDM requirement would not result in a significant administrative burden for State Exchanges because we believe most State Exchanges currently operate an integrated eligibility system and could be deemed to be in compliance with the proposed Medicaid/CHIP PDM requirements.

We did not propose specific penalties if State Exchanges do not comply with the proposed PDM requirements. However, we noted that, under current authority, HHS requires a State Exchange to take corrective action if it is not complying with applicable federal requirements. We utilize specific oversight tools (SMART, programmatic audits, etc., as described in the preamble to § 155.1200) to identify issues with, and place corrective actions on, the Exchanges, and to provide technical assistance and ongoing monitoring to track those actions until the Exchange comes into compliance.

Additionally, under section 1313(a)(4) of the PPACA, if HHS determines that an Exchange has engaged in serious misconduct with respect to compliance with Exchange requirements, it has the option to rescind up to 1 percent of payments due to a state under any program administered by HHS until it is resolved. These existing authorities would apply to the proposed periodic data matching requirements in § 155.330(d). If HHS were to determine that it is necessary to apply this authority due to non-compliance by an Exchange with § 155.330(d), HHS would also determine the HHS-administered program from which it would rescind payments that are due to that state.

Lastly, we proposed to make a technical correction in § 155.330(d)(1) by adding an additional reference to the process and authority in § 155.320(b). This reference was omitted previously, but the requirements in § 155.320(b), specifying that Exchanges must verify whether an applicant is eligible for MEC other than through an eligible employer-sponsored plan using information obtained by transmitting identifying information specified by HHS to HHS for verification purposes, apply to the PDM process in § 155.330.

We are finalizing this proposal to add paragraph (d)(3) as proposed, but have changed the implementation date to the 2021 calendar year, and have added some clarifying language with regard to fully integrated eligibility systems, as described below. A summary of comments received and our responses to those comments appear below.

Comment: We received multiple comments in support of PDM as an effort to improve Exchange program integrity. These commenters agreed that the process helps inform consumers of their enrollment in potentially duplicative other MEC such as certain Medicare and Medicaid coverage, CHIP, or, if applicable, the BHP, and to help consumers avoid a tax liability for having to repay APTC received during months of overlapping coverage when reconciling at the time of annual federal income tax filing. Many commenters suggested improvements that could be made to current PDM processes.

Some commenters suggested that consumers, especially Medicare beneficiaries, could benefit from additional education or outreach from assisters, Navigators, or call center representatives to help these dually enrolled consumers make informed choices about their coverage options. Another commenter recommended that HHS work closely with SSA to identify which Medicare beneficiaries are approaching Medicare eligibility so that notices can be sent during the beneficiary's initial enrollment period. Another commenter recommended that, in addition to periodic checks for other qualifying coverage, HHS should implement periodic checks for deceased enrollees and that these checks should occur before auto re-enrollment.

Response: We agree that the PDM process is an important tool to ensure that Exchange enrollees are enrolled in the appropriate coverage that best meets their needs and budget while reducing the risk for potential tax liabilities for having to repay APTC received during months of overlapping coverage. We also agree that outreach and education is critical for dual enrollees and we continue to work with Exchange stakeholders on education and outreach strategies, especially for the Medicare beneficiary population to ensure that consumers can make well-informed choices and sign up for Medicare coverage during the appropriate timeframes. In 2018, we added additional resources to the Exchange application that provided information on the appropriate timeframes to enroll in Medicare Parts A and B to help consumers avoid incurring any late enrollment penalties. We also believe that periodic checks for deceased enrollees are a critical aspect to ensuring Exchange program integrity. Beginning in late 2019, Exchanges using the federal platform will conduct periodic checks for deceased enrollees in single member applications and subsequently end deceased enrollees' QHP coverage. As noted previously, to ensure State Exchanges have appropriate time to implement the technical and operational changes necessary to conduct Medicare, Medicaid/CHIP, and, if applicable, BHP, PDM, we are not requiring that State Exchanges perform checks for deceased enrollees twice yearly, and will be considering changes as part of future rulemaking.

Comment: We received mixed comments regarding our proposal to require Exchanges to conduct Medicare, Medicaid/CHIP and, if applicable, BHP PDM twice a year. Many commenters stated that increasing the frequency of PDM, particularly Medicare PDM, may be burdensome on both consumers and State Exchanges, and could lead to increased consumer confusion, diversion of resources from customer service and outreach efforts, and potential loss of APTC due to potentially outdated data sources for Medicare enrollment and Medicaid/CHIP eligibility and enrollment. One commenter recommended that additional verification checks be incorporated into the final rule to ensure consumers are not removed from coverage due to outdated data. Two commenters noted that the twice yearly frequency was too infrequent and would not provide timely notice for those consumers who are dually enrolled in Medicare and Exchange coverage. One commenter recommended requiring that Exchanges only perform PDM checks once yearly, which taken together with the annual renewal process, would allow a check every 6 months. Another commenter expressed concerns that our proposed language would allow State Exchanges to perform PDM more than twice a year, which could cause consumers to lose coverage erroneously.

Response: We continue to believe that conducting Medicare, Medicaid/CHIP

and, if applicable, BHP PDM serves a critical role in ensuring that consumers are enrolled in the appropriate coverage and ensures that APTC is paid appropriately. We continue to work with our partners throughout HHS to ensure the accuracy of Medicare, Medicaid, and CHIP data, and will continue to provide guidance to State Exchanges on notice language, especially regarding the availability of special enrollment periods for consumers who erroneously lose APTC or QHP coverage, as well as the consumer's right to appeal an Exchanges' determination. We disagree that conducting PDM checks twice yearly would cause consumer confusion or divert resources away from customer service and outreach because PDM provides valuable information to consumers regarding their dual enrollment in Medicare and/or Medicaid/CHIP and serves an important program integrity function by ensuring that only consumers eligible for APTC/CSRs receive them. We continue to prioritize consumer and stakeholder education related to dual enrollment and transitioning between coverage, including webinar, newsletter, and fact sheet content for assisters, agents, brokers, and issuers, as well as direct consumer notification and application help text. We encourage State Exchanges to prioritize these education efforts as well.

We appreciate commenters' suggestions regarding the frequency of PDM checks, but we believe that requiring these checks at least twice a year strikes the appropriate balance between providing timely notice for dually enrolled consumers and not overburdening Exchanges with potentially costly system changes and notice requirements. With respect to the comment regarding Exchanges conducting a Medicaid/CHIP or Medicare PDM check during the annual renewal process, this rule specifies the frequency, and not the precise timing, for when Exchanges must conduct the Medicaid/CHIP and Medicare PDM checks. Exchanges have the flexibility to conduct one of the required PDM checks during the annual renewal process.

Finally, we disagree that the changes outlined to PDM would increase burden on all Exchanges. We will deem State Exchanges that have implemented fully integrated eligibility systems with their respective Medicaid programs to be in compliance with the proposed Medicaid/CHIP PDM requirement. Thus, we anticipate the change to the Medicaid/CHIP PDM requirement will not increase burden for those State Exchanges because they will not have to build new functionality to meet this requirement. However, we do agree that any significant burden on State Exchanges would likely be on those that currently do not perform any Medicare PDM, or those that currently do not operate integrated eligibility systems and do not perform any Medicaid/CHIP PDM and, therefore, are not already in compliance with § 155.330(d). Those Exchanges would likely be required to engage in information technology (IT) system development activities in order to communicate with these programs and act on enrollment data in a new way.

Comment: We received multiple comments that the proposed date of January 1, 2020 for the implementation of twice yearly Medicare, Medicaid/CHIP, and, if applicable, BHP PDM provides insufficient time for State Exchanges to implement the required technical changes. Commenters noted that State Exchanges that do not currently conduct Medicare PDM, or do not have integrated eligibility systems with their State Medicaid programs and do not currently conduct Medicaid/CHIP PDM, would have to make significant changes to their eligibility systems and processes to to confirm enrollment in Medicare or to verify Medicaid or CHIP eligibility, respectively. One commenter suggested 2021 as an appropriate implementation date. Two commenters also requested that HHS finalize a clear and certain definition of a fully integrated eligibility system to mean eligibility systems that have one eligibility rules engine, shared between the State Exchange and its respective Medicaid program, for MAGI-based Medicaid, CHIP, APTC, and if applicable, BHP, eligibility determinations.

Response: We agree with commenters that requiring implementation by the 2020 calendar year may not provide State Exchanges with a sufficient timeframe to implement these changes, especially for Exchanges without integrated eligibility systems that do not currently perform Medicaid/CHIP PDM or those that currently do not perform Medicare PDM. These Exchanges would need to implement new interfaces with their respective Medicaid programs and/or a new connection to federal data to confirm Medicare enrollment. Therefore, we are finalizing the proposal in § 155.330(d)(3) to take effect beginning with the 2021 calendar year. We also agree on the importance of providing a clear and specific definition of ''fully integrated eligibility system.'' As described in the preamble to the proposed rule, by ''fully integrated eligibility system,'' we mean one where a State Exchange and its respective Medicaid program shares a single eligibility rules engine for determining eligibility for MAGI-based Medicaid/CHIP, APTC, and if applicable, BHP. We are finalizing paragraph (d)(3) with some additional language to codify this meaning.

Comment: We received three comments that were opposed to the proposed requirement to conduct Medicare, Medicaid/CHIP and, if applicable, BHP PDM, cautioning us that defining the precise frequency and nature of PDM encroaches upon the sovereignty of the State Exchanges. Two commenters noted that HHS has not provided enough evidence that there is a significant problem with duplicative enrollment in other qualifying coverage such as Medicare, Medicaid/CHIP, and BHP. One commenter expressed concern that additional requirements on State Exchanges could discourage consumers from applying for coverage.

Response: Ensuring that consumers are enrolled in the appropriate coverage remains a top priority for HHS. Additionally, ensuring that APTC is paid appropriately is a requirement set forth in § 155.330(d)(1)(ii). Several Government Accountability Office (GAO) reviews have underscored the importance of continually re-verifying enrollee eligibility for APTC through PDM with other government entities.[3] As such, we believe PDM plays a vital role in ensuring the health and integrity of all Exchanges by ensuring consumers are enrolled in the appropriate coverage, and reduces the risk that consumers will have to pay back all or some of APTC paid on their behalf during months of overlapping coverage when they file their annual federal income taxes. We disagree that the twice yearly requirement to conduct Medicare, Medicaid/CHIP and, if applicable, BHP PDM would discourage consumers from applying for and enrolling in QHP coverage, as the majority of consumers become dually enrolled inadvertently, such as by aging into Medicare or experiencing fluctuations in household income.

4. General Program Integrity and Oversight Requirements (§ 155.1200)

As the Exchange Establishment grant program established under section 1311 of the PPACA has come to a conclusion and State Exchanges have become financially self-sustaining, HHS

[3] ''Improper Payments: Improvements Needed in CMS and IRS Controls over Health Insurance Premium Tax Credit'' (GAO 17–467); ''Federal Health-Insurance Marketplace: Analysis of Plan Year 2015 Application, Enrollment, and Eligibility-Verification Process'' (GAO–18–169).

continues to develop and refine its mechanisms and tools for overseeing the ongoing compliance of State Exchanges and SBE–FPs with federal requirements for Exchanges, including eligibility and enrollment requirements under 45 CFR part 155.

HHS approves or conditionally approves a state to establish a State Exchange based on an assessment of a state's attested compliance with applicable statutory and regulatory rules. Once approved or conditionally approved, State Exchanges must meet specific program integrity and oversight requirements identified at section 1313(a) of the PPACA, and the implementing regulations at §§ 155.1200 and 155.1210. These requirements outline HHS's authority to oversee the Exchanges after their establishment. Currently, annual reporting requirements for State Exchanges at § 155.1200(b) include the annual submission of (1) a financial statement in accordance with generally accepted accounting principles (GAAP); (2) eligibility and enrollment reports; and (3) performance monitoring data.

Additionally, under § 155.1200(c), each State Exchange is required to contract with an independent external auditing entity that follows generally accepted government auditing standards (GAGAS) to perform annual independent external financial and programmatic audits. State Exchanges are required to provide HHS with the results of the annual external audits, including corrective action plans to address any material weaknesses or significant deficiencies identified by the auditor.[4] All corrective action plans are monitored by HHS until closed. Currently, the audits must address compliance with all Exchange requirements under 45 CFR part 155.[5]

HHS designed and developed the SMART in 2014 to assist State Exchanges in conducting a defined set of oversight activities. The SMART was designed to facilitate State Exchanges' reporting to HHS on how they are meeting federal program and operational requirements, including State Exchanges reporting their compliance with federal eligibility and enrollment program requirements under 45 CFR part 155 subparts D and E. The SMART, thus, enables HHS to evaluate and monitor State Exchange progress in coming into compliance with federal requirements where needed. Since then, HHS has come to utilize the SMART, along with the annual programmatic and financial audit reports, as primary oversight tools for identifying and addressing State Exchange non-compliance issues. HHS requires State Exchanges to take corrective actions to address issues that are identified through the SMART and annual audits, and HHS monitors the implementation of the corrective actions.

In the proposed rule, we proposed to modify § 155.1200(b)(2) to reflect that HHS requires State Exchanges to submit annual compliance reports (such as the SMART), that encompass eligibility and enrollment reporting by State Exchanges, and also include reporting on compliance across other Exchange program requirements under 45 CFR part 155. We also proposed to modify § 155.1200(b)(1) to eliminate the April 1st date by which State Exchanges must provide a financial statement to HHS, to provide HHS the flexibility to align the financial statement deadline with the SMART deadline, which is set annually by HHS. Because we proposed to remove the April 1st date, but intend to maintain the requirement that State Exchanges submit the required reports by a deadline, we also proposed to modify the introductory text to § 155.1200(b) to specify that State Exchanges must provide the required annual reporting by deadlines to be set by HHS.

We proposed to retain the requirement at § 155.1200(c) that an annual programmatic audit be conducted by State Exchanges, but proposed a minor change from ''state'' to ''State Exchanges'' to be consistent and clear on the entities to which this rule applies. We also proposed to add specificity to the annual programmatic audit requirement by proposing a clarification of § 155.1200(d)(2) to make clear that HHS may specify or target the scope of a programmatic audit to address compliance with particular Exchange program areas or requirements. We explained that this would provide HHS with the ability to specify those Exchange functions that are most pertinent to a particular State Exchange model (either a traditional State Exchange that operates its own eligibility and enrollment system or an SBE–FP) and need to be regularly included in the audit; target those Exchange functions most likely to impact program integrity, such as eligibility verifications; and reduce burden on State Exchanges where possible. In addition, we proposed to modify § 155.1200(d) by replacing existing paragraph (d)(4) with new paragraphs (d)(4) and (5). These proposed new requirements specify that State Exchanges must ensure that the independent audits implement testing procedures or other auditing procedures that assess whether a State Exchange is conducting accurate eligibility determinations and enrollment transactions under 45 CFR part 155 subparts D and E. Such auditing procedures can include the use of statistically valid sampling methods in the testing or auditing procedures.

We indicated that we believe these proposed changes would strengthen our programmatic oversight and the program integrity of State Exchanges, while providing flexibility for HHS in the collection of information. We further explained that, through the Paperwork Reduction Act (PRA) process, we are able to make updates and refinements to the SMART reporting tool to align with our program integrity priorities for Exchanges as they evolve. In addition, allowing HHS to specify the scope of the programmatic audit at § 155.1200(d)(2) would provide us the ability to target our oversight to specific Exchange program requirements based on the particular State Exchange model, our program integrity priorities, and the goal of reducing burden on State Exchanges where possible. We explained our belief that this approach would provide HHS and states with greater insight into State Exchange compliance with federal standards in a more cost-effective manner.

We also noted our belief that this approach would allow HHS to identify State Exchange non-compliance issues with more precision and efficacy. It would allow HHS to provide more effective, targeted technical assistance to State Exchanges in developing corrective action plans to address issues that are identified. We discussed how this approach could reduce administrative burden on State Exchanges while maintaining the traditional role of State Exchanges in managing and operating their Exchanges, with HHS maintaining its role of overseeing State Exchange compliance with federal requirements through structured reporting processes. We sought comments on these proposals. After consideration of comments received, we are finalizing the amendments to § 155.1200 as proposed. A summary of comments received and our responses to those comments appear below:

Comment: Commenters generally expressed support for some of the proposed changes to the annual reporting and programmatic audit requirement. They expressed support for removal of the April 1st financial statement deadline as long as the new deadline accommodates the state budget cycles for all State Exchanges. Some

[4] 45 CFR 155.1200(c)(1) and (2).

[5] 45 CFR 155.1200(d)(2).

commenters supported the proposal to provide flexibility to specify the scope of the programmatic audit, such as focusing on eligibility and enrollment requirements under 45 CFR part 155 subparts D and E, while two commenters asked HHS to refrain from expanding the scope of the programmatic audit as it can divert funding from other Exchange functions and create administrative burden. Some commenters expressed concern with the timing and potential funding to implement the changes. These commenters urged HHS to provide State Exchanges with over a year of advanced notice to implement the changes, to ensure proper planning and funding.

One commenter requested that HHS clarify the proposed requirement for the State Exchange's independent external auditor to use statistically valid sampling in their review of the State Exchange eligibility and enrollment transactions, noting that statistically significant sampling in the programmatic audit can be larger in scope and more costly in comparison to random sampling which can also identify programmatic issues. Another commenter recommended that HHS consider changing the frequency of the programmatic audit to biennially unless the programmatic audit shows irregularities.

Another commenter urged HHS to clarify that the proposed changes to the programmatic audit specific to eligibility and enrollment activities do not pertain to SBE–FPs, since SBE–FPs rely on HHS and the federal platform to perform eligibility and enrollment functions.

Response: We believe these proposed changes will strengthen our programmatic oversight and the program integrity of State Exchanges and thus are finalizing these amendments as proposed. As detailed in the proposed rule, these amendments are intended to allow for more targeted audits that focus HHS and State Exchange resources on compliance with particular Exchange program areas that have higher program integrity risks in a more consistent manner, rather than covering all program areas. These amendments are also intended to address requirements that are applicable only to a particular State Exchange model, in a more standardized manner. We are removing the April 1st deadline from § 155.1200(b)(1) to allow HHS to align the deadline for submission of the financial statement to HHS with the deadline for submission of SMART reports, currently June 1. Going forward, we anticipate establishing the deadline for submission of the financial statement and SMART report on an annual basis through guidance and would seek to accommodate state budget cycles to the maximum extent practical when setting these dates. The general scope of these audits remains the same, that is, under the new paragraph (d)(2), HHS may specify that an audit focus on compliance with subparts D and E of 45 CFR part 155, or other requirements under 45 CFR part 155, as specified by HHS.[6] However, we appreciate and considered the comments received. We understand that most State Exchanges negotiate their contracts with external auditing entities a year or more in advance and would need sufficient time to update their contracts to reflect any changes in the scope of the external programmatic audits. We also recognize that State Exchanges that operate their own eligibility and enrollment platforms would also need time to work with their contracted auditors to implement new procedures for testing the accuracy of eligibility determinations if their auditors have not previously employed such procedures for this purpose. Thus, subsequent to this rule, we will provide State Exchanges with technical operational guidance that will specify the first plan year for which changes to the scope of the programmatic audit would apply, taking into account the need to allow for a period of time for State Exchanges to implement the changes finalized in this rule.

In response to the comments regarding use of a statistically-significant sampling methodology versus a random sampling methodology, we clarify that, in this rule, we are not specifying a particular sampling methology that must be used by all State Exchanges for testing the accuracy of eligibility determinations in the annual programmatic audits. In addition to State Exchanges and their contracted auditors using the generally accepted government auditing standards, CMS's technical operational guidance would also outline procedures the independent external auditor can chose to implement to assess whether a State Exchange is conducting accurate eligibility determinations and enrollment transactions under 45 CFR part 155 subparts D and E. Going forward we intend to provide State Exchanges with this technical operational guidance on an annual basis to outline the deadline for submission of the applicable year's reports, the scope of the applicable year's external programmatic audit, and the requirements under 45 CFR part 155 that are applicable to each State Exchange model. We intend to release this guidance around April each year, to align with our existing timeframe for providing guidance to State Exchanges on the annual SMART process, so that State Exchanges have sufficient time to prepare, and administrative burden is minimized to the extent practical. Lastly, we agree with the overall notion of taking a risk-based approach towards determining the frequency by which State Exchanges are required to conduct the external programmatic audit. Specifically, we considered the recommendation to change the frequency of State Exchange programmatic audits to biennially unless the audit shows irregulatrities. We decline to make this change at this time because some State Exchanges currently are addressing active findings or corrective actions as a result of past programmatic audits, which we believe annual re-evaluations are still appropriate. However, we will consider this recommendation going forward and may propose to decrease the frequency of State Exchange audits in future rule-making.

Comment: Some commenters requested that certain regulatory language remain unchanged or be modified. One commenter urged HHS to retain the language under §§ 155.1200(b)(2) and 155.1200(d)(2) because the proposed language is broader and targeted auditing can create administrative burden. Another commenter requested that HHS limit the scope of the programmatic audit under § 155.1200(d)(2) to solely cover the eligibility and enrollment requirements under 45 CFR part 155 subparts D and E and remove the language that allows HHS to include other Exchange requirements under 45 CFR part 155 in the scope of the programmatic audit. Another commenter requested that § 155.1200(d)(2) remain unchanged because the general reference to compliance with 45 CFR part 155 is consistent with the HHS's stated intent to specify the scope for programmatic audits, and recommended that HHS make clear that the proposed changes to the review of State Exchange eligibility determinations under § 155.1200(d)(4) applies to eligibility determinations for QHP/APTC only, and not to Medicaid eligibility determinations.

Response: We believe the proposed changes under § 155.1200(d) will strengthen our programmatic oversight and the program integrity of State Exchanges and provide appropriate

[6] This is consistent with the scope for audits in the existing regulation at 45 CFR 155.1200(d)(2), which currently requires State Exchanges to ensure these audits address compliance with ''the requirements under this part.''

flexibility to target oversight and enforcement activities, as well as HHS and State Exchange resources, which, in turn, will reduce burden. As State Exchanges continue to evolve and mature, HHS will be able to focus oversight efforts, including making refinements to annual compliance reporting tools (such as the SMART), in response to changes in federal policy, as well as federal program integrity priorities and processes. We further note that, while these amendments provide flexibility for HHS to target these audits, they also retain the authority for HHS to require the audits to address other requirements under 45 CFR part 155, as specified by HHS. As such, HHS can still require audits with a broader scope when deemed appropriate or necessary. While we generally intend to focus programmatic audits on those Exchange functions most likely to impact program integrity, such as eligibility verifications, we do not agree with commenters that these audits should only focus on eligibility and enrollment functions because there may be changes to federal policy, priorities, or processes that result in the need for HHS to focus our oversight on other Exchange functions besides eligibility and enrollment. Also, not all State Exchanges perform their own eligibility and enrollment functions. For instance, SBE–FPs rely on HHS and the federal platform to perform their eligibility and enrollment functions, and thus HHS's oversight of SBE–FPs would need to focus on other Exchange functions that are more relevant or critical to the SBE–FP model. That is why HHS retains the authority, and the flexibility, under the amended § 155.1200(d)(2) to require the audits to address other requirements under 45 CFR part 155, as specified by HHS. In addition, the amendments to § 155.1200(d)(2) finalized in this rule give HHS flexibility to specify the Exchange functions that are most pertinent to the State Exchange model and most likely to impact program integrity. In response to comments, we clarify that the changes to subparagraph § 155.1200(d)(4) apply to State Exchange eligibility determinations for QHP/APTC, and not to Medicaid eligibility determinations. We recognize that not all State Exchanges make Medicaid eligibility determinations, but also wish to clarify that in accordance with § 155.302, State Exchanges must conduct a MAGI-based assessment or determination of eligibility for Medicaid as part of determining eligibility for APTC. HHS will provide further guidelines on the auditing of State Exchange eligibility and enrollment transactions, and any other audit requirements applicable in a given year, in the annual technical operational guidance. We further clarify that the amendments to § 155.1200(b)(2) do not reflect an expansion of State Exchange reporting obligations and instead capture the existing annual compliance reports (such as the SMART), that encompass eligibility and enrollment reporting, as well as compliance across other Exchange program requirements under 45 CFR part 155, that State Exchanges currently submit to HHS.

Comment: One commenter requested transparency regarding HHS's oversight of the Federally-facilitated Exchanges' (FFEs') compliance with oversight standards. The commenter recommended that HHS publish a comparison of compliance standards and activities to ensure the FFEs and State Exchanges are held to the same oversight requirements. Another commenter generally supported the proposed changes as enhancing the oversight and transparency of the State Exchanges.

Response: We appreciate and strive for transparency in the oversight of all Exchanges and will consider these suggestions. However, we note that the oversight standards under § 155.1200, including the proposed amendments, are specific to State Exchanges. Therefore, the comments related to FFE oversight standards are outside the scope of this rulemaking. We also note that the FFEs are overseen through the efforts of other federal entities such as the Government Accountability Office and the HHS Office of the Inspector General.

Comment: Several commenters opposed HHS's proposed changes to the annual reporting and programmatic audit requirements for State Exchanges. They stated that the proposed language expands federal authority and can add administrative burden to State Exchanges. Some commenters disagreed that the Federalism implications are substantially mitigated since the proposed changes only add specificity to existing requirements, stating that the proposed changes are open-ended and remove specificity. Additionally, some of these commenters expressed concern that HHS is eliminating the requirement of eligibility and enrollment reports under § 155.1200(b)(2). These commenters also raised concerns with the disclosure of consumer information, as well as negative consumer impacts, due to the additional oversight on eligibility determinations being proposed.

Response: We believe these changes will strengthen our programmatic oversight and the program integrity of State Exchanges. Further, as detailed above, the amendments do not represent an expansion of HHS's authority to oversee and monitor compliance of State Exchanges. Under the existing language at § 155.1200(d)(2), State Exchanges are currently required to ensure their respective annual programmatic audits address compliance with ''the requirements under this part.'' The changes to this provision finalized in this rule provide HHS with the flexibility to target the scope of the audits to the requirements applicable to each State Exchange model under 45 CFR part 155 and that most impact program integrity, which should generally reduce the administrative burdens associated with these audits. For example, we anticipate tailoring the requirements regarding audit of eligibility and enrollment activities by State Exchange model. Since SBE–FPs rely on the federal platform for eligibility and enrollment functions, we believe that they should not be subject to the same audit requirements as State Exchanges that perform all eligibility and enrollment activities because they operate their own technology platform for such activities.

We also clarify that we are not eliminating eligibility and enrollment reporting under § 155.1200(b)(2). The amendments finalized to that provision reflect that HHS already requires State Exchanges to submit annual reporting (such as the SMART) that encompass eligibility and enrollment reporting, along with other information about compliance with requirements in other subparts under 45 CFR part 155. These changes recognize that HHS has come to utilize the SMART along with the annual programmatic and financial audit reports as the primary oversight tools to oversee State Exchange compliance with the applicable requirements under 45 CFR part 155, which includes compliance with eligibility and enrollment requirements. We further clarify that if we need additional information about a State Exchange's compliance with applicable requirements beyond what is reported through SMART, we would leverage the new flexibility under the new § 155.1200(d)(2) to conduct a targeted audit.

Finally, in response to the comments expressing concern about the increased risk of disclosure of consumer information as a result of the additional oversight and auditor review of individual eligibility determinations made by State Exchanges that is contemplated in this rule, we note that,

as part of the responsibilities of State Exchanges and their contracted entities in handling individual consumer data associated with core Exchange functions such as eligibility, enrollment, and consumer assistance, State Exchanges and their contracted non-Exchange entities must always comply with the privacy and security requirements under §§ 155.260 and 155.280 with respect to the protection and disclosure of personally identifiable information. Additionally, under § 155.285, State Exchanges and their contracted entities are subject to civil monetary penalties for improper use or disclosure of personally identifiable information. Finally, HHS has authority under § 155.280 to conduct audits and investigations to ensure compliance with Exchange privacy and security standards, and may pursue civil, criminal or adminstirative proceedings or actions as determined necessary.

After considering the comments received in response to the proposed rule and for the reasons discussed above, we are finalizing the modifications to § 155.1200.

B. Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges

1. Segregation of Funds for Abortion Services (§ 156.280)

We proposed an amendment at § 156.280(e)(2) relating to billing and payment of the policy holder's portion of the premium attributable to abortion services for which appropriated funds may not be used. Since 1976, Congress has included language, commonly known as the Hyde Amendment, in the Labor, Health and Human Services, Education and Related Agencies appropriations legislation.[7] The Hyde Amendment, as currently in effect, permits federal funds subject to its funding limitations to be used for abortion services only in the limited cases of rape, incest, or if a woman suffers from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death unless an abortion is performed (Hyde abortion services). Generally, when appropriated funds are subject to the Hyde Amendment's funding limitations, an agency is prohibited, among other things, from using those funds to pay for coverage of abortion beyond these specific limited exceptions (non-Hyde abortion services). Section 1303(b)(2) of the PPACA prohibits the issuer of a QHP offering coverage for abortion services that are not exempt from the Hyde Amendment's ban on the use of federal funds to pay for certain abortions, from using any amount attributable to PTC (including APTC) or CSRs (including advance payments of those funds to an issuer, if any) for abortions for which federal funds are prohibited, ''based on the law as in effect as of the date that is 6 months before the beginning of the plan year involved.'' [8]

Section 1303 of the PPACA outlines specific accounting and notice requirements that QHPs covering non-Hyde abortion services must follow to ensure that no federal funding is used to pay for services for which public funds are prohibited. Under sections 1303(b)(2)(B) and (b)(2)(D) of the PPACA, as implemented in § 156.280(e)(2)(i) and (e)(4), QHP issuers must collect a separate payment from each enrollee in such a plan without regard to the enrollee's age, sex, or family status, for an amount equal to the greater of the actuarial value of coverage of abortion services for which public funding is prohibited, or $1 per enrollee per month.

Section 1303(b)(2)(D) of the PPACA establishes certain requirements with respect to a QHP issuer's estimation of the actuarial value of non-Hyde abortion services. Under section 1303(b)(2)(D) of the PPACA, the QHP issuer ''may take into account the impact on overall costs of the inclusion of such coverage, but may not take into account any cost reduction estimated to result from such services, including prenatal care, delivery, or postnatal care.'' The QHP issuer is also required to estimate such costs as if such coverage were included for the entire population covered, and may not estimate such a cost at less than $1 per enrollee, per month. If an enrollee's premium is paid through employee payroll processes, section 1303(b)(2)(B) of the PPACA requires that the separate payments ''shall each be paid by a separate deposit.'' Accordingly, issuers that offer QHPs that provide coverage of non-Hyde abortion services must collect a separate payment of no less than $1 per enrollee in the plan per month, regardless of the actuarial value of coverage of non-Hyde abortion services and regardless of whether premiums are paid directly by enrollees or through payroll deductions.

In certain rare scenarios, the FFEs' system allocated an amount of APTC to a QHP such that the share of the aggregate premium attributable to coverage of non-Hyde abortion services is less than $1, which falls below the minimum requirement under section 1303 of the PPACA. We made system changes for the open enrollment period for plan year 2019 to ensure that the minimum premium amount of $1 per enrollee per month is assigned to all enrollments into plans offering coverage of non-Hyde abortion services, so that issuers can separately collect this amount directly from enrollees for the portion of the total premium attributable to coverage of non-Hyde abortion services.

Pursuant to section 1303(b)(2)(C) of the PPACA, as implemented at § 156.280(e)(3), QHP issuers must segregate funds for coverage of non-Hyde abortion services collected from enrollees into a separate allocation account that is to be used to pay for non-Hyde abortion services. Thus, if a QHP issuer disburses funds for a non-Hyde abortion on behalf of an enrollee, it must draw those funds from the segregated allocation account. The account cannot be used for any other purpose.[9]

Section 1303 of the PPACA and current implementing regulations at § 156.280 do not specify the method a QHP issuer must use to comply with the separate payment requirement under section 1303(b)(2)(B)(i) of the PPACA and § 156.280(e)(2)(i). In the 2016 Payment Notice, we provided guidance with respect to acceptable methods that a QHP issuer offering coverage of non-Hyde abortion services on an individual market Exchange may use to comply with the separate payment requirement. We stated that the QHP issuer could satisfy the separate payment requirement in one of several ways, including by sending the enrollee a single monthly invoice or bill that separately itemizes the premium amount for coverage of non-Hyde abortion services; sending the enrollee a separate monthly bill for these services; or sending the enrollee a notice at or soon after the time of enrollment that

[7] Accordingly, the Hyde Amendment is not permanent Federal law, but applies only to the extent reenacted by Congress from time to time in appropriations legislation.

[8] Section 1303(b)(1)(B)(i) of the PPACA.

[9] This means that funds from the allocation account into which premium amounts attributable to the non-Hyde abortion service benefit must be deposited are the only funds that may be used to pay for non-Hyde abortion services. It should not be read to suggest that the funds in the separate allocation account may not be used to cover administrative costs associated with coverage of non-Hyde abortion services. *See* 42 U.S.C. 18023(b)(2)(D)(ii)(I) (when estimating per member, per month cost of non-Hyde abortion services, issuers may take into account the impact on overall costs of the inclusion of such coverage).

the monthly invoice or bill will include a separate charge for such services and specify the charge. In the 2016 Payment Notice, we also stated that an enrollee may make the payment for coverage of non-Hyde abortion services and the separate payment for coverage of all other services in a single transaction. On October 6, 2017, we released a bulletin that discussed the statutory requirements for separate payment, as well as this previous guidance with respect to the separate payment requirement.[10]

As explained in the proposed rule, HHS now believes that some of the methods for billing and collection of the separate payment for coverage of non-Hyde abortion services described as permissible in the preamble to the 2016 Payment Notice do not adequately reflect Congress's intent. We believe Congress intended that QHP issuers collect two distinct (that is, ''separate'') payments, one for the coverage of non-Hyde abortion services, and one for coverage of all other services covered under the policy, rather than simply itemizing these two components in a single bill, or notifying the enrollee that the monthly invoice or bill will include a separate charge for these services.

We proposed an amendment at § 156.280(e)(2) relating to billing and payment of the policy holder's portion of the premium attributable to coverage of non-Hyde abortion services to reflect this interpretation of the statute. Specifically, we proposed that, as of the effective date of this final rule, QHP issuers (1) send an entirely separate monthly bill to the policy holder, the individual who is the party legally responsible for the payment of premiums (which we refer to in this final rule as the ''policy holder'') for only the portion of premium attributable to coverage of non-Hyde abortion services, and (2) instruct the policy holder to pay the portion of their premium attributable to coverage of non-Hyde abortion services in a separate transaction from any payment the policy holder makes for the portion of their premium not attributable to coverage of non-Hyde abortion services. We also proposed that if a policy holder pays the entire premium in a single transaction (both the portion attributable to coverage of non-Hyde abortion services, as well as the portion attributable to coverage for other services), the QHP issuer would not be permitted to refuse to accept such a combined payment on the basis that the policy holder did not send payment in two separate transactions as requested by the QHP issuer, and to then terminate the policy, subject to any applicable grace period, for non-payment of premiums. We also stated that the QHP issuer would be expected to counsel enrollees to pay in two separate transactions in the future. Finally, we proposed a technical change to § 156.280(e)(2)(iii), as redesignated, to insert an appropriate cross reference to the explanation of the separate payments.

We are finalizing these policies at § 156.280(e)(2), but with several changes explained below. We are also finalizing the technical revision to § 156.280(e)(2)(iii) as redesignated, on which we received no comments, and are revising the heading of § 156.280 so that it accurately describes the new requirements we are finalizing in this final rule.

Comment: Most commenters objected to the proposed changes to issuer billing for the portion of the premium attributable to coverage of non-Hyde abortion services, asking that we withdraw the proposals altogether. A minority of commenters summarily supported the policy.

Nearly all commenters objecting to the proposals stated that separately billing for one specific service would be an unnecessary change that would not enhance program integrity with respect to enrollee transparency or appropriate use of federal funds. These commenters noted that current requirements already adequately comply with the statute and ensure appropriate segregation of funds, without imposing the operational and administrative burdens of the proposed approach. These commenters asserted that the current regulatory structure allows enrollees to make and issuers to accept a single transfer of funds for the full amount of an enrollee's premium payment including the amount attributable to coverage of non-Hyde abortion services, while still ensuring that the funds are ultimately segregated appropriately. Many commenters noted that requiring a separate bill and instructing enrollees to pay in separate transactions would be against industry practice, which permits one single bill outlining charges and allows for enrollees to make payments using a single transfer of funds which can be administratively separated by the insurer after payment is received.

Some commenters who supported the proposed changes stated that section 1303 of the PPACA contains an unambiguous statutory command that issuers separately bill and collect payments for the portion of a policy holder's premium attributable to coverage of non-Hyde abortion services. These commenters stated that the proposals are necessary to remedy incorrect methods for billing and payment and will help to ensure issuer compliance with the segregation of funds and the requirement to collect separate payments under section 1303 of the PPACA.

Nearly all objecting commenters stated that the proposals would cause considerable and unnecessary confusion and frustration for enrollees that may jeopardize their health insurance coverage. Commenters expressed concern that these billing changes would make it more difficult for policy holders to pay their premium bills, and could result in coverage being terminated for unintentional non-payment. Commenters expressed concerns that, despite issuer notices and communications to explain the second bill and separate payment requirement, enrollees would likely not understand this change in billing.

Among the many scenarios that commenters asserted could result in enrollees failing to pay the separate bill, commenters noted that enrollees might not realize or understand that there is a separate bill covering different services under their plan; enrollees may not realize that such payment is mandatory in order to fully satisfy their premium liability each month and avoid termination of coverage; or enrollees may not notice a second bill since it would be delivered in a separate mailing with which they are unfamiliar. Commenters expressed concern that in any of these scenarios, the enrollee would enter a grace period and, in most cases, have 90 days from the date of the missed payment to reconcile their balance, resulting in enrollees who fail to do so losing their health insurance coverage. Commenters expressed concern that such slight enrollee confusion as a result of the proposal could lead to the complete loss of coverage.

Commenters also stated that the proposal to allow enrollees to ''not be penalized'' for sending back a combined payment, would only send conflicting messages to enrollees and add to their confusion. Commenters stated that our proposal that issuers could accept combined payments from enrollees, but would then be expected to counsel enrollees to pay in two separate payments in the future, requiring issuers to repeatedly instruct enrollees to pay in separate transactions for each bill despite not being able to penalize enrollees if they continuously fail to do

[10] CMS Bulletin Addressing Enforcement of Section 1303 of the Patient Protection and Affordable Care Act (October 6, 2017), available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Section-1303-Bulletin-10-6-2017-FINAL-508.pdf.*

so, adds additional burden on issuers and will lead to increased calls from confused enrollees.

Many commenters stated they appreciated the enrollee protections prohibiting QHP issuers from refusing to accept a combined payment or terminating an enrollee's coverage on this basis. However, commenters expressed concerns that this protection alone would not be enough for enrollees who fail to pay the second bill entirely and asked that HHS add protections to the policy to avoid termination of coverage for enrollees who inadvertently fail to make the additional payment due to confusion about the separate bill.

Response: We continue to believe that the statute contemplates issuers billing separately for coverage of non-Hyde abortion services, consistent with Congress's intent that issuers collect separate payments for such services. Requiring one bill for the portion of the policy holder's premium attributable to coverage of non-Hyde abortion services and a separate bill for the portion of the policy holder's premium attributable to coverage of all other services covered under the QHP will better align with the intent of section 1303 of the PPACA.

HHS intentionally sought comment on ways to mitigate possible enrollee confusion from these proposals. After considering these comments, we believe there may be less confusing and less burdensome ways to implement these billing changes while also fulfilling section 1303 of the PPACA's statutory mandates.

Therefore, we are finalizing, as proposed in a new paragraph at § 156.280(e)(2)(ii)(A), the requirement that QHP issuers must send an entirely separate monthly bill to the policy holder for only the portion of the premium attributable to coverage of non-Hyde abortion services. However, in an effort to mitigate issuer burden associated with added postage and mailing costs, we will not require separate mailings with separate postage, as proposed. Rather, we are codifying that the QHP issuer may include the separate bill for coverage of non-Hyde abortion services in the same envelope or mailing as the bill for the portion of the premium attributable to coverage of all other services. As a result of finalizing this proposal, and to more accurately reflect the contents of § 156.280, we are making a technical change to revise the section heading of § 156.280 to now read, ''Separate billing and segregation of funds for abortion services.''

We note that when issuers send a separate paper bill for the portion of the premim attributable to coverage of non-Hyde abortion services in the same mailing as the bill for the other portion of the policy holder's premium, the bills must remain distinct and separate, on separate pieces of paper with separate explanations of the charges to ensure the policy holder understands the distinction between the two bills and understands that they are expected to pay the separate bills in separate transactions.

We are also codifying that issuers transmitting bills through email or other electronic means will still be required to transmit the separate bill for coverage of non-Hyde abortion services in a separate email or electronic communication than for the bill for the portion of the premium attributable to coverage of all other services. We assume that bills sent electronically can be sent at minimal cost such that requiring separate electronic communications will not significantly increase the burden this requirement places on issuers. We also believe policy holders are more likely to make a separate payment for coverage of non-Hyde abortion services when they receive a separate bill for such amount, and that receiving the separate bill in a separate communication further bolsters that likelihood. In deciding to finalize that QHP issuers may send the separate bill in a single mailing when sending paper bills, but must send the separate bill in a separate email or electronic communication when sending bills electronically, we weighed the goal of separate payment with the competing concern of issuer burden resulting from sending separate paper bills, and the comparatively low burden in sending separate electronic bills.

We are also finalizing, as proposed in a new paragraph at § 156.280(e)(2)(ii)(B) the requirement that issuers must instruct policy holders to pay the separate bill in a separate transaction. QHP issuers should make reasonable efforts to collect the payment separately. However, we continue to believe that potential loss of coverage would be an unreasonable result of an enrollee paying in full, but failing to adhere to the QHP issuer's requested payment procedure. Therefore, at § 156.280(e)(2)(ii)(B) we are also codifying, with minor non-substantive revisions, that the QHP issuer would not be permitted to refuse a combined payment on the basis that the policy holder did not send two separate payments as requested by the QHP issuer, and to then terminate the policy for non-payment of premiums. QHP issuers that receive combined enrollee premiums in a single payment must treat the portion of the premium attributable to coverage of non-Hyde abortion services as a separate payment and must disaggregate the amounts into the separate allocation accounts, consistent with § 156.280(e)(2)(iii).

To mitigate enrollee confusion and satisfy the requirement to instruct policy holders to pay the separate bill in a separate transaction, QHP issuers should consider including—in the email or electronic communication containing the bill for the portion of the policy holder's premium not attributable to coverage of non-Hyde abortion services—language notifying policy holders that they will be receiving a second, separate email or electronic communication containing a separate bill for the portion of their premium attributable to coverage of non-Hyde abortion services that they should pay in a separate transaction. Regardless of whether the QHP issuer sends the bills as paper copies in a mailing or sends the bills through electronic communications, the QHP issuer must instruct their enrollees to pay the separate bill in a separate transaction and must still produce an invoice or bill that is distinctly separate from the invoice or bill for the other portion of the policy holder's premium that is not attributable to coverage of non-Hyde abortion coverage, whether in paper or electronic format. We also suggest that issuers state clearly for policy holders on both bills that the policy holder is receiving two bills to cover the total amount of premium due for the coverage period, that the policy holder's total premium due is inclusive of the amount attributable to coverage of non-Hyde abortion services, and that the policy holder should make separate payments for each bill. We believe including these statements on each bill, will help policy holders to understand that they are receiving two bills for the premiums due for the payment period, the total amount of premium they owe, and the need to make a separate payment for each bill. We believe this will help to ensure that policy holders return the full monthly amount due, thus preventing policy holders from entering grace periods for non-payment of the premium amounts for the non-Hyde abortion coverage.

We believe these changes will assist in managing enrollee confusion. However, we also acknowledge that additional outreach and education may still be necessary on the part of issuers and states to explain to enrollees why they are receiving a separate bill for a relatively small amount for which they are expected to submit payment in a separate transaction. As indicated above, we believe that QHP issuers

should explain to the policy holder in layperson terms on the separate bill for coverage non-Hyde abortion services, or otherwise communicate to enrollees through enrollee outreach and education, that non-payment of any premium due (including non-payment of the portion of the policy holder's premium attributable to coverage of non-Hyde abortion services) would continue to be subject to state and federal rules regarding grace periods (unless the QHP issuer elects to take advantage of the enforcement discretion we outline later in this section), clarifying for policy holders that failure to pay the portion of the premium attributable to coverage of non-Hyde abortion services could ultimately result in termination of coverage.

We believe that including explanatory language on the bills as well as additional outreach and education by QHP issuers will decrease the likelihood that policy holders would inadvertently fail to pay the separate bill for the portion of their premium attributable to coverage of non-Hyde abortion services. However, we acknowledge commenters' concerns that, even with fulsome outreach and education efforts to explain the billing scheme to the policy holder, consumer confusion could still lead to inadvertent coverage losses. This risk may be especially acute for enrollees whose plan choices likely were not motivated by the plan's coverage of non-Hyde abortion services, such as men purchasing a QHP solely for themselves, consumers buying coverage for babies or toddlers, and those who otherwise may be unaware that the plan covers non-Hyde abortion services. However, we note that this risk is mitigated by the steps we have taken to improve transparency regarding QHP offerings, to make it easier for consumers to select QHPs that they believe are best suited to their needs and preferences, such as information to more readily identify QHPs that offer coverage of non-Hyde abortion services.[11]

To address the risk of terminations related to inadvertent failure to pay the separately billed amount for coverage of non-Hyde abortion services, we intend to propose further rulemaking to change our regulations including, for example, our regulations governing termination for non-payment of premiums.[12] Although QHP issuers can implement premium payment thresholds under § 155.400(g), those thresholds may not be effective at preventing termination of coverage for policy holders receiving higher APTC amounts who would have greater difficulty meeting the issuer's premium payment threshold pursuant to § 155.400(g). Until we can finalize regulatory changes through a separate rulemaking, we will exercise enforcement discretion as an interim step. Specifically, HHS will not take enforcement action against a QHP issuer that adopts and implements a policy, applied uniformly to all its QHP enrollees, under which an issuer does not place an enrollee into a grace period and does not terminate QHP coverage based solely on the policy holder's failure to pay the separate payment for coverage of non-Hyde abortion services. In accordance with non-discrimination rules applicable to QHP issuers, we would expect issuers to apply such a policy uniformly to all of their enrollees for the duration of the applicable plan year. We also note that if a QHP issuer chooses to take this approach, the QHP issuer would still be prohibited from using any federal funds for coverage of non-Hyde abortion services. Moreover, the QHP issuer would still be required to collect the premium for the non-Hyde abortion coverage, which means that the QHP issuer cannot relieve the policy holder of the duty to pay the amount of the premium attributable to coverage for non-Hyde abortion services. This enforcement posture will take effect upon the effective date of the separate billing requirements under 45 CFR 156.280, which is 6 months after publication of this final rule in the **Federal Register**. We encourage states and State Exchanges to take a similar enforcement approach.

We acknowledge that the enforcement posture described above may not mitigate all concerns identified by commenters. Some commenters expressed concern that the lack of transparency under current section 1303 billing requirements has contributed to unknowing purchases of QHPs that include coverage of non-Hyde abortion services by consumers who object to purchasing such coverage. As noted above, this risk is mitigated by the steps the FFEs have taken to improve transparency of the coverage of non-Hyde abortion services under FFE QHPs.[13] However, even where consumers who hold religious or moral objections to coverage of non-Hyde abortion services may more easily detect whether a QHP offers coverage to which they object, they may still be deciding between purchasing a QHP that covers non-Hyde abortion services, or else going without the coverage they need, because there may not be a QHP available on the Exchange that omits coverage for non-Hyde abortion services.

Until we are able to address these concerns through future rulemaking or other appropriate action, we also will not take enforcement action against QHP issuers that modify the benefits of a plan either at the time of enrollment or during a plan year to effectively allow enrollees to opt out of coverage of non-Hyde abortion services by not paying the separate bill for such services. This would result in the enrollees having a modified plan that does not cover non-Hyde abortion services, meaning that they would no longer have an obligation to pay the required premium for such services. We recognize that a QHP issuer's ability to make changes to its QHPs to implement a policy holder's opt out would be subject to applicable state law. We encourage states and State Exchanges to take an enforcement approach that is consistent with the one we intend to take, as described in this section.

Where a QHP issuer allows an enrollee to opt out of coverage of non-Hyde abortion services by not paying the separate bill for such services, the user fee a QHP issuer in an FFE or SBE–FP would pay would continue to be based on the original premium, which includes the portion of the premium attributable to non-Hyde abortion coverage. This is being done for operational reasons and issuer convenience, as making changes to the user fee system for FFEs and SBE–FPs to reflect a reduction in premium would result in only a minimal reduction in user fees owed. We do not believe the minimal reduction justifies the additional expense to FFEs and SBE–FPs related to the development of systems to receive and process such

[11] "Frequently Asked Questions for Agents, Brokers, and Assisters Providing Consumers with Details on Plan Coverage of Certain Abortion Services" (November 21, 2018), available at *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQ-on-Providing-Consumers-with-Details-on-Plan-Coverage-of-Certain-Abortion-Services.pdf*.

[12] CMS has yet to make determinations regarding specific requirements or rule changes CMS will propose to address the risk of terminations related to inadvertent failures to pay the separately bill amounts for coverage of non-Hyde abortion services. Accordingly, although CMS will undertake the described rulemaking, nothing in this preamble discussion should be construed as a representation or guarantee that CMS will propose changes to any specific rule or requirement.

[13] "Frequently Asked Questions for Agents, Brokers, and Assisters Providing Consumers with Details on Plan Coverage of Certain Abortion Services" (November 21, 2018), available at *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQ-on-Providing-Consumers-with-Details-on-Plan-Coverage-of-Certain-Abortion-Services.pdf*.

reports (which could then result in higher user fees in the future) or the additional cost to QHP issuers related to reporting the minimal changes in premiums.

We expect QHP issuers taking this approach to take appropriate measures to distinguish between a policy holder's inadvertent non-payment of the separate bill for coverage of non-Hyde abortion services and a policy holder's intentional nonpayment of the separate bill. A policy holder who inadvertently fails to pay the separate bill may have failed to pay because of unfamiliarity with receiving a separate bill for this portion of their premium and may still wish to retain coverage for non-Hyde abortion services if provided the opportunity to rectify nonpayment of the separate bill. A policy holder who intentionally does not pay the separate bill is likely to have made the conscious choice to opt-out of such coverage. To help ensure any modifications made by a QHP issuer under this enforcement approach to a policy holder's plan align with the policy holder's intent, the QHP issuer could include on the separate bill for coverage of non-Hyde abortion services or separate electronic communication an option (such as a check box or option button) where the policy holder can affirmatively indicate their intent to opt-out of such coverage by not paying the separate bill. We also recommend including an explanation for the policy holder that by affirmatively opting out, the policy holder would no longer have coverage for non-Hyde abortion services and would no longer have an obligation to pay the required premium for such services.

To be clear, we intend that a policy holder's opt-out would have to be applied to all persons in the enrollment group under the policy. For example, if the policy holder does not pay the separate bill for the portion of the premium attributable to non-Hyde abortion coverage and therefore opts out of coverage for non-Hyde abortion, this opt-out would be applicable to all persons in the policy holder's enrollment group, such as the policy holder's spouse and/or family if they are also covered under the policy holder's policy. Further, our exercise of enforcement discretion would only permit issuers to make one-time changes to remove coverage of non-Hyde abortion services from the QHP coverage.

Accordingly, once a policy holder opts out of coverage for non-Hyde abortion services, the policy holder would not be allowed to retract their opt-out decision and reinstate coverage of non-Hyde abortion services for that benefit year, by paying premiums that could cover a portion of premium attributable to coverage of non-Hyde abortion services. Thus, an opt-out would be effective for the remainder of the benefit year.

Unlike the enforcement discretion policy we announce above to mitigate risk of inadvertent terminations, this enforcement posture will become effective on the effective date of this final rule, which will be 60 days after its publication in the **Federal Register**. The separate billing requirements we finalize here under 45 CFR 156.280 will address, among other things, stakeholder comments that the lack of transparency under current section 1303 billing requirements has contributed to unknowing purchases of QHPs that include coverage of non-Hyde abortion services by consumers who object to purchasing such coverage. Because the new billing requirements under these final rules will not take effect upon finalization of these rules, we believe it is important to take this enforcement posture as soon as possible to provide relief for the lack of transparency under current QHP billing requirements.

We are taking this approach to maintain protections against adverse selection, while mitigating the serious negative risks of coverage loss by enrollees who might experience difficulties adjusting from the manner in which enrollees are accustomed to paying for insurance coverage or services under a single plan or contract. These interim policies will also provide relief to persons who may unknowingly purchase coverage to which they object because of the lack of transparency under current QHP billing requirements that do not require separate bills for non-Hyde abortion coverage. We believe these interim enforcement policies strike an appropriate balance between honoring PPACA section 1303's requirement for collection of separate payments, protecting enrollees against inadvertent losses of coverage, and ensuring all enrollees have access to coverage that meets their needs and that does not result in their supporting coverage for non-Hyde abortion services to which they object.

Comment: Commenters stated that HHS greatly underestimated the burden on issuers caused by these proposals. Commenters stated that the proposed rule's analysis of the expected costs and benefits was incomplete, such that HHS cannot accurately determine whether the benefits outweigh the quantitative and qualitative costs to justify finalizing the proposals. Many commenters stated that the burden and costs far outweigh any benefit and, as such, the proposals should not be finalized.

Commenters also stated that requiring issuers to send the separate bill in a different envelope or separate email communication would cost QHPs significantly more resources than HHS estimated for the multiple mailings, email communications, and personnel hours spent managing enrollee confusion, termination notices, and multiple bills. For example, commenters noted requiring a separate mailing would double the mailing and postage costs associated with current issuer billing. Commenters also explained that the technical build issuers would need to implement to comply with these proposals would be both complex and time consuming, and would alone require substantial new upfront and annual costs for issuers that HHS did not account for. In general, commenters expressed concerns that requiring separate billing and instructing enrollees to make separate payments for a single policy would create substantial new operational administrative costs for health insurance issuers and, subsequently, for the enrollees they serve.

Commenters also expressed concerns with the burdens these changes would impose on Exchanges. Commenters noted Exchanges would need to make time consuming and resource intensive changes to their websites, enrollment systems, and customer service and outreach efforts to align with the separate billing and payment requirements, which would be costly and disrupt Exchange efficiency.

Commenters also expressed concern that HHS failed to address the adverse impacts on enrollees resulting from how issuers would react to being forced to allocate additional significant operational and administrative resources towards issuing and processing multiple bills and monthly payments from each policy holder. Many commenters stated that issuers would be required to consider these new costs when setting actuarially sound rates, which would lead to higher premiums for enrollees. Many commenters stated that the costs and requirements on QHP issuers that cover non-Hyde abortion services will in many cases be so high that it will result in QHP issuers dropping coverage for non-Hyde abortion services altogether, even if their enrollees desire such coverage. Commenters expressed concern that, in such scenarios, this would transfer the costs and burdens of accessing non-Hyde abortion services to enrollees who must seek coverage for non-Hyde abortion services elsewhere

or pay out-of-pocket. Other commenters noted that issuers are likely to drop coverage of non-Hyde abortion services if the alternative is terminating coverage for a substantial number of its enrollees due to enrollee confusion resulting in non-payment of miniscule amounts.

Many commenters stated that the proposals would threaten the mental and physical health, well-being, and economic security of enrollees, especially women, across the country. Commenters stated that health insurance should provide coverage for the full range of reproductive health care, including abortion, and that this rule threatens to take such coverage away by imposing burdensome requirements on issuers. Commenters also expressed concern that, should these proposals result in issuers ceasing to provide coverage of non-Hyde abortion services, it could impede a patient's ability to make the best medical decision for herself and her family in consultation with her physician given that many women would be unable to pay privately for such services due to high costs without insurance. Commenters noted that barriers to accessing affordable non-Hyde abortion services could have long-term, devastating effects on a woman and her family's economic future.

Commenters noted that the proposals would have a greater impact on subsidized enrollees and might have a discriminatory effect on enrollees receiving higher APTC amounts who would have greater difficulty meeting the issuer's premium payment threshold pursuant to § 155.400(g). Commenters also stated that it would have damaging consequences on enrollees with specific conditions (like patients with cancer or chronic conditions), as any gaps in coverage as a result of confusion over billing may interrupt disease treatment schedules and could jeopardize health outcomes. Commenters also stated that the proposals would threaten the coverage gains made by the PPACA and have a disproportionate impact on enrollees who already face barriers to care, such as low-income individuals and marginalized communities. HHS received many comments expressing concern that when legal abortion becomes inaccessible, women who seek to end their pregnancy turn to unsafe and illegal methods, risking arrest, serious injury, or even death. Commenters also expressed concern that HHS did not propose any requirements or guidelines for how issuers should educate, inform, and conduct outreach to enrollees regarding these changes in billing and payment if the proposed regulation is implemented as proposed. Commenters also expressed concern that the proposals didn't address how individuals with limited English proficiency (LEP) or individuals with disabilities may experience barriers in complying with the proposed changes which commenters found particularly concerning, since individuals with LEP and individuals with disabilities already experience hardships in navigating and accessing health care.

Response: As we acknowledged in the proposed rule, we recognize that QHP issuers that cover non-Hyde abortion services may experience an increase in burden as a result of the proposals. We have carefully considered the comments that shared information about how the proposals would likely impact markets, issuers, and enrollees.

We agree with commenters that separately mailing the separate bill with separate postage could cause unintended additional burden and cost for issuers. Therefore, we are not finalizing the requirement that the separate bills be mailed separately with separate postage. However, we also acknowledge that QHP issuers will nevertheless still incur significant burden and costs as a result of implementing this new separate billing policy. We agree with commenters that QHP issuers are likely to consider these new costs when setting actuarially sound rates and that this will likely lead to higher premiums for enrollees. The potential premiums increases are discussed in further detail in section III, ''Collection of Information Requirements,'' and section IV, ''Regulation Impact Analysis,'' of this rule. However, in spite of the potential premium increases, we do not agree that requiring issuers to send separate bills, instruct policy holders to pay in two separate transactions, and make reasonable efforts to collect the payments separately would be an inefficient use of resources. Rather, this instruction is important to achieving better alignment of the regulatory requirements for QHP issuer billing of enrollee premiums with the separate payment requirement in section 1303 of the PPACA. We understand commenters' concerns that the issuer burden associated with this policy may result in issuers withdrawing coverage of non-Hyde abortion services altogether, requiring some enrollees to pay for these services out-of-pocket.

Subject to applicable state law, it is ultimately at the issuer's discretion whether to cover non-Hyde abortion services in their QHPs, and thus to incur any associated burden, and it is ultimately the states' and HHS's duty to enforce the statutory provisions of the PPACA as they are written. Although section 1303 permits issuer flexibility in abortion coverage choices, it also requires that QHP issuers electing to cover non-Hyde abortion services take certain steps to ensure that no APTC or CSR funds are used to pay for these services, such as requiring the QHP issuer to collect a separate payment for these services. The finalized changes at § 156.280(e)(2)(ii) may add issuer burden with regard to their payment and billing operations. However, the statute contemplates such burden in section 1303(b)(2)(B)(i) of the PPACA when it requires that issuers collect a separate payment for the portion of the premium attributable to coverage of non-Hyde abortion services and in section 1303(b)(2)(D) of PPACA when it specifies how QHP issuers are to calculate the basic per enrollee, per month cost, determined on an average actuarial basis, for including coverage of non-Hyde abortions in QHPs. We believe that finalizing the rule to allow issuers to send both bills in a single mailing will mitigate the issuer and state burden that would be imposed if we were finalizing the policy as originally proposed, as well as any initial confusion on the part of enrollees. We estimate that these changes would eliminate much of the additional mailing costs for the second bill since issuers would no longer need to pay for additional postage and envelopes. We believe the changes we are finalizing at § 156.280(e)(2)(ii) strike a balance between requiring the separate bill that we believe is required for better alignment with section 1303 of the PPACA, while also avoiding unnecessary enrollee confusion, enrollee harm, and issuer burden.

We understand that non-Hyde abortion services are services for which some enrollees may desire coverage, as they may be costly when not covered by insurance. However, we believe that requiring separate billing for the portion of the premium attributable to coverage of non-Hyde abortion services is a necessary change to better align issuer billing with the statutory requirements specified in section 1303 of the PPACA, which requires non-Hyde abortion services be treated differently from other covered services. We believe the changes we are finalizing at § 156.280(e)(2)(ii) will impose less burden on issuers to implement this policy than if we were finalizing as originally proposed, decreasing the likelihood that issuers will drop this coverage or significantly raise their premiums. Although we acknowledge

the changes we are finalizing will increase the burden associated with personnel hours spent managing enrollee confusion, termination notices, and multiple bills, we also believe the changes we are finalizing at § 156.280(e)(2)(ii) minimize enrollee confusion surrounding receiving a separate bill, helping to prevent situations where enrollees enter grace periods and subsequently have their coverage terminated for failing to inadvertently pay the second bill. We also believe policy holder confusion regarding the separate bill may decrease in future plan years as policy holders acclimate to this billing structure and as consumer education continues. However, we acknowledge that a policy holder enrolling for the first time after this policy is finalized in a QHP covering non-Hyde abortion services may still experience confusion regarding the separate bill. As finalized, we believe the inclusion of a second separate bill for these services in the same mailing and requiring issuers to instruct enrollees to pay in a separate transaction for the separate bill (whether sent electronically or by mail), but allowing issuers to accept combined payments if the enrollee fails to pay separately, will allow QHP issuers to continue providing coverage for non-Hyde abortion services subject to state and federal law and allow policy holders to continue accessing such coverage when available through their QHPs.

We understand commenters' concern about how these proposals will impact individuals with LEP and other policy holders, especially those with disabilities. We note that, under the policy being finalized, issuers must still comply with all applicable enrollee assistance requirements for QHPs on the Exchange, such as those requirements at § 155.205. In particular, we believe that the requirements at § 155.205(c) will help to ensure that issuers are providing information regarding the separate bill and payment options to individuals with LEP and policy holders with disabilities in plain language and in an accessible manner as specified in regulation. We also suggest that issuers consider the needs of these enrollee groups when conducting enrollee education or outreach about the finalized changes.

A more detailed summary of comments discussing the potential burden associated with the proposals can be found in the sections III ''Collection of Information Requirements'' and IV ''Regulation Impact Analysis'' of this rule. In section III ''Collection of Information Requirements'' of this final rule, a detailed breakdown of the estimated one-time burden per issuer and the estimated one-time burden for all issuers can be found in tables 2 and 3, and a detailed breakdown of the estimated annual burden per issuer and the estimated annual burden for all issuers can be found in tables 4 and 5.

Comment: Many commenters expressed concern that the proposed effective date would be administratively and operationally infeasible. As proposed, issuers would be required to implement these proposals beginning on the effective date of the final rule, which is 60 days after the final rule is published in the **Federal Register**. Commenters explained that issuer billing and payment requirements are typically included in plan documents that are approved by the state regulator and provided to the enrollee at the time of enrollment. Commenters noted that a change in payment policies would mean that issuers would need to re-file their applications for all affected plans for approval by state regulators and that such a change could not be implemented mid-plan year. Commenters also stated that, given the substantial investment required to operationalize the new proposals and the associated complexities, issuers would need a minimum of 12 to 18 months to implement these changes. Further, because implementation would need to coincide with the beginning of a new plan year, many commenters stated that plan year 2021 would be the earliest at which implementation could occur given the likely publication timeline for this final rule. Commenters also stated that enrollees can more easily adapt to new payment arrangements at the beginning of a plan year, when they expect premiums to be different and other changes to their plan to occur. Commenters also emphasized that the earlier the effective date, the more burdensome these proposals become.

One commenter noted that although state regulators are able to accept the responsibility of primary enforcement of this rule given appropriate lead time, they will be ill-equipped to enforce it if it is made effective immediately, since regulators will need time to develop enforcement policies in consultation with state stakeholders. This commenter also noted that, due to the small amounts issuers would separately bill for coverage of non-Hyde abortion services, many issuers may choose to revise their premium payment threshold policies permitted under § 155.400, but would not have time to do so if the rule were made effective immediately.

Response: In response to comments that implementation will take longer than the proposed effective date would allow, we are finalizing that QHP issuers must be in compliance with the policies being finalized at § 156.280(e)(2) on or before the day that is 6 months after publication of the final rule. If the date that is 6 months after publication of the final rule falls in the middle of a QHP issuer's billing cycle (in other words, after the QHP issuer has already sent out bills to policy holders for that month), the QHP issuer would be expected to comply beginning with the next billing cycle immediately following that date. We acknowledge that requiring QHP issuers to begin complying mid-plan year may pose implementation challenges for some states and issuers. For example, as discussed further later in this response, QHP issuers offering coverage of non-Hyde abortion services will already have filed rates for the 2020 plan year and would be unable to update those rates until the following plan year to reflect the added administrative costs they may experience as a result of the finalized separate billing policy. We also acknowledge requiring QHP issuer compliance mid-plan year would not provide QHP issuers offering coverage of non-Hyde abortion services an opportunity, in their discretion, to revise their plan and benefit designs, such as to remove coverage of non-Hyde abortion services, in order to avoid requirements under the separate billing policy.

We anticipate that State Exchanges that perform premium billing and payment processing that have QHP issuers that offer coverage for non-Hyde abortion services will face similar challenges to comply with the separate billing requirements within 6 months after publication of this final rule as QHP issuers that offer coverage for non-Hyde abortion services. However, we believe 6 months is sufficient for State Exchanges performing premium billing and payment processing and QHP issuers to implement the administrative and operational changes to billing processes necessary to comply with this policy. We also believe a 6-month implementation timeline appropriately prioritizes the goals of improved statutory alignment with the additional time State Exchanges and issuers may need to implement this policy. For those State Exchanges and QHP issuers that may face uncommon or unexpected impediments to timely compliance, HHS will consider extending enforcement discretion to an Exchange or QHP issuer that fails to timely

comply with the separate billing policy as required under this final rule, if we find that the Exchange or QHP issuer attempted in good faith to timely meet the requirements.

Although we do not believe that it is necessary for state enforcement policies to have been developed prior to the effective and/or compliance date for the separate billing requirements, we believe this will offer state regulators enough time to develop enforcement policies in consultation with state stakeholders. We also believe this implementation timeline will provide sufficient time for enrollee outreach and education to help mitigate any enrollee confusion resulting from the finalized policies, and to explain to enrollees how the QHP issuer's previous payment policies will be changing to comply with these new billing requirements.

We believe it is important that QHP issuers implement these policy changes at the earliest date feasible to improve statutory alignment with section 1303 of the PPACA. Similarly, we do not believe that potential implementation challenges in connection with a mid-year implementation date should outweigh numerous commenters' concerns regarding the lack of transparency as to whether their QHP covers non-Hyde abortion services, transparency that would be delayed by approximately a year if compliance were required by the first day of the 2021 plan year. We believe that further delaying implementation would be imprudent given that we are now aware of these consumer concerns and given that we believe it is operationally and administratively feasible for State Exchanges and QHP issuers to comply with the policy within 6 months after publication of the final rule.

We acknowledge that if QHP issuers are not able to take these additional costs into consideration when setting rates for the 2020 plan year, it is possible that some issuers may seek to exit the individual market in a state or incur losses. We believe that any such risk is small. QHP issuers will have the opportunity to adjust their plan and benefits design and rates in response to the separate billing policy for their plan year 2021 plan offerings. Moreover, we are aware that the actuarial value of the non-Hyde abortion coverage under QHPs generally may be less than the minimum $1 per enrollee, per month QHP issuers must charge for such services under section 1303 of the PPACA; and we are not aware of any reason QHP issuers could not use funds from the allocation account into which premium amounts attributable to the non-Hyde abortion service benefit must be deposited to cover administrative costs associated with coverage of non-Hyde abortion services.[14] This should mitigate the financial consequences to issuers of their not being able to update individual market rates prior to the 2021 plan year to incorporate the costs of implementing the processes required by this rule. We therefore believe that finalizing a longer, 6-month implementation timeline sufficiently mitigates the risk that some issuers would seek to exit the individual market to avoid the separate billing requirements under this final rule.

We acknowledge that State Exchanges' and QHP issuers' ability to comply within 6 months may depend on the current status of their billing systems and operations, and that State Exchanges and QHP issuers may be confronted with unexpected impediments to timely compliance. For this reason, HHS will consider extending enforcement discretion to an Exchange or QHP issuer that fails to timely comply with the separate billing policy as required under this final rule, if HHS finds that the Exchange or QHP issuer attempted in good faith to timely meet the requirements. Evidence of such good faith efforts might include records showing that planning for compliance with this final rule's requirements was begun within a reasonable time following the publication of the final rule, but events outside the Exchange's or QHP issuer's control caused implementation delays. HHS will consider exercising this enforcement discretion based on the circumstances of the particular Exchange or QHP issuer. We do not anticipate that HHS would exercise such discretion for an Exchange or QHP issuer that fails to meet the separate billing requirements after more than 1 year following publication of this final rule.

Comment: Many commenters who supported the proposals stated that these proposals would increase issuer compliance with the segregation of funds and separate payment requirements under section 1303 of the PPACA, and that the proposals would clarify and correct the previous administration's interpretation of the statute. Many supporting commenters noted their dissatisfaction that abortion coverage of any kind is offered at all in the individual market, but expressed support that the proposals would better protect enrollees who object, based on their religious or moral beliefs (collectively, ''conscience''), to coverage of non-Hyde abortion services.

Many commenters stated that it is a direct violation of their conscience rights to have to pay for abortion in any form, including subsidizing it through insurance coverage. Commenters stated that these proposals would increase transparency for enrollees as to what their health insurance covers and would allow enrollees to use this information to seek a plan that does not cover non-Hyde abortion services, consistent with their conscience.

Although many commenters expressed support for the proposals, many also objected to being required to pay this separate bill at all if they object to coverage of non-Hyde abortion services. Many commenters asked that HHS accommodate individuals who have conscience objections to these services by allowing enrollees in plans covering non-Hyde abortion to ''opt out'' of this coverage by not paying the separate bill attributable to coverage of non-Hyde abortion services.

Many commenters stated they were unconvinced by the stated justification for the proposals (to better align the regulatory requirements for QHP issuer billing of enrollee premiums with the separate payment requirement in section 1303 of the PPACA) and instead stated that the motivation was to appease religious or political special interests. Commenters stated that the proposals would value the needs of enrollees with conscience objections to coverage of non-Hyde abortion services more highly than the needs of enrollees with a health interest in receiving coverage for non-Hyde abortion services. These commenters stated that the proposals address conscience objections of the few at the cost of the many women who need and value coverage of non-Hyde abortion services.

Many commenters asked that these proposals be withdrawn because they impose a narrow religious belief opposing a legal medical service on enrollees who do not share this viewpoint and need or value this coverage. Commenters also objected to the proposal because it singles out coverage of non-Hyde abortion services as the only service for which separate billing and payment is required, questioning why other services are not similarly subject to separate payment and billing requirements based on conscience objections. For example, one commenter expressed that they object based on their conscience to supporting coverage of individuals who get sick after refusing vaccinations for that illness. Another commenter noted that they object to having to pay for coverage

[14] *See* 42 U.S.C. 18023(b)(2)(D)(ii)(I) (when estimating per member, per month cost of non-Hyde abortion services, issuers may take into account the impact on overall costs of the inclusion of such coverage).

of services for tobacco-related illnesses as they believe persons who voluntarily choose to use tobacco products should not be subsidized by other enrollees for their unhealthy behaviors.

Response: Although we understand objecting commenters' concerns, the changes are primarily meant to better align the regulatory requirements for QHP issuer billing of enrollee premiums with the statutory separate payment requirement in section 1303 of the PPACA. We acknowledge that the finalized policy regarding separate billing may increase transparency for policy holders who object on the basis of conscience to coverage of non-Hyde abortion services in their QHPs. And while it is true that this final rule treats coverage of non-Hyde abortion services differently from other covered services for purposes of QHP billing and payment, this differential treatment is based on the statutory PPACA requirement that non-Hyde abortion services be treated differently for billing, collection, payment, and federal-subsidy purposes; we are obligated to enforce the statute. Section 1303 of the PPACA has always required QHP issuers to estimate the basic per enrollee per month cost based on the average actuarial basis of the QHP's coverage of non-Hyde abortion services, and prohibited QHP issuers from estimating that cost to be less than $1 per enrollee per month. Under the statute, QHP issuers must also collect a separate payment for that portion of the enrollee's QHP premium attributable to coverage of non-Hyde abortion services and must segregate these payments in a separate allocation account that is to be used to pay for non-Hyde abortion services. Furthermore, section 1303 of the PPACA bars the use of PTCs or CSRs for such coverage. The changes we are finalizing at § 156.280(e)(2)(ii) would strengthen regulatory alignment with the existing statutory requirements for QHP issuer billing of enrollee premiums with the separate payment requirement in section 1303 of the PPACA.

We further understand that policy holders who object, based on their conscience, to non-Hyde abortion services may prefer to not pay the separate bill attributable to coverage of these services, and thereby opt out of such coverage. We also acknowledge there may be other services covered by a plan that consumers object to or do not intend to use. As previously stated, the primary motivation for this rule is to better align the regulatory requirements for QHP issuer billing of premiums with the statutory separate payment requirement in section 1303 of the PPACA.

However, we agree that consumers are best served by the Exchanges when they can enroll in a QHP that meets their needs, from a conscience, as well as a care, perspective. In the Exchanges that use the federal platform, we have taken steps to improve transparency regarding QHP offerings to make it easier for consumers to select plans that they believe are best suited to their needs, preferences, and conscience concerns, such as information to more readily identify QHPs that offer coverage of non-Hyde abortion services.[15] State Exchanges that operate their own technology platforms have taken similar steps. For example, State Exchanges display different plan attributes to enrollees to foster the decision-making process, and allow consumers to view plan offerings by selecting filters that show plans with their desired plan characteristics. In addition, Summary of Benefits and Coverage (SBC) requirements help ensure that consumers have access to easy-to-understand information about coverage. Further, with regard to commenters that stated their dissatisfaction that abortion coverage is offered at all in the individual market, we note that section 1303(a)(1) of the PPACA specifies that states may enact laws prohibiting QHP issuer coverage of abortion services on the Exchange. We also note that section 1303(a)(2) of the PPACA provides that a state may repeal such a law and provide for the offering of abortion coverage through the Exchange, and section 1303(b)(1)(A)(ii) of the PPACA allows QHP issuers to decide whether or not to offer coverage for abortion services, consistent with applicable state law.

Comment: Some commenters objected to HHS stating that it would enforce the requirements of section 1303 of the PPACA as codified at § 156.280 directly in the event that State Exchanges do not enforce these requirements, arguing that it would be inconsistent with other HHS efforts to ensure that states can operate their programs with limited federal interference. Commenters also expressed concern that the proposed enforcement structure overrides the authority delegated to states in section 1303 of the PPACA over issuers that operate in their states, and will disrupt the nature of collaboration and partnership that the PPACA meant to create between the states and the federal government. Commenters also stated that the addition of new compliance reviews are unnecessary, as HHS does not articulate any facts or data establishing the current landscape of compliance—or lack of compliance—with existing regulations.

Many commenters stated that the 2014 U.S. Government Accountability Office report,[16] which the proposed rule cites as evidence of potential remaining issuer compliance concerns, predates the 2016 Payment Notice, which clarified for issuers how to comply with the separate payment requirement. These commenters assert that HHS offers no evidence that any compliance problems remain over 4 years later. Commenters also stated that the research to inform that report was conducted between February 2014 and September 2014, less than 1-full year after the Exchanges began operating and, as such, issuers were less likely to have fully implemented the compliance standards required under the PPACA.

Other commenters stated that compliance with section 1303 of the PPACA has been inconsistent and were supportive that the proposals would require greater oversight and transparency from State Exchanges and require them to meet the standards of section 1303 of the PPACA. Some commenters cited to the 2014 U.S. Government Accountability Office report [17] as evidence of this noncompliance, and others cited to a letter sent prior to publication of the proposed rule by 102 members of Congress to HHS Secretary Alex Azar, which requested that new regulations be implemented ''to remedy the severe problems with the ACA in regard to abortion coverage.'' [18]

Response: We agree that oversight of issuer compliance with section 1303 of the PPACA is important to achieving greater transparency for consumers. We acknowledge that section 1303(b)(2)(E)(i) of the PPACA, as implemented at § 156.280(e)(5), designates the state insurance commissioners as responsible for monitoring, overseeing, and enforcing

[15] ''Frequently Asked Questions for Agents, Brokers, and Assisters Providing Consumers with Details on Plan Coverage of Certain Abortion Services'' (November 21, 2018), available at *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQ-on-Providing-Consumers-with-Details-on-Plan-Coverage-of-Certain-Abortion-Services.pdf.*

[16] U.S. Government Accountability Office, ''Health Insurance Exchanges: Coverage of Non-excepted Abortion Services by Qualified Health Plans,'' (Sept. 15, 2014), available at *http://www.gao.gov/products/GAO-14-742R.*

[17] U.S. Government Accountability Office, ''Health Insurance Exchanges: Coverage of Non-excepted Abortion Services by Qualified Health Plans,'' (Sept. 15, 2014), available at *http://www.gao.gov/products/GAO-14-742R.*

[18] Letter from Chris Smith, Member of Congress, to Alex Azar, Secretary, U.S. Department of Health and Human Services (Aug. 6, 2018), available at *https://chrissmith.house.gov/uploadedfiles/2018-08-06_-_smith_letter_on_section_1303_-_abortion_funding_transparency.pdf.*

the provisions in section 1303 of the PPACA related to QHP segregation of funds for non-Hyde abortion services. That is different than assigning the exclusive enforcement authority, with respect to all provisions in section 1303, to the states or to State Exchanges. As is the case with many provisions in the PPACA, states are generally the entities primarily responsible for implementing and enforcing the provisions in section 1303 of the PPACA related to individual market QHP coverage of non-Hyde abortion services.

However, where we are charged with directly enforcing statutory requirements in the FFE, we intend to do so fully in instances of issuer non-compliance with the separate payment requirement under section 1303 of the PPACA. Moreover, to the extent a state operating its own Exchange fails to substantially enforce these requirements, HHS is authorized to enforce them directly. Pursuant to section 1321(c)(2) of the PPACA, after determining that a state (or State Exchange) has failed to substantially enforce a federal requirement related to Exchanges and the offering of QHPs through Exchanges, including section 1303 of the PPACA's separate payments requirement (or other requirements), the Secretary may step in to enforce the requirement against the non-compliant issuer. This enforcement structure strikes an appropriate balance between federal oversight and state flexibility with regard to the requirements of section 1303. Accordingly, unless HHS determines a state (or State Exchange) has failed to substantially enforce section 1303 of the PPACA requirements, we intend to continue to defer to states (or State Exchanges) that enforce section 1303 of the PPACA requirements. HHS disagrees that this enforcement structure in a state operating its own Exchange would override the state's exercise of authority expressly delegated to states in section 1303 of the PPACA.

The compliance reviews governing QHP issuers participating in the FFE include reviews of compliance with section 1303 of the PPACA and § 156.280. The compliance reviews for future benefit years will include the new requirements finalized in this rule for separate billing of the portion of the policy holder's premium attributable to coverage of non-Hyde abortion services, as finalized at § 156.280(e)(2). We continue to believe such compliance reviews will help to address remaining issuer compliance issues, if any, previously identified by the 2014 U.S. GAO report.[19] However, commenters also expressed concern that the 2014 U.S. GAO report is outdated and that there is no evidence of ongoing compliance issues to support the changes we are finalizing regarding separate billing. But regardless of whether there are ongoing compliance issues, the changes we are finalize are primarily meant to better align the regulatory requirements for QHP issuer billing of enrollee premiums with the statutory separate payment requirement in section 1303 of the PPACA. This goal is related to overall compliance with section 1303, but has a different compliance focus than the compliance issues cited in the 2014 U.S. GAO report. Additionally, because we are amending the acceptable methods for issuers to comply with the separate payment requirement, we believe additional oversight during this transition time will be necessary to ensure that issuers are modifying their billing procedures appropriately.

FFE issuers subject to compliance reviews under § 156.715 must retain all documents and records of compliance with section 1303 of the PPACA and these requirements in accordance with § 156.705, and should anticipate making available to HHS the types of records specified at § 156.715(b) that would be necessary to establish their compliance with these requirements. For example, FFE issuers subject to compliance reviews for § 156.280 should anticipate supplying HHS with documentation of their estimate of the basic per enrollee per month cost, determined on an average actuarial basis, for including coverage of non-Hyde abortion services; detailed invoice and billing records demonstrating they are separately billing for and instructing policy holders to pay for in a separate transaction the portion of the policy holder's premium attributable to coverage of non-Hyde abortion services as specified in this rule, the actuarial value which must be estimated to be no less than $1 per enrollee, per month; and appropriately segregating the funds collected from enrollees into a separate allocation account that is used to pay for non-Hyde abortion services.

We remind issuers that pursuant to § 156.280(e)(5)(ii), any issuer offering coverage of non-Hyde abortion services on the Exchange must submit a plan to the relevant state insurance regulator that details the issuer's process and methodology for meeting the requirements of section 1303(b)(2)(C), (D), and (E) of the PPACA (hereinafter, ''segregation plan'').[20] The segregation plan should describe the QHP issuer's financial accounting systems, including appropriate accounting documentation and internal controls, that would ensure the segregation of funds required by section 1303(b)(2)(C), (D), and (E) of the PPACA. Issuers should refer to § 156.280(e)(5)(ii) for more information on precisely what issuers should include in their segregation plans to demonstrate compliance with these requirements. We also remind QHP issuers that pursuant to § 156.280(e)(5)(iii) each QHP issuer participating in the Exchange must provide to the state insurance commissioner an annual assurance statement attesting that the plan has complied with section 1303 of the PPACA and applicable regulations.

We also remind issuers offering medical QHPs in the FFEs that they already must attest to adhering to all applicable requirements of 45 CFR part 156 as part of the QHP certification application, including those requirements related to the segregation of funds for abortion services implemented in § 156.280.[21] As finalized, issuers in the FFE completing this attestation would also attest to adhering to these new separate billing and collection requirements. As part of the QHP certification process, issuers in states with FFEs where the states perform plan management functions must also complete similar program attestations attesting to adherence with § 156.280.[22] Issuers in states with State Exchanges that offer QHPs that cover non-Hyde abortion services should contact their state regarding the QHP certification process.

Comment: HHS received comments expressing a variety of legal arguments against the proposals. Many commenters stated that the proposals violate the Administrative Procedure Act (APA) because the proposals advance an unreasonable interpretation

[19] U.S. Government Accountability Office, ''Health Insurance Exchanges: Coverage of Non-excepted Abortion Services by Qualified Health Plans,'' (Sept. 15, 2014), available at *http://www.gao.gov/products/GAO-14-742R.*

[20] While we included compliance with section 1303(b)(2)(D) in the segregation plan that QHP issuers are required to submit to state insurance commissioners under our regulations at 45 CFR 156.280(e)(5), we did not mean to suggest by that inclusion that such provision is part of the segregation requirements in the statutory subsection that are subject to the jurisdiction of state health insurance commissioners under section 1303(b)(2)(E).

[21] 2019 Qualified Health Plan Issuer Application Instructions, available at: *https://www.qhpcertification.cms.gov/s/2019QHPInstructionsVersion1.pdf?v=1.*

[22] State Partnership Exchange Issuer Program Attestation Response Form, available at: *https://www.qhpcertification.cms.gov/s/SuppDoc_SPE_Attestationsed._revised_508.pdf?v=1.*

of law, are arbitrary and capricious, fail to provide adequate reasons or satisfactory explanations why HHS seeks to adopt a newly preferred interpretation of the requirement, and fail to adequately assess the costs and harms. Commenters also stated the proposals raise Federalism concerns under the Tenth Amendment because the proposals allegedly are designed to penalize states that have laws requiring QHPs to provide coverage of non-Hyde abortion services by requiring states—through their respective Exchanges and the Department of Insurances (DOIs)—to adopt new oversight responsibilities, and make systemic changes to fit the alterations the proposals require. For these states, commenters stated that this effectively requires states to either divert extensive resources to implement these changes or change their sovereign laws to no longer require coverage of non-Hyde abortion services. Commenters also stated that the proposals exceed the federal government's spending power by implementing new reporting and oversight obligations in the Exchanges that impose post-acceptance or retroactive conditions on states that were not originally anticipated. Commenters also stated that the proposals serve as a tax penalty on issuers for doing business in states with non-Hyde abortion services coverage requirements. One commenter stated that HHS improperly excluded the proposed changes to § 156.280 among the rule changes with Federalism implications.

Commenters also stated that requiring QHP issuers to send a separate bill to enrollees about the plan's coverage of non-Hyde abortion services constitutes a second separate notice outside of the notice included in the SBC indicating whether the plan covers abortions services and that, as such, these proposals violate section 1303(b)(3)(A) of the PPACA, which specifies that QHP issuers covering these services ''shall provide a notice to enrollees, only as part of the summary of benefits and coverage explanation, at the time of enrollment, of such coverage.'' Commenters further assert that the proposals violate section 1303(b)(3)(B), which states that all advertising used by issuers, any information provided by the Exchange, and ''any other information specified by the Secretary'' shall only provide information with respect to the total amount of the combined payments for all services.

Commenters also stated that the proposals violate section 1554 of the PPACA because these proposals will limit access to health care services, conflict with section 1557 of the PPACA, violate the Equal Protection Clause because the proposals place a heavy burden on a unique health care service only applicable to women, constitute an undue burden on a woman's right to procreative choice, violate the unconstitutional conditions doctrine by penalizing those who choose to exercise a constitutionally-protected right by imposing unreasonable payment protocols to access abortion services, and violate the establishment clause of the First Amendment.

HHS also received many comments stating that the proposed interpretation of section 1303 of the PPACA violates congressional intent. Commenters stated that section 1303 of the PPACA makes clear that absent a state law to the contrary, issuers offering Exchange coverage can decide whether to cover non-Hyde abortion services and that these requirements effectively take that decision away from issuers. Commenters also stated that Congress specifically enacted section 1303 of the PPACA's provisions after rejecting more extreme and restrictive alternatives that would have eliminated abortion coverage in the Exchanges or prohibited enrollees from using federal financial assistance to purchase a plan including abortion coverage, and that HHS is ignoring that legislative history by proposing changes that would have a net effect of reducing abortion coverage where issuers decide to eliminate coverage due to the regulatory burden. Commenters also noted that, although Congress decided to treat abortion differently when passing section 1303 of the PPACA, it did so specifically to ensure that private insurance plans could continue to decide whether or not to cover abortion in states that did not ban such coverage, and that this rule threatens that right. One commenter also stated that HHS violated generally accepted principles of statutory interpretation and should have construed ''separate payment'' in line with industry practice.

Many commenters also stated that these proposals conflict with the Administration's stated goals of reducing economic and regulatory burden, in conflict with several recently issued Executive Orders. Specifically commenters stated that the proposals would undermine Executive Order 13765 because these proposals would increase the administrative and economic burden of the PPACA, Executive Order 13813 which called for rules and guidelines to improve access to and the quality of information that Americans need to make informed healthcare decisions, Executive Order 13777 which orders federal agencies to alleviate unnecessary regulatory burden placed on the American people, and Executive Order 12866 because HHS did not ''assess both the costs and the benefits of the intended regulation and . . . propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify the costs,'' as the Executive Order directs. Commenters also stated that the proposals would undermine CMS's ''Patients Over Paperwork'' initiative aimed at reducing administrative burden on health plans and providers.

HHS also received comments arguing that these changes advance the congressional intent for the separate payment requirement in section 1303 of the PPACA, arguing that both the congressional record and the statutory language clearly demonstrate that Congress intended that billing for coverage of non-Hyde abortion services be separate.

Response: HHS disagrees with comments questioning its legal authority to make these policy changes, and disagrees that interpreting section 1303 of the PPACA to require issuers to send a separate bill for the portion of the premium attributable to coverage of non-Hyde abortion services violates the APA. Section 1303 of the PPACA and regulations at § 156.280 do not specify the method a QHP issuer must use to comply with the separate payment requirement under section 1303(b)(2)(B)(i) of the PPACA and § 156.280(e)(2)(i). Although we recognized in the preamble to the proposed rule that the previous methods of itemizing or providing advance notice about the amounts noted as permissible in the preamble of the 2016 Payment Notice arguably identifies two ''separate'' amounts for two separate purposes, we continue to believe that requiring issuers to bill for two separate ''payments'' of these two amounts better aligns with, and better enables compliance with, the separate payment requirement in section 1303 of the PPACA. We also believe that consumers are more likely to make a separate payment for the non-Hyde abortion coverage when they receive a separate bill for such amount.

In fact, among the previously acceptable methods for QHP issuers to comply with the separate payment requirement outlined in the preamble to the 2016 Payment Notice was sending a separate monthly bill for these

services.[23] As such, amending the policy to only permit this method of complying with the separate payment requirement does not wholly depart from the previous interpretation, it merely refines it to better reflect the statute.

Additionally, we have carefully considered the comments we received estimating the burden the proposals would impose on issuers, states, enrollees, and other entities, and agree—without accepting the estimates provided by commenters—that, as originally proposed, the actual burden would have exceeded HHS's estimates. As such, we are finalizing several changes described in responses to comments earlier in this section of the preamble with the specific intent of mitigating the burden that would have been imposed if we were finalizing as originally proposed.

HHS disagrees that the policy as originally proposed or as revised in the final rule violates state sovereignty, exceeds the federal government's spending power, or raises other Federalism concerns. Because states are the entities primarily responsible for implementing and enforcing the provisions in section 1303 of the PPACA related to individual market QHP coverage of non-Hyde abortion services, we acknowledge that requiring issuers to separately bill for the portion of the premium attributable to these services means that states will likely adjust how they ensure issuer compliance with these new requirements. We also remind states concerned about enforcement and oversight of these requirements that, under section 1321(c) of the PPACA, states may elect not to establish and operate an Exchange, thereby deferring those responsibilities to HHS.

We are clarifying the existing statutory requirement by adding specificity to the regulatory requirement, for issuers to collect a separate payment for these services. As such, these changes do not directly impose new requirements on states other than to adjust how they check for compliance. We believe that any state oversight responsibility modified through these changes was already contemplated by section 1303 of the PPACA in identifying states as the entities primarily, but not exclusively, responsible for enforcing the provisions in section 1303. Further, as noted above, among the previously acceptable methods for QHP issuers to comply with the separate payment requirement was sending a separate monthly bill for coverage of non-Hyde abortion services. Therefore, states should already have developed mechanisms to confirm compliance with separate monthly billing and payment for these services for any issuers that previously elected this option.

Setting aside the question of whether state laws requiring coverage of non-Hyde abortion services on the Exchange are consistent with statutory conditions on federal funding from the Department to the States, we acknowledge that some states have such laws. However, the changes we are finalizing do not preempt state law regarding coverage of non-Hyde abortion services or otherwise attempt to coerce states into changing these laws or to deny QHP issuers the ability to offer plans on the Exchanges that provide coverage of non-Hyde abortion services. HHS is simply refining the method by which issuers comply with the separate payment requirement.

HHS does not agree with commenters' concerns that the proposals would inhibit enrollee access to appropriate and timely medical care in violation of section 1554 of the PPACA. We acknowledge that, as originally proposed, the combination of issuer burden and enrollee confusion could have potentially led to a reduction in the availability of coverage of non-Hyde abortion services (either by issuers choosing to drop this coverage to avoid the additional costs or by enrollees having their coverage terminated for failure to pay the second bill), thereby potentially increasing out-of-pocket costs for some women seeking those services. But such an effect of a separate billing requirement would not constitute a violation of section 1554. Moreover, we believe the changes we are finalizing will decrease the likelihood of these outcomes. Importantly, subject to state law, section 1303(b)(1)(A) of the PPACA makes it clear that it is ultimately at the issuer's discretion whether to cover non-Hyde abortion services in their QHP; requiring a separate bill for these services does not limit that right.

HHS also disagrees that the policy in the proposed rule, as revised in this final rule, is inconsistent with sections 1303(b)(3)(A) or 1303(b)(3)(B) of the PPACA. Reading section 1303(b)(3) alongside section 1303(b)(2), which requires collection of separate payments, suggests that section 1303(b)(3) pertaining to notices should be read harmoniously with the separate payment requirement, rather than in conflict with those requirements, as commenters suggest. For example, the separate bill for the portion of the policy holder's premium attributable to coverage of non-Hyde abortion services is primarily a means of ensuring separate QHP issuer collection of that portion of the policy holder's premium, as required under section 1303(b)(2). This separate bill does not circumvent or conflict with the independent requirement in section 1303(b)(3) pertaining to notices. Further, any insight the policy holder gains from the separate bill for coverage of non-Hyde abortion services about the QHP's coverage of non-Hyde abortion services is incidental to the primary purpose of the bill, which is to help ensure separate payment by the policy holder, and separate QHP issuer collection on this portion of the policy holder's premium. We also note that requiring a separate bill for coverage of non-Hyde abortion services is not a violation of section 1303(b)(3), just as the separate itemization of the premium amount for such coverage on a single bill (as was previously one of the acceptable billing and premium collection methods for this amount) was not a violation of that section. Therefore, we believe it is a more reasonable interpretation of section 1303 of the PPACA that section 1303(b)(2) and 1303(b)(3) of the PPACA need not conflict when read in context with one another.

Section 1557 of PPACA prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs or activities. HHS disagrees that the policy in the proposed rule and as revised in this final rule discriminates against women or constitutes gender discrimination in violation of section 1557 of the PPACA or of the Equal Protection Clause. Although only women access non-Hyde abortion services, the separate bill for the portion of the premium attributable to coverage of these services, and any enrollee burden associated with that bill, is broadly applicable to any policy holder in a plan that covers non-Hyde abortion services. In other words, both men and women in plans covering non-Hyde abortion services will receive a separate bill for the portion of the premium attributable to coverage of these services, not just the women who may ultimately access such services.

Similarly, HHS disagrees that the proposals violate the unconstitutional conditions doctrine, given that QHP issuers offering these services will be required to send the separate bill to all policy holders in their plan, not just those who choose to access non-Hyde abortion services. As such, although it

[23] Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016 (80 FR 10750, 10840).

may be true that enrollees who would be most likely to need access to coverage of non-Hyde abortion services would be most likely to intentially enroll in a QHP with such coverage, any additional burden these enrollees experience related to understanding and paying the second bill is unrelated to whether enrollees actually do access coverage of non-Hyde abortion services. Therefore, the finalized policy does not penalize enrollees for accessing their constitutionally protected right to abortion. All policy holders would receive the separate bill for the portion of their premium attributable to coverage of non-Hyde abortion services, regardless of whether they could, intend to, or do, access the coverage for these services.

HHS also disagrees that the policy in the proposed rule, or as revised in this final rule, violates the Establishment Clause or otherwise impedes the free exercise of religion. Although it may be a secondary impact that the billing changes serve the interests of enrollees who object to coverage of non-Hyde abortion services based on their conscience, the objective for this policy change continues to be achieving better alignment with the statutory requirement for issuers to collect a separate payment for coverage of non-Hyde abortion services, as specified in section 1303 of the PPACA. As such, we reject commenter's arguments that these proposals are religiously motivated.

We also disagree with commenters that this interpretation of section 1303 of the PPACA violates congressional intent. We acknowledge that, in drafting section 1303 of the PPACA, Congress rejected language that would have imposed more restrictive requirements on QHP issuers offering coveage of non-Hyde abortion services.[24] However, although the language in section 1303 of the PPACA that Congress ultimately enacted into law permits issuers to offer coverage for non-Hyde abortion services subject to state law, this flexibility is not without limitations. As enacted, section 1303 of the PPACA requires that QHP issuers offering non-Hyde abortion coverage on the Exchanges follow specific actuarial, accounting, and notice requirements to ensure that federal funds are not used to pay for the costs of including coverage of these services under the QHP. We believe that by requiring issuers to collect separate payments, section 1303 of the PPACA contemplates sending to enrollees separate bills for these services to help ensure appropriate segregation of these funds. Furthermore, HHS previously listed ''sending a separate monthly bill for these services'' as one of the permissible methods for issuers to comply with the separate payment requirement in the 2016 Payment Notice.

HHS also disagrees with claims that the proposals impermissibly undermine the Executive Orders mentioned in comments. We interpret the proposals and the policy as finalized in this rule as consistent with Executive Order 13765 because the law is being ''efficiently implemented'' through better aligning the issuer requirements related to fulfilling section 1303 of the PPACA's separate payment requirements with the statute. We also believe Executive Order 13813 supports the changes to the policy as finalized in this rule, since providing a separate bill to policy holders for the portion of the premium attributable to coverage of non-Hyde abortion services will ''improve access to and the quality of information that Americans need to make informed healthcare decisions.'' [25] We note that we also believe Executive Order 13877 supports the policy changes by enhancing the ability of enrollees ''to choose the healthcare that is best for them'' and to make ''fully informed decisions about their healthcare.'' Indeed, many commenters highlighted that this would be one of the positive impacts of the proposal—that the separate bill would serve to clarify for enrollees that their plan covers non-Hyde abortion services and at what cost, information which many commenters would use to decide whether to remain enrolled in that QHP or seek a QHP without such coverage. We also believe Executive Order 13777 supports the proposals and changes being finalized in this rule, since requiring a separate bill for coverage of these services helps to ensure that HHS is ''prudent and financially responsible in the expenditure of funds,'' by better aligning the requirements with the statute in a manner that will help to ensure that QHP issuers that offer coverage for non-Hyde abortion services collect a separate payment from policy holders for the portion of their premium attributable to non-Hyde abortion coverage which also helps to ensure that APTC or CSR funds are not used pay for such services.

Additionally, HHS did ''assess both the costs and the benefits'' of the proposed rule. However, we note that Executive Order 12866's directive to only issue net-beneficial regulations applies only ''to the extent permitted by law.'' Although we have since adjusted the policy as well as the estimated burden to reflect a larger burden estimate, we continue to believe that requiring QHP issuers to separately bill the portion of the policy holder's premium attributable to coverage of non-Hyde abortion services is a better interpretation of the statutory requirement for QHP issuers to collect a separate payment for coverage of these services, and, thus, justifies the costs.[26]

Lastly, although CMS's ''Patients Over Paperwork'' initiative does include the goal of reducing unnecessary burden, HHS believes these changes and the added burdens associated with the changes are necessary, as the changes will better align issuer billing with the statutory requirements of the PPACA. Moreover, in line with this initiative, we believe enrollees will benefit from the additional clarity that the separate bill provides about their plan's coverage of non-Hyde abortion services.

III. Collection of Information Requirements

This final rule contains information collection requirements as defined under the Paperwork Reduction Act of 1995 (PRA). We proposed and solicited comments on these information collection requirements (ICRs) in the notice of proposed rulemaking that published on November 9, 2018 (84 FR 56015). The information collection requirements and the reconciliation of any comment received on the requirements are discussed below.

In order to fairly evaluate whether an information collection should be approved by the Office of Management and Budget (OMB), section 3506(c)(2)(A) of the PRA 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

[24] *See* Amendment to H.R. 3962, 111th Cong. (2009) (offered by Rep. Stupak and Rep. Pitts), 155 Cong. Rec. H12,921 (Nov. 7, 2009); *See* 155 Cong. Rec. S12,665 (2009).

[25] Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First (issued on June 24, 2019, *available at https://www.whitehouse.gov/presidential-actions/executive-order-improving-price-quality-transparency-american-healthcare-put-patients-first/*.

[26] This rule has been subject to interagency (including OMB) review under Executive Order 12866 and cleared by OMB for issuance and publication, indicating that the rule is consistent with Executive Orders.

affected public, including automated collection techniques.

In our November 9, 2018 (83 FR 56015) proposed rule, we solicited public comment on each of the required issues under section 3506(c)(2)(A) of the PRA for the following ICRs.

A. Wage Estimates

To derive average costs, we generally used data from the Bureau of Labor Statistics to determine average labor costs (including a 100 percent increase for fringe benefits and overhead) for estimating the burden associated with the ICRs.[27] Table 1 in this final rule presents the mean hourly wage (calculated at 100 percent of salary), the cost of fringe benefits and overhead, and the adjusted hourly wage.

As indicated, employee hourly wage estimates have been adjusted by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly across employers, and because methods of estimating these costs vary widely across studies. However, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

TABLE 1—ADJUSTED HOURLY WAGES USED IN BURDEN ESTIMATES

Occupation title	Occupational code	Mean hourly wage ($/hour)	Fringe benefits and overhead ($/hour)	Adjusted hourly wage ($/hour)
General and Operations Manager	11–1021	$59.56	$59.56	$119.12
Computer and Information Systems Manager	11–3021	73.49	73.49	146.98
Computer Programmer	15–1131	43.07	43.07	86.14
Computer System Analyst	15–1121	45.01	45.01	90.02
Business Operations Specialist	13–1199	37.00	37.00	74.00
Secretaries and Administrative Assistants	43–6014	18.28	18.28	36.56

B. Information Collection Requirements (ICRs)

1. ICRs Regarding General Program Integrity and Oversight Requirements (§ 155.1200)

The burden associated with State Exchanges meeting the program integrity reporting requirements in § 155.1200 have already been assessed and encompassed through SMART currently approved under OMB control number: 0938–1244 (CMS–10507). While we are finalizing proposals in this rule that would provide HHS the ability to focus State Exchange oversight and audit activities towards particular Exchange functions that have higher program integrity risks in a more consistent manner, and require State Exchanges and their auditors to employ auditing techniques or procedures in a more consistent manner, we do not envision these changes to have a material impact on the burden for State Exchanges. As detailed in the proposed rule and in the preamble of this rule, these amendments are intended to allow for more targeted oversight and audits of State Exchanges that focus and direct existing HHS and State Exchange resources towards particular Exchange program areas that have higher program integrity risks, rather than having those Federal and State Exchange resources covering all program areas or covering program areas that have lower program integrity risks. Because existing resources would be directed away from certain program areas and towards program areas with higher program integrity impact across all State Exchanges, we believe the overall burden on State Exchanges would not change. Further, we are not specifying a particular sampling methodology that must be used by all State Exchanges for testing the accuracy of eligibility determinations in annual programmatic audits. This final rule therefore does not impose any new burden or revised information collection requirements pertaining to § 155.1200.

2. ICRs Regarding Rules Relating To Segregation of Funds for Abortion Services (§ 156.280)

In § 156.280(e)(2), we are finalizing that QHP issuers must send an entirely separate monthly bill to the policy holder covering only the portion of premium attributable to coverage of non-Hyde abortion, and instruct the policy holder to pay the portion of their premium attributable to coverage of non-Hyde abortion services in a separate transaction from any payment the policy holder makes for the portion of their premium not attributable to coverage of non-Hyde abortion services. Based on 2020 QHP certification data in the FFEs and SBE–FPs, we estimate that 23 QHP issuers will offer a total of 338 plans with coverage of non-Hyde abortion services in 9 FFE and SBE–FP states. For the 12 State Exchanges that will operate their own technology platforms in 2020 and have QHPs that offer coverage of non-Hyde abortion services, we have updated our methodology for identifying issuers with QHPs that offer coverage of non-Hyde abortion services, and now estimate that 71 QHP issuers will offer a total of approximately 1,129 plans that include coverage for non-Hyde abortions services. Three of those State Exchanges perform premium billing and payment processing, while the other 9 have their issuers perform premium billing and payment processing. In total, we now estimate that will be 94 QHP issuers offering a total of 1,467 plans (representing approximately 32 percent of individual market, on-Exchange plans) covering non-Hyde abortion services across 21 states in plan year 2020. As such, the ICRs associated with these proposals create a new burden on QHP issuers and State Exchanges that perform premium billing and payment processing, and thus will be submitted to OMB for final approval (OMB control number: 0938–1358 (Billing and Collection of the Separate Payment for Certain Abortion Services (CMS–10681)).

Comment: We used the estimated numbers of impacted issuers and plans to estimate the costs associated with the proposals regarding separate billing and payment for coverage of non-Hyde abortion services.

We received many comments from issuers, issuer associations, states, State Exchanges, state regulators, and other organizations arguing that we greatly underestimated the burden on issuers to implement the original proposals. For example, commenters stated that actual one-time costs for issuers to implement

[27] See May 2018 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates at *https://www.bls.gov/oes/current/oes_stru.htm.*

these proposals would be anywhere from $50,000 to $7,500,000 per issuer. Commenters also stated that annual costs per issuer would be anywhere from $40,000 to $10,800,000 annually. One commenter stated that the operational burden of a mid-size issuer (serving approximately 70,000 Exchange enrollees) would exceed HHS's estimate by approximately 2,666 times for the first year alone. Commenters explained that the proposals would require changes to nearly every aspect of the enrollment and billing processes to identify impacted enrollees, generate and send multiple accurate invoices, collect multiple payments, and reconcile payment amounts.

Some commenters noted that many issuers do not have the ability to generate two separate bills for one policy and that, as such, the proposals would require them to issue two policies per policy holder (and enroll every policy holder into two separate policies to be able to bill them in the required way). Commenters stated that the proposals would consequently require that many issuers create separate member IDs in order to facilitate every enrollee receiving two bills and making two payments. Commenters stated that this would be an extraordinarily costly and difficult change for such issuers to make.

Commenters also expressed concern that requiring issuers to send the separate bill in a separate mailing would double an issuer's postage and associated mailing costs, costing issuers an additional $15.6 to $31.2 million nationally per year, and expressed further concern that this cost was not accounted for in the proposed rule's impact estimates. Many commenters explained that it is unrealistic to assume that issuers can save costs by enrollees switching to electronic billing, since many enrollees still elect to receive and pay their health coverage bills through the mail. Other commenters explained that many enrollees have no choice but to receive paper bills and send paper checks, as many enrollees in rural areas and many low-income individuals still do not have access to the internet.

Response: We appreciate these comments and after consideration, have adjusted the estimated burden below. In response to these comments, we have updated the associated ICRs to reflect an increase in burden and costs for issuers. We believe that the original burden estimate in the proposed rule would not accurately reflect the actual costs issuers would have incurred if we finalized the provisions as proposed.

We estimate that allowing issuers to send the separate bill in the same mailing (though not in the same email or electronic communication) as the bill for other services would eliminate much of the commenter estimated $15.6 to $31.2 million that the second bill would have cost annually if we had finalized as proposed. By finalizing this policy to allow for combined mailings when sending paper bills, we ensure that issuers will not be required to incur the costs associated with additional postage and envelopes.

Issuers will incur burden to complete the one-time technical build to implement the necessary changes, which will involve activities such as planning, assessment, budgeting, contracting, building and testing their systems; as well as one-time changes such as billing-related outreach and call center training. We assume that this one-time burden will be incurred primarily in 2020. We estimate that, for each issuer, on average, it will take business operations specialists 2,500 hours (at $74 per hour), computer system analysts 6,500 hours (at $90.02 per hour), computer programmers 22,000 hours (at $86.14 per hour), computer and information systems managers 200 hours (at $146.98 per hour) and operations managers 300 hours (at $119.12 per hour) to complete this task. The total burden for an issuer will be approximately 31,500 hours on average, with an equivalent cost of approximately $2.7 million. We anticipate that implementing these changes within 6 months would result in issuers incurring additional costs such as higher contracting costs and overtime payments, which will increase the total cost for each issuer by 50 percent, to approximately $4.1 million. For all 94 issuers, the total one-time burden will be 2,961,000 hours for a total cost of approximately $385 million.

We anticipate that the burden incurred by State Exchanges that perform premium billing and payment processing and have QHP issuers that offer coverage for non-Hyde abortion services will be similar to the burden incurred by QHP issuers offering coverage for non-Hyde abortion services. Therefore the total burden for a State Exchange that performs premium billing and payment processing will be approximately 31,500 hours on average, with a total cost of approximately $4.1 million. For all 3 State Exchanges that perform premium billing and payment processing, the total one-time burden will be 94,500 hours for a total cost of approximately $12.3 million.

TABLE 2—ESTIMATED ONE-TIME BURDEN PER ISSUER OR STATE EXCHANGE PERFORMING PREMIUM BILLING AND PAYMENT PROCESSING

Occupation	Burden hours per respondent	Labor cost per hour	Total cost per respondent
General and Operations Manager	300	$119.12	$35,736
Computer and Information Systems Manager	200	146.98	29,396
Computer Programmer	22,000	86.14	1,895,080
Computer System Analyst	6,500	90.02	585,130
Business Operations Specialist	2,500	74.00	185,000
Total Burden and Labor Cost per respondent	31,500	.....	2,730,342
Additional Costs due to Expedited Implementation	.....	.....	1,365,171
Total per respondent	31,500	.....	4,095,513

TABLE 3—ESTIMATED ONE-TIME BURDEN FOR ALL ISSUERS AND STATE EXCHANGES PERFORMING PREMIUM BILLING AND PAYMENT PROCESSING

Type of respondent	Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
Issuer	94	94	31,500	2,961,000	$384,978,222
State Exchange	3	3	31,500	94,500	12,286,539
Total	97	97	31,500	3,055,500	397,264,761

In addition to the one-time costs estimated, issuers will incur ongoing annual costs, such as those related to identifying impacted enrollees, ensuring billing accuracy, reconciliation, quality assurance, printing, recordkeeping, and document retention. We estimate that for each issuer, on average, it will take administrative assistants 20,000 hours (at $36.56 per hour), business operations specialists 2,000 hours (at $74 per hour), computer programmers 2,000 hours (at $86.14 per hour), and operations managers 120 hours (at $119.12 per hour) each year to perform these tasks. The total annual burden for each issuer will be 24,120 hours, with an equivalent cost of approximately $1.07 million. Assuming that issuers will start sending separate bills in July, 2020, the total burden for all 94 issuers for the 6 months in 2020 is estimated to be 1,133,640 hours with an equivalent cost of approximately $50.1 million. From 2021 onwards, we estimate the total annual burden for all 94 issuers will be approximately 2,267,280 hours with an associated cost of approximately $100.2 million.

We anticipate that State Exchanges performing premium billing and payment processing and which have QHP issuers that offer coverage for non-Hyde abortion services will incur costs similar to QHP issuers offering coverage of non-Hyde abortion services. Therefore, we estimate that for all 3 State Exchanges performing premium billing and payment processing, the total annual burden will be approximately 36,180 hours with an equivalent cost of approximately $1.6 million in 2020 and 72,360 hours with an associated cost of approximately $3.2 million starting in 2021.

TABLE 4—ESTIMATED ANNUAL BURDEN PER ISSUER OR STATE EXCHANGE PERFORMING PREMIUM BILLING AND PAYMENT PROCESSING

Occupation	Burden hours per respondent	Labor cost per hour	Total cost per respondent
Secretaries and Administrative Assistants	20,000	$36.56	$731,200
General and Operations Manager	120	119.12	14,294
Business Operations Specialist	2,000	74.00	148,000
Computer Programmer	2,000	86.14	172,280
Total per Respondent	24,120		1,065,774

TABLE 5—ESTIMATED ANNUAL BURDEN FOR ALL ISSUERS AND STATE EXCHANGES PERFORMING PREMIUM BILLING AND PAYMENT PROCESSING FOR 2020, 2021 AND 2022

Type of respondent	Year	Number of respondents	Number of responses	Burden hours per respondent	Total burden hours per year	Total labor cost per year
Issuer	2020	94	94	12,060	1,133,640	$50,091,397
State Exchange	2020	3	3	12,060	36,180	1,598,662
Total	2020	97	97	12,060	1,169,820	51,690,058
Issuer	2021, 2022	94	94	24,120	2,267,280	100,182,794
State Exchange	2021, 2022	3	3	24,120	72,360	3,197,323
Total	2021, 2022	97	97	24,120	2,339,640	103,380,117

In response to comments, we reviewed our original enrollee estimates and have updated our estimates for accuracy. Based on 2019 QHP Certification Data in the FFEs and SBE–FPs, we now estimate that there are approximately 442,400 enrollees in QHPs covering non-Hyde abortion services. In the 11 State Exchanges that operated their own technology platform and had issuers that offered coverage of non-Hyde abortion services in 2019, we estimate that there are approximately 2,597,700 enrollees in QHPs covering non-Hyde abortion services. The total number of enrollees in QHPs covering non-Hyde abortion services is approximately 3.04 million in 2019. The number of QHPs covering non-Hyde abortion services will be higher in 2020 compared to 2019. Therefore, we are using the number of enrollees in such QHPs in 2019 as a lower bound for the number of enrollees who will experience an increase in burden as a result of the finalized policies.

Assuming 1.5 enrollees per policy, issuers and State Exchanges performing premium billing and payment processing will be required to send a separate bill to approximately 2 million

policy holders. We understand that, although enrollees can often choose to pay electronically or by phone, choose to utilize automatic payment deductions, and often opt out of receiving paper bills, many enrollees still opt to receive physical mail detailing their coverage. We also understand that many enrollees face barriers to accessing the internet and have little choice but to receive paper bills. Because enrollees typically receive paper bills and because many enrollees already face barriers to accessing the internet, issuers are likely to experience an increased administrative cost in having to print an additional monthly bill for the majority of their policy holders. According to one commenter, issuers send paper bills to 92 percent of Exchange customers. We anticipate that the number of consumers opting for electronic bills will increase over time. Therefore, we assume that approximately 90 percent of policy holders will receive paper bills in 2020 and issuers and State Exchanges performing premium billing and payment processing will need to print and send approximately 1.82 million separate paper bills per month. Assuming materials and printing cost of $0.05 per page, issuers will incur additional monthly costs of approximately $91,200 to print separate bills for impacted policy holders in 2020. Assuming that issuers start sending separate bills in July 2020, for the 6 months in 2020, total cost for all issuers is estimated to be approximately $547,225. Assuming that more consumers will opt to receive electronic bills over time, we estimate that approximately 88 percent of policyholders will receive paper bills in 2021, and the annual cost for all issuers to send separate paper bills will be approximately $1,070,129. We assume that, in 2022, approximately 86 percent of policyholders will receive paper bills, and the annual cost for all issuers to send separate paper bills will be approximately $1,045,808. The average annual materials and printing cost over 3 years (2020 to 2022) will be approximately $887,721. Since issuers and State Exchanges performing premium billing and payment processing will be permitted to send both bills together when sending bills in a physical mailing, they will not incur any additional mailing costs. We assume that bills sent electronically can be sent at minimal cost and note that we have incorporated any associated IT changes to accommodate electronic billing changes based on this rule above, where we discussed premium billing and payment processing costs to issuers and State Exchanges.

FFE issuers are subject to future HHS compliance reviews, requiring issuers in the FFE to maintain and submit records to HHS showing compliance with separately billing for the portion of the policy holder's premium attributable to non-Hyde abortion services as specified in this rule. Commenters stated that HHS excluded an evaluation of the burden and cost for FFE issuers to participate in the additional HHS compliance reviews, ignoring the potential for any new costs associated with this requirement, such as documenting all efforts for audit purposes. We have revised our burden estimates to account for additional recordkeeping costs not reflected in the proposed rule's estimates but reiterate that the requirements associated with compliance reviews were already assessed and subsumed within issuer burdens described in previously finalized rules, including the information collection currently approved under OMB control number: 0938–1277 (Program Integrity: Exchange, Premium Stabilization Programs, and Market Standards; Amendments to the HHS Notice of Benefit and Payment Parameters for 2014 (CMS–10516)).

To show compliance with FFE standards and program requirements, all issuers seeking QHP certification in FFEs are required to submit responses to program attestations as part of their QHP application. This response already includes an attestation that the issuer agrees to adhere to the requirements related to the segregation of funds for abortion services implemented in § 156.280. We have determined that the requirements associated with QHP certification have already been assessed and encompassed by the information collection currently approved under OMB control number: 0938–1187 (Establishment of Exchanges and Qualified Health Plans; Exchange Standard for Employers (CMS–10433)).

C. Summary of Annual Burden Estimates for Proposed Requirements

TABLE 6—ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulation section(s)	OMB control number	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Total labor cost of reporting ($)	Capital costs (printing and materials) ($)	Total cost ($)
§ 156.280	0938–NEW	97	97	30,600	2,968,200	$218,571,684	$887,721	$219,459,405
Total		97	97	30,600	2,968,200	218,571,684	887,721	219,459,405

D. Submission of PRA-Related Comments

We have submitted a copy of this final rule to OMB for its review of the rule's information collection and recordkeeping requirements. The requirements are not effective until they have been approved by OMB.

IV. Regulatory Impact Analysis

A. Statement of Need

This final rule implements standards to ensure enrollees receive the correct amount of APTC and CSRs at the time of enrollment or re-enrollment via periodic data matching requirements. In addition, the provisions in this rule strengthen the mechanisms and tools for overseeing ongoing compliance by State Exchanges with federal program requirements. Finally, the provisions in this rule refine some of the methods for billing of the separate payment for the portion of the policy holder's premium attributable to non-Hyde abortion services to better align with congressional intent regarding the separate payments provision of section 1303 of the PPACA. The following summary focuses on the benefits and costs of the requirements in this final rule.

B. Overall Impact

We have examined the impact 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 1102(b) of the Act, 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), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

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), to the extent permitted by law. Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects ($100 million or more in at least 1 year). This final rule is economically significant within the meaning of section 3(f)(1) of the Executive Order. Therefore, OMB has reviewed these regulations and HHS has provided an assessment of the potential costs, benefits, and transfers associated with this rule. Accordingly, we have prepared an RIA that presents the costs and benefits of this final rule.

C. Impact Estimates of the Program Integrity Provisions and Accounting Table

In accordance with OMB Circular A–4, Table 7 depicts an accounting statement summarizing HHS's assessment of the benefits, costs, and transfers associated with this regulatory action. Table 8 includes a summary of annualized values of costs, over a perpetual time horizon at 7 percent discount rate for Executive Order 13771 (E.O. 13771). This final rule implements standards that will have numerous effects, including ensuring that eligible enrollees receive the correct amount of APTC and CSR (as applicable); improving alignment with the separate payment requirement in section 1303 of the PPACA by requiring QHP issuers to send separate bills to policy holders for the portion of their premium attributable to non-Hyde abortion services; conducting effective and efficient monitoring and oversight of State Exchanges to ensure that enrollees are receiving the correct amount of APTC and CSRs in State Exchanges, and that State Exchanges are meeting the standards of federal law in a transparent manner; and protecting the interests of taxpayers, and enrollees, and the financial integrity of Exchanges through oversight of health insurance issuers, including ensuring compliance with the requirements of section 1303 of the PPACA. We are unable to quantify certain benefits and costs of this final rule—such as benefits to enrollees for timely notification of their dual enrollment in other qualifying coverage such as Medicare, Medicaid/CHIP, and, if applicable, the BHP, potential increases in cost to states for increased oversight activities and to establish access to federal data systems to verify eligibility for or enrollment in Medicaid/CHIP or Medicare, and potential costs to enrollees such as increased out-of-pocket costs related to billing changes due to the separate payment requirements for non-Hyde abortion services. The effects in Table 7 reflect qualitatively assessed impacts and estimated direct monetary costs and transfers resulting from the provisions of this final rule for health insurance issuers. States impacted by PDM requirements will incur costs of up to $6.9 million in 2020. In addition, we estimate that issuers, State Exchanges, FFEs, and consumers impacted by the separate billing and payment requirements will incur costs of approximately $546.1 million in 2020, $232.1 million in 2021, $230.7 million in 2022, and $229.3 million 2023 onwards (see Table 10 below). We also expect that transfers from the federal government to consumers in the form of premium tax credits will decrease as a result of Exchanges conducting Medicare, Medicaid/CHIP, and, if applicable, BHP PDM, and increase as a result of separate billing and payment requirements. The net increase in premium tax credits is estimated to be approximately $106 million in 2021 and $96 million in 2022 onwards.

TABLE 7—ACCOUNTING TABLE

Benefits:

Qualitative:

- Better alignment of the regulatory requirements for QHP issuer billing of premiums with the separate payment requirement in section 1303 of the PPACA.
- Clearer regulatory requirements for how frequently Exchanges should be conducting periodic checks for dual enrollment in other qualifying coverage.
- Clearer regulatory requirements for State Exchanges around CMS's oversight and reporting process that allows for more effective oversight of State Exchanges.

Costs:	Estimate (million).	Year Dollar	Discount Rate (percent).	Period Covered
Annualized Monetized ($/year)	$304.09	2019	7	2020–2024
	$298.92	2019	3	2020–2024

Quantitative:

- Burden incurred by issuers, states, federal government and enrollees to comply with provisions related to coverage of non-Hyde abortion services and the segregation of premiums for such services.
- Costs for State Exchanges not in compliance with regulatory requirements to conduct Medicare, Medicaid/CHIP, and, if applicable, BHP PDM.

TABLE 7—ACCOUNTING TABLE—Continued

Qualitative:				
• Potential increase in costs to states for increased oversight of separate payment requirements. • Potential increased costs incurred by enrollees who choose to make separate payments for coverage of non-Hyde abortion services. • Potential increased burden and costs for State Exchanges to authorize access to federal data sources to verify Medicare and Medicaid/CHIP eligibility and/or enrollment, notifying enrollees when dual enrollment is detected, and process QHP coverage terminations. • Potential increased burden for assisters, agents and brokers to explain new billing process. • Potential increase in public spending and out-of-pocket costs to enrollees if there is an increase in unplanned pregnancies due to loss of abortion coverage and, with respect to public spending, if those unplanned pregnancies are experienced by individulas who would be eligible for public benefit programs.				
• Potential decrease in broker and issuer revenue due to decrease in QHP enrollment.				
Transfers:	Estimate (million).	Year Dollar percent.	Discount Rate	Period Covered
Federal Annualized Monetized ($/year)	$76.2	2019	7	2020–2024
	$77.7	2019	3	2020–2024
Quantitative: • Total transfers from the federal government to enrollees due to an increase in premium tax credit payments.				
Qualitative: • Increase in premiums beginning in plan year 2021. • Potential increase in out-of-pocket costs for enrollees who experience lapse in coverage for failing to make payments for coverage of non-Hyde abortion services due to confusion with new billing system. • Potential increase in out-of-pocket costs for individuals who lose health insurance coverage due to increase in premiums. • Potential increase in uncompensated care costs for people who lose health insurance coverage.				

TABLE 8—E.O. 13771 SUMMARY TABLE

[In $ millions 2016 dollars, over a perpetual time horizon]

	Estimate (7% discount rate)
Annualized Costs	$182.98
Annualized Cost Savings	0
Annualized Net Costs	182.98

1. Functions of an Exchange (§ 155.200)

Our revisions to § 155.200(c) specifying that Exchanges must perform oversight functions or cooperate with activities related to oversight and financial integrity requirements are a clarification and not a new function. Therefore, they will not impose additional burdens on State Exchanges.

2. Eligibility Redetermination During a Benefit Year (§ 155.330)

Our requirement that Exchanges conduct Medicare PDM, Medicaid/CHIP PDM, and, if applicable, BHP PDM at least twice a year beginning with the 2021 calendar year, adds specificity to the existing requirement that Exchanges must periodically examine available data sources to determine whether Exchange enrollees have been determined eligible for or enrolled in other qualifying coverage such as Medicare, Medicaid, CHIP, or, if applicable, the BHP. Therefore, we expect the costs associated with this requirement to be minimal. However, State Exchanges that are not already conducting PDM with the required frequency, or deemed in compliance with the Medicaid, CHIP, and, if applicable, BHP PDM requirements, will be required to engage in IT system development activity in order to communicate with these programs and act on enrollment data either in a new way, or in the same way more frequently. Thus, there may be additional associated administrative cost for these State Exchanges to implement the proposed PDM requirements. We anticipate a majority (up to eight) of the twelve State Exchanges that operate their own technology platforms would be exempt from the requirement to perform Medicaid/CHIP, and, if applicable, BHP PDM because they have shared, integrated eligibility systems with their respective Medicaid programs, as such they would be deemed in compliance with this requirement. However, we are not able to confirm the exact number because we have not yet set specific criteria and process to assess and confirm which State Exchanges would be exempt, and would need additional operational information from State Exchanges to confirm our assessment. We will establish and engage in that process after finalization of the rule. For a State Exchange not already conducting Medicare, Medicaid/CHIP, and, if applicable, BHP PDM at least twice a year, and that does not already have a shared, integrated eligibility system with its respective Medicaid/CHIP, and, if applicable, BHP programs, we estimate that it will cost approximately $1,740,000 per State Exchange (a total of $6,960,000 for all 4 nonexempt State Exchanges) to build such capabilities in their system. We assume that this cost will be incurred primarily in 2020. These costs would be incurred by the State Exchange as they are required to be financially self-sustaining and do not receive federal funding for their establishment or operations.

We believe these changes will support HHS's program integrity efforts regarding the Exchanges by helping promote a balanced risk pool for the individual market as Medicare and Medicaid/CHIP beneficiaries tend to be higher utilizers of medical services, ensuring that consumers are accurately

determined eligible for APTC and income-based CSRs, and safeguarding consumers against enrollment in unnecessary or duplicative coverage. Such unnecessary or duplicative coverage, coupled with typically higher utilization, generally results in higher premiums across the individual market, leading to unnecessarily inflated expenditures of federal funds on PTC for taxpayers eligible for PTC in the individual market. We estimate that requiring State Exchanges to perform Medicare PDM twice a year will result in a reduction in PTC payments of approximately $500 million over a 9-year period (Table 9). We believe this will not have any discernable impact on premiums.

TABLE 9—MEDICARE PDM EFFECT ON PREMIUM TAX CREDIT OUTLAYS

Fiscal year	2021	2022	2023	2024	2025	2026	2027	2028	2029	Total
PTC ($ millions)	−40	−50	−50	−50	−60	−60	−60	−60	−70	−500

3. General Program Integrity Oversight Requirements (§ 155.1200)

We do not anticipate the changes to § 155.1200(b)(2) will result in any additional cost for State Exchanges because the changes leverage an existing reporting mechanism currently used by all State Exchanges, the annual SMART, for meeting eligibility and enrollment reporting requirements. Additionally, State Exchanges are already required to annually contract with, and budget accordingly for, an external independent audit entity to perform an annual financial and programmatic audit as required under § 155.1200(c). We believe the flexibility under the new § 155.1200(d)(2) to permit HHS to target the scope of annual programmatic audits to focus on the program areas that are most pertinent to a State Exchange model (including SBE–FPs), or have the greatest program integrity implications, would allow State Exchanges to utilize the funds that they already allocate to contracting with an external independent audit entity in the most cost-effective manner. We also believe the flexibility we are providing to State Exchanges in the sampling method employed by their external independent audit entities for testing the accuracy of eligibility determinations in the annual programmatic audits, along with the flexibility for HHS to set the reporting deadlines for State Exchanges under § 155.1200 on an annual basis, will also allow State Exchanges to utilize the funds that they have already allocated to these activities in the most cost-effective manner.

4. Segregation of Funds for Abortion Services (§ 156.280)

In § 156.280, we proposed to amend billing and premium collection requirements related to the separate payment requirement for coverage of abortions for which public funding is prohibited pursuant to section 1303 of the PPACA, as implemented at § 156.280. We originally proposed that QHP issuers send an entirely separate monthly bill in a separate envelope to the policy holder for only the portion of premium attributable to coverage of non-Hyde abortion services, and instruct the policy holder to pay the portion of their premium attributable to coverage of non-Hyde abortion services in a separate transaction from any payment the policy holder makes for the portion of their premium not attributable to coverage of non-Hyde abortion services. We are also finalizing that QHP issuers must begin complying with these billing changes on or before the date that is 6 months after publication of the final rule. If the date that is 6 months after publication of the final rule falls in the middle of the QHP issuer's billing cycle (in other words, after the QHP issuer has already sent out bills to policy holders for that month), QHP issuers would be expected to begin complying the next billing cycle immediately following that date. We will consider extending enforcement discretion to an Exchange or QHP that fails to timely comply with the separate billing policy as required under this final rule, if we find that the Exchange or QHP issuers attempted in good faith to timely meet the requirements. We believe these changes to the proposed policy will advance HHS's goal of more closely aligning the regulatory requirements for QHP issuer billing of premiums with the separate payment requirement in section 1303 of the PPACA, while also mitigating the overall burden to affected issuers, states, and enrollees.

HHS received many comments stating that we greatly underestimated the burden caused by these proposals. Although we recognized in the proposed rule that QHP issuers that cover non-Hyde abortion services would experience an increase in burden as a result of finalizing these changes, we are committed to mitigating issuer burden where possible and, as such, are finalizing changes to § 156.280(e)(2) that we believe will result in a lower overall regulatory burden than what issuers would have incurred if the provisions were finalized as originally proposed. Specifically, we are amending the proposals at § 156.280(e)(2) to finalize in a new paragraph at § 156.280(e)(2)(ii)(A) that QHP issuers offering coverage of non-Hyde abortion services through an Exchange must send an entirely separate monthly bill to the policy holder for the portion of premium attributable to coverage of non-Hyde abortion services, but they will be permitted to send this separate bill in the same mailing (although not in the same email or electronic communication) as the bill for the portion of the policy holder's premium not attributable to coverage of non-Hyde abortion services when sending paper copies of bills to policy holders. We are finalizing that, when issuers sending or issuing bills electronically, the issuer must send or issue a separate bill for the portion of the premium attributable to coverage of non-Hyde abortion services in a separate email or electronic communication from the bill for the rest of the policy holder's premium. We are also finalizing at a new paragraph § 156.280(e)(2)(ii)(B) the requirement that, although the QHP issuer would not be permitted to refuse a combined payment on the basis that the policy holder did not send two separate payments as requested by the QHP issuer, and to then terminate the policy, subject to any applicable grace period, for non-payment of premiums, the QHP issuer must continue to instruct the policy holder to pay the portion of their premium attributable to coverage of non-Hyde abortion services in a separate transaction from any payment the policy holder makes for the portion of their premium not attributable to coverage of non-Hyde abortion services. We are also finalizing that QHP issuers must begin complying with these billing changes on or before the date that is 6 months after publication of the final rule. We believe these changes to the proposed policy will advance HHS's goal of more closely aligning the regulatory requirements for QHP issuer billing of premiums with the separate payment requirement in

section 1303 of the PPACA, while also mitigating the overall burden to affected issuers, states, and enrollees.

However, we acknowledge that the changes we are finalizing will still result in additional burden for issuers. HHS received many comments on the original proposals arguing that the burden imposed on issuers would significantly exceed the estimated burden included in the proposed rule. Some commenters from the issuer community conducted internal surveys, providing detailed accounts to HHS of the various ways in which they believe HHS underestimated the burden and detailing the various issuer and Exchange activities that would be necessary for implementation that HHS failed to account for in estimating the burden.

The following one-time changes are issuer activities that commenters stated HHS should account for in response to the proposed policy, and that we expect may still be necessary for issuers under the amendments we are finalizing: Planning, assessment, budgeting, funding approval, and allocating funds and resources for the actual technical build (a process of 6 to 9 months); changes to system architecture to allow multiple billing statements per policy holder; changes to enrollment systems to identify enrollees subject to separate billing and payment requirements; automating the processes to send separate invoices (mail or electronic communication); adding electronic communications and payment links (for example, to issuer's online payment portal) for enrollees to pay separately for the separate bill; changes to call center training/scripting, response processes, billing-related outreach, and interactive voice response (IVR) technology; changes to enrollee notifications related to non-payment and the 3-month grace period; updating Health Insurance Casework System (HICS) and DOI complaint processes, changes to grievance/appeals processes; and testing to ensure accuracy of separate billing processes. Commenters also stated that HHS should have accounted for the development of new training materials. Commenters explained that issuers would need to develop additional materials and training modules for customer service representatives, brokers, and agents, so that they could address member questions and educate them, particularly on the risk of losing coverage should members fail to pay the multiple bills.

We expect the following one-time activities to add burden for issuers as issuers must still make system changes to accommodate policy holders paying separately, potential changes to binder payment processing to collect two separate payments to effectuate enrollment; changes to processes to intake payments, including automating ability to match identity and match multiple payments from a policy holder; changes to pay-by-phone and online payment portal to support dual invoices and separate payments, while also supporting combined payments for enrollees who do not make separate payments; changes to processes for enrollment and payment reconciliation, including 834 matching to effectuate enrollments; and adding new processes to address scenarios where an enrollee's payment is not processed because the bank flags payment as potentially fraudulent (expected to occur for multiple payments in the same day or $1 payments).

Commenters also noted several activities issuers would have to complete annually to effectively implement these proposals would also significantly raise the annual burden for issuers. The following annual changes are activities raised by commenters in response to the proposed policy, but that we expect will still be relevant under the amendments we are finalizing: Generating separate billing statements (paper or electronic) and additional member education materials to explain separate billing; administrative expenses in generating twice as many bills; quality assurance to ensure accuracy of separate billing statements; additional customer service resources, including additional staffing and training, to address enrollee questions, confusion, frustration, etc.; increased resources for HICS/DOI case resolution; system testing for billing accuracy; identifying enrollees who did not meet an issuer's premium payment threshold and enter a grace period for non-payment of premium if they fail to pay the second bill; managing the grace period process for a higher volume of enrollees who enter a non-payment grace period (notices, termination, appeals process, reinstatement), and verification and reconciliation of the two separate bills. Commenters also stated that issuer costs should account for additional staffing since issuers would need to hire additional FTEs for reconciliation and auditing of the enrollment, billing, delinquency and payment processes and to manage the added complexity for the Exchange back-end processes.

Because the policy as finalized will require QHP issuers to instruct the policy holder to pay the portion of their premium attributable to coverage of non-Hyde abortion services in a separate transaction from any payment the policy holder makes for the portion of their premium not attributable to coverage of non-Hyde abortion services, we anticipate that the burden associated with the following annual activities raised by commenters will still be relevant: Budgeting for fees for collecting and processing multiple payments, such as bank processing fees; processing and reconciling separate payments (paper and electronic) sent by enrollees; additional resources for manual review where automated processes are not able to reconcile enrollments and payments; and managing the grace period process for a higher volume of enrollees who enter a non-payment grace period (notices, termination, appeals process, reinstatement).

Comment: Many commenters expressed concerns that these burdens would fall hardest on those issuers in states that require QHPs to cover non-Hyde abortion services, and that if issuers in these states find the requirements overly burdensome they would not have an option to eliminate coverage of non-Hyde abortion services and would thus have to absorb all associated costs or pass those costs onto enrollees. One commenter stated that the proposals are also likely to have an impact off-Exchange, as issuers offering plans on the Exchange are also generally required under guaranteed availability to offer the plans off the Exchange, and that because these administrative processes are fixed investments across all plans, it is likely that many plans would simply change their systems to apply to all plans even though the proposals would only require QHPs to comply.

Response: Setting aside the question of whether state laws requiring coverage of non-Hyde abortion services on the Exchange are consistent with statutory conditions on federal funding from the Department to the States, we acknowledge that some states have such laws. The changes we are finalizing do not preempt state law regarding coverage of non-Hyde abortion services or otherwise attempt to coerce states into changing these laws. Although we acknowledge that issuers in these states would incur additional costs if they choose to continue offering individual market plans, HHS is refining the method issuers use to comply with the separate payment requirement, changes that we believe are necessary to align issuer billing with the separate payment requirement in section 1303 of the PPACA.

The burden and costs related to the one-time technical changes have been

previously estimated in section III ''Collection of Information Requirements'' of this final rule. We have also updated HHS's estimates in the Collection of Information Requirements section to reflect some of the increased annual burden to be incurred by issuers. Additionally, based on comments we received, we estimate that issuers will incur ongoing annual costs associated with activities such as processing and reconciling separate payments, support for enrollees who enter grace period for non-payments, customer service, outreach and compliance. We estimate that each issuer will incur additional annual costs of approximately $1 million for these activities. Assuming that issuers will start sending separate bills in July 2020, the total annual cost of for all 94 issuers will be approximately $47 million for the 6 months in 2020 and $94 million for 2021 onwards. Since issuers will not be able to take the costs incurred in 2020 into consideration when setting rates for the 2020 plan year, it is possible that some issuers will exit the individual market or incur losses. We acknowledge that QHP issuers may choose to make similar billing changes off-Exchange to maximize their investment in making system changes to comply with the separate billing policy required for on-Exchange QHPs. However, we note that the separate billing policy we are finalizing only requires QHP issuers to implement the required changes for their on-Exchange QHPs offering non-Hyde abortion coverage.

Comment: Commenters also stated that issuers would be required to consider the added operational and administrative costs when setting actuarially sound rates, which would lead to higher premiums for enrollees. Commenters also expressed concern that the additional administrative costs would be so high that they would place issuers at risk of not meeting the required Medical Loss Ratio (MLR) limits.

Response: We believe that the changes we are finalizing to § 156.280(e)(2) will result in a lower burden than the provisions as originally proposed and as such will lessen the degree to which issuers have to raise enrollee premiums. However, we acknowledge that issuers will still incur significant burden and costs as estimated above. Based on the total premiums in the 21 states that have QHP issuers offering non-Hyde abortion coverage, we estimate that there will be no premium impact in 2020 (as plan year 2020 premium rates will already be finalized), and an approximate premium impact of up to 1.0 percent in plan year 2021 and each year thereafter.

We also estimate that enrollment will be reduced in the impacted states very slightly as a result of the increase to premiums. In plan year 2021 and each year after, we estimate that APTC amounts will be increased by up to $146 million when premium rates reflect the projected additional administrative and operational expense burdens. We do not anticipate that the policies finalized at § 156.280(e)(2) will measurably increase MLR rebates as we believe that QHP issuers would either cease offering coverage of non-Hyde abortion services (unless state law requires QHP issuers to offer coverage of non-Hyde abortion services) in the plan year following the effective date to avoid issuing additional MLR rebates or would pay for the increased administrative costs from a different revenue source. Further, as noted elsewhere in this rule, among the previously acceptable methods for QHP issuers to comply with the separate payment requirement was sending a separate monthly bill for these services. Therefore, if any issuers already elected this option, there should be no change or impact on MLR rebates as a result of the policies finalized at § 156.280(e)(2). We believe these additional costs are necessary to achieve better alignment of issuer billing with the statute, and strikes a better balance between burden and benefit than if HHS were to require issuers to send the separate bill in a separate mailing.

Comment: Commenters also expressed concerns with the burdens these changes would impose on Exchanges, which commenters noted would need to make time consuming and resource intensive changes to their websites, enrollment systems, and customer service and outreach efforts (including the reallocation of marketing funds that currently provide critical enrollee outreach which drives Exchange success) to align with the separate billing and payment requirements, which would be costly and disrupt states' Exchange efficiency. Commenters noted a variety of changes Exchanges would be required to make, including communicating the new separate billing and payment requirement to enrollees during the enrollment process; updating the online payment portal (the ''Pay Now'' button on *HealthCare.gov*) to collect the binder payment through two separate transactions; updating the enrollment materials and notices that reference binder payment requirements to effectuate coverage, updating call center scripting and customer service to address questions related to separate billing and payment (since questions related to payments should be referred to the issuer, but that the call center should be prepared to answer questions about why enrollees are required to make multiple payments); and update complaint processes to address complaints and questions related to separate bills and payments.

One commenter estimated that the proposed changes would cost $250,000 annually for its State Exchange customer service center, $152,000 annually for customer outreach, and $19,000 annually to resolve customer complaints and appeals. Another commenter estimated that the proposals would cost its state Exchange an additional $2.9 million annually in customer service costs, $2.25–$2.75 million for IT system changes, and $3.6 million annually for outreach and education, which reflects one-quarter of that state Exchange's annual advertising and outreach budget. Commenters also stated that, because the proposed changes would lead to decreased QHP enrollment, the proposed rule would cause a corresponding loss of revenue to the Exchange. Commenters also highlighted how any lapse or loss of enrollee coverage due to these proposals would result in more individuals turning to state-funded programs or emergency care for their treatment needs and that any loss of coverage would decrease the size of the risk pool and increase the cost of uncompensated care, driving medical costs and health insurance rates higher generally. For example, one commenter estimated that each one percentage point decline in the uninsured rate is associated with a $167 million drop in uncompensated care.

Response: We acknowledge that these provisions will impact Exchange operations. Exchanges perform important enrollee-facing functions that could be integral to issuer and enrollee compliance with the new requirements. Ultimately, we believe the changes we are finalizing will mitigate some of the burden on Exchanges that would have been incurred if we were finalizing as proposed by decreasing potential enrollee confusion and lessening potential issuer burden.

We anticipate that State Exchanges will incur additional one-time costs associated with technical changes such as updating online payment portals to accept separate payments and updating enrollment materials and notices that reference binder payments. In addition, State Exchanges will incur ongoing annual costs associated with increased customer service, outreach, and compliance. Based on comments, we estimate that each State Exchange will

incur, on average, one-time costs of $750,000 in 2020, and ongoing annual costs of approximately $200,000 for the 6 months in 2020 and $400,000 in 2021. We anticipate that ongoing annual costs will decrease over time as consumers become used to receiving and paying separate bills. We estimate that ongoing annual costs will be approximately $300,000 for each State Exchange in 2022 and $200,00 in 2023 and after. The total one-time cost for all 12 State Exchanges affected by these requirements will be approximately $9 million in 2020. Total ongoing costs for all 12 State Exchanges is estimated to be approximately $2.4 million in 2020, $4.8 million in 2021, $3.6 million in 2022 and $2.4 million 2023 onwards. In addition, we anticipate that the 3 State Exchanges that perform premium billing and payment processing will incur annual ongoing costs similar to QHP issuers that offer coverage of non-Hyde abortion services, as discussed above. We estimate that each State Exchange that performs premium billing and payment processing will incur additional annual costs of approximately $1 million. The total annual cost for all 3 State Exchanges performing premium billing and payment processing will be approximately $1.5 million in 2020 and $3 million for 2021 onwards.

Comment: One commenter also stated that the federal government will incur additional expenses due to additional personnel time and other resources needed to ensure that QHPs on the FFEs comply with the proposed rule's requirements and to ensure compliance if a State Exchange is unable to do so, costs that will be passed on to consumers in the form of taxes.

Response: We acknowledge that the FFEs will experience added burden as a result of the final policy. However, because federal government compliance efforts will be covered primarily by FFEs user fees, we disagree that the added costs on the FFEs will be passed on to consumers in the form of taxes (though any increase in user fees may be passed on to enrollees in the form of increased premiums). We do, however, anticipate that the FFEs will incur additional costs due to one-time technical changes and increased call volumes and additional customer services efforts. We do not anticipate that the FFEs will need to make any operational changes to comply with these final policies. We estimate that the FFEs will incur a one-time cost of $750,000 in 2020 and ongoing annual cost of approximately $400,000 in 2020 and $800,000 in 2021 to implement these provisions. As consumers become used to receiving and paying separate bills, the ongoing costs should decrease. We estimate that ongoing costs will be approximately $600,000 in 2022 and $400,000 in 2023 onwards.

Comment: Commenters stated that Navigators and in-person assisters will also need to invest time and training resources necessary to ensure that they can provide support to enrollees (especially populations who would be disproportionately impacted by these proposals, including the most financially vulnerable and those with limited English proficiency) as they become acquainted with additional steps needed to maintain coverage as a result of the proposed changes. Commenters also noted that any level of QHP disenrollment resulting from the proposed changes will result in decreased broker revenue and potential loss of broker participation in the market.

Response: Although there also may be an impact on Navigators, brokers, and other assisters, we believe these entities receive training and generally keep abreast of policy changes as part of their normal duties. As such, we believe these requirements will not amount to any additional burden above that already experienced by Navigators, brokers, and other assisters as a result of providing support to enrollees who are navigating these new billing requirements.

Comment: Many commenters also stated that enrollees would incur ancillary costs that would further drive up administrative costs and burden for enrollees, including postage costs, money order fees, or other banking fees for the second bill and cautioned that these costs will be felt most strongly by low income enrollees.

Many commenters stated that these proposals would transfer the costs and burdens of accessing non-Hyde abortion services to enrollees who must seek coverage for abortion elsewhere or pay out-of-pocket. Commenters estimated that non-Hyde abortions can cost between $400 and $1900. Commenters noted that low-income women who lack insurance coverage for abortion often struggle to pay for the procedure out-of-pocket, causing financial hardship that can drive families further into poverty. Commenters also expressed concern that when legal abortion is inaccessible, people who seek to end their pregnancy turn to unsafe and illegal methods, risking arrest, serious injury, or even death. Commenters also suggested that the changes would have a disproportionate effect on enrollee groups who already face barriers to care at higher rates such as low-income individuals, young people, people of color, individuals with LEP, lesbian, gay, bisexual, transgender and queer enrollees, the Latinx community, people with disabilities, rural residents, individuals without access to the internet, and American Indian/Alaskan Native populations.

Response: We acknowledge that as originally proposed, the combination of issuer burden and enrollee confusion could have potentially led to a reduction in the availability of coverage of non-Hyde abortion services in insurance (either by issuers choosing to drop this coverage to avoid the additional costs or by enrollees having their coverage terminated for failure to pay the second bill), thereby increasing out-of-pocket costs for those seeking those services.

We understand that, even with the changes we are finalizing, the increased burden associated with issuers complying with the separate billing policy, could influence whether a QHP issuer continues offering coverage of non-Hyde abortion services in states that do not require it. However, we believe allowing the separate bill to be included in the same mailing (although not in the same email or other electronic communication), and allowing issuers to accept combined payments when policy holders fail to pay separately for the separate bill will mitigate some of the potential issuer and Exchange burden and consumer confusion associated with the proposed policy, thereby decreasing the likelihood that issuers will drop coverage of non-Hyde abortion services solely to avoid the burden associated with these changes or solely to avoid having to terminate enrollees coverage for non-payment of miniscule amounts.

We are also finalizing an enforcement posture that will further mitigate the risk of potential coverage loss. We intend to propose further rulemaking to change our regulations to mitigate this risk. Until we can effectuate such changes, we will exercise enforcement discretion as an interim step. Specifically, HHS will not take an enforcement action against a QHP issuer that adopts and implements a policy, beginning on or after the effective date for the separate billing policies, applied uniformly to all its QHP enrollees, under which an issuer does not place an enrollee into a grace period and does not terminate QHP coverage based solely on the policy holder's failure to pay the separate payment for coverage of non-Hyde abortion services. We note that the QHP issuer would still be required to collect the premium for the non-Hyde abortion coverage. We also

will not take enforcement action against QHP issuers that, beginning upon the effective date of the final rule, modify the benefits of a plan either at the time of enrollment or during a plan year to effectively allow enrollees to opt out of coverage of non-Hyde abortion services by not paying the separate bill for such services, resulting in the enrollee having a modified plan that does not cover non-Hyde abortion services and that no longer obligates the enrollee to pay the required premium for such services. QHP issuers taking this approach should implement appropriate measures to distinguish between a policy holder's inadvertent non-payment of the separate bill for non-Hyde abortion services and a policy holder's intentional nonpayment of the separate bill. Although both of these approaches would be entirely optional for a QHP issuer, we believe that offering this enforcement discretion strikes an appropriate balance between honoring section 1303's requirement for issuers to calculate the actuarial cost of non-Hyde abortion coverage and bill and collect premiums for such coverage in separate transactions, protecting enrollees against inadvertent losses of coverage, and ensuring all enrollees have access to coverage that meets their needs and that does not result in their supporting coverage for non-Hyde abortion services to which they object. We acknowledge that QHP issuers that do not utilize this available enforcement discretion may subsequently experience a higher number of enrollee terminations as a result of delinquent premium payments, which could influence whether a QHP issuer continues offering coverage of non-Hyde abortion services in states that do not require it.

Because enrollees will be instructed to make separate payments, those that follow the instructions may need to pay for additional postage, money order fees, credit card fees, or other banking fees for the second bill depending on how the QHP issuer implements this policy. For example, policy holders who have funds automatically withdrawn from their bank accounts may need to arrange for a second withdrawal and may encounter additional fees. Additionally, because QHP issuers often incur fees for credit card transactions and these fees would double when a policy holder is paying in two separate transactions, QHP issuers may decide to transfer the cost of those credit card transaction fees onto policy holders choosing to pay via credit card rather than covering the cost of those transactions themselves. Policy holders that pay their premium bills via money order may need to pay an additional fee for the additional money order they submit for payment of the separate bill.

Comment: Many commenters stated that the proposals would cause considerable and unnecessary confusion and frustration for enrollees that may jeopardize their health insurance coverage by making it more difficult for policy holders to pay their premium bills, which could potentially result in their coverage being terminated for unintentional non-payment. Commenters also expressed concerns that despite consumer education and outreach, enrollees would likely not understand this change in billing.

Many commenters also stated that we underestimated the number of enrollees who would be impacted by these proposals. One commenter stated that there are 2 million enrollees alone in states where non-Hyde abortion coverage is required in all plans. Another commenter conducted an internal member survey, to which ten issuers responded, indicating that 2.4 million enrollees would be impacted across these ten issuers. This commenter noted that these ten issuers do not represent all health insurance issuers who would be required to comply with the proposals and that, thus, the number of affected enrollees would be greater than 2.4 million. Another commenter stated that the rule would impact 3 million enrollees. As such, commenters stated that we underestimated how much it would cost enrollees annually to comply with the proposals. Commenters also objected that we excluded the cost of enrollees learning in our estimate.

Response: We based our initial estimates on 2018 QHP Certification data, and we acknowledge that the estimates may not have captured the exact number of enrollees that may be impacted by this final rule. In response to comments, we have reviewed our methodology and have updated our enrollee estimates accordingly. We also acknowledge that enrollees may initially be confused by receiving a separate bill for the portion of their premium attributable to coverage of non-Hyde abortion services in the same envelope as the bill for the rest of their premium. We believe that the provisions as finalized will minimize enrollee confusion surrounding the second bill for those receiving paper bills and will help to ensure that policy holders pay the entire premium due including the portion attributable to non-Hyde abortion services. There is still potential for confusion and loss of coverage for enrollees who receive electronic bills, due to failure to pay the second bill sent through a separate electronic communication, but the mechanisms by which electronic bills are paid may mitigate or lessen the potential for confusion over separate bills. We believe enrollee outreach and education will assist in further mitigating this risk.

Based on 2019 QHP certification data for the FFEs and SBE–FPs, we now estimate that there are approximately 442,400 enrollees in QHPs covering non-Hyde abortion services. In the 11 State Exchanges that operated their own technology platforms and had issuers that offered coverage of non-Hyde abortion services in 2019, we estimate that there are approximately 2,597,700 million enrollees enrolled in QHPs offering coverage for non-Hyde abortion. As noted previously in section III ''Collection of Information Requirements'' of this final rule, we estimate that there are approximately 3.04 million enrollees impacted by these provisions. Assuming 1.5 enrollees per policy, issuers will be required to send a separate bill to approximately 2 million policy holders. We believe that finalizing the policies to allow for the separate bill to be sent in the same mailing with the bill for the rest of the policy holder's premium will minimize enrollee confusion and burden.

We acknowledge that some policy holders will fail to pay in a separate transaction for both bills, and acknowledge that the burden may be moderately higher for those policy holders who follow instructions to pay in separate transactions. We also acknowledge that enrollees may experience burden in receiving a separate bill to which they are not yet accustomed in the same mailing as for the other portions of their premium or in a separate electronic communication. As such, using the May 2018 National Occupational Employment and Wage Estimates United States, Department of Labor's Bureau of Labor Statistics (BLS) (*https://www.bls.gov/oes/current/oes_stru.htm*), listed national mean hourly wage for the 25th percentile,[28] we estimate that for the 2020 plan year each policy holder will incur a burden of approximately 1 hour (at a cost of $12.37 per hour) to read and understand the separate bills received the first time and seek help from customer service if necessary, and approximately 5 minutes for each of the subsequent 5 months, resulting in a total estimated annual burden of 1.42 hours with an associated annual cost of approximately $18. For

[28] The 25th percentile mean hourly wage most closely resembles the group of enrollees likely to be affected by this change as most enrollees enrolled in QHPs on the Exchange are between 100 percent and 400 percent of the federal poverty level.

all policy holders we estimate that the initial 2020 burden will be approximately 2.9 million hours with and associated annual cost of $35.5 million. For subsequent years we estimate that enrollees will require approximately 5 minutes per month to read and understand their statements, resulting in an estimated annual burden of 1 hour with an associated annual cost of approximately $12. For all policy holders, we estimate that the annual enrollee burden will be approximately 2 million hours with an associated annual cost of approximately $25.1 million.

We also note that, although policy holders may experience burden related to reading and understanding the separate bills, there are non-quantifiable benefits to policy holders in QHPs covering non-Hyde abortion who hold conscience objections to such coverage or policy holders who seek a better understanding of what their health care dollars are purchasing.

HHS continues to believe that, although these changes will increase enrollee burden, this burden is reasonable and justified because it will achieve better alignment of the regulatory requirements for QHP issuer billing of premiums with the separate payment collection requirement in section 1303 of the PPACA.

TABLE 10—SUMMARY OF COSTS RELATED TO SEPARATE BILLING AND PAYMENT REQUIREMENTS

	2020	2021	2022	2023	2024
Issuers	$482,616,844	$195,252,923	$195,228,601	$195,216,441	$195,216,441
States	11,400,000	4,800,000	3,600,000	2,400,000	2,400,000
State Exchanges with payment portals	15,385,201	6,197,323	6,197,323	6,197,323	6,197,323
Consumers	35,517,268	25,071,013	25,071,013	25,071,013	25,071,013
Federal Government	1,150,000	800,000	600,000	400,000	400,000
Total	546,069,313	232,121,259	230,696,938	229,284,777	229,284,777

D. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique reviewers on similar Exchange-related CMS rules will be the number of reviewers of this final rule. We acknowledge this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all reviewers will review the rule in detail. For these reasons, we consider the number of past reviewers on similar CMS rules will be a fair estimate of the number of reviewers of this rule.

We recognize that different types of entities may be affected by only certain provisions of this final rule, and therefore, for the purposes of our estimate, we assume that each reviewer reads approximately 50 percent of the rule.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $109.36 per hour, including overhead and fringe benefits.[29] We estimate that it would take approximately 1 hour for each reviewer to review the relevant portions of this final rule. We received 75,439 comments, including 70,396 comments that were substantially similar to one of 13 different form letters, resulting in 5,043 unique comments on the proposed rule. We further assume that for the form letters received, only the staff at the organization that arranged for those letters will review the final rule. Therefore, we estimate that there will be 5,056 individuals that review the final rule resulting in an estimated total cost of review of approximately $552,924 ($109.36 × 5,056 reviewers).

E. Regulatory Alternatives Considered

In developing the policies contained in this final rule, we considered numerous alternatives. Below we discuss the key regulatory alternatives that we considered.

For the eligibility determination during a benefit year, we considered not defining ''periodically'' for the frequency of Medicare, Medicaid/CHIP, or BHP, if applicable, PDM as twice a year in lieu of further outreach, education, and coordination with State Exchanges to identify and notice consumers who may also be enrolled in other qualifying coverage with APTC/CSRs. However, we believe it is critical that consumers receive timely notification of their potential dual enrollment in other qualifying coverage to ensure that consumers are accurately determined eligible for APTC and income-based CSRs, and to ensure that consumers are not enrolling in unnecessary or duplicative coverage. As previously discussed in the preamble of the proposed rule, such unnecessary or duplicative coverage, coupled with typically higher utilization generally results in higher premiums across the individual market leading to unnecessary expenditures of federal funds on PTC for taxpayers eligible for PTC in the individual market.

In finalizing the proposed changes to the general program integrity and oversight requirements in § 155.1200, we considered not taking any action. However, because the existing requirements under § 155.1200(b) did not accurately reflect the current structure of CMS's oversight approach and reporting requirements for State Exchanges, not taking any action could have prevented HHS from being able to accurately describe our reporting requirements and strengthen our oversight processes for State Exchanges. In particular, we needed to clarify that the eligibility and enrollment reports required under § 155.1200(b)(2) were part of the annual compliance reports that State Exchanges were submitting to us, and did not require submission of a separate report. Thus, the amendments to § 155.1200(b) do not reflect an expansion of State Exchange reporting obligations but instead were intended to capture the existing annual compliance reports (such as the SMART) that encompass eligibility and enrollment reporting, as well as compliance across other Exchange program reqirements under 45 CFR part 155, that State Exchanges currently submit to HHS. Also, because the existing external programmatic audit requirements under § 155.1200(d) did not specify how the audits needed to verify the accuracy of eligibility determinations made by State Exchanges, not taking any action would have prevented CMS from strengthening oversight processes by identifying a consistent procedure for these State Exchanges and their auditors to

[29] *https://www.bls.gov/oes/current/oes_nat.htm.*

implement in order to ensure accurate eligibility determinations.

In finalizing the proposed changes to § 155.1200(c) and (d), we also considered the alternative of narrowing the focus of the external programmatic audits to only 45 CFR part 155 subparts D and E, which cover Exchange eligibility and enrollment requirements. This approach would have focused the State Exchange's auditing resources to the areas with highest program integrity impact. However, this approach would essentially exclude SBE–FPs from the external programmatic audit requirements altogether because SBE–FPs utilize the federal platform to carry out their eligibility and enrollment functions. Additionally, this approach would have limited our oversight in other program integrity areas that are important for all State Exchanges, such as consumer outreach and assistance. Because the external audit requirements under § 155.1200 is one of the only oversight tools we have for State Exchanges, we did not want to limit the scope of the Exchange functions that the external programmatic audits must cover. Instead, the approach finalized in this rulemaking allows us to specify the Exchange functions that are applicable to each State Exchange model through annual technical operational guidance. As State Exchanges continue to evolve and mature, this approach also provides HHS with the flexibility to focus the audits on emerging issues that raise program integrity concerns, while minimizing burden on State Exchanges to the extent possible.

In finalizing the requirement that issuers separately bill for the portion of the policy holder's premium attributable to the cost of including coverage of non-Hyde abortion services in the QHP, and permit policy holders to pay for these amounts in a separate transaction if they so choose, as described at § 156.280(e)(2), we considered maintaining the current methods of billing and collection without modification. We acknowledge that maintaining the current policy would promote stability for issuers and conserve administrative and operational resources by allowing QHP issuers to maintain their current process for billing for and collecting these separate payments. However, by requiring QHP issuers to separately bill for the portion of the policy holder's premium attributable to coverage of non-Hyde abortion services, we believe we are strengthening alignment of issuer billing with the statutory requirements for collecting a separate payment for these services required under section 1303 of the PPACA.

We also considered finalizing the changes as originally proposed. However, we believe the changes we are finalizing will help to maximize the net benefit of achieving better statutory alignment while also mitigating burden where possible. For example, we considered finalizing the proposed requirement that issuers would be required to send the separate bill in a separate mailing or electronic communication. This would have resulted in additional mailing costs of approximately $11 million in 2021 for all issuers. However, we believe allowing issuers to send the separate bill in the same mailing (although not in the same electronic communication) and allowing issuers to accept combined payments if a policy holder fails to pay the separate bill in a separate transaction will assist in mitigating the burden associated with this policy change by preventing unnecessary postage and mailing related costs and will mitigate issuer and Exchange burden and enrollee confusion generally associated with the proposed policy. We also believe the separate bill could assist in clarifying for enrollees that their plan covers non-Hyde abortion services and at what cost, increasing overall QHP transparency. Furthermore, we believe these changes will still better align issuer billing with section 1303 of the PPACA.

We also considered finalizing the rule without a requirement that issuers instruct policy holders to pay in a separate transaction. We understand that requiring issuers make this instruction and make reasonable efforts to collect the payment separately carries up-front and annual costs for issuers. However, we believe that instructing policy holders to pay the separate bill in a separate transaction is important to achieving better alignment of the regulatory requirements for QHP issuer billing of enrollee premiums with the separate payment requirement in section 1303 of the PPACA.

In addition, we considered requiring issuers to comply with the separate billing requirements within 3 months after the publication date of this final rule. We rejected this option because we estimated that one-time costs would have increased by 100 percent due to the shortened implementation period and estimated that total costs for issuers, State Exchanges, FFEs, and consumers would have been approximately $740 million in 2020. We opted to finalize a later effective date to avoid such a burden increase.

F. Regulatory Flexibility Act

The RFA requires agencies to prepare an initial RFA 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 revenue 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 standards for certain issuers related to the collection of a separate payment for the premium portion attributable to coverage for certain abortion services. 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 the purposes of the RFA, we expect health insurance issuers to be affected by this final rule. We believe that health insurance issuers would be classified under the North American Industry Classification System code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of $38.5 million or less would be considered small entities for these North American Industry Classification System 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.[30] We believe that few, if any, insurance companies underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) fall below these size thresholds.

Therefore, we are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this final rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Social Security Act requires us to

[30] *https://www.sba.gov/document/support-table-size-standards.*

prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This final rule will not have a significant impact on small rural hospitals. Therefore, the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

G. 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 any rule that includes any federal mandate that may result in expenditures in any 1 year by a state, local, or Tribal government, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately $154 million. We anticipate that costs incurred by state, local, or tribal governments and the private sector will cross this threshold. States impacted by the separate billing and payment requirements at § 156.280 may incur costs of approximately $26.8 million in 2020, 11 million in 2021, $9.8 million in 2022 and $8.6 million in 2023 and each year after. In addition, states impacted by PDM requirements will incur costs of up to $6.9 million in 2020. Issuers impacted by the separate billing and payment requirements will incur costs of approximately $482.6 million in 2020 and approximately $195.3 million each year after.

H. 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 requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This final rule does not impose substantial direct costs on state and local governments or preempt state law. However, we believe the rule has Federalism implications.

In HHS's view, this regulation has Federalism implications due to our requirements that Exchanges conduct Medicare, Medicaid/CHIP, and, if applicable, BHP PDM at least twice a year, beginning with the 2021 calendar year. As discussed earlier in this final rule, we received three comments that were opposed to the requirement to conduct Medicare, Medicaid/CHIP and, if applicable, BHP PDM at least twice yearly, cautioning us that defining the exact precise frequency and nature of PDM encroached upon the sovereignty of the State Exchanges. However, HHS believes that the Federalism implications are substantially mitigated because the requirement sets only a minimum frequency with which Exchanges must conduct Medicare, Medicaid/CHIP, and, BHP, if applicable, PDM, which is already required to be conducted periodically; State Exchanges continue to have the flexibility to conduct PDM with greater frequency and the best way they see fit to implement the requirements set forth in § 155.330(d). Additionally, as discussed earlier in this final rule, ensuring consumers are enrolled in the appropriate coverage remains a top priority for HHS and ensuring that APTC is paid appropriately is a requirement set forth in § 155.330(d)(1)(ii) to mitigate the risk of federal dollars incorrectly leaving the federal Treasury in the form of APTC during the year. HHS believes that PDM plays a vital role in ensuring the health of all Exchanges, ensuring all consumers are enrolled in the appropriate coverage and in the case of Medicare enrollment, signing up at the appropriate time to avoid late enrollment penalties, and finally reduces the risk that consumers have to pay back all or some of APTC paid on their behalf during months of overlapping coverage when they file their federal income taxes.

Additionally, the changes to State Exchange oversight and reporting requirements in § 155.1200 have Federalism implications since those rules require State Exchanges to submit certain reports to HHS and require them to enter into contracts with an external independent audit entity to perform audits, and incur the associated costs. However, HHS believes that the Federalism implications are substantially mitigated because the changes do not impose new requirements on State Exchanges, but rather add specificity and flexibility with respect to the existing requirements. Therefore, HHS believes it has balanced states' interests in operating State Exchanges with the need to ensure proper federal oversight. By doing so, it is HHS's view that we have complied with the requirements of Executive Order 13132.

As discussed earlier in this final rule, commenters stated that the separate billing and payment proposals at § 156.280 raise Federalism concerns under the Tenth Amendment because the proposals are designed to penalize states that have laws requiring QHPs to provide coverage of non-Hyde abortion services by requiring states—through their respective Exchanges and DOIs—to adopt new oversight responsibilities, and make systemic changes to fit the alterations the proposals require. As explained previously, we disagree that this policy raises Federalism concerns. Setting aside the question of whether state laws requiring coverage of non-Hyde abortion services on the Exchange are consistent with statutory conditions on federal funding from the Department to the States, we acknowledge that some states have such laws. However, the changes we are finalizing do not preempt state law regarding coverage of non-Hyde abortion services or otherwise attempt to coerce states into changing these laws. HHS is simply refining the method with which issuers use to comply with the separate payment requirement. We refer readers to section II.B of this final rule regarding the discussion of § 156.280 for further information.

I. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, entitled ''Reducing Regulation and Controlling Regulatory Costs,'' was issued on January 30, 2017 and requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' This final rule is expected to be an Executive Order 13771 regulatory action. We estimate that this rule generates $182.98 million in annualized costs, discounted at 7 percent relative to year 2016, over a perpetual time horizon. Details on the estimated costs of this rule can be found in the preceding analyses.[31]

J. 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

[31] We estimate costs of approximately $553.6 million in 2020, approximately $232.1 million in 2021, approximately $230.7 million in 2022, and annual costs of approximately $229.3 million thereafter. Thus the annualized value of costs, as of 2016 and calculated over a perpetual time horizon with a 7 percent discount rate, is $182.98 million.

containing a copy of the rule along with other specified information, and has been transmitted to the Congress and the Comptroller General for review.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

45 CFR Part 155

Administrative practice and procedure, Advertising, Brokers, Conflict of interests, Consumer protection, Grants administration, Grant programs-health, Health care, Health insurance, Health maintenance organizations (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Intergovernmental relations, Loan programs-health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, Technical assistance, Women and youth.

45 CFR Part 156

Administrative practice and procedure, Advertising, Advisory committees, Brokers, Conflict of interests, Consumer protection, Grant programs-health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Loan programs-health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, State and local governments, Sunshine Act, Technical assistance, Women, Youth.

For the reasons set forth in the preamble, the Departement of Health and Human Servcies amends 45 CFR parts 155 and 156 as set forth below:

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

■ 1. The authority citation for part 155 continues to read as follows:

Authority: 42 U.S.C. 18021–18024, 18031–18033, 18041–18042, 18051, 18054, 18071, and 18081–18083.

■ 2. Section 155.200 is amended by revising paragraph (c) to read as follows:

§ 155.200 Functions of an Exchange.

* * * * *

(c) *Oversight and financial integrity.* The Exchange must perform required functions and cooperate with activities related to oversight and financial integrity requirements in accordance with section 1313 of the Affordable Care Act and as required under this part, including overseeing its Exchange programs and non-Exchange entities as defined in § 155.260(b)(1).

* * * * *

■ 3. Section 155.330 is amended by revising paragraph (d)(1) introductory text and adding paragraph (d)(3) to read as follows:

§ 155.330 Eligibility redetermination during a benefit year.

* * * * *

(d) * * *

(1) *General requirement.* Subject to paragraph (d)(3) of this section, the Exchange must periodically examine available data sources described in §§ 155.315(b)(1) and 155.320(b) to identify the following changes:

* * * * *

(3) *Definition of periodically.* Beginning with the 2021 calendar year, the Exchange must perform the periodic examination of data sources described in paragraph (d)(1)(ii) of this section at least twice in a calendar year. State Exchanges that have implemented a fully integrated eligibility system with their respective State Medicaid programs, that have a single eligibility rules engine that uses MAGI to determine eligibility for advance payments of the premium tax credit, cost-sharing reductions, Medicaid, CHIP, and the BHP, if a BHP is operating in the service area of the Exchange, will be deemed in compliance with the Medicaid/CHIP PDM requirements and, if applicable, BHP PDM requirements, in paragraphs (d)(1)(ii) and (d)(3) of this section.

* * * * *

■ 4. Section 155.1200 is amended by—
■ a. Revising paragraphs (b) introductory text, (b)(1) and (2), and (c) introductory text;
■ b. Revising paragraphs (d)(2) and (3);
■ c. Redesignating (d)(4) as paragraph (d)(5);
■ d. Adding a new paragraph (d)(4); and
■ e. Revising newly redesignated paragraph (d)(5).

The revisions and addition read as follows:

§ 155.1200 General program integrity and oversight requirements.

* * * * *

(b) *Reporting.* The State Exchange must, at least annually, provide to HHS, in a manner specified by HHS and by applicable deadlines specified by HHS, the following data and information:

(1) A financial statement presented in accordance with GAAP,

(2) Information showing compliance with Exchange requirements under this part 155 through submission of annual reports,

* * * * *

(c) *External audits.* The State Exchange must engage an independent qualified auditing entity which follows generally accepted government auditing standards (GAGAS) to perform an annual independent external financial and programmatic audit and must make such information available to HHS for review. The State Exchange must:

* * * * *

(d) * * *

(2) Compliance with subparts D and E of this part 155, or other requirements under this part 155 as specified by HHS;

(3) Processes and procedures designed to prevent improper eligibility determinations and enrollment transactions, as applicable;

(4) Compliance with eligibility and enrollment standards through sampling, testing, or other equivalent auditing procedures that demonstrate the accuracy of eligibility determinations and enrollment transactions; and

(5) Identification of errors that have resulted in incorrect eligibility determinations, as applicable.

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 5. The authority citation for part 156 is revised to read as follows:

Authority: 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.

■ 6. Section 156.280 is amended by—
■ a. Revising the section heading;
■ b. Redesignating paragraph (e)(2)(ii) as paragraph (e)(2)(iii);
■ c. Adding a new paragraph (e)(2)(ii); and
■ d. Revising newly redesignated paragraph (e)(2)(iii).

The addition and revision read as follows:

§ 156.280 Separate billing and segregation of funds for abortion services.

* * * * *

(e) * * *

(2) * * *

(ii) Beginning on or before the first billing cycle following June 27, 2019, to satisfy the obligation in paragraph (e)(2)(i) of this section—

(A) Send to each policy holder of a QHP monthly bills for each of the amounts specified in paragraphs (e)(2)(i)(A) and (B) of this section, either by sending separate paper bills which may be in the same envelope or mailing,

or by sending separate bills electronically, which must be in separate emails or electronic communications; and

(B) Instruct the policy holder to pay each of the amounts specified in paragraphs (e)(2)(i)(A) and (B) of this section through separate transactions. Notwithstanding this instruction, if the policy holder fails to pay each of these amounts in a separate transaction as instructed by the issuer, the issuer may not refuse the payment and initiate a grace period or terminate the policy holder's QHP coverage on this basis.

(iii) Deposit all such separate payments into separate allocation accounts as provided in paragraph (e)(3) of this section. In the case of an enrollee whose premium for coverage under the QHP is paid through employee payroll deposit, the separate payments required under paragraph (e)(2)(i) of this section shall each be paid by a separate deposit.

* * * * *

Dated: December 16, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: December 18, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2019–27713 Filed 12–20–19; 8:45 am]

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FOR THE NINTH CIRCUIT

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