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9  
10 \*Application for admission pending

11 **UNITED STATES DISTRICT COURT**  
12 **EASTERN DISTRICT OF WASHINGTON**

13 STATE OF WASHINGTON,

14 Plaintiff,

15 v.

16 ALEX M. AZAR II, in his  
17 official capacity as Secretary of  
18 the United States Department of  
19 Health and Human Services;  
20 UNITED STATES  
21 DEPARTMENT OF HEALTH  
22 AND HUMAN SERVICES;  
SEEMA VERMA, in her official  
capacity as Administrator of the  
Centers for Medicare and  
Medicaid Services; and  
CENTERS FOR MEDICARE  
AND MEDICAID SERVICES,

Defendants.

NO. 2:20-CV-00047 SAB

PLAINTIFF STATE OF  
WASHINGTON'S MOTION  
FOR PARTIAL SUMMARY  
JUDGMENT ON NON-  
PREEMPTION

NOTED FOR: April 9, 2020  
With Oral Argument: 9:00 a.m.  
Spokane, Washington

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## I. INTRODUCTION

In 2010, Congress enacted the Patient Protection and Affordable Care Act (ACA). The ACA contains multiple express non-preemption provisions, which unequivocally establish that the ACA does not preempt state insurance laws—including, specifically, state laws regarding coverage or funding for abortion care. Although the ACA requires issuers of qualified health plans to segregate moneys paid for abortion coverage (to ensure compliance with certain restrictions on the use of federal funds), the ACA does not require issuers to use a particular method for billing such amounts to enrollees. Instead, it preserves states' traditional authority to regulate such matters within their respective marketplaces. From 2015 to 2019, the U.S. Department of Health and Human Services (HHS) explained through formal rulemaking and guidance that plan issuers could use a variety of methods to collect and segregate these moneys, including by simply sending enrollees a single, itemized invoice and allocating the payments into appropriate separate accounts.

15        In December 2019, HHS published a new regulation (the “Double-Billing  
16        Rule” or the “Rule”) that reverses the agency’s prior guidance and suddenly requires  
17        all plan issuers whose qualified health plans cover abortion care to send enrollees  
18        two separate bills each month, with instructions to pay the separate bills in two  
19        separate transactions. Patient Protection and Affordable Care Act: Exchange  
20        Program Integrity, 84 Fed. Reg. 71,674 (Dec. 27, 2019). Under this Double-Billing  
21        Rule, one bill must cover the premium cost of coverage for all health care services  
22        except abortion care, and the second bill must address only the comparatively

## 1 | minuscule cost of covering abortion care.

In promulgating the Double-Billing Rule, HHS recognized its federalism limitations and disclaimed any intention to preempt state law. However, it failed to address the Rule’s direct conflict with existing Washington law mandating that plan issuers must send enrollees a single invoice for each billing period. Wash. Rev. Code § 48.43.074 (the “Single-Invoice Statute”). If the Double-Billing Rule is enforced in Washington State, it would improperly preempt the Single-Invoice Statute, in violation of the ACA’s express non-preemption provisions.

9           The State of Washington moves for summary judgment on Counts I and II of  
10          its Complaint, which both concern the narrow issue of preemption. There is no need  
11          to examine the administrative record to resolve this purely legal issue. The State is  
12          entitled to a ruling declaring that HHS's Double-Billing Rule does not preempt  
13          Washington's Single-Invoice Statute as a matter of law, and that the state law will  
14          remain in full force and effect. Because federal agency rules are invalid when they  
15          conflict with state law contrary to a non-preemption provision, *see Oregon v.*  
16          *Ashcroft*, 368 F.3d 1118 (9th Cir. 2004), the Court should declare that the Double-  
17          Billing Rule does not apply and has no force or effect in Washington State. Such a  
18          ruling would be sufficient to resolve the entire case.

## II. BACKGROUND

## 20 | A. The ACA and Washington's Health Benefit Exchange

21 Title 1 of the ACA provides for the establishment of state health benefit  
22 exchanges on which issuers may offer qualified health plans (QHPs). 42 U.S.C.

1 § 18031(b). Section 1301 of the ACA defines a QHP as a health care coverage plan  
 2 offered on a state exchange that meets the relevant statutory criteria, including that  
 3 it must offer “essential health benefits” as defined in the Act. *Id.* § 18021(a). Section  
 4 1302 specifies that “[n]othing in this title shall be construed to prohibit a health plan  
 5 from providing benefits in excess of the essential health benefits described in this  
 6 subsection.” *Id.* § 18022(b)(5). Section 1311 provides that states may require QHPs  
 7 to offer benefits in addition to the “essential health benefits” required by federal law.  
 8 *Id.* § 18031(d)(3)(B).

9 Pursuant to the ACA, in 2011 Washington created the State’s Health Benefit  
 10 Exchange (the “State Exchange”) as a public–private partnership. *See* Wash. Rev.  
 11 Code Chapter 43.71. QHPs are offered by private insurance carriers on the State  
 12 Exchange, and are subject to oversight by Washington’s Office of the Insurance  
 13 Commissioner (OIC). Under Washington law, any plan that includes coverage for  
 14 maternity care or services must also include substantially equivalent coverage for  
 15 abortion services. Wash. Rev. Code § 48.43.073. The OIC determined as early as  
 16 2012 that neither federal nor Washington law require separate premium billing to  
 17 enrollees for a plan’s coverage of such abortion services. *See* Wash. Admin. Code  
 18 § 284-07-540 (OIC regulations for Section 1303 compliance).

19 **B. Funding Segregation Requirements for QHP Issuers**

20 Federal law generally prohibits the use of federal funds to pay for abortion  
 21 care. Accordingly, Section 1303 of the ACA provides that QHP issuers cannot use  
 22 federal tax credits or cost-sharing reductions to pay for “abortions for which public

1 funding is prohibited[.]” 42 U.S.C. § 18023(b)(1)(B)(i). The ACA imposes specific  
 2 funding segregation obligations on any issuer offering a QHP that includes abortion  
 3 coverage. *Id.*; *accord* 45 C.F.R. § 156.280 (current HHS regulations). The ACA  
 4 makes clear, however, that federal law does not otherwise affect QHP issuers’  
 5 “voluntary choice of coverage of abortion services.” *Id.* § 18023(b)(1).

6 Specifically, if a QHP covers abortion care, Section 1303 of the ACA requires  
 7 that the QHP “collect” from each enrollee a “separate payment” for the portions of  
 8 the premium that pay for abortion and non-abortion coverage, respectively. *Id.*  
 9 § 18023(b)(2)(B)(i). These separate payments must be deposited into “separate  
 10 allocation accounts,” thereby segregating funds that are collected and used to pay  
 11 for coverage of abortion services from funds collected and used to pay for all other  
 12 health services. *Id.* § 18023(b)(2)(B)(ii).

13 Section 1303 of the ACA does not specify the method an issuer must use to  
 14 comply with the requirement to “collect . . . a separate payment.” (Nor do the HHS  
 15 regulations that have been in place since 2012, *see* 45 C.F.R. § 156.280(e).) This  
 16 choice was intentional; in 2015, HHS promulgated a final rule explaining that  
 17 Section 1303 “do[es] not specify the method an issuer must use to comply with the  
 18 separate payment requirement.” Patient Protection and Affordable Care Act: HHS  
 19 Notice of Benefit and Payment Parameters for 2016, 80 Fed. Reg. 10,840 (Feb. 27,  
 20 2015) (2015 Rule). The 2015 Rule informed health plan issuers and state regulators  
 21 that the requirement “may be satisfied in a number of ways,” including but not  
 22 limited to (i) sending the enrollee a single monthly invoice that separately itemizes

1 the premium amount for abortion services, (ii) sending a separate monthly bill for  
 2 abortion services, or (iii) sending the enrollee a notice upon enrollment that the  
 3 monthly invoice will include a separate, specified charge for abortion services. *Id.*  
 4 The 2015 Rule further explained that the enrollee may make the separate payments  
 5 for abortion services and other services in a “single transaction.” *Id.* As HHS  
 6 explained, these standards offered QHP issuers “several ways to comply with  
 7 [Section 1303’s] requirements, while minimizing burden on QHP issuers and  
 8 consumers.” *Id.* at 10,841.

9 In October 2017, the Centers for Medicare and Medicaid Services (CMS)  
 10 issued its own guidance listing the same options for complying with Section 1303’s  
 11 funding segregation requirements. *CMS Bulletin Addressing Enforcement of Section*  
 12 *1303 of the Patient Protection and Affordable Care Act* (Oct. 6, 2017), available at  
 13 [https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/](https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Section-1303-Bulletin-10-6-2017-FINAL-508.pdf)  
 14 [Section-1303-Bulletin-10-6-2017-FINAL-508.pdf](https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Section-1303-Bulletin-10-6-2017-FINAL-508.pdf) (2017 Guidance).

15 **C. The ACA’s Non-Preemption Provisions**

16 The ACA contains multiple provisions expressly disclaiming federal  
 17 preemption and preserving state insurance-regulation laws.

18 First, Section 1303 of the ACA—the same section that establishes the funding  
 19 segregation requirements discussed above—contains an express non-preemption  
 20 provision. The relevant subsection, entitled “No preemption of State laws regarding  
 21 abortion,” provides in full:

22 Nothing in this Act shall be construed to preempt or otherwise have any

1 effect on State laws regarding the prohibition of (or requirement of)  
 2 coverage, funding, or procedural requirements on abortions, including  
 3 parental notification or consent for the performance of abortion on a  
 4 minor.

5 42 U.S.C. § 18023(c)(1).

6 Second, Section 1321 of the ACA, entitled “State flexibility in operation and  
 7 enforcement of Exchanges and related requirements,” contains a general non-  
 8 preemption provision. That subsection, entitled “No interference with State  
 9 regulatory authority,” provides in full: “Nothing in this title shall be construed to  
 10 preempt any State law that does not prevent the application of the provisions of this  
 11 title.” 42 U.S.C. § 18041(d). In other words, this provision establishes that state laws  
 12 are not preempted unless they directly conflict with Title 1 of the ACA. This general  
 13 principle is reflected in other ACA non-preemption provisions as well. *E.g.*, 42  
 14 U.S.C. § 300gg-23(a)(1) (“[T]his part . . . shall not be construed to supersede any  
 15 provision of State law which establishes, implements, or continues in effect any  
 16 standard or requirement solely relating to health insurance issuers in connection with  
 17 individual or group health insurance coverage . . . .”).

18 **D. Relevant Washington Law**

19 Washington’s Single-Invoice Statute, enacted in May 2019,<sup>1</sup> codifies the

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20 21 22 <sup>1</sup> While formally enacted after HHS released its proposed rule, the Single-Invoice Statute reflects Washington’s 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

1 State's policy of requiring health insurance carriers to bill enrollees with a single  
 2 invoice, while noting the State's compliance with Section 1303 of the ACA. Wash.  
 3 Rev. Code § 48.43.074; *see also* Wash. Admin. Code § 284-07-540 (OIC regulations  
 4 for Section 1303 compliance). The Single-Invoice Statute provides in full:

5 (1) The legislature intends to codify the state's current practice of  
 6 requiring health carriers to bill enrollees with a single invoice and to  
 7 segregate into a separate account the premium attributable to abortion  
 8 services for which federal funding is prohibited. Washington has  
 9 achieved full compliance with section 1303 of the federal patient  
 10 protection and affordable care act by requiring health carriers to submit  
 11 a single invoice to enrollees and to segregate into a separate account the  
 12 premium amounts attributable to coverage of abortion services for  
 13 which federal funding is prohibited. Further, section 1303 states that  
 14 the act does not preempt or otherwise have any effect on state laws  
 15 regarding the prohibition of, or requirement of, coverage, funding, or  
 16 procedural requirements on abortions.

17 (2) In accordance with RCW 48.43.073 related to requirements for  
 18 coverage and funding of abortion services, an issuer offering a qualified  
 19 health plan must:

20 (a) Bill enrollees and collect payment through  
 21 a single invoice that includes all benefits and services covered by the  
 22 qualified health plan; and

23 (b) Include in the segregation plan required under applicable  
 24 federal and state law a certification that the issuer's billing and payment  
 25 processes meet the requirements of this section.

26 Wash. Rev. Code § 48.43.074.

27 **E. The Double-Billing Rule**

28 On November 9, 2018, HHS and CMS published a Notice of Proposed

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29 the inevitable confusion engendered by double-billing is not required by either the  
 30 ACA or Washington law. *See* Wash. Admin. Code § 284-07-540.

1 Rulemaking (NPRM) proposing to reverse the flexibility enshrined in the ACA and  
 2 the policies reflected in the agencies' 2015 Rule and the 2017 Guidance, and to  
 3 require QHP issuers to send enrollees two separate bills for their monthly premium  
 4 if the plan includes coverage for non-federally-fundable abortion services. 83 Fed.  
 5 Reg. 56,015 (Nov. 9, 2018). As set forth in the NPRM, the agencies reinterpreted  
 6 Section 1303's requirement that QHP issuers "collect . . . a separate payment" for  
 7 such coverage to mean that the "separate payment" must be both separately *billed*  
 8 by the issuer and separately *submitted* by the enrollee. Specifically, the proposed  
 9 rule would require QHP issuers to (1) "send an entirely separate monthly bill" to  
 10 each enrollee "for only the portion of the premium attributable to" non-federally-  
 11 fundable abortion coverage and (2) "instruct the policy subscriber" to pay each bill  
 12 in a "separate transaction." 83 Fed. Reg. 56,022 (proposed 45 C.F.R. § 156.280).

13 Despite opposition from "most commenters," HHS and CMS promulgated the  
 14 Double-Billing Rule on December 27, 2019. 84 Fed. Reg. 71,684. The final Rule  
 15 adopts the proposed requirements for separate billings and payments without  
 16 material change. *Id.* The agencies' stated rationale for the Double-Billing Rule is  
 17 that "HHS now believes" the Rule will "better align with congressional intent  
 18 regarding the separate payments provision of section 1303 of the PPACA." *Id.* at  
 19 71,699. The agencies did not offer any evidence for this rationale, nor did they take  
 20 the position that separate billing and separate payment transactions are *required* by  
 21 Section 1303 (only that they "better align" with the purported intent behind it).

22 The Double-Billing Rule's preamble contains a section entitled "Federalism."

1 There, the agencies recognize that there are “Federalism implications” arising from  
 2 other provisions of the Rule not at issue here. *Id.* at 71,709. In contrast, the agencies  
 3 disclaimed any federalism implications arising from the Rule’s double-billing  
 4 requirements, and declared that “[t]his final rule does not impose substantial direct  
 5 costs on state and local governments **or preempt state law.**” *Id.* (emphasis added).

6 The relevant provisions of the Double-Billing Rule are scheduled to go into  
 7 effect on June 27, 2020. 84 Fed. Reg. 71,684, 71,710, *to be codified at* 45 C.F.R.  
 8 § 156.280; *see also id.* at 71,686, 71,689–690.

### 9 III. ARGUMENT

10 The State of Washington moves for summary judgment on the single  
 11 dispositive issue of whether HHS’s Double-Billing Rule improperly preempts  
 12 Washington’s Single-Invoice Statute. As a matter of law, the Rule purports to do  
 13 what it cannot: each of the ACA’s clear non-preemption provisions forbids the result  
 14 that would occur if the Rule were to be enforced in Washington. Thus, the Rule is  
 15 contrary to law and invalid. *See* 5 U.S.C. § 706(2).

16 **A. The ACA Forbids HHS’s Double-Billing Rule from Preempting  
 17 Washington’s Single-Invoice Statute**

18 Congress’s ability to preempt state law emanates from the Supremacy Clause  
 19 of the United States Constitution. *See English v. Gen. Elec. Co.*, 496 U.S. 72, 78  
 20 (1990); U.S. Const. art. VI, cl. 2. There are three types of preemption: “(1) *express  
 21 preemption*—where Congress explicitly defines the extent to which its enactments  
 22 preempt state law; (2) *field preemption*—where state law attempts to regulate

1 conduct in a field that Congress intended the federal law exclusively to occupy; and  
 2 (3) *conflict preemption*—where it is impossible to comply with both state and federal  
 3 requirements, or where state law stands as an obstacle to the accomplishment and  
 4 execution of the full purposes and objectives of Congress.” *Williamson v. Gen.*  
 5 *Dynamics Corp.*, 208 F.3d 1144, 1149 (9th Cir. 2000) (internal quotation marks  
 6 omitted). Regardless of the type of preemption analysis, “[c]onsideration of the  
 7 issues arising under the Supremacy Clause start[s] with the assumption that the  
 8 historic police powers of the states [are] not to be superseded by . . . [a] Federal Act  
 9 unless that [is] the clear and manifest purpose of Congress.” *Id.* (internal quotation  
 10 marks omitted). Here, classic preemption analysis demonstrates that Congress  
 11 specifically intended **not** to supersede state laws such as the Single-Invoice Statute,  
 12 and the agencies cannot accomplish by rule what Congress has forbidden by statute.

13 Federal agencies may preempt state law, but only where authorized by statute.  
 14 *See, e.g.*, Exec. Order 13132 § 4 (“Agencies, in taking action that preempts State  
 15 law, shall act in strict accordance with governing law.”). Agencies “seeking to  
 16 invalidate a state law based on preemption ‘bear the considerable burden of  
 17 overcoming the starting presumption that Congress does not intend to supplant state  
 18 law.’” *Stengel v. Medronic Inc.*, 704 F.3d 1224, 1227–28 (9th Cir. 2013) (en banc)  
 19 (quoting *De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 814  
 20 (1997)). Courts must determine Congress’s intent “from the language of the pre-  
 21 emption statute and the ‘statutory framework’ surrounding it.” *Medtronic, Inc. v.*  
 22 *Lohr*, 518 U.S. 470, 486 (1996). Courts must consider the “structure and purpose of

1 the statute as a whole, . . . as revealed not only in the text, but through the reviewing  
 2 court's reasoned understanding of the way in which Congress intended the statute  
 3 and its surrounding regulatory scheme to affect business, consumers, and the law.”  
 4 *Id.* (internal quotation marks and citation omitted). Courts are cautioned to “not be  
 5 guided by a single sentence or member of a sentence, but [to] look to the provisions  
 6 of the whole law, and to its object and policy.” *Pilot Life Ins. Co. v. Dedeaux*, 481  
 7 U.S. 41, 51 (1987) (internal quotation marks and citations omitted).

8 Here, there is no need to rely on presumptions. Congress clearly defined the  
 9 preemptive force of the ACA and expressly reserved to the states their regulatory  
 10 powers. In light of this, Defendants cannot overcome their burden to show that it  
 11 was the “clear and manifest purpose of Congress” to preempt state laws like  
 12 Washington’s Single-Invoice Statute. The ACA’s multiple *non-preemption*  
 13 provisions conclusively show that Congress intended the opposite.

14 **1. Because Congress decided the ACA does not preempt state laws  
 15 regarding abortion, HHS’s preemptive rule is forbidden.**

16 “The purpose of Congress is the ultimate touchstone of pre-emption analysis.”  
 17 *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) (cleaned up). As the  
 18 Supreme Court instructs: “The case for federal pre-emption is particularly weak  
 19 where Congress has indicated its awareness of the operation of state law in a field of  
 20 federal interest, and has nonetheless decided to stand by both concepts and to tolerate  
 21 whatever tension there is between them.” *CTS Corp. v. Waldburger*, 573 U.S. 1, 18  
 22 (2014) (cleaned up).

1       Accordingly, the Supreme Court has repeatedly and consistently rejected  
 2 arguments that state law is preempted where the relevant federal statute contains a  
 3 non-preemption provision. *See Va. Uranium, Inc. v. Warren*, 139 S. Ct. 1894, 1902–  
 4 03 (2019) (statute’s “*non-preemption* clause” preserved states’ traditional regulatory  
 5 authority over mining); *Chamber of Commerce of U.S. v. Whiting*, 563 U.S. 582,  
 6 600 (2011) (under federal immigration statute that “expressly preserves” some state  
 7 powers, Arizona licensing law was “well within the confines of the authority  
 8 Congress chose to leave to the States”); *Brown v. Hotel & Rest. Emps. & Bartenders*  
 9 *Int'l Union Local 54*, 468 U.S. 491, 505–06 (1984) (statute’s “express disclaimer of  
 10 pre-emption” “preserving the operation of state laws” showed that Congress did not  
 11 “seek to impose a uniform federal standard”); *Askew v. Am. Waterways Operators,*  
 12 *Inc.*, 411 U.S. 325, 328–29 (1973) (declining to “allow federal admiralty jurisdiction  
 13 to swallow most of the police power of the States over oil spillage” where the statute  
 14 “does not preclude, but *in fact allows*, state regulation”) (emphasis added).

15       Therefore, where the governing federal statute includes a non-preemption  
 16 provision, agency rules that conflict with state law are contrary to that statute, are  
 17 invalid, and cannot be applied in the affected state. *Oregon v. Ashcroft*, 368 F.3d  
 18 1118 (9th Cir. 2004), *aff'd sub nom. Gonzales v. Oregon*, 546 U.S. 243 (2006), is  
 19 directly on point. There, the Ninth Circuit upheld a district court’s injunction  
 20 preventing the application of the U.S. Attorney General’s interpretive rule declaring  
 21 that physician-assisted suicide violates the federal Controlled Substances Act (CSA)  
 22 in a state with contrary existing law. *Oregon*, 368 F.3d at 1131. In 1994, Oregon

1 enacted its Death With Dignity Act, which authorized the use of controlled  
 2 substances for physician-assisted suicide. *Id.* at 1122. The CSA generally permits  
 3 the Attorney General to revoke a medical practitioner's federal registration upon a  
 4 finding that the practitioner improperly prescribed a controlled substance or acted  
 5 inconsistent with the public interest, but includes a non-preemption provision that  
 6 preserves state law absent a "positive conflict" with the CSA. 21 U.S.C. § 903. In  
 7 2001, Attorney General Ashcroft issued a rule interpreting the CSA to permit him to  
 8 revoke Oregon practitioners' licenses if they participated in physician-assisted  
 9 suicide using controlled substances, even though this was permitted by state law. *Id.*  
 10 at 1123. The Ninth Circuit held that "the Attorney General's expansive interpretation  
 11 of the CSA clearly conflicts with the Oregon law and therefore cannot be squared  
 12 with the CSA's non-preemption clause." *Oregon*, 368 F.3d at 1126.

13 Here, just as in *Oregon v. Ashcroft*, the Double-Billing Rule "clearly  
 14 conflicts" with Washington's Single-Invoice Statute and "cannot be squared" with  
 15 the ACA's multiple non-preemption provisions. As one court recently put it,  
 16 "Congress recognized the potential conflict between section 1303 and . . . state  
 17 statutes," but directed that "nothing in the ACA shall be construed to preempt or  
 18 effect state laws on abortion . . ." *New York v. U.S. Dep't of Health & Human*  
 19 *Servs.*, 414 F. Supp. 3d 475, 502 (S.D.N.Y. 2019). Likewise, in Section 1321,  
 20 Congress expressly decided not to preempt *any* state laws that do not directly conflict  
 21 with the text of the ACA itself. *Supra* Part II.C; *see Conway v. United States*, 145  
 22 Fed. Cl. 514, 522 (Fed. Cl. 2019) (Section 1321 prohibits preemption by agency

1 rule); *UnitedHealthcare of N.Y., Inc. v. Vullo*, 323 F. Supp. 3d 470, 481 (S.D.N.Y.  
 2 2018) (state law not preempted under Section 1321 or 42 U.S.C. § 300gg-23).<sup>2</sup>

3 Washington’s Single-Invoice Statute—which explicitly references Section  
 4 1303—is a state law “regarding” abortion coverage and funding addressed by  
 5 Section 1303’s non-preemption provision. *See Lamar, Archer & Cofrin, LLP v.*  
 6 *Appling*, 138 S. Ct. 1752, 1759–60 (2018) (the word “regarding,” like “respecting”  
 7 and “relating to,” has a “broadening effect”); *Coventry Health Care of Mo., Inc. v.*  
 8 *Neivils*, 137 S. Ct. 1190, 1197 (2017) (the phrase “relate to” in a preemption clause  
 9 should be read broadly “to reach any subject that has ‘a connection with, or reference  
 10 to,’ the topics the statute enumerates”); Wash. Rev. Code § 48.43.074(1) (expressly  
 11 referencing Section 1303); Wash. Admin. Code § 284-07-540 (same). The breadth  
 12 of Section 1303’s preemption disclaimer is further supported by its title—“No  
 13 preemption of state laws regarding abortion”—which indicates Congress’s intent to  
 14 preserve broad categories of state laws. *See United States v. Nader*, 542 F.3d 713,  
 15 717 (9th Cir. 2008) (“[t]itles are . . . an appropriate source from which to discern  
 16 legislative intent”). Likewise, as to Section 1321’s general disclaimer of preemption

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17

18 <sup>2</sup> Relatedly, other courts have rejected ACA preemption as a defense to state-  
 19 law claims on the grounds that the ACA “was not enacted to preempt state law.”  
 20 *Tex. Med. Res., LLP v. Molina Healthcare of Tex., Inc.*, 356 F. Supp. 3d 612, 617  
 21 (N.D. Tex. 2019) (preemption not “applicable”); *Desai v. CareSource, Inc.*, No.  
 22 3:18-CV-118, 2019 WL 1109568, at \*4 (S.D. Ohio Mar. 11, 2019) (same).

1 for state laws that do not conflict with the ACA, Washington’s Single-Invoice  
 2 Statute is consistent with the ACA. As HHS itself long recognized—and apparently  
 3 still recognizes—the ACA does *not* require separate bills or consumer transactions.  
 4 *See* 42 U.S.C. § 18023(b)(2)(B); 2015 Rule at 10,840; *supra* at 8. Thus, the state law  
 5 falls, almost by definition, squarely within the relevant non-preemption provisions  
 6 Congress included in the ACA.

7 It is of no moment that HHS and CMS are purporting to adopt a new  
 8 “interpretation” of Section 1303. *Oregon v. Ashcroft* teaches that an agency’s new  
 9 interpretation cannot override a statute’s express non-preemption provision. 368  
 10 F.3d at 1130; *see also Solberg v. Victim Servs., Inc.*, 415 F. Supp. 3d 935, 955 (N.D.  
 11 Cal. 2019) (arguments based on purported legislative intent “cannot override an  
 12 ‘anti-preemption provision’ . . . that embodies legislative intent”); *Conway*, 145  
 13 Fed. Cl. at 522–23 (preemptive HHS rule was not “authorize[d]” given ACA Section  
 14 1321’s non-preemption provision). Even if the agencies’ reinterpretation were one  
 15 *possible* reading of Section 1303 (despite the ACA’s non-preemption provisions),  
 16 “[w]ell-established preemption principles favor upholding state law if it can  
 17 plausibly coexist with the federal statute.” *Cal. Ins. Guar. Ass’n v. Azar*, 940 F.3d  
 18 1061, 1071 (9th Cir. 2019) (citing *Altria Grp., Inc. v. Good*, 555 U.S. 70, 77 (2008)).  
 19 The 2015 Rule and 2017 Guidance affirm that Section 1303 can—and should—be  
 20 read in perfect harmony with the Single-Invoice Statute.

21 The ACA’s non-preemption provisions are dispositive; the Rule’s purported  
 22 reinterpretation of a statutory phrase is not. An analysis of the three types of

1      preemption, discussed below, underscores that inevitable conclusion.

2      **2. Washington's statute is not expressly preempted by the ACA.**

3      Express preemption “arises when the text of a federal statute explicitly  
 4      manifests Congress’s intent to displace state law.” *Valle del Sol Inc. v. Whiting*, 732  
 5      F.3d 1006, 1022 (9th Cir. 2013) (cleaned up). Here, the ACA contains no express  
 6      preemption clause: rather, it contains multiple applicable *non-preemption* clauses.

7      **3. There is no field preemption in the ACA.**

8      “Field preemption occurs when federal law occupies a ‘field’ of regulation ‘so  
 9      comprehensively that it has left no room for supplementary state legislation.’” *Knox*  
 10     *v. Brnovich*, 907 F.3d 1167, 1174 (9th Cir. 2018) (quoting *Murphy v. Nat'l*  
 11     *Collegiate Athletic Ass'n*, 138 S. Ct. 1461, 1480 (2018)). “‘Congress must clearly  
 12     manifest an intention to ‘enter and completely absorb the field’ in order to preclude  
 13     state regulation in that field[.]’” *Id.* (quoting *Ry. Mail Ass'n v. Corsi*, 326 U.S. 88, 97  
 14     (1945)). “Where, as here, the field . . . has been traditionally occupied by the States,  
 15     we start with the assumption that the historic police powers of the States were not to  
 16     be superseded by the Federal Act unless that was the clear and manifest purpose of  
 17     Congress.” *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 116 (1992).

18      Here, again, Congress “clearly manifest[ed]” its intention *not* to preempt state  
 19      law through the ACA’s non-preemption provisions. *Cf. Palmer v. Sprint Nextel*  
 20      *Corp.*, 674 F. Supp. 2d 1224, 1229 (W.D. Wash. 2009) (non-preemption clause  
 21      made it “clear that Congress anticipated continuing state involvement . . . and that  
 22      Congress did not intend to occupy the field”). This Court should join those that have

1     considered and rejected field preemption arguments based on the ACA. *See Conway*,  
 2     145 Fed. Cl. at 522; *Vullo*, 323 F. Supp. 3d at 481.

3     **4. There is no conflict preemption because Washington's Single-  
 4       Invoice Statute is consistent with the ACA.**

5     Conflict preemption occurs when state law “stands as an obstacle to the  
 6     accomplishment and execution of the full purposes and objectives of Congress,’ or  
 7     when it ‘interferes with the methods by which the federal statute was designed to  
 8     reach [its] goal.’” *Arellano v. Clark Cty. Collection Serv., LLC*, 875 F.3d 1213, 1216  
 9     (9th Cir. 2017) (internal citations omitted). Where, as here, “Congress has made its  
 10    intent known through explicit statutory language, the courts’ task is ‘an easy one’  
 11    and largely a matter of statutory interpretation.” *Palmer*, 674 F. Supp. 2d at 1230  
 12    (citing *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990)).

13    Here, there can be no “implied” preemption because no party appears to  
 14    contend that Section 1303 *requires* separate billing, and the ACA’s *express non-*  
 15    *preemption* provisions are dispositive. *Supra* Part III.A.1. These provisions  
 16    appropriately reflect longstanding principles of federalism respecting the states’  
 17    historical prerogative to regulate matters of health, safety, and consumer protection.  
 18    *See Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 536 (2012) (“[T]he facets  
 19    of governing that touch on citizens’ daily lives are normally administered by smaller  
 20    governments closer to the governed.”); *Medtronic*, 518 U.S. 485 (noting the  
 21    “historic primacy of state regulation of matters of health and safety”); *Oregon*, 368  
 22    F.3d at 1125 (federal preemption is improper in “an area of law traditionally reserved

1 for state authority” absent Congress’s “unmistakably clear” authorization).. In  
 2 particular, “state laws enacted for the purpose of regulating the business of insurance  
 3 do not yield to conflicting federal statutes unless a federal statute specifically  
 4 requires otherwise.” *U.S. Dep’t of Treasury v. Fabe*, 508 U.S. 491, 507 (1993)  
 5 (internal quotation marks omitted). In other regulations governing QHPs under the  
 6 ACA, Defendants themselves recognize that “[s]tates are the primary regulators of  
 7 their insurance markets.” 83 Fed. Reg. 16,956 (Apr. 17, 2018). In enacting the ACA,  
 8 Congress properly left states like Washington free to regulate the health insurance  
 9 industry to protect consumers and the public, while ensuring compliance with federal  
 10 law, as the Single-Invoice Statute does.

11       Indeed, HHS has *acknowledged* these federalism limitations and *disclaimed*  
 12 any preemption of state law.<sup>3</sup> The “Federalism” section of the Double-Billing Rule’s  
 13 preamble states that “[i]t]his final rule does not . . . preempt state law.” 84 Fed. Reg.  
 14 71,709 (emphasis added). The preamble also states that the Rule’s changes “**do not**  
 15 **preempt state law regarding coverage of non-Hyde abortion services** or otherwise

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17       <sup>3</sup> Any reversal of HHS’s disclaimer of preemption would be procedurally  
 18 improper: if it intended its Rule to preempt state law, HHS was required to (but did  
 19 not) follow “Special Requirements for Preemption,” including providing notice of  
 20 the proposal to preempt state law and consulting with affected state officials “in an  
 21 effort to avoid such a conflict.” Exec. Order 13132 § 4; *see Washington v. Geo Grp.,*  
 22 *Inc.*, 283 F. Supp. 3d 967, 977 (W.D. Wash. 2017).

1 coerce states into changing these laws . . . .” 84 Fed. Reg. 71,709 (emphasis added).  
 2 These statements indicate a clear intention to avoid any implication that the agency  
 3 is attempting to preempt state law through its rulemaking. *See Hillsborough County*  
 4 *v. Automated Med. Labs., Inc.*, 471 U.S. 707, 714–15 (1985) (FDA’s statement that  
 5 particular regulations did not preempt state law was “dispositive on the question of  
 6 implicit intent to pre-empt unless either the agency’s position is inconsistent with  
 7 clearly expressed congressional intent, or subsequent developments reveal a change  
 8 in that position”). The Court should take HHS at its word and declare that the  
 9 Double-Billing Rule does not preempt Washington’s Single-Invoice Statute.

10 Furthermore, the Single-Invoice Statute does not pose any obstacle to  
 11 Congress’s objectives in Section 1303. As the statute’s plain text and structure  
 12 indicate, Section 1303 effectuates a “Prohibition on the use of Federal funds” for  
 13 non-federally-fundable abortions. 42 U.S.C. § 18023(b)(2); *see Univ. of Texas Sw.*  
 14 *Med. Ctr. v. Nassar*, 570 U.S. 338, 353–54 (2013) (Congress’s “structural choices”  
 15 are “presumed to be deliberate”). In particular, subsection (A) describes the  
 16 underlying principle (i.e., federal subsidies should not be used to pay for abortion  
 17 services covered by a QHP), while subsections (B) and (C) describe how to  
 18 implement that principle (i.e., issuers must establish allocation accounts and  
 19 segregate funds into those accounts to ensure they remain separate). Subsection (E)  
 20 emphasizes that state health insurance commissioners shall ensure compliance with  
 21 these “segregation requirements” through the “segregation of plan funds . . . .” There  
 22 is no dispute that Washington complies with these funding segregation requirements.

1 | *See Wash. Rev. Code § 48.43.074; Wash. Admin. Code § 284-07-540.*

2 | Washington's Single-Invoice Statute differs not from the ACA, but from a  
 3 | new *regulation* that itself violates the ACA. HHS is not authorized to unilaterally  
 4 | rescind traditional state powers—in fact, the ACA expressly forbids this. The Court  
 5 | should find that the Double-Billing Rule is unlawful at least to the extent it would  
 6 | preempt Washington's Single-Invoice Statute.

7 | **B. The Court Should Invalidate the Double-Billing Rule, or at Least  
 8 | Prohibit Its Enforcement in Washington**

9 | The Double-Billing Rule does not and cannot preempt the Single-Invoice  
 10 | Statute. Accordingly, the Court should rule in favor of the State on Counts I and II  
 11 | and find the Rule's relevant provisions contrary to law under 5 U.S.C. § 706(2). The  
 12 | “normal remedy” for such unlawful agency action is *vacatur*. *Allina Health Servs. v.*  
 13 | *Sebelius*, 746 F.3d 1102, 1110 (D.C. Cir. 2014). Alternatively, the Court may  
 14 | exercise its equitable discretion to craft a narrower remedy in the form of a  
 15 | declaration that the Rule has no force or effect in Washington to the extent it  
 16 | unlawfully purports to preempt Washington's Single-Invoice Statute. *See* 5 U.S.C.  
 17 | § 703; *cf. Oregon*, 368 F.3d at 1131 (affirming grant of state-specific injunction  
 18 | against preemptive federal rule). Either way, the Court may enter a final judgment  
 19 | on this issue without reaching Counts III–VII. *See* Fed. R. Civ. P. 54(b).

20 | **IV. CONCLUSION**

21 | For the foregoing reasons, the State respectfully requests that this Court grant  
 22 | summary judgment in its favor on Counts I and II of its Complaint.

1 DATED this 6th day of March, 2020.  
2  
3

4 ROBERT W. FERGUSON  
5 Attorney General  
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**CERTIFICATE OF SERVICE**

I hereby certify that on this day true copies of the foregoing document were electronically filed with the Clerk of the Court using the CM/ECF System, which in turn automatically generated a Notice of Electronic Filing (NEF) to all parties in the case who are registered users of the CM/ECF system.

DATED this 6th day of March, 2020, at Seattle, Washington.

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## Appendix of Selected Statutes and Regulatory Provisions

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## 42 U.S.C. § 18023 (Section 1303)

 KeyCite Yellow Flag - Negative Treatment

Unconstitutional or PreemptedNegative Treatment Reconsidered by [Florida ex rel. Atty. Gen. v. U.S. Dept. of Health and Human Services](#), 11th Cir.(Fla.), Aug. 12, 2011

 KeyCite Yellow Flag - Negative TreatmentProposed Legislation

## United States Code Annotated

### Title 42. The Public Health and Welfare

#### Chapter 157. Quality Affordable Health Care for All Americans

##### Subchapter III. Available Coverage Choices for All Americans

###### Part A. Establishment of Qualified Health Plans

42 U.S.C.A. § 18023

§ 18023. Special rules

Effective: March 23, 2010

[Currentness](#)

#### **(a) State opt-out of abortion coverage**

##### **(1) In general**

A State may elect to prohibit abortion coverage in qualified health plans offered through an Exchange in such State if such State enacts a law to provide for such prohibition.

##### **(2) Termination of opt out**

A State may repeal a law described in paragraph (1) and provide for the offering of such services through the Exchange.

#### **(b) Special rules relating to coverage of abortion services**

##### **(1) Voluntary choice of coverage of abortion services**

###### **(A) In general**

Notwithstanding any other provision of this title (or any amendment made by this title)--

**(i)** nothing in this title (or any amendment made by this title), shall be construed to require a qualified health plan to provide coverage of services described in subparagraph (B)(i) or (B)(ii) as part of its essential health benefits for any plan year; and

**(ii)** subject to subsection (a), the issuer of a qualified health plan shall determine whether or not the plan provides coverage of services described in subparagraph (B)(i) or (B)(ii) as part of such benefits for the plan year.

**(B) Abortion services**

**(i) Abortions for which public funding is prohibited**

The services described in this clause are abortions for which the expenditure of Federal funds appropriated for the Department of Health and Human Services is not permitted, based on the law as in effect as of the date that is 6 months before the beginning of the plan year involved.

**(ii) Abortions for which public funding is allowed**

The services described in this clause are abortions for which the expenditure of Federal funds appropriated for the Department of Health and Human Services is permitted, based on the law as in effect as of the date that is 6 months before the beginning of the plan year involved.

**(2) Prohibition on the use of Federal funds**

**(A) In general**

If a qualified health plan provides coverage of services described in paragraph (1)(B)(i), the issuer of the plan shall not use any amount attributable to any of the following for purposes of paying for such services:

**(i)** The credit under [section 36B of Title 26](#) (and the amount (if any) of the advance payment of the credit under [section 18082](#) of this title).

**(ii)** Any cost-sharing reduction under [section 18071](#) of this title (and the amount (if any) of the advance payment of the reduction under [section 18082](#) of this title).

**(B) Establishment of allocation accounts**

In the case of a plan to which subparagraph (A) applies, the issuer of the plan shall--

**(i)** collect from each enrollee in the plan (without regard to the enrollee's age, sex, or family status) a separate payment for each of the following:

**(I)** an amount equal to the portion of the premium to be paid directly by the enrollee for coverage under the plan of services other than services described in paragraph (1)(B)(i) (after reduction for credits and cost-sharing reductions described in subparagraph (A)); and

**(II)** an amount equal to the actuarial value of the coverage of services described in paragraph (1)(B)(i), and

(ii) shall<sup>1</sup> deposit all such separate payments into separate allocation accounts as provided in subparagraph (C).

In the case of an enrollee whose premium for coverage under the plan is paid through employee payroll deposit, the separate payments required under this subparagraph shall each be paid by a separate deposit.

**(C) Segregation of funds**

**(i) In general**

The issuer of a plan to which subparagraph (A) applies shall establish allocation accounts described in clause (ii) for enrollees receiving amounts described in subparagraph (A).

**(ii) Allocation accounts**

The issuer of a plan to which subparagraph (A) applies shall deposit--

(I) all payments described in subparagraph (B)(i)(I) into a separate account that consists solely of such payments and that is used exclusively to pay for services other than services described in paragraph (1)(B)(i); and

(II) all payments described in subparagraph (B)(i)(II) into a separate account that consists solely of such payments and that is used exclusively to pay for services described in paragraph (1)(B)(i).

**(D) Actuarial value**

**(i) In general**

The issuer of a qualified health plan shall estimate the basic per enrollee, per month cost, determined on an average actuarial basis, for including coverage under the qualified health plan of the services described in paragraph (1)(B)(i).

**(ii) Considerations**

In making such estimate, the issuer--

(I) 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;

(II) shall estimate such costs as if such coverage were included for the entire population covered; and

(III) may not estimate such a cost at less than \$1 per enrollee, per month.

**(E) Ensuring compliance with segregation requirements**

**(i) In general**

Subject to clause (ii), State health insurance commissioners shall ensure that health plans comply with the segregation requirements in this subsection through the segregation of plan funds in accordance with applicable provisions of generally accepted accounting requirements, circulars on funds management of the Office of Management and Budget, and guidance on accounting of the Government Accountability Office.

**(ii) Clarification**

Nothing in clause (i) shall prohibit the right of an individual or health plan to appeal such action in courts of competent jurisdiction.

**(3) Rules relating to notice**

**(A) Notice**

A qualified health plan that provides for coverage of the services described in paragraph (1)(B)(i) 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.

**(B) Rules relating to payments**

The notice described in subparagraph (A), any advertising used by the issuer with respect to the plan, any information provided by the Exchange, and any other information specified by the Secretary shall provide information only with respect to the total amount of the combined payments for services described in paragraph (1)(B)(i) and other services covered by the plan.

**(4) No discrimination on basis of provision of abortion**

No qualified health plan offered through an Exchange may discriminate against any individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions<sup>2</sup>

**(c) Application of State and Federal laws regarding abortion**

**(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 an abortion on a minor.

**(2) No effect on Federal laws regarding abortion**

**(A)<sup>3</sup> In general**

Nothing in this Act shall be construed to have any effect on Federal laws regarding--

- (i)** conscience protection;
- (ii)** willingness or refusal to provide abortion; and
- (iii)** discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion.

**(3) No effect on Federal civil rights law**

Nothing in this subsection shall alter the rights and obligations of employees and employers under title VII of the Civil Rights Act of 1964.

**(d) Application of emergency services laws**

Nothing in this Act shall be construed to relieve any health care provider from providing emergency services as required by State or Federal law, including section 1867 of the Social Security Act (popularly known as “EMTALA”).

**CREDIT(S)**

(Pub.L. 111-148, Title I, § 1303, Title X, § 10104(c), Mar. 23, 2010, 124 Stat. 168, 896.)

**EXECUTIVE ORDERS**

**EXECUTIVE ORDER NO. 13535**

<March 24, 2010, 75 F.R. 15599>

**ENSURING ENFORCEMENT AND IMPLEMENTATION OF ABORTION  
RESTRICTIONS IN THE PATIENT PROTECTION AND AFFORDABLE CARE ACT**

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the “Patient Protection and Affordable Care Act” (Public Law 111-148), I hereby order as follows:

**Section. 1. Policy.** Following the recent enactment of the Patient Protection and Affordable Care Act (the “Act”), it is necessary to establish an adequate enforcement mechanism to ensure that Federal funds are not used for abortion services (except in cases of rape or incest, or when the life of the woman would be endangered), consistent with a longstanding Federal statutory restriction that is commonly known as the Hyde Amendment. The purpose of this order is to establish a comprehensive, Government-wide set of policies and procedures to achieve this goal and to make certain that all relevant actors--Federal officials, State officials (including insurance regulators) and health care providers--are aware of their responsibilities, new and old.

The Act maintains current Hyde Amendment restrictions governing abortion policy and extends those restrictions to the newly created health insurance exchanges. Under the Act, longstanding Federal laws to protect conscience (such as the Church Amendment, [42 U.S.C. 300a-7](#), and the Weldon Amendment, section 508(d)(1) of Public Law 111-8) remain intact and new protections prohibit discrimination against health care facilities and health care providers because of an unwillingness to provide, pay for, provide coverage of, or refer for abortions.

Numerous executive agencies have a role in ensuring that these restrictions are enforced, including the Department of Health and Human Services (HHS), the Office of Management and Budget (OMB), and the Office of Personnel Management.

**Sec. 2. Strict Compliance with Prohibitions on Abortion Funding in Health Insurance Exchanges.** The Act specifically prohibits the use of tax credits and cost-sharing reduction payments to pay for abortion services (except in cases of rape or incest, or when the life of the woman would be endangered) in the health insurance exchanges that will be operational in 2014. The Act also imposes strict payment and accounting requirements to ensure that Federal funds are not used for abortion services in exchange plans (except in cases of rape or incest, or when the life of the woman would be endangered) and requires State health insurance commissioners to ensure that exchange plan funds are segregated by insurance companies in accordance with generally accepted accounting principles, OMB funds management circulars, and accounting guidance provided by the Government Accountability Office.

I hereby direct the Director of the OMB and the Secretary of HHS to develop, within 180 days of the date of this order, a model set of segregation guidelines for State health insurance commissioners to use when determining whether exchange plans are complying with the Act's segregation requirements, established in section 1303 of the Act, for enrollees receiving Federal financial assistance. The guidelines shall also offer technical information that States should follow to conduct independent regular audits of insurance companies that participate in the health insurance exchanges. In developing these model guidelines, the Director of the OMB and the Secretary of HHS shall consult with executive agencies and offices that have relevant expertise in accounting principles, including, but not limited to, the Department of the Treasury, and with the Government Accountability Office. Upon completion of those model guidelines, the Secretary of HHS should promptly initiate a rulemaking to issue regulations, which will have the force of law, to interpret the Act's segregation requirements, and shall provide guidance to State health insurance commissioners on how to comply with the model guidelines.

**Sec. 3. Community Health Center Program.** The Act establishes a new Community Health Center (CHC) Fund within HHS, which provides additional Federal funds for the community health center program. Existing law prohibits these centers from using Federal funds to provide abortion services (except in cases of rape or incest, or when the life of the woman would be endangered), as a result of both the Hyde Amendment and longstanding regulations containing the Hyde language. Under the Act, the Hyde language shall apply to the authorization and appropriations of funds for Community Health Centers under section 10503 and all other relevant provisions. I hereby direct the Secretary of HHS to ensure that program administrators and recipients of Federal funds are aware of and comply with the limitations on abortion services imposed on CHCs by existing law. Such actions should include, but are not limited to, updating Grant Policy Statements that accompany CHC grants and issuing new interpretive rules.

**Sec. 4. General Provisions.** **(a)** Nothing in this order shall be construed to impair or otherwise affect: (i) authority granted by law or Presidential directive to an agency, or the head thereof, or (ii) functions of the Director of the OMB relating to budgetary, administrative, or legislative proposals.

**(b)** This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

**(c)** This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees or agents, or any other person.

BARACK OBAMA

Notes of Decisions (2)

Footnotes

1 So in original. The word “shall” probably should not appear.

2 So in original. Probably should be followed by a period.

3 So in original. No subparagraph (B) enacted.

42 U.S.C.A. § 18023, 42 USCA § 18023

Current through P.L. 116-91. Some statute sections may be more current, see credits for details.

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## 42 U.S.C. §18041 (Section 1321)

 KeyCite Yellow Flag - Negative Treatment

Unconstitutional or PreemptedNegative Treatment Reconsidered by [Florida ex rel. Atty. Gen. v. U.S. Dept. of Health and Human Services](#), 11th Cir.(Fla.), Aug. 12, 2011

 KeyCite Yellow Flag - Negative TreatmentProposed Legislation

## United States Code Annotated

### Title 42. The Public Health and Welfare

#### Chapter 157. Quality Affordable Health Care for All Americans

##### Subchapter III. Available Coverage Choices for All Americans

###### Part C. State Flexibility Relating to Exchanges

42 U.S.C.A. § 18041

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

Effective: March 23, 2010

[Currentness](#)

#### **(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, and the amendments made by this title, 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.

##### **(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) of the Public Health Services <sup>1</sup> Act 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).

**(d) No interference with 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.

**(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.

**CREDIT(S)**

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

**Notes of Decisions (13)**

**Footnotes**

<sup>1</sup> So in original. Probably should be “Service”.

42 U.S.C.A. § 18041, 42 USCA § 18041

Current through P.L. 116-91. Some statute sections may be more current, see credits for details.

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## **Wash. Rev. Code § 48.43.074 (Single-Invoice Statute)**

West's Revised Code of Washington Annotated  
Title 48. Insurance (Refs & Annos)  
Chapter 48.43. Insurance Reform (Refs & Annos)

West's RCWA 48.43.074

48.43.074. Qualified health plans--Single invoice billing--Certification of compliance required in the segregation plan for premium amounts attributable to coverage of abortion services

Effective: May 13, 2019  
Currentness

(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. Washington has achieved full compliance with section 1303 of the federal patient protection and affordable care act <sup>1</sup> 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.

**Credits**

[2019 c 399 § 5, eff. May 13, 2019.]

**OFFICIAL NOTES**

**Effective date--2019 c 399 § 5:** "Section 5 of this act is necessary for the immediate preservation of the public peace, health, or safety, or support of the state government and its existing public institutions, and takes effect immediately [May 13, 2019]." [2019 c 399 § 10.]

**Findings--Short title--2019 c 399:** See notes following [RCW 74.09.875](#).

**Recommendations--Preexposure and postexposure prophylaxis financial support awareness--2019 c 399:** See note following [RCW 48.43.072](#).

<(Formerly: Certified Health Plans)>

Footnotes

<sup>1</sup> 42 USCA § 18023

West's RCWA 48.43.074, WA ST 48.43.074

Current with Chapter 2 of the 2020 Regular Session of the Washington Legislature.

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*Patient Protection and Affordable Care Act:  
HHS Notice of Benefit and Payment Parameters  
for 2016, 80 Fed. Reg. 10,750-51, 10,840-41  
(Feb. 27, 2015) (relevant excerpts) (2015 Rule)*



# FEDERAL REGISTER

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## Part II

### Department of Health and Human Services

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45 CFR Parts 144, 147, 153, et al.

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016; Final Rule

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****45 CFR Parts 144, 147, 153, 154, 155, 156 and 158**

[CMS-9944-F]

RIN 0938-AS19

**Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016****AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Final rule.

**SUMMARY:** This final rule sets forth payment parameters and provisions related to the risk adjustment, reinsurance, and risk corridors programs; cost sharing parameters and cost-sharing reductions; and user fees for Federally-facilitated Exchanges. It also finalizes additional standards for the individual market annual open enrollment period for the 2016 benefit year, essential health benefits, qualified health plans, network adequacy, quality improvement strategies, the Small Business Health Options Program, guaranteed availability, guaranteed renewability, minimum essential coverage, the rate review program, the medical loss ratio program, and other related topics.

**DATES:** These regulations are effective on April 28, 2015 except the amendments to §§ 156.235, 156.285(d)(1)(ii), and 158.162 are effective on January 1, 2016.

**FOR FURTHER INFORMATION CONTACT:**

For general information: Jeff Wu, (301) 492-4305.

For matters related to guaranteed availability, guaranteed renewability, rate review, or the applicability of Title I of the Affordable Care Act in the U.S. Territories: Jacob Ackerman, (301) 492-4179.

For matters related to risk adjustment or the methodology for determining the reinsurance contribution rate and payment parameters: Kelly Horney, (410) 786-0558.

For matters related to reinsurance generally, distributed data collection good faith compliance policy, or administrative appeals: Adrienne Glasgow, (410) 786-0686.

For matters related to the definition of common ownership for purposes of reinsurance contributions: Adam Shaw, (410) 786-1019.

For matters related to risk corridors: Jaya Ghildiyal, (301) 492-5149.

For matters related to essential health benefits, network adequacy, essential community providers, or other

standards for QHP issuers: Leigha Basini, (301) 492-4380.

For matters related to the qualified health plan good faith compliance policy: Cindy Yen, (301) 492-5142.

For matters related to the Small Business Health Options Program: Christelle Jang, (410) 786-8438.

For matters related to the Federally-facilitated Exchange user fee or minimum value: Krutika Amin, (301) 492-5153.

For matters related to cost-sharing reductions or the premium adjustment percentage: Pat Meisol, (410) 786-1917.

For matters related to re-enrollment, open enrollment periods, or exemptions from the individual shared responsibility payment: Christine Hammer, (301) 492-4431.

For matters related to special enrollment periods: Rachel Arguello, (301) 492-4263.

For matters related to minimum essential coverage: Cam Moultrie Clemmons, (206) 615-2338.

For matters related to quality improvement strategies: Marsha Smith, (410) 786-6614.

For matters related to the medical loss ratio program: Julie McCune, (301) 492-4196.

For matters related to meaningful access to QHP information, consumer assistance tools and programs of an Exchange, or cost-sharing reduction notices: Tricia Beckmann, (301) 492-4328.

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## Acronyms

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

AHFS American hospital formulary system

AV Actuarial value

CFR Code of Federal Regulations

CMS Centers for Medicare & Medicaid Services

COBRA Consolidated Omnibus Budget Reconciliation Act of 1985 (Pub. L. 99–272) (29 U.S.C. 1161, *et seq.*)

ECP Essential community provider

EHB Essential health benefits

ERISA Employee Retirement Income Security Act of 1974 (Pub. L. 93–406)

FFE Federally-facilitated Exchange

FF–SHOP Federally-facilitated Small Business Health Options Program

FPL Federal Poverty Level

FQHC Federally qualified health center

HCC Hierarchical condition category

HHS United States Department of Health and Human Services

HIPAA Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191)

IRS Internal Revenue Service

LEP Limited English proficient/proficiency

MLR Medical loss ratio

MV Minimum value

NAIC National Association of Insurance Commissioners

OMB Office of Management and Budget

OPM United States Office of Personnel Management

PHS Act Public Health Service Act

PRA Paperwork Reduction Act of 1995

P&T committee Pharmacy and therapeutics committee

QHP Qualified health plan

QIS Quality improvement strategy

SADP Stand-alone Dental Plan

SEP Special enrollment period

SHOP Small Business Health Options Program

The Code Internal Revenue Code of 1986

TPA Third-party administrator

URL Uniform resource locator

USP United States Pharmacopeia

## I. Executive Summary

Qualified individuals and qualified employers are now able to purchase private health insurance coverage through competitive marketplaces called Affordable Insurance Exchanges, or “Exchanges” (also called Health Insurance Marketplaces, or “Marketplaces”). Individuals who enroll in qualified health plans (QHPs) through individual market Exchanges may be eligible to receive a premium tax credit to make health insurance more affordable and for cost-sharing reductions to reduce out-of-pocket expenses for health care services. Additionally, in 2014, HHS began operationalizing the premium stabilization programs established by the Affordable Care Act. These programs—the risk adjustment, reinsurance, and risk corridors programs—are intended to mitigate the potential impact of adverse selection and stabilize the price of health insurance in the individual and small group markets. These programs, together with other reforms of the Affordable Care Act, are making high-quality health insurance affordable and accessible to millions of Americans.

We have previously outlined the major provisions and parameters related to the advance payments of the premium tax credit, cost-sharing reductions, and premium stabilization programs. This rule finalizes additional

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).<sup>70</sup> 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

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.

<sup>70</sup>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).

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-exceptioned 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-exceptioned 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-exceptioned 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-exceptioned abortion services on the monthly premium bill to comply with the separate payment requirement. A consumer may pay the premium payment for non-exceptioned 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

per enrollee, per month cost, determined on an average actuarial basis, for including coverage of non-exceptioned abortion services. In making this estimate, a QHP issuer may not estimate the basic cost of coverage for non-exceptioned 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-exceptioned abortion services.

*Comment:* Some commenters supported enrollees paying premiums in one single transaction for both non-exceptioned 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-exceptioned 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-exceptioned 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.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES  
 Centers for Medicare & Medicaid Services  
 Center for Consumer Information and Insurance Oversight  
 200 Independence Avenue SW  
 Washington, DC 20201




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**Date:** October 6, 2017

**From:** Randy Pate, Director, Center for Consumer Information and Insurance Oversight

**Subject:** CMS Bulletin Addressing Enforcement of Section 1303 of the Patient Protection and Affordable Care Act

Since inception, section 1303 of the Patient Protection and Affordable Care Act (PPACA) has applied certain prohibitions, restrictions, and requirements with respect to coverage of certain abortion services by qualified health plans (QHPs) offered through the individual market Exchanges. Section 1303 prohibits the use of certain Federal funds to pay for coverage by QHPs of abortions for which payment would not be permitted under the Hyde Amendment. Thus, QHP issuers may not use premium tax credits or cost-sharing reductions (CSRs) to pay for such abortion services. In addition, if the QHP includes coverage of such abortion services, issuers must provide notice of such coverage. Section 1303 also requires issuers to charge and collect at least \$1 per enrollee per month for coverage of such abortion services, deposit the collected funds into a separate account, maintain the segregation of such funds, and use only such funds to pay for such abortions. Failure to adhere to these requirements could result in decertification or civil monetary penalties. This Bulletin discusses these restrictions in greater detail and sets forth guidance for how these restrictions are to be enforced beginning in plan year 2018.

## I. Background and Purpose

Every year since 1976, Congress has included a provision known as the Hyde Amendment in annual appropriations legislation, which funds the activities and services provided by the U.S. Department of Health and Human Services (HHS), including the activities and services provided by the Centers for Medicare & Medicaid Services (CMS). The Hyde Amendment as currently in effect prohibits taxpayer funding for abortion, except for pregnancies that are the result of rape or incest, or if a woman suffers from a life-threatening physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself, as certified by a physician. Similarly, section 1303 of the PPACA explicitly prohibits issuers from using any portion of premium tax credits or CSR payments, to pay for coverage for abortions that do not fall under a Hyde exception (non-Hyde abortions).<sup>1</sup> A 2014

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<sup>1</sup> Section 1303(b)(2)(A) of PPACA, Pub. L. 111-148, as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. 111-152, 42 U.S.C. § 18023(b)(2)(A).

U.S. Government Accountability Office (GAO) report (2014 GAO Report) identified issues related to section 1303 compliance with respect to certain issuers.<sup>2</sup>

Section 1303 of the PPACA also requires QHP issuers to take specific steps to prevent use of certain Federal taxpayer funds for non-Hyde abortion services. First, QHP issuers must provide notice to enrollees if non-Hyde abortions are covered by their QHP. The statute requires that this notice be provided as part of the summary of benefits and coverage explanation at the time of enrollment.<sup>3</sup> QHP issuers may, if they so choose, provide consumers with additional notice. Similarly, the Exchanges may provide notice to consumers on whether QHPs provide such coverage at earlier points during the QHP selection process.

Second, QHP issuers must determine the amount of, and collect from enrollees, a separate payment that equals the cost, determined on an average actuarial basis, for covering non-Hyde abortion services.<sup>4</sup> However, section 1303 requires that such payment must be at least \$1 per enrollee per month. Where premiums are paid through employee payroll deposit, the statute provides that separate payment must be made by a separate deposit.<sup>5</sup>

Finally, pursuant to section 1303(b)(2)(C) of the PPACA, QHP issuers must segregate funds for non-Hyde abortion services collected from enrollees into a separate allocation account that is to be used exclusively to pay for non-Hyde abortions. Thus, if an 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.

Despite the clear statutory requirements, the following information indicates that compliance with, and enforcement of, section 1303 has been inconsistent. The above-referenced 2014 GAO Report suggests that many QHP issuers are not following the requirements of section 1303.<sup>6</sup> Of the 18 QHP issuers surveyed for the 2014 GAO Report that covered non-Hyde abortion services,<sup>7</sup> four failed to provide notice to enrollees that such abortion services were included in the QHPs they sold.<sup>8</sup> Two of the eighteen QHP issuers charged less than the statutorily required minimum of \$1 per enrollee per month for coverage of non-Hyde abortion services.<sup>9</sup> Finally, seventeen of the eighteen QHP issuers surveyed failed to satisfy the requirement for collecting separate payments, even though CMS had provided informal guidance allowing issuers to send enrollees an invoice that separately itemizes the premium amount for non-Hyde abortion services or to bill separately for such services.<sup>10</sup> Subsequent to the 2014 GAO Report, CMS issued guidance reiterating QHP issuers' legal obligation to charge no less than \$1 per enrollee per

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<sup>2</sup> 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>.

<sup>3</sup> PPACA section 1303(b)(3)(A)

<sup>4</sup> PPACA section 1303(b)(2)(D); PPACA section 1303(b)(2)(b)(i)(II)

<sup>5</sup> PPACA section 1303(b)(2)(B)

<sup>6</sup> See, e.g., 2014 GAO Study at 3.

<sup>7</sup> At the time of the GAO Study, these issuers operated in the 28 States that had no laws restricting non-Hyde abortion services and accounted for approximately 25 percent of QHPs that covered non-Hyde abortion services within these 28 States. GAO Study at 3.

<sup>8</sup> 2014 GAO Report at 8.

<sup>9</sup> 2014 GAO Report at 7.

<sup>10</sup> 2014 GAO Report at 7.

month for non-Hyde abortion services, for QHPs that cover such services.<sup>11</sup> CMS has also issued guidance that a single notice itemizing the separate amounts collected with each premium payment for non-Hyde abortion services and for all other covered services, could satisfy the separate payment requirement.<sup>12</sup>

## II. Guidance

Here, CMS reminds QHP issuers of their obligation to comply with section 1303. Issuers must be able to demonstrate compliance with the following:

- Issuers may not seek premium tax credit payments for coverage of non-Hyde abortion services.<sup>13</sup>
- Issuers may not seek reimbursement for CSRs for non-Hyde abortion services.<sup>14</sup>
- Issuers must provide an annual notice in the summary of benefits and coverage that describes whether non-Hyde abortion services are covered by the QHP.<sup>15</sup>
- Issuers must charge and collect no less than \$1 per enrollee per month for coverage of non-Hyde abortion services, and deposit such amounts collected into a separate allocation account that is used exclusively to cover non-Hyde abortions. To demonstrate compliance with the requirement to collect a separate payment, issuers should provide enrollees with notice stating that a portion of the total premium amount owed is a separate payment for non-Hyde abortion services (e.g., providing the enrollee with such a notice at the time of enrollment, on a monthly invoice that itemizes the premium charge for coverage of non-Hyde abortion services, or a separate monthly bill for such coverage).

Where we are charged with directly enforcing these statutory requirements in the FFEs, we intend to do so fully, beginning with the 2018 plan year and later years, and call upon States that operate their own Exchanges to do so as well. To the extent such a State operating its own Exchange fails to substantially enforce these requirements, CMS would expect to enforce them in the State's place. Failure to comply with these requirements could result in civil monetary penalties beginning in the 2018 plan year. The PPACA clearly says that issuers are subject to these restrictions with respect to the abortion coverage at issue. Regulations implementing Section 1303 that were promulgated in 2012 also reiterated the statutory requirements. Accordingly, issuers have had ample time and notice to bring their operations into compliance with Section 1303 and its implementing regulations.

We are also in the process of evaluating whether there are additional steps that we should take to ensure compliance with the requirements of section 1303 and its implementing regulations, including reevaluating the guidance issued in 80 Fed. Reg. 10750, 10840-41. Additionally, we are exploring options for the Federally-facilitated Exchanges to provide more meaningful notice to consumers at the point of sale, beyond the summary of benefits and coverage, such as more

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<sup>11</sup> 80 F.R. 10750, 10840-41 (Feb. 27, 2015).

<sup>12</sup> 80 F.R. 10750, 10840-41 (Feb. 27, 2015).

<sup>13</sup> PPACA section 1303(b)(2)(A)(i)

<sup>14</sup> PPACA section 1303(b)(2)(A)(ii)

<sup>15</sup> PPACA section 1303(b)(3)(A), 45 C.F.R. §156.280(f)(1)

prominently displaying whether a plan includes non-Hyde abortion services on HealthCare.gov. We welcome comments on these subjects.

### **III. Where to Get More Information**

If you have any questions regarding this guidance, please e-mail [marketreform@cms.hhs.gov](mailto:marketreform@cms.hhs.gov).

*Patient Protection and Affordable Care Act:  
Exchange Program Integrity, Proposed Rule, 83  
Fed. Reg. 56,015 (Nov. 9, 2018) (Proposed  
Rule)*

Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and

- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

#### List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by Reference, Intergovernmental relations, Reporting and recordkeeping requirements, Sulfur oxides.

**Authority:** 42 U.S.C. 7401 *et seq.*

Dated: November 1, 2018.

**Onis "Trey" Glenn, III,**  
Regional Administrator, Region 4.

[FR Doc. 2018-24582 Filed 11-8-18; 8:45 am]

**BILLING CODE 6560-50-P**

#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 60

[EPA-HQ-OAR-2018-0696; FRL-9986-28-OAR]

**RIN 2060-AU33**

#### Adopting Subpart Ba Requirements in Emission Guidelines for Municipal Solid Waste Landfills; Correction

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule; correction.

**SUMMARY:** This document corrects the preamble to a proposed rule published in the **Federal Register** on October 30, 2018, regarding the implementing regulations that govern the Emission Guidelines for Municipal Solid Waste (MSW) Landfills. The listed docket number in that preamble was incorrect. Any comments received prior to this correction have been redirected to the correct docket.

**DATES:** *Comments.* Comments must be received on or before December 14, 2018.

**FOR FURTHER INFORMATION CONTACT:** For questions about this proposed action, contact Andrew Sheppard, Sector Policies and Programs Division (E143-03), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541-4161; fax number: (919) 541-0516; and email address: [sheppard.andrew@epa.gov](mailto:sheppard.andrew@epa.gov).

**SUPPLEMENTARY INFORMATION:** In proposed rule FR 2018-23700, in the issue of Tuesday, October 30, 2018, on page 54527, in the third column, correct the docket numbers listed in the **ADDRESSES** section to read:

**“ADDRESSES:** *Comments.* Submit your comments, identified by Docket ID No. EPA-HQ-OAR-2018-0696 at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. See **SUPPLEMENTARY INFORMATION** for detail about how the EPA treats submitted comments. *Regulations.gov* is our preferred method of receiving comments. However, the following other submission methods are also accepted:

- *Email:* [a-and-r-docket@epa.gov](mailto:a-and-r-docket@epa.gov). Include Docket ID No. EPA-HQ-OAR-2018-0696 in the subject line of the message.
- *Fax:* (202) 566-9744. Attention Docket ID No. EPA-HQ-OAR-2018-0696.

• *Mail:* To ship or send mail via the United States Postal Service, use the following address: U.S. Environmental Protection Agency, EPA Docket Center, Docket ID No. EPA-HQ-OAR-2018-0696, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.

• *Hand/Courier Delivery:* Use the following Docket Center address if you are using express mail, commercial delivery, hand delivery, or courier: EPA Docket Center, EPA WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. Delivery verification signatures will be available only during regular business hours.”

In proposed rule FR 2018-23700, in the issue of Tuesday, October 30, 2018, on page 54528, make the following correction to the docket numbers listed in the **SUPPLEMENTARY INFORMATION** section. In the second paragraph of the section, in the first column, revise the docket number in the first sentence to say, “Docket. The EPA has established a docket for this rulemaking under Docket ID No. EPA-HQ-OAR-2018-0696.”

In the third paragraph of the section, in the first column, revise the docket

number in the first sentence to say, “*Instructions.* Direct your comments to Docket ID No. EPA-HQ-OAR-2018-0696.”

In the sixth paragraph of the section, in the third column, revise the docket number in the last sentence to say, “Send or deliver information identified as CBI only to the following address: OAQPS Document Control Officer (C404-02), OAQPS, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, Attention Docket ID No. EPA-HQ-OAR-2018-0696.”

Dated: November 2, 2018.

**William L. Wehrum,**  
Assistant Administrator, Office of Air and Radiation.

[FR Doc. 2018-24581 Filed 11-8-18; 8:45 am]

**BILLING CODE 6560-50-P**

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### 45 CFR Parts 155 and 156

[CMS-9922-P]

**RIN 0938-AT53**

#### Patient Protection and Affordable Care Act; Exchange Program Integrity

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

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would revise standards relating to oversight of Exchanges established by states, periodic data matching frequency and authority, and the length of a consumer's authorization for the Exchange to obtain updated tax information. This proposed rule would also propose new requirements for certain issuers related to the collection of a separate payment for the premium portion attributable to coverage for certain abortion services. Many of these proposed changes would help strengthen Exchange program integrity.

**DATES:** *Comments:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 8, 2019.

**ADDRESSES:** In commenting, please refer to file code CMS-9922-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation

to <http://www.regulations.gov>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-9922-P, P.O. Box 8016, Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-9922-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:**

Emily Ames, (301) 492-4246, or Christine Hammer, (202) 260-6089, for general information.

**SUPPLEMENTARY INFORMATION:**

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments.

## I. Executive Summary

American Health Benefit Exchanges, or “Exchanges” (also called “Marketplaces”) are entities established under the Patient Protection and Affordable Care Act (Pub. L. 111-148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) (collectively referred to as PPACA) through which qualified individuals and qualified employers can purchase health insurance coverage. Exchanges that were established by states (State Exchanges) include State-based Exchanges (SBEs) which perform eligibility and enrollment functions, as well as State-based Exchanges on the Federal platform (SBE-FPs) that utilize the Federally-facilitated Exchange’s infrastructure to perform eligibility and enrollment functions. Many individuals who enroll in qualified health plans (QHPs) through individual market Exchanges are eligible to receive a premium tax credit (PTC) to reduce

their costs for health insurance premiums, and receive reductions in required cost-sharing payments to reduce out-of-pocket expenses for health care services. Eligible individuals can receive the estimated amount of the PTC on an advance basis, known as advance payments of the premium tax credit (APTC), in accordance with section 1412 of the PPACA.

Strengthening program integrity with respect to subsidy payments in the individual market is a top priority of this Administration. Key areas of focus include—(1) ensuring that eligible enrollees receive the correct amount of APTC and cost-sharing reduction (CSR) (as applicable), and do not receive APTC or CSRs for abortion coverage and/or services for which such payments are not available under section 1303 of the PPACA; (2) conducting effective and efficient monitoring and oversight of State Exchanges to ensure that consumers are receiving the correct amount of APTC and CSRs in SBEs, and that State Exchanges are meeting the standards of federal law in a transparent manner; and (3) protecting the interests of taxpayers, and consumers, and the financial integrity of Federally-facilitated Exchanges (FFEs) through oversight of health insurance issuers, including ensuring compliance with Exchange requirements, such as maintenance of records and participation in investigations and compliance reviews, and with the requirements of section 1303 of the PPACA.

The Department of Health and Human Services (HHS) has recently made significant strides in these areas. For example, we have implemented policy-based payments in the FFEs and almost all of the SBEs, a critical system change across Exchanges and issuers that ensures the data used to generate APTC and CSR payments to issuers are verified and associated with particular enrollees.

We also recently implemented pre-enrollment verification of eligibility for applicable individual market special enrollment periods for all Exchanges served by the federal eligibility and enrollment platform (the *HealthCare.gov* platform), ensuring that only those who qualify for special enrollment periods receive them. In the HHS Notice of Benefit and Payment Parameters for 2019 Final Rule (83 FR 16930) (April 17, 2018), we established a policy to require documentary evidence for certain consumers who attest to income that is significantly higher than the amount found in the Exchange’s income data. This new check will be conducted for applicants for whom trusted data

sources (such as the Internal Revenue Service, the Social Security Administration, the Department of Homeland Security, Veterans Health Administration, Peace Corps, the Department of Defense, Experian, and Carahsoft).<sup>1</sup> This new check will not be performed with respect to non-citizen applicants who are ineligible for Medicaid based on their immigration status, as these applicants may be statutorily eligible for APTC with annual household income below 100 percent of the FPL. An accurate eligibility determination is critical for consumers near this threshold to ensure APTC is not paid on behalf of consumers who are statutorily ineligible for APTC.

In late 2017, we developed an innovative approach to provide additional notification to tax filers who, based on Internal Revenue Service (IRS) data, had received APTC for a prior benefit year but failed to reconcile these payments on their tax returns. The notices explained that the tax filer was required to take action to reconcile these prior APTC payments, or APTC associated with all enrollees for whom the individual is the tax filer would be terminated. While HHS was already contacting these affected households through its standard annual notification processes, this supplemental notice provided further clarification and instruction for the tax filer, while adhering to IRS’ protocols regarding the safe disclosure of protected federal tax information.

We continue to explore opportunities to improve program integrity. We work on an ongoing basis on improving program oversight and procedures to conduct comprehensive audits of FFE processes to verify their integrity. These efforts further our goal of protecting consumers enrolled in FFEs and safeguarding taxpayer dollars. We review consumer complaints and allegations of fraud and abuse received by the FFE call center from insurers, as well as law enforcement and states. Additionally, we analyze data to identify issues and vulnerabilities, share relevant information with issuers, and identify administrative actions to stop bad actors and protect consumers.

We are proposing several changes targeting these priorities. First, we are planning changes to the current periodic data matching (PDM) processes, which are the processes through which Exchanges periodically examine

<sup>1</sup> One criterion for eligibility for APTC is an income equal to or greater than 100 percent but not greater than 400 percent of an amount equal to the poverty line based on family size.

available data sources to identify changes that would affect enrollees' eligibility for subsidies. Second, we are planning to add an optional authorization to the Exchange application that would allow an individual to authorize the FFE to receive Medicare eligibility and enrollment information about the enrollee. If an applicant provides this authorization and elects to have the Exchange automatically terminate QHP coverage if the applicant is found to be dually enrolled, then the FFE will end enrollees' QHP coverage on their behalf in such a circumstance, even if the enrollee is not receiving APTC or CSRs. Third, we propose to specify that Exchanges must conduct PDM for Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and the Basic Health Program (BHP), if applicable, at least twice a year, beginning with the 2020 calendar year, to ensure that Exchanges make adequate efforts to discontinue APTC and CSR for those who are eligible for or enrolled in other minimum essential coverage (MEC) and, therefore, are ineligible for APTC or CSRs.

We are also proposing changes to improve program integrity related to State Exchanges. To strengthen the mechanisms and tools HHS uses in its oversight of compliance by State Exchanges with federal requirements, including eligibility and enrollment requirements under 45 CFR part 155, subparts D and E, we are proposing changes that provide further specificity to their program reporting requirements. In addition, to ensure proper eligibility determinations and enrollments in SBEs, we are proposing to clarify the scope of the annual programmatic audits that SBEs are required to conduct and submit results of annually to HHS, and include testing of SBE eligibility and enrollment transactions in the annual programmatic audits.

Lastly, we are proposing changes related to the separate payment requirement in section 1303 of the PPACA. To align the regulatory requirements for issuer billing of the portion of the enrollee's premium attributable to certain abortion services with the separate payment requirement applicable to issuers offering coverage of these services, we are proposing changes to the billing and payment collection requirements for QHP issuers in connection with their plans offered through an individual market Exchange that include coverage for abortion services for which federal funding is prohibited.

## II. Background

### *A. Legislative and Regulatory Overview*

Sections 1311(b) and 1321(b) of the 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 both facilitates the purchase of QHPs by individuals and families, and provides for the establishment of a Small Business Health Options Program (SHOP) that is designed to assist qualified employers in the state who are small employers 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 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.

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 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.

Section 1303 of the PPACA, as implemented in 45 CFR 156.280, specifies standards for issuers of 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 regulations 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 PTC or CSR funds are used to pay for abortion services for which public funding is prohibited. 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,<sup>2</sup> 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 exclusively to pay for non-Hyde abortion services.

In the 2012 Exchange Establishment Rule, we codified the statutory provisions of section 1303 of the PPACA in regulation at 45 CFR 156.280. On February 27, 2015, we published the Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016, (80 FR 10750) (herein after referred to as the 2016 Payment Notice) providing guidance regarding acceptable billing and premium collection methods for the portion of the consumer's total premium attributable to non-Hyde abortion coverage for purposes of satisfying the statutory separate payment requirement.

<sup>2</sup> Section 1303 also specifies how such actuarial value is to be calculated.

### 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.

## III. Provisions of the Proposed Regulations

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

#### 1. Functions of an Exchange (§ 155.200)

Section 155.200 of the PPACA establishes the functions that an Exchange must perform. Section 155.200(c) of the PPACA specifies that the Exchange must perform oversight and financial integrity functions, specifically that the Exchange must perform required functions related to oversight and financial integrity requirements 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 SBEs have generally interpreted this requirement broadly as well, as evidenced by their engagement in activities designed to combat fraud and abuse related to the Exchange.

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.<sup>3</sup>

<sup>3</sup> 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 Code. One of the permitted uses and disclosures is

Specifically, we have received questions about whether Exchanges are permitted under § 155.260 to disclose applicant PII to certain entities, such as the state departments of insurance, when investigating fraudulent behavior related to Exchange enrollments on the part of agents and brokers. We believe that use and disclosure related to Exchange program integrity efforts, like combatting fraud, currently fall under § 155.200(c), but believe the regulation is not as clear as it could be. Therefore, we propose 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). Because this change is a clarification and not a new function, we do not believe it would impose additional burdens on State Exchanges, but instead would help resolve questions about whether states have the necessary tools and authority to enable them to effectively oversee and combat potentially fraudulent behavior. We seek comment on this proposal, including with respect to our understanding of the potential imposition of additional burden on State Exchanges.

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

Currently, under § 155.330, Exchanges are required to periodically examine available data sources to identify, with respect to enrollees on whose behalf APTC or CSRs are being paid, eligibility or enrollment determinations for Medicare, Medicaid, CHIP, or the 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.

If a consumer 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 the statutory requirements

for the Exchange to carry out the functions described in § 155.200.

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 statutory reinsurance and risk adjustment 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.

Section 155.320(b)(2) specifies that the disclosure to HHS of information regarding eligibility for and enrollment in a health plan that is a government program, which may be considered protected health information (PHI), is expressly authorized for the purposes of verification of applicant eligibility for MEC as part of the eligibility determination process for APTC or CSRs. Section 155.430(b)(1)(ii) requires an Exchange to 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 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, we added language to the existing single, streamlined application used by Exchanges using the federal eligibility and enrollment platform to allow consumers to authorize the Exchange to obtain eligibility and enrollment data and, if desired, to end their QHP coverage if the Exchange finds that the consumer has become eligible for or enrolled in other qualifying coverage, such as Medicare, Medicaid/CHIP, or BHP, during periodic checks.

In addition, for plan years beginning with the 2020 plan year, we also plan to add a new authorization to the single, streamlined application used by Exchanges using the federal eligibility and enrollment platform, which will meet Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104-191) standards regarding how one's PHI is collected and used. This new authorization will expand the current scope of Medicare PDM to individuals in the Exchange population not receiving financial assistance who authorize the FFE to conduct certain PDM for them. Specifically, this new authorization will allow applicants or QHP enrollees, whether or not they have applied for or are receiving APTC or CSRs, to authorize the Exchange, when conducting Medicare PDM, to request 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 simultaneously enrolled in Medicare and, if requested, to act on the enrollee's behalf to terminate QHP coverage in cases of dual enrollment. We note that, because entitlement to premium-free Medicare Part A is based on age and information held by the Social Security Administration (that is, the number of quarters of coverage toward a Social Security benefit under Title II of the Act), the Exchange will not be able to identify through this process any consumer who is eligible for premium-free Part A; we encourage all consumers who are age 65 and older to apply with the Social Security Administration to receive an eligibility determination with respect to Medicare. Our adoption of this new optional authorization to access Medicare enrollment information does not extend to access to Medicaid, CHIP, or BHP information for applicants who are not receiving APTC or CSRs, because these programs are targeted to relatively lower income consumers and we would not expect to identify a significant number of enrollees dually enrolled in one of these programs and an unsubsidized QHP through the Exchange.

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 the Exchange to provide notice of the updated information the Exchange has found and a 30-day period for the enrollee to respond. For example, 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 consumers 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). Again, as

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 to receive an eligibility determination with respect to Medicare.

Based on our experience performing Medicare PDM, we believe that many consumers are inadvertently enrolled in Medicare and QHP coverage at the same time, and that their dual enrollment does not represent an informed decision. For example, we have found that, once consumers are informed of the consequences of their dual enrollment, such as paying full price for a QHP and risk for financial penalties for delaying Medicare Part B enrollment, the majority of consumers end their QHP coverage shortly thereafter. Furthermore, our own internal analyses show that the majority of QHP enrollees who become dually enrolled do so by aging into Medicare and failing to terminate the APTC or CSRs they are receiving through the Exchange (and, if desired, their Exchange coverage itself) during their Medicare initial enrollment period. We believe that Exchanges should play an important role in helping to ensure that consumers, regardless of whether the consumer has applied for, or is receiving, APTC or CSRs through the Exchange, are aware of their dual enrollment, the fact that their QHP coverage may duplicate coverage available to them through Medicare at potentially lower expense, and their potential risk for tax liability for APTC received during months of overlapping coverage (for consumers receiving APTC) or financial penalties (such as the Medicare Part B late enrollment penalty if they delay enrolling in Medicare during their initial eligibility period).

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 also encourage

SBEs and enhanced direct enrollment partners to adopt these changes if they are not already using the single, streamlined application. We seek comment on these plans.

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

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, FFEs conduct Medicare PDM and Medicaid/CHIP PDM twice a year. To ensure that all Exchanges are taking adequate steps to check for enrollees who have become eligible for or enrolled in these other forms of MEC, and to terminate APTC and CSRs if so, we propose to add a clearer requirement to conduct Medicare, Medicaid/CHIP, and BHP, if applicable, periodic data matching with regular frequency. Specifically, we propose to add paragraph (d)(3) to specify that Exchanges conduct Medicare, Medicaid/CHIP, and BHP, if applicable, PDM at least twice a year, beginning with the 2020 calendar year. We believe this timeframe will 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. Based on HHS's experience, Exchanges should consider spacing Medicare, Medicaid/CHIP, and BHP, if applicable, PDM checks evenly throughout the year, which we believe would help ensure the greatest number of potentially affected enrollees are identified and notified. Further, we do not anticipate that the proposal—to apply Medicare PDM to those enrollees who are not receiving APTC/CSRs but authorize the Exchange to receive Medicare enrollment information—would add significant costs to performing Medicare PDM. Based on HHS's experience, the dually enrolled unsubsidized population is significantly smaller than the population receiving APTC/CSRs. We believe this policy would likely reduce QHP premiums and improve program integrity for all Exchanges, 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 of the typically increased utilization of services expected for these populations,

which include significant numbers of older and disabled beneficiaries or poorer health outcomes associated with lower income statuses.<sup>4</sup> As noted above, this negative effect on the risk pool likely results in higher premiums across the individual market, leading to increased expenditures of federal funds on PTC for taxpayers eligible for PTC resulting from unnecessary or duplicative coverage. So that the FFEs and SBEs may prioritize the implementation of the proposed requirement to conduct PDM for Medicare, Medicaid, CHIP, and BHP (if applicable) eligibility or enrollment at least twice yearly, we are not proposing to require Exchanges to perform PDM for death at least twice in a calendar year. We will consider whether to require this check to be performed at a particular frequency through future rulemaking.

Since most SBEs have shared, integrated eligibility systems with their respective Medicaid programs, Medicaid/CHIP and BHP, if applicable, PDM requirements may be met differently for SBEs than for the FFEs. While there is some variation among SBEs in their Medicaid/CHIP and BHP, if applicable, PDM processes, most SBEs have implemented fully integrated eligibility systems where the design of the system mitigates risk of dual enrollment in, or inconsistent eligibility results regarding, APTC/CSRs and Medicaid/CHIP and BHP, if applicable, coverage by having one eligibility rules engine for eligibility determinations for all these programs. In these SBEs, an individual cannot be enrolled in both a QHP through the Exchange with APTC/CSRs, and Medicaid/CHIP or BHP, if applicable, coverage, at any given time. At paragraph (d)(3), we propose to specify that we will deem these SBEs to be in compliance with the requirement to perform Medicaid/CHIP PDM or BHP PDM, if applicable. SBEs that do not have fully integrated eligibility systems for APTC/CSRs and Medicaid/CHIP would be required to perform Medicaid/CHIP PDM at least twice a year. Similarly, SBEs in states that have implemented the BHP, but where the BHP is not integrated into the state's shared eligibility system, would be required to perform BHP PDM at least twice a year. We anticipate most SBEs will meet or exceed the proposed requirements for Medicaid/CHIP PDM and BHP PDM, if applicable, based on

current or planned operations for calendar year 2018, as reported to us through the State-based Marketplace Annual Reporting Tool and through technical assistance engagements. Therefore, we anticipate that the proposed requirement to conduct Medicaid/CHIP PDM and BHP PDM, if applicable, at least twice a year would not result in a significant administrative burden for SBEs that are not deemed to be in compliance (and no administrative burden for those that are so deemed).

Although we believe that compliance by SBEs with these proposed requirements is critically important for program integrity, we are not proposing specific penalties if SBEs do not comply. However, we note that under current authority HHS requires a SBE to take corrective action if it is not complying with federal guidance and regulations. 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 Exchanges, and provide technical assistance and ongoing monitoring to track those actions until the Exchange comes into compliance.

Additionally, under section 1313(a)(4) 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 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 determines 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 will rescind payments that are due to that state.

Lastly, we propose 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.

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

As section 1311 of the PPACA Exchange Establishment grant program has come to a conclusion and State

Exchanges are financially self-sustaining, HHS has a need for strengthening the mechanisms and tools for overseeing SBE and SBE-FP ongoing compliance 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 (either an SBE or SBE-FP) based on an assessment of a state's attested compliance with statutory and regulatory rules. Once approved or conditionally approved, State Exchanges must meet specific program integrity and oversight requirements specified at section 1313(a) of the PPACA, §§ 155.1200 and 155.1210. These requirements provide HHS with the 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 governmental 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. 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.

HHS designed and developed the State-based Marketplace Annual Reporting Tool (SMART) in 2014 to assist 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 requirements and operational requirements set forth in statute, regulations, and applicable guidance that implements the statutory and regulatory requirements, including reporting compliance with Federal eligibility and enrollment program requirements under 45 CFR 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

<sup>4</sup> 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>.

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 programmatic and financial audits, and HHS monitors the implementation of the corrective actions. We propose 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, but also include reporting on compliance across other Exchange program requirements under 45 CFR part 155. We also propose to modify § 155.1200(b)(1) to eliminate the April 1st date in which states 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 are proposing to remove the April 1st date, but intend to maintain the requirement that State Exchanges submit the required reports by a deadline, we also propose 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 propose to retain the requirement at § 155.1200(c) that an annual programmatic audit be conducted by SBEs and SBE-FPs, but make a minor change from “state” to “State Exchanges” to be consistent and clear on the entities to which this rule applies. We also propose 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. This would provide HHS with the ability to specify those Exchange functions that are most pertinent to a particular State Exchange model (SBE or 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 propose to modify § 155.1200(d) by replacing existing paragraph (d)(4) with new paragraphs (d)(4) and (5). These requirements specify that SBEs must ensure that the independent audits implement testing procedures or other auditing procedures that assess whether

an SBE is conducting accurate eligibility determinations and enrollment transactions under 45 CFR 155 subparts D and E. Such auditing procedures include the use of statistically valid sampling methods in the testing or auditing procedures.

We believe these proposed changes will strengthen our programmatic oversight and the program integrity of State Exchanges, while providing flexibility for HHS in the collection of information. Through the Paperwork Reduction Act (PRA) process, we are able to make updates and refinements to the SMART reporting tool to align with our oversight and 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. For instance, this would allow the audits to focus on SBE compliance with Exchange eligibility and enrollment requirements in 45 CFR 155 subparts D and E, and SBE-FP compliance with Exchange requirements in 45 CFR 155 subpart C. We believe this approach will provide HHS and states with greater insight into SBE and SBE-FP compliance with federal standards in a more cost-effective manner. We believe these two tools, state reporting and independent testing, coupled with our ongoing oversight activities would strengthen program integrity in State Exchanges.

We believe this approach would allow HHS to identify State Exchange non-compliance issues with more precision and efficacy. It would also allow HHS to provide more effective, targeted technical assistance to State Exchanges in developing corrective action plans to address issues that are identified, thus mitigating the need for more drastic or severe enforcement actions against a State Exchange. We believe this approach can 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 seek comment on these proposals.

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

**Segregation of Funds for Abortion Services (§ 156.280)**

Since 1976, the Congress has included language, commonly known as the Hyde Amendment, in the Labor, Health and Human Services, Education and Related Agencies appropriations legislation.<sup>5</sup> The Hyde Amendment as currently in effect permits federal funds to be used for abortion services only in the limited cases of rape, incest, or if a woman suffers from a life-threatening 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 coverage). The Hyde Amendment prohibits the use of federal funds for abortion coverage in instances beyond those limited circumstances (non-Hyde abortion coverage). Consistent with the Hyde Amendment, section 1303(b)(2) of the PPACA prohibits the issuer of a QHP that includes non-Hyde abortion coverage from using any amount attributable to PTC (including APTC) or CSRs (including advance payments of those funds to the issuer, if any) for abortions for which federal funds appropriated for HHS 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.”<sup>6</sup>

Section 1303 of the PPACA outlines specific accounting and notice requirements that QHPs covering non-Hyde abortion services on the Exchanges must follow to ensure that no federal funding is used to pay for those services. Under section 1303(b)(2)(B) of the PPACA, as implemented in § 156.280(e)(2)(i), QHP issuers must collect a “separate payment,” from each enrollee in 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 the coverage for abortions for which public funding is prohibited or \$1 per enrollee per month. Section 1303(b)(2)(D) of the PPACA, implemented in § 156.280(e)(4), provides that the estimation is to be determined on an average actuarial basis and that QHP issuers may take into account the impact on overall costs of the inclusion of such coverage, but may

<sup>5</sup> 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.

<sup>6</sup> Section 1303(b)(1)(B)(I) of the PPACA.

not take into account any cost reduction estimated to result from such services, including prenatal care, delivery, or postnatal care. Section 1303(b)(2)(D) of the PPACA as implemented in § 156.280(e)(4) further states that QHP issuers are to estimate these costs as if the coverage were included for the entire population covered. With respect to the “separate payment” requirement, if an enrollee’s premium for coverage under the plan is paid through employee payroll deposit (or deduction) under section 1303(b)(2)(B), the separate payments “shall each be paid by a separate deposit.”

As mentioned above, QHP issuers that offer coverage for non-Hyde abortion may not use APTC to pay for such coverage, or use CSR funds to pay for such services. Pursuant to section 1303(b)(2)(D)(ii)(III) of the PPACA, these QHP issuers may not estimate the premium attributable to the benefit to be less than \$1 per enrollee per month, regardless of the actual cost of the benefit. Currently, in certain rare scenarios, the FFE system allocates an amount of APTC to a policy such that the share of the aggregate premium for which the consumer is responsible is too low to meet this minimum standard. We intend to make system changes for open enrollment 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, so that issuers may separately collect this amount directly from consumers for the portion of the total premium attributable to coverage of non-Hyde abortion services.

Under section 1303(b)(3)(A) of the PPACA as implemented in § 156.280(f), QHP issuers must provide notice to enrollees as part of the Summary of Benefits and Coverage (SBC) at the time of enrollment if non-Hyde abortion services are covered by the QHP. As required under § 155.205(b)(1)(ii), each Exchange must maintain an up-to-date website that provides the SBCs. Section 147.200(a)(4) requires that individual market QHP issuers that provide the SBC electronically must place it in a prominent and readily accessible location on the QHP issuer’s internet website. Additionally, pursuant to section 1303(b)(2)(C) of the PPACA, as implemented at § 156.280(e)(3), QHP issuers must segregate funds for non-Hyde abortion services collected from consumers into a separate allocation account that is to be used exclusively to pay for non-Hyde abortion services. Thus, if a QHP issuer disburses funds for a non-Hyde abortion on behalf of a consumer, it must draw those funds

from the segregated allocation account. The account cannot be used for any other purpose.

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). In the 2016 Payment Notice, we provided guidance with respect to acceptable methods that a QHP issuer offering non-Hyde abortion coverage on the 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 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 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 a consumer may make the payment for non-Hyde abortion services and the separate payment for 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.<sup>7</sup>

HHS now believes that some of the methods for billing and collection of the separate payment for non-Hyde abortion services noted as permissible in the preamble to the 2016 Payment Notice do not adequately reflect what we see as Congressional intent that the QHP issuer bill separately for two distinct (that is, “separate”) payments, one for the non-Hyde abortion services, and one for all other services covered under the policy, rather than simply itemizing these two components of a single total billed amount or notifying the enrollee, at or soon after the time of enrollment, that the monthly invoice or bill will include a separate charge for these services. Although we recognize that itemizing or providing advance notice about the amounts arguably identifies two “separate” amounts for two separate purposes, we believe that the statute contemplates issuers billing for two separate “payments” of these two

<sup>7</sup> 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>.

amounts (for example, two different checks or two distinct transactions), consistent with the requirement on issuers in section 1303(b)(2)(B)(i) of the PPACA to collect two separate payments. HHS, thus, believes that requiring QHP issuers to separately bill the portion of the consumer’s premium attributable to non-Hyde abortion services and instruct consumers to make a separate payment for this amount is a better implementation of the statutory requirement for issuers to collect a separate payment for these services.

As such, we are proposing an amendment at § 156.280(e)(2) relating to billing and payment of the consumer’s portion of the premium attributable to non-Hyde abortion services to reflect this interpretation of the statute. Specifically, we are proposing that, if these policies are finalized, as of the effective date of the final rule, QHP issuers (1) send an entirely separate monthly bill to the policy subscriber for only the portion of premium attributable to non-Hyde abortion coverage, and (2) instruct the policy subscriber to pay the portion of their premium attributable to non-Hyde abortion coverage in a separate transaction from any payment the policy subscriber makes for the portion of their premium not attributable to non-Hyde abortion coverage. We believe that these proposals would better align the regulatory requirements for QHP issuer billing of enrollee premiums with the separate payment requirement in section 1303 of the PPACA. If these proposals are finalized, QHP issuers would no longer be permitted to send the enrollee a single monthly invoice or bill that separately itemizes the premium amount for non-Hyde abortion services, or send 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 in order to meet the separate payment requirement. Instead, QHP issuers would have to send a separate bill and instruct enrollees to send a separate payment in the manner specified by the final rule.<sup>8</sup> We invite comment on these proposals.

To better align the regulatory requirements for issuer billing of enrollee premiums with the separate payment requirement in section 1303 of the PPACA, our proposal would require

<sup>8</sup> We noted above the situation where, as a result of APTCs, the out-of-pocket premium payable by the consumer is less than \$1 per enrollee per month. Under this proposed rule, and to ensure compliance with section 1303, if the QHP includes non-Hyde abortion coverage, the QHP issuer would be required to bill the consumer at least \$1 per enrollee per month.

the QHP issuer to send this separate bill in a separate mailing with separate postage. If a QHP issuer sends bills electronically, we propose that it provide consumers with the two bills in separate emails or other electronic communications. We believe this approach will help reduce consumer confusion about receiving two separate bills in a single envelope. For example, consumers may inadvertently miss or discard a second paper bill included in a single envelope, increasing terminations of coverage for failure to pay premiums. The QHP issuer would also be required to produce an invoice or bill that is distinctly separate from the invoice or bill for the other portion of the consumer's premium that is not attributable to non-Hyde abortion coverage, whether in paper or electronic format. We solicit comment on any operational issues that may arise from this aspect of the proposed rule.

We also seek comment on ways to mitigate any possible confusion, for example through an annual notice or standard explanatory language on each of the two monthly bills. To meet the requirements of this new proposal, QHP issuers would be required to instruct policy subscribers to pay the separately billed or invoiced portion of the premium for non-Hyde abortion coverage in a transaction separate from the transaction for payment of the other portion of the premium that is not attributable to non-Hyde abortion coverage and make reasonable efforts to collect the payment separately, such as by including a separate payment stub on each of the separately mailed bills or invoices (if sent on paper) or providing a separate payment link in the separate email or electronic communication with a separate payment field on the payment web page for each separate payment to be collected (if sending an electronic bill, or accepting electronic payments regardless of how the bills were transmitted). Under this proposal, consumer non-payment of any premium due (including non-payment of the portion of the consumer's premium attributable to non-Hyde abortion coverage) would continue to be subject to state and federal rules regarding grace periods. In the event that a policy subscriber does not follow the separate payment instructions, however, and pays the entire premium in a single transaction (both the portion attributable to non-Hyde abortion coverage, 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 subscriber did not send two checks as requested by the QHP issuer, and to then terminate the policy, subject to any applicable grace period, for non-payment of premiums. We believe that potential loss of coverage would be an unreasonable result of a consumer paying in full but failing to adhere to the QHP issuer's requested payment procedure. Under our new interpretation, a QHP issuer would thus be required to accept a combined payment, to the extent necessary to avoid this result.

QHP issuers that do receive combined consumer premiums covering the portion attributable to non-Hyde abortion coverage as well as the portion attributable to coverage for other services in one single payment would treat the portion of the premium attributable to non-Hyde abortion services as a separate payment for which the QHP issuer would be expected to disaggregate into the separate allocation account used solely for these services. We would expect the QHP issuer in this scenario to again explain to the consumer the separate payment requirement in the law, and take steps to inform the consumer not complying with this policy that he or she should do so in future months, including documentation of such outreach and educational efforts. Again, if the consumer still declines to do so, however, the combined payment must be accepted to avoid a loss of coverage. Likewise, QHP issuers would not be permitted to refuse to accept separate premium payments paid to the issuer in a single return envelope (for example, two separate checks returned to the issuer in a single return envelope) on the basis that the consumer did not separately return each premium payment in a separate mailing. We seek comment on these proposals.

We are also proposing a technical change, to Section 156.280(e)(2)(iii) as redesignated, to insert appropriate cross reference to the explanation of the separate payments.

Consistent with § 156.715, HHS has broad authority to perform compliance reviews to monitor FFE issuer compliance. HHS conducts compliance reviews throughout the year, and issuer notification of selection for a review may occur at any time during the year. Detailed examples of regulatory and operational areas that will be reviewed are included in the *Key Priorities for FFM Compliance Review*, which is updated each year with new key oversight priorities.<sup>9</sup> Consistent with

this authority, we propose updating our compliance reviews governing QHP certification to include new reviews of FFE issuer compliance with § 156.280, including the segregation of funds requirement and the new proposals for separate billing of the portion of the consumer's premium attributable to coverage of non-Hyde abortion services as specified in this rule. FFE issuers subject to these compliance reviews should maintain 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 coverage of non-Hyde abortion services; detailed invoice and billing records demonstrating they are separately billing in a separate mailing or separate electronic communication and collecting the portion of the premium attributable to coverage of non-Hyde abortion services as specified in this rule; and appropriately segregating the funds collected from consumers into a separate allocation account that is used exclusively to pay for non-Hyde abortion services. We believe the addition of these compliance reviews will help to address remaining issuer compliance issues, if any, previously identified by the 2014 U.S. Government Accountability Office report.<sup>10</sup> We seek comment on this proposal.

As is the case with many provisions in the PPACA, 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. Section 1303(b)(2)(E)(i) of the PPACA, as implemented at § 156.280(e)(5), designates the state insurance commissioners as the entities responsible for monitoring, overseeing, and enforcing the provisions in section 1303 of the PPACA related to QHP segregation of funds for non-Hyde abortion services. However, as stated in

[www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Exams\\_Audits\\_Reviews\\_Issuer-Resources-.html](http://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Exams_Audits_Reviews_Issuer-Resources-.html).

<sup>10</sup> U.S. Government Accountability Office, "Health Insurance Exchanges: Coverage of Non-Exceptioned Abortion Services by Qualified Health Plans," (Sept. 15, 2014), available at <http://www.gao.gov/products/GAO-14-742R>.

<sup>9</sup> CCIIO Examinations, Audits and Reviews of Issuers: Issuer Resources, available at [https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Exams\\_Audits\\_Reviews\\_Issuer-Resources-.html](https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Exams_Audits_Reviews_Issuer-Resources-.html).

2017 guidance,<sup>11</sup> where we are charged with directly enforcing these statutory requirements in the FFEs, we intend to do so fully in instances of issuer non-compliance. We call upon states that operate their own Exchanges to fully enforce these requirements as codified in the federal regulations governing the Exchanges. To the extent such a state operating its own Exchange fails to substantially enforce these requirements, HHS would expect to enforce them in the state's place. However, as states remain the primary enforcers of these requirements, we propose that HHS involvement in enforcement would be limited to ensuring that federal funds are appropriately managed. For example, HHS enforcement would be limited to instances where it becomes clear that the state department of insurance is not overseeing the requirement for the QHP issuer to determine the actuarial value of the coverage of non-Hyde abortions, to separately bill (and collect) premium of at least \$1 per enrollee per month for such coverage, or to segregate funds effectively; a state department of insurance or other entity notifies HHS of suspected misuse of federal funding for coverage of non-Hyde abortion services; or the state's enforcement actions are inadequate and fail to result in compliance from the QHP issuer. The Office of Personnel Management may issue guidance related to these provisions for multi-state plan issuers.<sup>12</sup>

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 its state department of insurance 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, "separation plan") to the state health insurance commissioner. The separation 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 separation plans to demonstrate compliance with these requirements.

As mentioned previously, consistent with HHS's authority under § 156.715, we propose monitoring FFE issuer compliance with the requirements under § 156.280 by requiring QHP issuers in FFEs to show documentation of compliance with the requirement to estimate the basic per enrollee per month cost, determined on an average actuarial basis, for coverage of non-Hyde abortion services and charge at least \$1 per enrollee per month for such coverage, as well as with the segregation of funds requirements when undergoing compliance reviews, including detailed records and documentation demonstrating compliance with the separate billing (including mailing, as applicable) and collection requirements proposed in this rule, as well as the segregation of funds requirements. We also remind issuers offering medical QHPs in the FFEs that they must already 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.<sup>13</sup> If the separate billing and premium collection proposals at § 156.280(e)(2) are finalized as proposed, 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.<sup>14</sup> Issuers in states with SBEs that offer QHPs including non-Hyde abortion coverage should contact their state for attestation requirements as part of the QHP certification process.

We seek comment on these proposals.

#### IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information

requirement is submitted to the Office of Management and Budget (OMB) for review and approval. This proposed rule contains information collection requirements (ICRs) that are subject to review by OMB. A description of these provisions is given in the following paragraphs.

In order to fairly evaluate whether an information collection should be approved by 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 affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain ICRs:

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

The burden associated with State Exchanges meeting the proposed 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). This proposed rule does not impose any new burden or add any additional requirements to the existing collection.

##### B. ICRs Regarding Segregation of Funds for Abortion Services (§ 156.280)

In the preamble to § 156.280, we explain that the proposals to require separate issuer billing for, and collection of, the portion of the premium attributable to non-Hyde abortion coverage would be subject to future HHS compliance reviews of FFE issuers, requiring issuers in the FFE to maintain and submit records showing compliance with these requirements to HHS. We have determined that the requirements associated with compliance reviews have already been assessed and encompassed by the Program Integrity: Exchange, Premium Stabilization Programs, and Market Standards; Amendments to the HHS Notice of Benefit and Payment Parameters for 2014; Final Rule II ICR currently approved under OMB control number: 0938-1277 (CMS-10516).

To show compliance with FFE standards and program requirements, all

<sup>11</sup> 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>.

<sup>12</sup> Section 1334(a)(6) of the PPACA requires that at least one multi-state plan in each Exchange excludes coverage of non-Hyde abortion services. Currently, no multi-state plan options cover non-Hyde abortion services. See OPM's Frequently Asked Questions: Insurance, available at <https://www.opm.gov/faqs/QA.aspx?fid=fd635746-de0a-4dd7-997d-b5706a0fd8d2&pid=8313a65b-c5b8-4d58-a58f-9d81f26856a2>.

<sup>13</sup> 2019 Qualified Health Plan Issuer Application Instructions, available at: <https://www.qhpcertification.cms.gov/s/2019QHPInstructionsVersion1.pdf?v=1>.

<sup>14</sup> State Partnership Exchange Issuer Program Attestation Response Form, available at: [https://www.qhpcertification.cms.gov/s/SuppDoc\\_SPE\\_Attestations\\_revised\\_508.pdf?v=1](https://www.qhpcertification.cms.gov/s/SuppDoc_SPE_Attestations_revised_508.pdf?v=1).

issuers seeking QHP certification in FFE states 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 Establishment of Exchanges and Qualified Health Plans; Exchange Standard for Employers approved under OMB control number 0938-1187 (CMS-10433). Therefore, proposed § 156.280(e)(2) adds no new ICRs as it relates to program attestations.

In § 156.280(e)(2), we propose that QHP issuers must send an entirely separate monthly bill in a separate mailing or separate electronic communication to the policy subscriber for only the portion of premium attributable to non-Hyde abortion coverage, and instruct the policy subscriber to pay the portion of their premium attributable to non-Hyde abortion coverage in a separate transaction from any payment the policy subscriber makes for the portion of their premium not attributable to non-Hyde abortion coverage. Based on 2018 QHP certification data in the FFEs and SBE-FPs, we estimate that 15 QHP issuers

offered a total of 111 plans with coverage of non-Hyde abortion services in 7 States. In SBEs, we estimate that 60 QHP issuers offered a total of approximately 1,000 plans offering this coverage across 10 SBEs. In total, this leads to an estimated 75 QHP issuers offering a total of 1,111 plans covering non-Hyde abortion services across 17 states. As such, the ICRs associated with these proposals would create a new burden on QHP issuers and plans and are subject to the Paperwork Reduction Act. Salaries for the positions cited below were taken from the May 2017 National Occupational Employment and Wage Estimates United States Department of Labor's Bureau of Labor Statistics (BLS) ([http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm)) based on the listed national median hourly wage. All wages on the following pages are inflated by 100 percent to account for the cost of fringe benefits and overhead costs.

We anticipate that populating the enrollee information on the separate electronic or paper bill, transmitting the separate electronic or paper bill in a separate mailing or separate electronic communication, and processing the enrollee's separate electronic or mailed payment, will be an automated process that occurs monthly after a computer programmer adds this functionality to the QHP issuer's billing and payment

operating system. We estimate that, on a one-time basis, a computer programmer will require 10 hours to add this functionality to an affected QHP issuer's systems (at a rate of \$84.16 per hour) for a total burden of 10 hours. We estimate that this will result in a one-time cost of \$841.60 per QHP issuer that offers plans that cover non-Hyde abortion services to meet this reporting requirement. This would be a one-time cost, such that the overall burden for all 75 QHP issuers would be 750 hours, with an associated total cost of \$63,120.

Because an estimated 75 QHP issuers offered a total of 1,111 plans with coverage of non-Hyde abortion services across 17 states, we estimate that the total number of QHP issuers that offer plans with coverage of non-Hyde abortion, for which they would be required to send separate bills in a separate mailing or separate electronic communication and collect separate payments as proposed at § 156.280(e)(2), would be 75 per year, for a total one-time burden of 750 hours. Below is the estimate of the burden imposed on a single QHP issuer subject to the reporting requirements of this rule. The aggregate burden for 3 years will be same as for 1 year: \$841.60 per respondent and \$63,120 for all respondents.

Labor category	Respondents	Responses	Burden per response (hours)	Wage rate (p/hr) including 100% fringe benefits	Total annual burden per response (hours)	Labor cost of one-time reporting (\$)	Total one-time cost for all respondents (\$)
Computer programmer to add automated billing & payment processing functionality ...	75	75	10	\$42.08	10	\$841.60	\$63,120
Total .....	75	75	10	42.08	10	841.60	63,120

Although we anticipate that populating the enrollee information on the separate electronic or paper bill and transmitting that bill in a separate mailing or separate electronic communication would be an automated process, we estimate that a general office clerk working for an affected QHP issuer would require 2 hours monthly (at a rate of \$30.28 per hour) per plan to determine which enrollees are enrolled in plans that cover non-Hyde abortion and to oversee the process of sending a separately packaged complete and accurate bill in a separate mailing or separate electronic communication to these enrollees for the portion of their premium attributable to that coverage, for an annual burden of 24 hours. This estimate includes the amount of time

the office clerk would spend determining which enrollees prefer paper billing versus electronic billing, and ensuring that the bills are complete and accurate and are being sent in a separate mailing or separate electronic communication. We estimate that it would cost \$726.72 annually per plan that covers non-Hyde abortion services to meet the reporting requirement, with a total annual burden for all 1,111 plans of 26,664 hours and an associated total annual cost of \$807,385.92.

We similarly anticipate that processing the payment made by enrollees for this portion of their premium would be an automated process. However, we estimate that a general office clerk working for an affected QHP issuer would require 2 hours monthly (at a rate of \$30.28 per

hour) per plan to review for accuracy the separate payment an enrollee in a plan covering non-Hyde abortion services sends for the portion of their premium attributable to that coverage and to process any payments or paper checks made by enrollees through the mail, for an annual burden of 24 hours. This estimate includes the amount of additional time the office clerk would need to spend reviewing for accuracy the separate payments returned in separate mailings from the payments received for the portion of the policy subscriber's premium not attributable to non-Hyde abortion. We estimate that it would cost \$726.72 annually per plan that covers non-Hyde abortion services to meet the reporting requirement, with a total annual burden for all 1,111 plans

of 26,664 hours and an associated total cost of \$807,385.92.

As such, we estimate that the total number of plans for which QHP issuers would need to send separate bills in a separate mailing or separate electronic

communication and collect separate payments as proposed at § 156.280(e)(2) would be 1,111 per year, for a total burden of 53,328 hours to meet these reporting requirements per year. Below is the estimate of the burden imposed

on a single plan subject to the reporting requirements of this rule. The aggregate burden for 3 years will be \$4,360.32 per respondent and \$4,844,315.52 for all respondents.

Labor category	Respondents	Responses	Burden per response (hours)	Total annual burden per response (hours)	Wage rate (p/hr) including 100% fringe benefits	Labor cost of reporting annually (\$)	Total annual cost for all respondents (\$)
General office clerk for preparing and sending the bill .....	1,111	1,111	2	24	\$30.28	\$726.72	\$807,385.92
General office clerk for receiving and processing the separate payment .....	1,111	1,111	2	24	30.28	726.72	807,385.92
<b>Total .....</b>	<b>2,222</b>	<b>2,222</b>	<b>4</b>	<b>48</b>	<b>60.56</b>	<b>1,453.44</b>	<b>1,614,771.84</b>

### C. Submission of PRA-Related Comments

We have submitted a copy of this proposed 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.

We invite public comments on these information collection requirements. If you wish to comment, please identify the rule (CMS-9922-P) and, where applicable, the ICR's CFR citation, CMS ID number, and OMB control number.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS's website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).

3. Call the Reports Clearance Office at (410) 786-1326.

See this rule's **DATES** and **ADDRESSES** sections for the comment due date and for additional instructions.

### V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

### VI. Regulatory Impact Statement

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 Social Security 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).

Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a regulation: (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 must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year), and an "economically significant" regulatory action is subject to review by the Office of Management and Budget (OMB). As discussed below regarding their anticipated effects, these proposals are not likely to have economic impacts of \$100 million or more in any 1 year, and therefore do not meet the definition of "economically significant" under Executive Order 12866. However, OMB has determined that the actions are significant within the meaning of section 3(f)(4) of the Executive Order. Therefore, OMB has reviewed these final rules and the Departments have provided the following assessment of their impact.

#### A. Need for Regulatory Action

HHS is committed to promoting program integrity throughout its programs to ensure that federal statutory requirements are met and federal monies are not being inappropriately spent. Ensuring that consumers receive the correct amount of APTC and CSRs at the time of enrollment or re-enrollment is a top priority for us, and necessitates regulatory action. Accurate and up-to-date eligibility determinations help reduce the possibility that an individual or family is paying a premium amount that is either higher or lower than they should have to, the latter of which could result in the individual or family needing to pay a large amount back to the federal

Treasury on their federal income tax returns. We propose a number of changes in this rule to help mitigate the risk of federal dollars incorrectly leaving the federal Treasury in the form of APTC during the year. To further improve program integrity and ensure that individuals receiving APTC/CSRs are appropriately enrolled in insurance affordability programs, we are also proposing to specify that Exchanges must conduct Medicare PDM, Medicaid/CHIP PDM, and BHP PDM, if applicable, pursuant to § 155.330(d)(1)(ii), at least twice a year beginning with the 2020 calendar year. We also believe this policy would likely reduce QHP premiums and improve program integrity for all Exchanges, 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 of the typically increased utilization of services expected for these populations, which include significant numbers of older and disabled beneficiaries or poorer health outcomes associated with lower income statuses.<sup>15</sup> As noted above, this negative effect on the risk pool results in higher premiums across the individual market, leading to increased expenditures of federal funds on PTC for taxpayers eligible for PTC resulting from duplicative coverage.

As part of our efforts to strengthen program integrity with respect to subsidy payments in the individual market, we also believe improvements should be made to our ability to conduct effective and efficient oversight of State Exchanges to ensure consumers receive the correct amount of APTC and CSRs (as applicable). As section 1311 of the PPACA Exchange Establishment grant program has come to a conclusion and State Exchanges are financially self-sustaining, HHS has a need to strengthen the mechanisms and tools for overseeing ongoing compliance by State Exchanges with federal program requirements, including eligibility and enrollment requirements under 45 CFR part 155. For these reasons, we are proposing to add specificity to the reporting requirements for State Exchanges at § 155.1200 to focus on activities that speak to compliance with Exchange program requirements, including eligibility and enrollment requirements. We are also proposing changes at § 155.1200 to clarify the

scope of annual programmatic audits that State Exchanges are required to conduct, and include new requirements that focus on ensuring proper eligibility determinations and enrollments in SBEs. It is our intent that these changes would enable us to better identify and address State Exchange non-compliance issues.

HHS believes that some of the methods for billing and collection of the separate payment for non-Hyde abortion services noted as permissible in the preamble to the 2016 Payment Notice do not adequately reflect what we see as Congressional intent that the QHP issuer bill separately for two distinct (that is, “separate”) payments as required by section 1303 of the PPACA. To remedy this, we are proposing at § 156.280(e)(2) that: (1) QHP issuers send an entirely separate monthly bill to the policy subscriber for only the portion of premium attributable to non-Hyde abortion coverage, and (2) instruct the policy subscriber to pay the portion of their premium attributable to non-Hyde abortion coverage in a separate transaction from any payment the policy subscriber makes for the portion of their premium not attributable to non-Hyde abortion coverage. We believe that these proposals are necessary to better align the regulatory requirements for QHP issuer billing of enrollee premiums with the separate payment requirement in section 1303 of the PPACA. HHS believes that requiring QHP issuers to separately bill the portion of the policy subscriber’s premium attributable to non-Hyde abortion services and instruct policy subscribers to make a separate payment for this amount is a better interpretation of, and would result in greater compliance with this interpretation of, the statutory requirement for QHP issuers to collect a separate payment for these services.

#### *B. Anticipated Effects*

Revising § 155.200(c) to clarify that the Exchanges must perform oversight functions or cooperate with activities related to oversight and financial integrity requirements is a clarification and not a new function. Therefore, it would not impose additional burdens on State Exchanges.

Our proposal that Exchanges conduct Medicare PDM, Medicaid/CHIP PDM, and BHP PDM, if applicable, at least twice a year beginning with the 2020 calendar year, merely 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 the BHP, if applicable. Therefore, we expect the costs associated with this proposal to be minimal. However, SBEs that are not already conducting PDM with the frequency proposed, or deemed in compliance with the Medicaid, CHIP, and BHP (where applicable) PDM requirements, would likely 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 SBEs to implement the proposed PDM requirements. We anticipate a majority (about eight) of the twelve SBEs would be exempt from the requirement to perform Medicaid, CHIP, and BHP (where applicable) PDM because they have shared, integrated eligibility systems, as they would be deemed in compliance with this requirement. However, at this point we are not able to confirm the exact number because we have not yet set specific criteria and process to assess and confirm which SBEs would be exempt, and would need additional operational information from SBEs to confirm our assessment. We would establish and engage in that process after finalization of the rule. For an SBE not already conducting Medicare, Medicaid/CHIP, and BHP PDM at least twice a year, and that does not already have a shared, integrated eligibility system with its respective Medicaid/CHIP, and BHP (where applicable) programs, we estimate that it would cost approximately \$1,740,000 per SBE to build such capabilities in their system. These costs would be incurred by the SBE as they are required to be financially self-sustaining and do not receive federal funding for their establishment or operational activities.

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.

<sup>15</sup> 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>.

We expect our plan to permit HHS to verify applicant eligibility for or enrollment in MEC in order for HHS to perform the periodic checks required under § 155.330(d) for those consumers who provide consent to the Exchange to obtain their eligibility and enrollment data, and, if desired, to end their QHP coverage if found dually enrolled in other qualifying coverage, to have minimal economic impact. Based on HHS's experience, the dually enrolled unsubsidized population is significantly smaller than those receiving APTC or CSRs. This plan would help expand the scope of the population that is part of Medicare PDM, rather than adding new Exchange requirements.

We do not anticipate the proposed changes to § 155.1200 will result in any additional cost for the State Exchanges because the changes leverage an existing reporting mechanism, the annual State Based Marketplace Reporting Tool, for meeting eligibility and enrollment reporting requirements in § 155.1200(b). 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 proposed requirement that HHS be able to specify the scope of annual programmatic audits to focus on the program areas that are most pertinent to a State Exchange model (SBE or SBE-FP), 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.

In § 156.280, we propose to amend billing and premium collection requirements related to the separate payment requirement for abortions for which public funding is prohibited pursuant to section 1303 of the PPACA, as implemented at § 156.280. Specifically, the proposals described at § 156.280(e)(2) would require QHP issuers offering non-Hyde abortion coverage through an Exchange to send an entirely separate monthly bill in a separate mailing or separate electronic communication to the policy subscriber for only the portion of premium attributable to non-Hyde abortion coverage, and instruct the policy subscriber to pay the portion of their premium attributable to non-Hyde abortion coverage in a separate transaction from any payment the policy subscriber makes for the portions of the premium not attributable to coverage for non-Hyde abortion services. These proposals aim to better align the

regulatory requirements for QHP issuer billing of premiums with the separate payment requirement in section 1303 of the PPACA.

As reflected in the associated ICRs for the proposals at § 156.280(e)(2), we recognize that QHP issuers that cover non-Hyde abortion services may experience an increase in burden if these proposals are finalized. We anticipate that QHP issuers would need to invest additional time and resources to develop a separate invoice for non-Hyde abortion services, separately mail with separate postage the bill for the portion of the premium attributable to non-Hyde abortion coverage or separately email or electronically send the separate bill, as well as additional time and resources for receipt and processing of the separate payment through a separate transaction as proposed at § 156.280(e)(2). Specifically, we anticipate QHP issuers would need to invest time and resources to oversee the process of sending in a separate mailing or separate electronic communication a complete and accurate bill to these enrollees for the portion of their premium attributable to that coverage, to review for accuracy the separate payment a policy subscriber in a QHP covering non-Hyde abortion sends for the portion of their premium attributable to that coverage, and to process separate payments, whether made electronically or by mail. We also anticipate that QHP issuers would need to add functionality to their operating systems to develop an automated process to populate the enrollee information on the separate bill, transmit the separate bill in a separate mailing or separate electronic communication, and process the separate payment.

Based on 2018 QHP certification data in FFEs and SBE-FPs, 15 QHP issuers offered a total of 111 plans with coverage of non-Hyde abortion services in 7 states. In SBEs, we estimate that 60 issuers offered a total of 1,000 QHPs offering non-Hyde abortion coverage across 10 SBEs. In total, this leads to an estimated 75 QHP issuers offering a total of 1,111 QHPs covering non-Hyde abortion services across 17 states. This rule could significantly increase the administrative burden for QHP issuers covering non-Hyde abortion services in developing, sending, and processing the separate invoices required under this proposal.

Based on 2018 QHP Certification data in FFEs and SBE-FPs, there were approximately 300,000 enrollees across the 111 QHPs covering non-Hyde abortion coverage. In SBEs, we estimate that there were approximately 1,000,000

enrollees across the approximate 1,000 QHPs offering non-Hyde abortion coverage. If finalized, these requirements would also increase burden on those 1,300,000 consumers, related to paying the portion of the premium attributable to non-Hyde abortion services through a separate paper check or electronic transaction; that burden, however, is contemplated by the specific language of section 1303 which requires a QHP issuer "to collect from each enrollee in the plan . . . a separate payment" for the coverage of non-Hyde abortion services. In order to develop a preliminary estimate of the consumer cost of this proposed provision, we assume that a policy subscriber reading their separately received paper or electronic bill and writing out an additional paper check or filling in the necessary information for completion of a separate electronic payment adds approximately ten minutes per month to a policy subscriber's monthly payment process for payment of their QHP premiums, for a total of 2 hours per year. Based on the May 2017 National Occupational Employment and Wage Estimates United States Department of Labor's Bureau of Labor Statistics (BLS) ([http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm)), using the listed national mean hourly wage for the 25th percentile,<sup>16</sup> it would cost a policy subscriber \$11.91 for an additional hour of burden, or approximately \$1.98 for an additional 10 minutes of burden. As such, the 10 minute monthly estimated burden for filling out a separate check or online payment for a policy subscriber would be \$1.98, and the yearly added burden for each policy subscriber would be \$23.76. We note that many consumers are enrolled on the Exchange for an average of 10 months. For those enrollees, the annual consumer burden would be \$19.80 for a total annual burden of \$25,740,000. However, in total for all affected enrollees in QHPs covering non-Hyde abortion enrolled in plans for 12 months, we estimate that it would annually cost \$30,888,000 for policy subscribers to comply with these proposals. This estimate excludes the cost of consumer learning (which may have significant upfront costs and could also continue to be resource intensive on an ongoing basis given the potential confusion of consumers in receiving multiple bills. In some cases, these may entail costs not just to consumers but

<sup>16</sup> The 25th percentile mean hourly wage most closely resembles the group of consumers likely to be affected by this proposal as most enrollees enrolled in QHPs on the Exchange are between 100% and 400% of the federal poverty level.

also to QHP issuers, such as in increased volume of requests for customer service assistance and follow up needed to consumers to pay their full bill). However, HHS believes that, if finalized as proposed, the proposed changes would better align the regulatory requirements for QHP issuer billing of premiums with the separate payment requirement in section 1303 of the PPACA. As such, HHS believes that this outweighs the estimated consumer burden. We solicit comments on the impact of the proposed policy at § 156.280(e)(2) and on whether other impacts should be considered or quantified.

We request comment on both our assessment of the need for the regulatory action and an explanation of how the regulatory action will meet that need, as well as our assessment of the potential costs and benefits of the regulatory action. To be sure our analysis is as accurate as possible with respect to any additional costs to states, issuers, or other entities, we encourage robust comment in this area.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Individuals and states are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this proposed rule would not have a significant economic impact on a substantial number of small entities.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2018, that threshold is approximately \$150 million. This rule will have no consequential effect on state, local, or tribal governments or on the private sector.

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 proposed 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

proposal that Exchanges conduct Medicare, Medicaid/CHIP, and, if applicable, BHP PDM at least twice a year, beginning with the 2020 calendar year. However, HHS believes that the Federalism implications are substantially mitigated because the proposed requirement sets only a minimum frequency with which Exchanges must conduct Medicare, Medicaid/CHIP, and, if applicable, BHP PDM, which is already required to be conducted periodically; SBEs would continue to have the flexibility to conduct PDM with greater frequency.

Additionally, the proposed changes to State Exchange oversight and reporting requirements in § 155.1200 have Federalism implications since those rules would 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 proposed changes do not impose new requirements on State Exchanges, but rather add specificity to the existing requirements.

This proposed rule is subject to the Congressional Review Act (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 the Congress and the Comptroller General for review.

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. Section 2(a) of Executive Order 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment, or otherwise promulgates, a new regulation. In furtherance of this requirement, section 2(c) of Executive Order 13771 requires that the new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations. OMB Guidance Implementing Executive Order 13771 (April 5, 2017) defines a regulatory action as (1) a significant regulatory action as defined in section 3(f) of Executive Order 12866, or (2) a significant guidance document (for example, significant interpretive guidance) that has been reviewed by OMB under the procedures of Executive

Order 12866 and that, when finalized, is expected to impose total costs greater than zero. This proposed rule, if finalized as proposed, is expected to be an E.O. 13771 regulatory action. Details on the estimated costs appear in the preceding analysis.

#### C. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed 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 commenters on similar Exchange-related CMS rules will be the number of reviewers of this proposed rule. We acknowledge this assumption may underestimate or overstate the costs of reviewing this rule. It is possible that not all commenters will review the rule in detail, and it is also possible that some reviewers will choose not to comment on the proposed rule. For these reasons, we consider the number of past commenters on similar CMS rules will be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule.

We recognize that different types of entities may be affected by only certain provisions of this proposed 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 Bureau of Labor and Statistics (BLS) for medical and health service managers (Code 11-9111), we estimate that the cost of reviewing this rule is \$107.38 per hour, including overhead and fringe benefits.<sup>17</sup> We estimate that it would take approximately 1 hour for the staff to review the relevant portions of this proposed rule. Based on previous and similar CMS rules, we assume that 321 entities will review this proposed rule. Therefore, we estimate that the total cost of reviewing this regulation is approximately \$34,469 (\$107.38 × 321 reviewers).

This may underestimate the review costs, since not all reviewers may have submitted comments. In addition, stakeholders may need to do a detailed analysis in order to implement the unanticipated provisions of this rule will need additional time and personnel, which will vary depending

<sup>17</sup> [https://www.bls.gov/oes/current/oes\\_nat.htm](https://www.bls.gov/oes/current/oes_nat.htm).

on the extent to which they are affected. To estimate an upper bound, we assume that on average 530 issuers and 50 states will spend 10 hours each, 100 other organizations will spend 5 hours each and 100 individuals will spend 1 hour each to review the rule. Under these assumptions, total time spent reviewing the rule would be 6,400 hours with an estimated cost of approximately \$673,024.

In accordance with the provisions of Executive Order 12866, this proposed rule 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 Department of Health and Human Services proposes to amend 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 is revised 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, assisters, and other 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 2020 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. SBEs that have implemented a fully integrated eligibility system that determines 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 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), (c) introductory text, and (d)(2) and (3);
- b. Redesignating (d)(4) as paragraph (d)(5);
- c. Adding a new paragraph (d)(4); and
- d. 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 governmental 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. Redesignating paragraph (e)(2)(ii) as (e)(2)(iii);
- b. Adding a new paragraph (e)(2)(ii); and
- c. Revising newly redesignated paragraph (e)(2)(iii).

The revisions and addition read as follows:

### § 156.280 Segregation of funds for abortion services.

\* \* \* \* \*

(e) \* \* \*

(2) \* \* \*

(ii) Send to each policy subscriber (without regard to the policy subscriber's age, sex, or family status) in the QHP separate monthly bills for each of the amounts specified in paragraphs (e)(2)(i)(A) and (B) of this section, and

instruct the policy subscriber to pay each of these amounts through separate transactions. If the policy subscriber fails to pay each of these amounts in a separate transaction as instructed by the issuer, the issuer may not terminate the policy subscriber's coverage on this basis, provided the amount due is otherwise paid.

(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: October 11, 2018.

**Seema Verma,**

*Administrator, Centers for Medicare & Medicaid Services.*

Dated: October 18, 2018.

**Alex M. Azar II,**

*Secretary, Department of Health and Human Services.*

[FR Doc. 2018-24504 Filed 11-7-18; 4:15 pm]

**BILLING CODE 4120-01-P**

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Parts 1 and 73

[AU Docket No. 17-329; DA 18-1038]

#### Auction of Cross-Service FM Translator Construction Permits; Comment Sought on Competitive Bidding Procedures for Auction 100

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule; proposed auction procedures.

**SUMMARY:** The Wireless Telecommunications and Media Bureaus (Bureaus) announce an auction of certain cross-service FM translator construction permits. This document also seeks comment on competitive bidding procedures and proposed minimum opening bids for Auction 100.

**DATES:** Comments are due on or before November 15, 2018, and reply comments are due on or before November 28, 2018.

**ADDRESSES:** Interested parties may submit comments in response to the Auction 100 Comment Public Notice by any of the following methods:

- **FCC's Website:** Federal Communications Commission's Electronic Comment Filing System (ECFS): <http://apps.fcc.gov/ecfs>. Follow

the instructions for submitting comments.

- **Mail:** FCC Headquarters, 445 12th Street SW, Room TW-A325, Washington, DC 20554.

- **People with Disabilities:** To request materials in accessible formats for people with disabilities (braille, large print, electronic files, or audio format), send an email to [FCC504@fcc.gov](mailto:FCC504@fcc.gov) or call the Consumer & Governmental Affairs Bureau at 202-418-0530 (voice), 202-418-0432 (TTY). For detailed instructions for submitting comments, see the **SUPPLEMENTARY INFORMATION** section of this document.

**FOR FURTHER INFORMATION CONTACT:** For auction legal questions, Lynne Milne in the Wireless Telecommunications Bureau's Auctions and Spectrum Access Division at (202) 418-0660. For general auction questions, the Auctions Hotline at (717) 338-2868. For FM translator service questions, James Bradshaw, Lisa Scanlan or Tom Nessinger in the Media Bureau's Audio Division at (202) 418-2700.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Auction 100 Comment Public Notice in AU Docket No. 17-329, DA 18-1038, released on October 19, 2018. The complete text of this document, including its attachment, is available for public inspection and copying from 8:00 a.m. to 4:30 p.m. Eastern Time (ET) Monday through Thursday or from 8:00 a.m. to 11:30 a.m. ET on Fridays in the FCC Reference Information Center, 445 12th Street SW, Room CY-A257, Washington, DC 20554. The Auction 100 Comment Public Notice and related documents also are available on the internet at the Commission's website: <https://www.fcc.gov/auction/100/>, or by using the search function for AU Docket No. 17-329 on the Commission's ECFS web page at <https://www.fcc.gov/ecfs/>.

All filings in response to the Auction 100 Comment Public Notice must refer to AU Docket No. 17-329. The Bureaus strongly encourage interested parties to file comments electronically, and request that an additional copy of all comments and reply comments be submitted electronically to the following address: [auction100@fcc.gov](mailto:auction100@fcc.gov).

**Electronic Filers:** Comments may be filed electronically using the internet by accessing ECFS: <http://apps.fcc.gov/ecfs>. Follow the instructions for submitting comments.

**Paper Filers:** Parties who choose to file by paper must file an original and one copy of each filing. Filings can be sent by hand or messenger delivery, by commercial overnight courier or by first-class or overnight U.S. Postal Service

mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission (FCC). All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to the FCC Headquarters at 445 12th Street SW, Room TW-A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. Eastern Time (ET). All hand deliveries must be held together with rubber bands or fasteners. Any envelope or box must be disposed of before entering the building. Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701. U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW, Washington, DC 20554.

### I. Introduction

1. On December 4, 2017, the Bureaus announced a second auction filing window for AM broadcasters seeking new cross-service FM translator station construction permits. By this Public Notice, the Bureaus seek comment on the procedures to be used for Auction 100. Auction 100 will be a closed auction: Only those entities listed in Attachment A of the Auction 100 Comment Public Notice will be eligible to participate further in Auction 100.

2. The Bureaus anticipate that the bidding for Auction 100 will commence in fiscal year 2019. The Bureaus will announce a schedule for bidding in Auction 100 by public notice, to provide applicants with sufficient time to submit upfront payments and prepare for bidding in the auction.

### II. Construction Permits in Auction 100

3. Auction 100 will resolve by competitive bidding mutually exclusive (MX) engineering proposals for construction permits for up to 13 new cross-service FM translator stations. The locations and channels of these proposed stations are identified in Attachment A of the Auction 100 Comment Public Notice. Attachment A also specifies a proposed minimum opening bid and a proposed upfront payment amount for each construction permit listed.

4. An applicant listed in Attachment A may become qualified to bid only if it complies with the additional filing, qualification, and payment requirements, and otherwise complies with applicable rules, policies, and procedures. Each qualified bidder will be eligible to bid on only those construction permits specified for that qualified bidder in Attachment A of the

*Patient Protection and Affordable Care Act:  
Exchange Program Integrity, 84 Fed. Reg.  
71,674 (Dec. 27, 2019) (Double-Billing Rule)*

**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.<sup>1</sup>

<sup>1</sup> 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

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

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.

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

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 initial 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.<sup>2</sup> 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

<sup>2</sup> 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 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.<sup>3</sup> 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

<sup>3</sup> "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.<sup>4</sup> 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.<sup>5</sup>

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

<sup>4</sup> 45 CFR 155.1200(c)(1) and (2).

<sup>5</sup> 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.<sup>6</sup> 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 methodology 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 irregularities. 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

<sup>6</sup> 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 administrative 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.<sup>7</sup> 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

<sup>7</sup> 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.

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."<sup>8</sup>

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.

<sup>8</sup> Section 1303(b)(1)(B)(i) of the PPACA.

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.<sup>9</sup>

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

<sup>9</sup> 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.<sup>10</sup>

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

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

<sup>10</sup>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

premium 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

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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.<sup>11</sup>

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.<sup>12</sup> 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.<sup>13</sup> 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

<sup>11</sup> "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>.

<sup>12</sup> 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.

<sup>13</sup> "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 minuscule 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.<sup>14</sup> 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

<sup>14</sup> 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).

(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

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.<sup>15</sup> 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,<sup>16</sup> 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<sup>17</sup> 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.”<sup>18</sup>

**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

<sup>16</sup> U.S. Government Accountability Office, “Health Insurance Exchanges: Coverage of Non-Exceptioned Abortion Services by Qualified Health Plans,” (Sept. 15, 2014), available at <http://www.gao.gov/products/GAO-14-742R>.

<sup>17</sup> U.S. Government Accountability Office, “Health Insurance Exchanges: Coverage of Non-Exceptioned Abortion Services by Qualified Health Plans,” (Sept. 15, 2014), available at <http://www.gao.gov/products/GAO-14-742R>.

<sup>18</sup> 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](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.<sup>19</sup> 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 finalizing 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

<sup>19</sup> U.S. Government Accountability Office, "Health Insurance Exchanges: Coverage of Non-Exceptioned Abortion Services by Qualified Health Plans," (Sept. 15, 2014), available at <http://www.gao.gov/products/GAO-14-742R>.

requirements of section 1303(b)(2)(C), (D), and (E) of the PPACA (hereinafter, "segregation plan").<sup>20</sup> 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.<sup>21</sup> 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.<sup>22</sup> 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

<sup>20</sup> 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).

<sup>21</sup> 2019 Qualified Health Plan Issuer Application Instructions, available at: <https://www.qhpcertification.cms.gov/s/2019QHPIInstructionsVersion1.pdf?v=1>.

<sup>22</sup> State Partnership Exchange Issuer Program Attestation Response Form, available at: [https://www.qhpcertification.cms.gov/s/SuppDoc\\_SPE\\_AttestationSed\\_revised\\_508.pdf?v=1](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.<sup>23</sup> 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

<sup>23</sup> 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 intentionally 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 coverage of non-Hyde abortion services.<sup>24</sup> 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

<sup>24</sup> 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).

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.”<sup>25</sup> 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

<sup>25</sup> 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>).

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.<sup>26</sup>

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

<sup>26</sup> 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.<sup>27</sup> 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

<sup>27</sup> See May 2018 Bureau of Labor Statistics, Occupational Employment and Wage Estimates at [https://www.bls.gov/oes/current/oes\\_stru.htm](https://www.bls.gov/oes/current/oes_stru.htm).

Occupational Employment and Wage Estimates at [https://www.bls.gov/oes/current/oes\\_stru.htm](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

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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:

Annualized Monetized (\$/year) .....	Estimate (million). \$304.09 .....	Year Dollar ..... 2019 .....	Discount Rate (percent). 7 .....	Period Covered 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 individuals 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 .....	7 .....	2020–2024
.....	\$77.7 .....	2019 .....	3 .....	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 \$200,000 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 minuscule 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](https://www.bls.gov/oes/current/oes_stru.htm)), listed national mean hourly wage for the 25th percentile,<sup>28</sup> 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

<sup>28</sup> 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 an 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
<b>Total .....</b>	<b>546,069,313</b>	<b>232,121,259</b>	<b>230,696,938</b>	<b>229,284,777</b>	<b>229,284,777</b>

#### 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 underestimate 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.<sup>29</sup> 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 requirements 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

<sup>29</sup> [https://www.bls.gov/oes/current/oes\\_nat.htm](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.<sup>30</sup> 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

<sup>30</sup> <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.<sup>31</sup>

#### 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

<sup>31</sup> 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 Department of Health and Human Services 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]

**BILLING CODE 4120-01-P**

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10 \*Application for admission pending

11 **UNITED STATES DISTRICT COURT**  
12 **EASTERN DISTRICT OF WASHINGTON**

13 STATE OF WASHINGTON,

14 Plaintiff,

15 v.

16 ALEX M. AZAR II, in his  
17 official capacity as Secretary of  
18 the United States Department of  
19 Health and Human Services;  
20 UNITED STATES  
DEPARTMENT OF HEALTH  
AND HUMAN SERVICES;  
SEEMA VERMA, in her official  
capacity as Administrator of the  
Centers for Medicare and  
Medicaid Services; and  
CENTERS FOR MEDICARE  
AND MEDICAID SERVICES,

21 Defendants.

22 NO. 2:20-CV-00047

23 ORDER GRANTING  
24 PLAINTIFF STATE OF  
25 WASHINGTON'S MOTION  
26 FOR PARTIAL SUMMARY  
27 JUDGMENT ON NON-  
28 PREEMPTION  
29 [PROPOSED]

30 NOTED FOR: APRIL 9, 2020  
31 WITH ORAL ARGUMENT

32 ORDER GRANTING PLAINTIFF STATE OF  
33 WASHINGTON'S MOTION FOR SUMMARY  
34 JUDGMENT ON NON-PREEMPTION  
35 [PROPOSED]  
36 NO. 2:20-CV-00047

37 1

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1

**ORDER**

2

This matter came before the Court on Plaintiff State of Washington's Motion for Partial Summary Judgment on Non-Preemption. The Court has considered the Motion, Defendants' Response, Plaintiff's Reply, and any documents filed therewith; the arguments of counsel; and the entire record in this matter.

6

The Court finds that the provisions of the agency rule entitled *Patient Protection and Affordable Care Act: Exchange Program Integrity*, 84 Fed. Reg. 71,674 (Dec. 27, 2019) to be codified at 45 C.F.R. § 156.280 are not in accordance with law. 5 U.S.C. § 706(2). These provisions are contrary to the Affordable Care Act's non-preemption provisions, 42 U.S.C. § 18023 and 42 U.S.C. § 18041, to the extent they conflict with Washington's statute requiring single-invoice billing, Wash. Rev. Code § 48.43.074.

13

The Court therefore **ORDERS** that Plaintiff's Motion for Partial Summary Judgment on Non-Preemption is **GRANTED**. Judgment is entered in favor of Plaintiff State of Washington on Counts I and II of Plaintiff's Complaint.

16

The Court hereby **DECLARES** that the provisions of the agency rule entitled *Patient Protection and Affordable Care Act: Exchange Program Integrity*, 84 Fed. Reg. 71,674 (Dec. 27, 2019) to be codified at 45 C.F.R. § 156.280 have no force or effect in the State of Washington. The Court further **DECLARES** that Washington's statute requiring single-invoice billing, Wash. Rev. Code § 48.43.074, remains in full force and effect notwithstanding the agency rule.

22

1 Pursuant to Federal Rule of Civil Procedure 54(b), the Court directs entry of  
2 a final judgment as to Counts I and II of Plaintiff's Complaint, finding no just reason  
3 for delay.

4 DATED this \_\_\_\_\_ day of \_\_\_\_\_, 2020.

5  
6  
7 THE HONORABLE STANLEY A. BASTIAN  
8  
9 Presented by:

10 ROBERT W. FERGUSON  
11 Attorney General

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24 \*Application for admission pending

25 ORDER GRANTING PLAINTIFF STATE OF  
26 WASHINGTON'S MOTION FOR SUMMARY  
27 JUDGMENT ON NON-PREEMPTION  
28 [PROPOSED]  
29 NO. 2:20-CV-00047