

DEPARTMENT OF HEALTH AND HUMAN SERVICES**45 CFR Parts 144, 146, 147, 153, 155, and 156**

[CMS–9957–F2; CMS–9964–F3]

RIN 0938–AR82; RIN 0938–AR74

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

SUMMARY: This final rule implements provisions of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 (collectively referred to as the Affordable Care Act). Specifically, this final rule outlines financial integrity and oversight standards with respect to Affordable Insurance Exchanges, qualified health plan (QHP) issuers in Federally-facilitated Exchanges (FFE), and States with regard to the operation of risk adjustment and reinsurance programs. It also establishes additional standards for special enrollment periods, survey vendors that may conduct enrollee satisfaction surveys on behalf of QHP issuers, and issuer participation in an FFE, and makes certain amendments to definitions and standards related to the market reform rules. These standards, which include financial integrity provisions and protections against fraud and abuse, are consistent with Title I of the Affordable Care Act. This final rule also amends and adopts as final interim provisions set forth in the Amendments to the HHS Notice of Benefit and Payment Parameters for 2014 interim final rule, published in the **Federal Register** on March 11, 2013, related to risk corridors and cost-sharing reduction reconciliation.

DATES: These regulations are effective on December 30, 2013.**FOR FURTHER INFORMATION CONTACT:** Leigha Basini at (301) 492–4380 for general information.

Jacob Ackerman at (301) 492–4179 for matters relating to Parts 144 and 147, single risk pool and catastrophic plans.

Adam Shaw at (410) 786–1091 for matters relating to the oversight of risk adjustment and reinsurance.

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Shelley Bain at (301) 492–4453 or Anne Pesto at (410) 786–3492 for matters relating to Part 155, Subpart M.

Ariel Novick at (301) 492–4309 for matters relating to the oversight of cost-sharing reductions and advance payments of the premium tax credit.

Johanna Lauer at (301) 492–4397 for matters relating to cost-sharing reduction reconciliation.

Rebecca Zimmermann at (301) 492–4396 for matters relating to quality standards, Part 156, Subpart L.

Cindy Yen at (301) 492–5142 for matters relating to Part 156 other than cost-sharing reductions, advance payments of the premium tax credit, and quality standards.

Pat Meisol at (410) 786–1917 for matters relating to confirmation of HHS payment and collections reports.

SUPPLEMENTARY INFORMATION:**Electronic Access**

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Executive Summary

Starting October 1, 2013, qualified individuals and qualified employees may purchase private health insurance coverage through competitive marketplaces called Affordable Insurance Exchanges, or “Exchanges” (also called Health Insurance Marketplaces). This final rule sets forth oversight and financial integrity standards with respect to Exchanges, Qualified Health Plan (QHP) issuers in Federally-facilitated Exchanges (FFE), and States with regard to the operation of risk adjustment and reinsurance programs. It establishes additional standards for special enrollment periods, survey vendors that may conduct enrollee satisfaction surveys on behalf of QHP issuers in Exchanges, and issuer participation in an FFE, and makes certain amendments to definitions and standards related to the market reform rules. These standards were proposed in a proposed rule, titled “Patient Protection and Affordable Care Act; Program Integrity: Exchange, SHOP, Premium Stabilization Programs, and Market Standards” (78 FR 37032), which was published in the **Federal Register** on June 19, 2013. Finally, this final rule amends standards and adopts as final interim provisions set forth in the Amendments to the HHS Notice of Benefit and Payment Parameters for 2014 interim final rule, published in the **Federal Register** on March 11, 2013 (78

FR 15541), related to risk corridors and cost-sharing reduction reconciliation.

Although many of the provisions in this rule become effective by January 1, 2014, we believe that affected parties will not have difficulty complying with the provisions by their effective dates, because most of the standards are based on existing standards currently in effect in the private market, were previously proposed through the Blueprint process, were discussed in agency-issued sub-regulatory guidance, or were discussed in the preambles to the Exchange Establishment Rule,¹ Premium Stabilization Rule,² Market Reform Rule,³ or the HHS Notice of Benefit and Payment Parameters for 2014 (2014 Payment Notice).⁴ In addition to soliciting general comments on the substance of the proposed provisions, we sought input on ways to implement these policies to minimize burden.

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² Patient Protection and Affordable Care Act; Standards Related to Reinsurance, Risk Corridors and Risk Adjustment, 77 FR 17220 (March 23, 2012).

³ Patient Protection and Affordable Care Act; Health Insurance Market Rules; Rate Review, 78 FR 13406 (February 27, 2013).

⁴ Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2014, 78 FR 15410 (March 11, 2013).

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Acronyms and Short Forms

Because of the many organizations and terms to which we refer by acronym in this final rule, we are listing these acronyms and their corresponding terms in alphabetical order below:

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))

ALJ Administrative Law Judge

ARF Allowable Rating Factor

AV Actuarial Value

CAHPS® Consumer Assessment of Healthcare Providers and Systems

CFR Code of Federal Regulations

CMP Civil money penalty

CMS Centers for Medicare & Medicaid Services

DOI State Department of Insurance

DOL U.S. Department of Labor

EHB Essential Health Benefits

FEHB Federal Employees Health Benefits

FFE Federally-facilitated Exchange

FF-SHOP Federally-facilitated Small Business Health Options Program

GAAP Generally accepted accounting principles

GAAS Generally accepted auditing standards

GAGAS Generally accepted governmental auditing standards

GAO U.S. Government Accountability Office

HHS U.S. Department of Health and Human Services

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

IRS Internal Revenue Service

MAGI Modified Adjusted Gross Income

MLR Medical Loss Ratio

NCQA National Committee for Quality Assurance

OIG Office of the Inspector General of the U.S. Department of Health and Human Services

OMB Office of Management and Budget

PHSAct Public Health Service Act

PRA Paperwork Reduction Act

QHP Qualified Health Plan

SHOP Small Business Health Options Program

The Code Internal Revenue Code of 1986

TIN Taxpayer Identification Number

I. Background

A. Legislative Overview

The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010. In this final rule, we refer to the two statutes collectively as the “Affordable Care Act.”

Subtitles A and C of Title I of the Affordable Care Act reorganized, amended, and added to the provisions of Title XXVII of the Public Health Service Act (PHS Act) relating to health insurance issuers in the group and individual markets and to group health plans that are non-Federal governmental plans. As relevant here, section 2702 of the PHS Act (guaranteed availability of coverage) directs a health insurance issuer offering non-grandfathered health insurance coverage in the group or individual market in a State to accept every employer and individual in the State who applies for coverage, subject to certain exceptions. Section 2703 of the PHS Act (guaranteed renewability of coverage) requires a health insurance issuer offering non-grandfathered health insurance coverage in the group or individual market to renew or continue in force such coverage at the option of the plan sponsor or individual, subject to certain exceptions.

As of October 2013 for coverage starting as soon as January 1, 2014, qualified individuals and qualified employers will be able to enroll in QHPs—private health insurance that has

been certified as meeting certain standards—through competitive marketplaces called “Exchanges” or “Health Insurance Marketplaces.” The Departments of Health and Human Services, Labor, and the Treasury have been working in close coordination to release guidance related to QHPs and Exchanges in several phases. The word “Exchanges” refers to both State Exchanges, also called State-based Exchanges, and FFEs. In this final rule, we use the terms “State Exchange” or “FFE” when we are referring to a particular type of Exchange. When we refer to “FFEs,” we are also referring to State Partnership Exchanges, which are a form of FFE.

In this final rule, we encourage State flexibility within the boundaries of the law. Sections 1311(b) and 1321(b) of the Affordable Care Act provide that each State has the opportunity to establish an Exchange. Section 1311(b)(1) gives each State the opportunity to establish an Exchange that both facilitates the purchase of QHPs and provides for the establishment of a Small Business Health Options Program (SHOP) that will help qualified employers enroll their employees in QHPs.

Section 1302(e) of the Affordable Care Act outlines standards for offering catastrophic plans in the individual market for certain young adults and people who obtain certification of exemption from the requirement to maintain minimum essential coverage because they cannot afford health insurance or experience other hardship.

Section 1311(c)(4) of the Affordable Care Act directs the Secretary to establish an enrollee satisfaction survey system that would evaluate the level of enrollee satisfaction with QHPs offered through an Exchange for each such QHP with more than 500 enrollees in the previous year.

Section 1311(d)(4)(A) of the Affordable Care Act directs that each Exchange must implement procedures for the certification, recertification, and decertification of health plans as QHPs, consistent with guidelines developed by the Secretary.

Section 1311(d)(5)(A) of the Affordable Care Act provides that States, when establishing Exchanges, must ensure that such Exchanges are self-sustaining beginning on January 1, 2015, and permits Exchanges to charge assessments or user fees to participating health insurance issuers to generate funding to support their operations. When operating an FFE under section 1321(c)(1) of the Affordable Care Act, HHS has the authority under sections 1321(c)(1) and 1311(d)(5)(A) to collect and spend such user fees. In addition,

31 U.S.C. 9701 permits a Federal agency to establish a charge for a service provided by the agency. Office of Management and Budget (OMB) Circular A–25 Revised establishes Federal policy regarding user fees and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public. Section 1311(d)(5)(B) contains a prohibition on the wasteful use of funds.

Section 1312(c) of the Affordable Care Act directs a health insurance issuer to consider all enrollees in all health plans (other than grandfathered health plans) offered by such issuer to be members of a single risk pool for each of its individual and small group markets. Section 1312(c) of the Affordable Care Act gives States the option to merge the individual and small group markets within the State into a single risk pool (merged market).

Section 1313 of the Affordable Care Act, combined with section 1321 of the Affordable Care Act, provides the Secretary with the authority to oversee financial integrity, compliance with HHS standards, and efficient and non-discriminatory administration of State Exchange activities. Section 1313(a)(6)(A) of the Affordable Care Act specifies that payments made by, through, or in connection with an Exchange are subject to the False Claims Act (31 U.S.C. 3729, et seq.) if those payments include any Federal funds.

Section 1341 of the Affordable Care Act establishes a transitional reinsurance program that begins in 2014 and is designed to provide issuers with greater stability as insurance market reforms are implemented and individuals begin to enroll in QHPs sold through Exchanges. Section 1342 of the Affordable Care Act establishes a temporary risk corridors program which permits the Federal government and QHPs to share in gains or losses resulting from inaccurate rate setting from 2014 through 2016. Section 1343 of the Affordable Care Act establishes a permanent risk adjustment program which is intended to provide payments to health insurance issuers that attract higher-risk populations, such as those with chronic conditions, and eliminate incentives for issuers to avoid higher-risk enrollees.

Section 1321(a)(1) of the Affordable Care Act provides general authority for the Secretary of Health and Human Services (referred to throughout this rule as the Secretary) to establish standards and regulations to implement the statutory requirements related to Exchanges, QHPs, and other

components of Title I of the Affordable Care Act.

Section 1401 of the Affordable Care Act amended the Internal Revenue Code (26 U.S.C.) to add section 36B, allowing a refundable premium tax credit to help individuals and families afford health insurance coverage. Under sections 1401, 1411, and 1412 of the Affordable Care Act and 45 CFR part 155, subpart D, an Exchange will make a determination of advance payments of the premium tax credit for individuals who enroll in QHP coverage through an Exchange and seek financial assistance. Section 1402 of the Affordable Care Act provides for the reduction of cost sharing for certain individuals enrolled in a QHP through an Exchange, and section 1412 of the Affordable Care Act provides for the advance payment of these reductions to issuers.

Under section 1411 of the Affordable Care Act, the Secretary is directed to establish a program for determining whether an individual meets the eligibility standards for Exchange participation, advance payments of the premium tax credit, cost-sharing reductions, and exemptions from the shared responsibility payment under section 5000A of the Code.

Sections 1412 and 1413 of the Affordable Care Act and section 1943 of the Social Security Act (the Act), as added by section 2201 of the Affordable Care Act, contain additional provisions regarding eligibility for advance payments of the premium tax credit and cost-sharing reductions, as well as provisions regarding simplification and coordination of eligibility determinations and enrollment with other health programs.

Unless otherwise specified, the provisions in this final rule related to the establishment of minimum functions of an Exchange are based on the general authority of the Secretary under section 1321(a)(1) of the Affordable Care Act.

B. Stakeholder Consultation and Input

HHS has consulted with stakeholders on a number of policies related to the operation of Exchanges, including the SHOP and premium stabilization programs. HHS has held a number of listening sessions with consumers, providers, employers, health plans, and State representatives to gather public input. HHS consulted with stakeholders through regular meetings with the National Association of Insurance Commissioners; regular contact with States through the Exchange establishment grant process and the Exchange Blueprint approval process; and meetings with tribal leaders and

representatives, health insurance issuers, trade groups, consumer advocates, employers, and other interested parties. We considered all of the public input as we developed the policies in the proposed rule, the interim final rule, and this final rule.

II. Provisions of the Final Regulations and Analysis of and Responses to Public Comments

A proposed rule, titled “Patient Protection and Affordable Care Act; Program Integrity: Exchange, SHOP, Premium Stabilization Programs, and Market Standards” (78 FR 37032), was published in the **Federal Register** on June 19, 2013 with a comment period ending on July 19, 2013. In total, we received approximately 99 public comments from various stakeholders including States, health insurance issuers, consumer groups, agents and brokers, provider groups, Members of Congress, tribal organizations, and other stakeholders. We received a few comments that were outside the scope of the proposed rule. A number of the provisions in the proposed rule were finalized in the final rule published in the **Federal Register** on August 30, 2013, titled “Patient Protection and Affordable Care Act; Program Integrity: Exchange, SHOP, and Eligibility Appeals” (78 FR 54070), hereinafter referred to as the “first Program Integrity final rule.” We are finalizing the remaining provisions of the proposed rule here.

The interim final rule, titled “Patient Protection and Affordable Care Act; Amendments to the HHS Notice of Benefit and Payment Parameters for 2014” (78 FR 15541) was published in the **Federal Register** on March 11, 2013 with a comment period that ended on April 30, 2013. Provisions of this rule align risk corridors calculations with the single risk pool provision, and finalize standards permitting issuers of QHPs the option of using an alternate methodology for calculating the value of cost-sharing reductions provided for the purpose of reconciliation of advance payments of cost-sharing reductions. We received seven comments on the interim final rule from issuers, advocacy organizations, and tribal organizations. We amend standards from the interim final rule and adopt interim provisions as final.

In this final rule, we provide a summary of each proposed or interim provision, a summary of the public comments received and our responses to them, and the provisions we are finalizing. We note that nothing in these regulations would limit the authority of the Office of the Inspector General (OIG)

as set forth by the Inspector General Act of 1978 or other applicable law.

A. Part 144—Requirements Relating to Health Insurance Coverage

1. Subpart A—General Provisions

a. Scope and Applicability (§ 144.102(c))

In § 144.102(c), we proposed a technical amendment to clarify whether coverage sold through associations is group or individual coverage under the PHS Act. Specifically, we proposed to delete a reference to coverage offered in connection with a “group health plan that has fewer than two participants who are current employees on the first day of the plan year” (very small plans) as being individual health insurance coverage under title XXVII of the PHS Act. This correction aligns with the amendments made by the Affordable Care Act redefining a small employer to include groups consisting of only one common law employee.

Comment: Commenters expressed support for the proposed clarification in § 144.102(c).

Response: We are finalizing the regulation as proposed.

Summary of Regulatory Changes

We are finalizing the amendments to § 144.102(c) as proposed.

b. Definitions (§ 144.103)

Under § 144.103, we proposed to amend several definitions of terms that are used throughout parts 146 (group market requirements), 148 (individual market requirements), and 150 (enforcement) of subchapter B of title 45 of the Code of Federal Regulations (CFR), consistent with the Affordable Care Act. These included definitions of “group market,” “individual market,” “large employer,” “policy year,” and “small employer.” Unless otherwise provided, the definitions in § 144.103 also apply for purposes of part 147 (group and individual market insurance reform requirements), and we make this explicit in this final rule.

We noted that, although the Affordable Care Act made changes to the definition of “small employer” for purposes of the PHS Act, the Employee Retirement Income Security Act (ERISA) and the Internal Revenue Code (the Code) continue to define a “small employer” as having 2 to 50 employees. Similarly, we noted that the Affordable Care Act deleted the exception for very small plans in PHS Act section 2721,⁵ without removing parallel provisions in ERISA section 732(a) and Code section

9831(a)(2). We requested comments on how to interpret the PHS Act, ERISA, and the Code to ensure that shared provisions of the Departments of HHS, Labor, and the Treasury are administered consistently.

Comment: Several commenters were in favor of adopting a consistent definition of “small employer” for purposes of the PHS Act, ERISA, and the Code. Some commenters thought the upper limit of small employer size should be 50 employees consistent with ERISA and the Code, while others suggested an upper limit of 100 employees consistent with the PHS Act and the Affordable Care Act. One commenter requested clarification that, although employers with one common law employee are now treated as small employer groups under the Affordable Care Act, retiree-only plans continue to be exempt from the group market reforms under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Affordable Care Act.

Response: Consistent with section 2791(e)(4) of the PHS Act and section 1304(b) of the Affordable Care Act, in this final rule, we maintain the definition of “small employer,” for purposes of health coverage, as an employer who employed an average of at least one but not more than 100 employees on business days during the preceding calendar year and who employs at least one employee on the first day of the plan year. Prior to 2016, States have discretion to set the upper limit of small employer size at 50 employees. Additionally, we conform the definitions of “individual market” and “group market,” as proposed, by removing references to group health plans with fewer than two participants who are current employees from being treated as being in the individual market rather than the group market. In the proposed rule, we noted the change to the law and proposed to make conforming amendments to update our rules to reflect the law with the intention of doing so for all applicable rules. While we inadvertently omitted reference to the exception for certain small group plans in § 146.145(b), we note that we believe that our intention to conform our rules to the law amended by the Affordable Care Act was clear and, accordingly, we make this conforming amendment in this final rule. As we pointed out earlier, identical language exempting group health plans with fewer than two participants from certain provisions of the PHS Act that formerly was in PHS Act section 2721(a) was stricken by the Affordable Care Act. We note that nothing in this final rule

⁵ The Affordable Care Act redesignated section 2721 as section 2722 of the PHS Act.

should be construed as affecting the Departments' position regarding retiree-only plans.⁶

Comment: Several commenters addressed the issue of how employees should be counted in determining employer size. Commenters noted that States use different methods to calculate employer group size and noted that there are also different Federal methods for determining employer size for different purposes. These commenters suggested that there are compelling practical and efficiency reasons to use a consistent counting method for all Affordable Care Act purposes and between Federal and State law.

Response: HHS has previously set forth the method for determining employer size for purposes relating to the Exchange and SHOP regulations based on the full-time equivalent method used in section 4980H(c)(2) of the Code, generally effective for plan years beginning on or after January 1, 2016.⁷ We expect to address the counting method for purposes of the PHS Act in future rulemaking or guidance.

Summary of Regulatory Changes

We are finalizing the provisions proposed in § 144.103 of the proposed rule with the following minor modifications for consistency and clarity. We state expressly that the definitions in this section which are based on PHS Act requirements enacted by HIPAA and other statutes (implemented in parts 146, 148, and 150) are equally applicable to PHS Act requirements enacted by the Affordable Care Act (implemented in part 147). In the proposed definition of "policy year," we replace the reference to January 1, 2015 with the phrase, "for coverage issued or renewed beginning January 1, 2014," to clarify the definition's applicability to calendar year plans, as discussed in connection with § 147.104(b)(2) of this final rule. Finally, we remove the exception for certain small group health plans in § 146.145(b) to conform to the amendments in § 144.102 and § 144.103 of this final rule.

⁶ Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act, 75 FR at 34539–40 (June 17, 2010).

⁷ For operations of a Federally-facilitated SHOP, the method set forth in section 4980H(c)(2) of the Code is effective for plan years beginning on or after January 1, 2014, including in connection with open enrollment activities beginning October 1, 2013.

B. Part 147—Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets

1. Guaranteed Availability and Renewability of Coverage (§ 147.104 and § 147.106)

In the proposed rule, we proposed to recognize the distinction of the large group and small group segments of the group market for purposes of sections 2702 and 2703 of the PHS Act, as amended by the Affordable Care Act, and their implementing regulations at 45 CFR 147.104 and 147.106, respectively. These proposed amendments would clarify that under the guaranteed availability provisions, an issuer is required to offer to an employer only those products that are approved for sale in the applicable market segment (large group or small group market) based on the employer's group size (rather than all group market products). The proposed amendments would also clarify that under the guaranteed renewability provisions, an issuer could, in accordance with applicable State law and subject to the other requirements of § 147.106(d), elect to discontinue all products in one segment of the group market (for example, the large group market) without having to discontinue all products in the other segment of the group market (for example, small group market).⁸

We also proposed to clarify in § 147.104(b)(2) that all non-grandfathered coverage in the individual or merged market must be offered on a calendar year basis as of January 1, 2015. We specified that, for purposes of new enrollment effective on any date other than January 1, the first policy year following such enrollment may comprise a prorated policy year ending on December 31.

Comment: Commenters generally expressed support for the proposed revisions in § 147.104 and § 147.106. However, one commenter disagreed with proposed § 147.104(b)(2), in which all non-grandfathered individual or merged market plans would be offered on a calendar year basis. The commenter suggested that individuals with non-calendar year plans should be permitted to maintain their plans' current renewal date.

Response: We seek consistency between the Exchange and non-Exchange markets to mitigate adverse

⁸ These clarifications were consistent with the information we provided in "Frequently Asked Questions on Health Insurance Marketplaces" (May 14, 2013). Available at: <http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/marketplace-faq-5-14-2013.pdf>.

selection, reduce consumer confusion, and ensure compliance with the single risk pool requirements. For these reasons, in the Market Reform Rule at § 147.104(b), we aligned individual market open enrollment periods and coverage effective dates with those in the individual market Exchanges (which are based on a calendar policy year) and, to facilitate the transition to calendar policy years, established a one-time enrollment period allowing individuals with non-calendar year plans the opportunity to enroll in a calendar year plan upon renewal in 2014. This final rule simply affirms the intent of the Market Reform Rule and does not represent a change in policy. We reiterate that, for purposes of new enrollment effective on any date other than January 1, the first policy year following such enrollment may comprise a prorated policy year ending on December 31 of that year.

Comment: A few commenters sought clarification on whether an issuer is required to renew coverage purchased by an employer whose size shifts between the small and large group markets.

Response: HHS has previously issued guidance on how the guaranteed renewability requirement applies to employers whose size shifts between the small and large group markets after purchasing coverage in one or the other of these markets.⁹ The general rule set forth in section 2703 of the PHS Act and its implementing regulations at § 147.106 makes clear that a health insurance issuer must guarantee the renewal of coverage at the option of the plan sponsor. The exceptions to this rule do not include the situation in which the employer that sponsors the group health plan grows from a small employer to a large employer, or the reverse, between the time the policy is purchased and the time it comes up for renewal. Therefore, the law guarantees the employer the right to renew or continue in force the coverage it purchased in the small (or large) group market even though the employer ceases to be a small (or large) employer by reason of an increase (or decrease) in its number of employees.

For example, an employer that originally purchased coverage in the small group market and that increases in size beyond the definition of a small employer has the option of keeping the product it purchased in the small group market. Furthermore, any changes to

⁹ HCFA Insurance Standards Bulletin Series No. 99–03 (September 1999). Available at: <https://www.cms.gov/HealthInsReformforConsume/downloads/HIPAA-99-03.pdf>.

that product must satisfy the uniform modification of coverage requirements set forth in section 2703(d) of the PHS Act and § 147.106(e). Under these provisions, an issuer is permitted at the time of renewal to modify the coverage for that product, but only if the modification is consistent with State law and effective uniformly to all employers with that product. Thus, if other employers with that product were still participating in the small group market, the issuer could not modify the benefits or cost sharing for the product in a manner inconsistent with the rules that apply to small group coverage. We note that under this scenario, if the employer drops coverage it purchased in the small group market, it will not be able to purchase the same coverage again if it no longer meets the definition of a small employer.

The requirements of guaranteed renewability do not change the underlying employer group's size for other provisions of the PHS Act and the Affordable Care Act. For example, the premium rating rules (PHS Act section 2701 and implementing regulations at § 147.102) and the single risk pool provision (Affordable Care Act section 1312(c) and implementing regulations at § 156.80) apply to health insurance coverage in the individual and small group markets, but generally do not apply to health insurance coverage in the large group market.¹⁰ These provisions of Federal law generally would not therefore apply where an employer increases in size to become a large employer, even if the employer is renewing a product originally purchased in the small group market.¹¹

Summary of Regulatory Changes

We are finalizing these provisions with the following minor modification.

¹⁰ Beginning in 2017, States will have the option to allow issuers to offer QHPs in the large group market through the SHOP. If a State elects this option, the rating rules under PHS Act section 2701 will apply to all coverage offered in such State's large group market (except for self-insured group health plans) pursuant to section 2701(a)(5) of the PHS Act and § 147.102(f).

¹¹ However, pursuant to section 1304(b)(4)(D) of the Affordable Care Act, a qualified employer that is a small employer participating in the SHOP may continue to participate in the SHOP, and will continue to be treated as a small employer for purposes of subtitle D of the Affordable Care Act, even if the employer ceases to be a small employer by reason of an increase in its number of employees. Subtitle D includes the provisions governing SHOP Exchanges, EHB, the single risk pool, and the premium stabilization programs but not premium rating requirements under section 2701 of the PHS Act. We intend to propose in future rulemaking how plans that are sold through the SHOP to employers that grow from small to large will be required to comply with single risk pool and premium rating requirements and how these plans, therefore, participate in the risk corridors programs.

In § 147.104(b)(2), we remove the reference to January 1, 2015 to avoid unwarranted confusion as to when non-grandfathered plans in the individual or merged market must be offered on a calendar year basis. Pursuant to § 147.104(f), all non-grandfathered individual and merged market coverage issued or renewed on or after January 1, 2014 must be offered on a calendar year basis, with a policy year ending on December 31 of each year and the next policy year beginning on January 1 of the following year. The proposed rule included January 1, 2015 as the latest date by which a non-calendar year plan renewing in 2014 (i.e., a plan renewing on December 31, 2014) would be subject to this requirement. We believe the proposed text may have been subject to unintended ambiguity and are finalizing revised text to eliminate that concern.

C. Part 153—Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment Under the Affordable Care Act

In the proposed rule, we proposed certain provisions related to program integrity for State-operated risk adjustment and reinsurance programs, including provisions governing reporting requirements and restricting the use of reinsurance funds for administrative expenses. In addition, we proposed record retention standards for States operating risk adjustment, for contributing entities, and for reinsurance-eligible plans when HHS operates reinsurance on behalf of a State. We intend to propose additional standards related to the oversight of the premium stabilization programs in future regulations and guidance.

We also note that, to alleviate the upfront burden of the reinsurance contributions, we intend to propose in future rulemaking to collect reinsurance contributions in two installments—the reinsurance contributions for reinsurance payments and administrative expenses would be collected at the beginning of the calendar year following the applicable benefit year, and the contributions for payments to the U.S. Treasury would be collected at the end of the calendar year following the applicable benefit year. We also intend to propose in future rulemaking to exempt certain self-insured, self-administered plans from the requirement to make reinsurance contributions for the 2015 and 2016 benefit years.

1. Subpart A—General Provisions

a. Definitions (§ 153.20)

We proposed an amendment to the definition of a “contributing entity” to address a situation in which the healthcare coverage provided to a participant under a group health plan is partially insured and partially self-insured—for example, if medical benefits are provided under a self-insured arrangement but prescription drug benefits are provided under an insured arrangement. We proposed this amendment to clarify that, for purposes of determining whether an entity bears liability for reinsurance contributions, a self-insured group health plan includes a group health plan that is partially self-insured and partially insured, but only where the insured coverage does not constitute major medical coverage (whether or not the self-insured coverage is major medical coverage). This amendment clarifies that if a group health plan is structured in such a manner, the group health plan would be liable for reinsurance contributions under the counting rules applicable to self-insured group health plans at 45 CFR 153.405(f), but if the insured component of the group health plan is major medical coverage, the issuer remains liable for the contributions.

We also sought comment on whether we should adopt a definition for “major medical coverage” that would provide additional clarity on when a contributing entity would have the responsibility to make reinsurance contributions.

Comment: Several commenters supported the proposed amendment. One commenter sought clarification as to which party is liable for reinsurance contributions with respect to a group health plan that is partially self-insured and partially insured when both forms of coverage are major medical coverage. The commenter recommended that the issuer be liable for reinsurance contributions in a situation in which the in-network coverage is insured, because the insured in-network coverage would account for the majority of the total health coverage for the covered individuals.

Response: We clarify that the amendment to the definition of “contributing entity” does not alter the responsibility of the issuer for the reinsurance contributions under these facts. The amendment to the definition of “contributing entity” addresses a scenario in which a self-insured plan includes insured coverage that is *not* major medical coverage; however, the fact pattern described above concerns a self-insured plan that includes insured

major medical coverage. Under § 153.400(a)(1)(i) and § 153.20, an issuer that offers major medical coverage to its covered lives is a “contributing entity,” and is responsible for reinsurance contributions for the covered lives, and under these facts the self-insured plan under this proposed amendment would not be a contributing entity because the insured component of the plan is major medical coverage.

Comment: Certain commenters requested that HHS codify a definition of major medical coverage for purposes of reinsurance contributions. One commenter asked HHS to codify in regulation text the definition of major medical coverage set forth in the preamble to the 2014 Payment Notice (78 FR at 15456), while continuing to carefully examine this issue to determine if the definition should be revised, expanded, or made more specific in the future. One commenter asked HHS to include in a definition of “major medical coverage” the set of health benefits defined in the American Academy of Pediatrics’ *Scope of Health Care Benefits for Children from Birth through Age 26*.

Response: We agree that a more specific definition of “major medical coverage” for purposes of reinsurance contributions would add certainty for some contributing entities. We therefore intend to propose a specific definition in the HHS Notice of Benefit and Payment Parameters for 2015.

Summary of Regulatory Changes

We are finalizing the amendment to the definition of “contributing entity” as proposed.

2. Subpart C—State Standards Related to the Reinsurance Program

a. Maintenance of Records (§ 153.240(c))

We proposed to amend 45 CFR 153.240(c) to be consistent with the maintenance of records requirement for State-operated risk adjustment programs proposed in § 153.310(c)(4). We proposed to amend § 153.240(c) such that a State establishing a reinsurance program would be directed to maintain documents and records relating to the reinsurance program, whether paper, electronic, or in other media, for each benefit year for at least 10 years, and make them available upon request from HHS, the OIG, the Comptroller General, or their designees, to any such entity. The documents and records must be sufficient to enable HHS to evaluate whether the State-operated reinsurance program complies with Federal standards. States would also be directed to ensure that their contractors,

subcontractors, and agents similarly maintain and make relevant documents and records available upon request from HHS, the OIG, the Comptroller General, or their designees.

Comment: Several commenters asked that HHS reduce the 10-year record retention standard, while other commenters supported the 10-year retention timeframe. One commenter suggested that a 10-year record retention standard is not needed for the False Claims Act.

Response: We are finalizing the maintenance of records provisions as proposed, in alignment with the statute of limitations for the False Claims Act and existing related regulations. A civil action may be brought under the False Claims Act “no more than 10 years after the date on which the violation is committed.” Additionally, similar 10-year record retention standards were previously finalized in the Exchange Establishment Rule and the Premium Stabilization Rule. We believe that maintaining consistency in our record retention standards will help ensure that entities maintain records across programs in a consistent manner, allowing HHS and States to coordinate oversight efforts across those program areas and reduce the burden on stakeholders. We note that the 10-year obligation to retain records begins when the record is created.

Comment: One commenter recommended that electronic maintenance of records should satisfy the maintenance of records standard.

Response: An entity subject to the maintenance of records standard may satisfy the standard by maintaining the records electronically and ensuring that they are accessible if needed in the event of an investigation, audit, or other review.

Comment: Several commenters asked HHS to provide details on the specific documents and records that States, contributing entities or issuers would be required to maintain for oversight purposes. In particular, one commenter suggested that issuers should not be required to retain medical records in connection with the risk adjustment program.

Response: We will provide further details on the documents and records to be maintained in future guidance or rulemaking. Because risk adjustment-eligible claims, medical documents, and medical records will be subject to medical record review as part of the risk adjustment data validation process, issuers of risk adjustment covered plans must maintain these documents. We note that this record maintenance and medical record review is subject to

applicable privacy law, including the protections of HIPAA.

Comment: One commenter asked that HHS reserve the authority to use the documents and records maintained pursuant to these provisions to verify whether issuers are in compliance with certain other requirements under the Affordable Care Act. For example, these documents and records could be used to help determine whether issuers are in compliance with the single risk pool premium rating requirement.

Response: We do not intend to use the documents and records maintained pursuant to these provisions for purposes other than monitoring compliance with the applicable statutes and regulations for those programs. In general, primary enforcement jurisdiction over the single risk pool premium rating requirement lies with the States.

Summary of Regulatory Changes

We are finalizing the maintenance of records provision set forth in § 153.240(c) as proposed, as well as the maintenance of records provisions set forth in § 153.310(c)(4). We are also finalizing the maintenance of records provision set forth in § 153.405(h), § 153.410(c) and § 153.620(b) with conforming technical corrections. In these provisions, to conform with our other record retention standards in this rule, we are clarifying that in each provision it is the “documents and records” that must be made available upon request. In § 153.620(b), we clarify that records must be maintained for 10 years. Finally, we are making a conforming amendment to § 153.520(e) so that the risk corridors recordkeeping requirement is consistent with the foregoing provisions. Section 153.520(e) will read: “A QHP issuer must maintain documents and records whether paper, electronic, or in other media, sufficient to enable the evaluation of the issuer’s compliance with applicable risk corridors standards, for each benefit year for at least 10 years, and must make those documents and records available upon request from HHS, the OIG, the Comptroller General, or their designees, to any such entity, for purposes of verification, investigation, audit or other review.”

b. General Oversight Requirements for State-Operated Reinsurance Programs (§ 153.260)

HHS expects that States will operate the reinsurance program under section 1341 of the Affordable Care Act in an effective and efficient manner and in accordance with the provisions of subparts B and C of 45 CFR part 153.

Therefore, pursuant to our authority under sections 1321(a)(1) and 1341 of the Affordable Care Act, we proposed certain general oversight requirements for State-operated reinsurance programs. In § 153.260(a), we proposed that a State establishing the reinsurance program ensure that its applicable reinsurance entity keeps, for each benefit year, an accounting of the following: (1) All reinsurance contributions received from HHS for reinsurance payments and for administrative expenses; (2) all claims for reinsurance payments received from issuers of reinsurance-eligible plans; (3) all reinsurance payments made to issuers of reinsurance-eligible plans; and (4) all administrative expenses incurred for the State's reinsurance program. We proposed to require that this accounting be kept in accordance with GAAP, consistently applied.

In § 153.260(b), we proposed that a State that establishes the reinsurance program submit to HHS and make public a summary report on its reinsurance program operations for each benefit year. This report would include a summary of the accounting for the benefit year as set forth in proposed § 153.260(a).

In § 153.260(c), we proposed that a State that establishes the reinsurance program engage an independent qualified auditing entity to perform a financial and programmatic audit of the program for each benefit year in accordance with GAAS. Pursuant to § 153.260(c)(2), the State would be directed to ensure that this audit addresses the prohibitions set forth in § 153.265 (concerning improper use of reinsurance funds for administrative expenses).

In paragraph (c)(1), we proposed that the State provide to HHS the results of the independent external audit for each benefit year, and in paragraph (c)(3), we proposed that the State identify to HHS any material weakness or significant deficiency identified in the audit (as these terms are defined in GAAS issued by the American Institute of Certified Public Accountants, and Government Auditing Standards issued by the Government Accountability Office (GAO)¹²). We further proposed that the State address in writing to HHS how the State intends to correct any such material weakness or significant

deficiency. To ensure transparency and accountability of a State-operated reinsurance program's finances and activities, we proposed in paragraph (c)(4) that the State make public a summary of the results of the external audit, including any material weakness or significant deficiency. We believe that these measures are necessary to ensure the proper use of reinsurance contributions under the uniform contribution rate, which HHS will collect from all contributing entities pursuant to 45 CFR 153.220. We received several comments supporting these provisions.

Summary of Regulatory Changes

We are finalizing these provisions as proposed. We are finalizing these provisions with one modification. We are clarifying in paragraph (c)(4) that in making public any material weakness or significant deficiency from the external audit, the State must also make public how it intends to correct the material weakness or significant deficiency.

Summary of Regulatory Changes

We are finalizing these provisions with one modification. We are clarifying that when the State makes public a summary of the results of the external audit, including any material weakness or significant deficiency, it must also make public how it intends to correct the material weakness or significant deficiency, in the manner and timeframe to be specified by HHS.

c. Restrictions on Use of Reinsurance Funds for Administrative Expenses (§ 153.265)

To achieve the intended purpose of the reinsurance program, reinsurance contributions collected must be spent on reinsurance payments, payments to the U.S. Treasury, and on reasonable expenses to administer the reinsurance program. In § 153.260(a), we proposed that a State operating reinsurance would be directed to keep an accurate accounting of the reinsurance funds received from HHS for administrative expenses and all the administrative expenses incurred for the State-operated reinsurance program. If a State incurs fewer expenses in operating reinsurance for a benefit year than are allocated to it under the uniform reinsurance contribution rate the State would be directed to use those funds to operate reinsurance in subsequent benefit years.

Section 1311(d)(5)(B) of the Affordable Care Act prohibits an Exchange from using any funds intended for the administrative and operational expenses of the Exchange for staff retreats, promotional giveaways,

excessive executive compensation, or the promotion of Federal or State legislative and regulatory modifications. In § 153.265, we proposed to extend these prohibitions to State-operated reinsurance programs, so that a State establishing a reinsurance program would be directed to ensure that its applicable reinsurance entity did not use funds that were intended to support reinsurance program operations (including any reinsurance contributions collected under the national contribution rate for administrative expenses) for any purpose prohibited in section 1311(d)(5)(B) of the Affordable Care Act. We received comments supporting this provision.

Summary of Regulatory Changes

We are finalizing this provision as proposed.

3. Subpart D—State Standards Related to the Risk Adjustment Program

In the first Program Integrity final rule (78 FR 54070), we revised the definition of "Exchange" in § 155.20 and amended various other provisions of Part 155 to permit a State to establish and operate only a State-based SHOP while the individual market Exchange for the State is established and operated as an FFE. Because § 153.310(a)(1) provides that a State that elects to operate an Exchange is eligible to establish a risk adjustment program, when proposing these amendments, we sought comment on whether a State that elects to establish and operate a SHOP but not an individual market Exchange should also be eligible to establish a risk adjustment program. Additionally, we sought comment on whether such a State would be eligible to establish a risk adjustment program only for the small group market or would be required to establish the program for both markets. All these amendments were finalized in the first Program Integrity final rule, and we are not re-proposing or finalizing any of them in this rulemaking. However, we elected to address the comments we received on the risk adjustment options for States electing to establish and operate only a SHOP in the preamble to this final rule, rather than in the preamble to the first Program Integrity final rule.

Comment: Several commenters asked that HHS permit a State that is operating a SHOP-only Exchange to operate a risk adjustment program for both the small group market and the individual market. One commenter opposed permitting a State that elects to operate a SHOP-only Exchange to establish a risk adjustment program only in the small group market.

¹² See, Government Auditing Standards (2011 Revision), available at: <http://www.gao.gov/yellowbook>. For public companies, the Public Company Accounting Oversight Board (PCAOB) sets audit standards. See, <http://pcaobus.org/Standards/Auditing/Pages/default.aspx>. For non-public companies, the AICPA sets audit standards. See, <http://www.aicpa.org/Research/Standards/AuditAttest/Pages/SAS.aspx>.

Several commenters stated that restricting a State's ability to operate risk adjustment to the small group market could deprive the State of economies of scale, add compliance burdens to issuers who operate in both markets, and add complexity to operational requirements such as data collection and reporting.

Response: For 2015 and later years, HHS will permit a State operating a SHOP-only Exchange to propose an alternate risk adjustment methodology that covers both the individual and small group markets, and to apply for approval to operate a risk adjustment program in both markets. HHS will evaluate the proposed alternate risk adjustment methodology using the same alternate risk adjustment methodology certification process set forth in the Premium Stabilization Rule and 2014 Payment Notice, in accordance with the standards set forth in 45 CFR 153.330(b), to ensure that it appropriately addresses risk selection in both markets, and will evaluate the State's application to operate risk adjustment in accordance with the standards set forth in 45 CFR 153.310(d) to ensure the State is ready to operate risk adjustment in both markets. We emphasize that this policy does not alter the definition of "Exchange" or any of the other amendments to provide States with the option of establishing and operating only a SHOP Exchange that we finalized in the first Program Integrity final rule.

a. Maintenance of Records (§ 153.310(c)(4))

In § 153.310(c)(4), we proposed that a State operating a risk adjustment program would be directed to maintain documents and records relating to the risk adjustment program, whether paper, electronic, or in other media, for each benefit year for at least 10 years, and make them available upon request from HHS, the OIG, the Comptroller General, or their designees, to any such entity. The documents and records must be sufficient to enable the evaluation of a State-operated risk adjustment program's compliance with Federal standards. States would also be directed to ensure that their contractors, subcontractors, and agents maintain and make those documents and records available upon request from HHS, the OIG, the Comptroller General, or their designees. We noted that a State may satisfy this standard by archiving these documents and records and ensuring that they are accessible if needed in the event of an investigation, audit, or other review. This provision is consistent with the requirements set forth in

§ 153.240(c), which contains record retention standards for State-operated reinsurance programs. We note that the 10-year obligation to retain records begins when the record is created.

We addressed the comments received on the proposed maintenance of records provisions in the preamble discussion of § 153.240(c) above. Below we address a comment specific to this provision.

Comment: One commenter asked HHS to amend this standard to provide that these documents and records be made available to the State validation auditor as well as HHS, the OIG, the Comptroller General, or their designees.

Response: We are not making this amendment because risk adjustment data validation validates the records of an issuer, not the records of the State entity operating risk adjustment. Thus, a State validation auditor should not need to review the State risk adjustment entity's documents.

Summary of Regulatory Changes

We are finalizing this provision as proposed.

b. Interim Report and State Summary Report (§ 153.310(d))

In § 153.310(d)(3), we proposed that, in addition to the requirements set forth in 45 CFR 153.310(d)(1) and (d)(2), a State would be directed to provide to HHS an interim report, in a manner specified by HHS, that includes a detailed summary of its risk adjustment activities in the first 10 months of the benefit year in order to obtain re-approval from HHS to operate risk adjustment for a third benefit year.¹³ This report would be due no later than December 31 of the first benefit year for which a State operates risk adjustment. We note that because the process for obtaining re-approval to operate risk adjustment begins more than one year before the beginning of the applicable benefit year, the first benefit year for which an interim report based on the first year's operations could be used for approval purposes is the third benefit year.

We proposed to amend 45 CFR 153.310(f) and re-designate it as § 153.310(d)(4). In § 153.310(d)(4), we

¹³ In the 2014 Payment Notice, we finalized a process for approving the operational aspects of a State's risk adjustment program. This process is distinct from the previously established process through which a State may obtain Federal certification of an alternate risk adjustment methodology. In an attempt to clarify these two related but distinct concepts, we have made minor technical corrections to ensure that the terms "approval" and "re-approval" refer to HHS's evaluation of a State's risk adjustment operations and the terms "certification" and "recertification" refer to our evaluation of a proposed alternate risk adjustment methodology.

proposed that in order to obtain re-approval from HHS to operate risk adjustment for each benefit year after the third benefit year for which it is approved, each State operating a risk adjustment program would be directed to submit to HHS and make public a detailed summary of risk adjustment program operations for the most recent benefit year for which risk adjustment operations have been completed, in the manner and timeframe specified by HHS. We proposed that the summary report must include the results of a programmatic and financial audit for the benefit year of the State-operated risk adjustment program conducted by an independent qualified auditing entity in accordance with GAAS. In § 153.310(d)(4)(ii), we proposed that the summary report would identify to HHS any material weakness or significant deficiency (as these terms are defined in GAAS issued by the American Institute of Certified Public Accountants, and Government Auditing Standards issued by the GAO¹⁴) identified in the independent external audit and address in writing to HHS how the State intends to correct any such material weakness or significant deficiency.

We are finalizing these provisions with minor changes in paragraph (d)(4)(ii). We are deleting references in that paragraph to HHS to make clear that any material weakness or significant deficiency identified in the audit, including the methods the State intends to use to correct any such material weakness or significant deficiency, must be made public, and not only provided to HHS.

Comment: One commenter asked HHS to clarify its expectations for the interim report and summary report, and the programmatic components HHS anticipates a State would report through audit findings.

Response: The interim report will help HHS verify the ongoing implementation of the risk adjustment program and review concerns identified by HHS or stakeholders (for example, we may request more information on the State's oversight plan). We will expect the State to report to HHS regarding the State's implementation of the processes outlined in the State's application for certification of its alternate risk adjustment methodology (or

¹⁴ See, Government Auditing Standards (2011 Revision), available at: <http://www.gao.gov/yellowbook>. For public companies, the Public Company Accounting Oversight Board (PCAOB) sets audit standards. See, <http://pcaob.us.org/Standards/Auditing/Pages/default.aspx>. For non-public companies, the AICPA sets audit standards. See, <http://www.aicpa.org/Research/Standards/AuditAttest/Pages/SAS.aspx>.

recertification), if applicable, and its application for approval of its operations.

We expect that the summary report will include a review of the State-operated program's operations over a benefit year, including the State's implementation of the risk adjustment methodology over a full payment transfer cycle. A full year of risk adjustment operations will extend beyond a benefit year because payment transfers are not determined until the year following the applicable benefit year. Therefore, the State will not need to submit this summary report until after the end of the benefit year, upon completion of the full payment transfer cycle. We will provide further details on the risk adjustment interim and summary reports in future guidance.

Comment: One commenter asked HHS to permit State flexibility in reporting, and asked that re-approval be based on an assessment of a State's success in meeting the goals specific to its risk adjustment program.

Response: We anticipate that we will require standardized reporting of certain metrics, but that a State will be able to focus on the specific characteristics of the State's risk adjustment program within the report.

Comment: One commenter asked whether the summary report in § 153.310(d)(4) will also be required at the conclusion of the first benefit year and whether an interim report would be required at any time after the first benefit year.

Response: As required by § 153.310(d)(4), each State operating a risk adjustment program is required to submit to HHS an annual summary of risk adjustment program operations in the manner and timeframe specified by HHS. The summary report will be required after the conclusion of the first benefit year's risk adjustment operations (and after the conclusion of each later benefit year's risk adjustment operations), including the completion of the payment transfer cycle. However, an interim report will be required only for the first benefit year.

Comment: One commenter asked whether the interim report must include an independent external audit.

Response: An independent external audit will not be required for the interim report.

Comment: One commenter asked how HHS will review a State-operated risk adjustment program's operations in the second year of operation, including whether any additional information will be required during the second year of operation.

Response: Only a summary report, as required by § 153.310(d)(4), will be required for the second year of operation. We are requiring an interim report for the first year of operations to inform HHS re-approval for a third benefit year of operation because we will not yet have access to any summary reports covering a full year at the time of re-approval. For example, a State operating risk adjustment in 2014 would submit an interim report no later than December 31, 2014. HHS would use the information provided in this interim report to determine if the State will be re-approved to operate risk adjustment for the 2016 benefit year. We would indicate this re-approval in the HHS Notice of Benefit and Payment Parameters for 2016, which is published in 2015.

Comment: One commenter supported the requirement that a State-operated risk adjustment program submit summary reports, and recommended that the summary report include an analysis of coding intensity trends.

Response: We will not require a State operating risk adjustment to include an analysis of coding intensity trends in the State's summary report. However, a State may choose to review this information as part of the State's oversight strategy.

Summary of Regulatory Changes

We are finalizing these provisions with minor changes. We are deleting references to HHS in paragraph (d)(4)(ii) to make clear that any material weakness or significant deficiency identified in the audit, including the methods the State intends to use to correct any such material weakness or significant deficiency, must be made public, and not only provided to HHS. We are also including minor conforming changes so that references to "certification" and "recertification" in connection with the evaluation of a State's operation of risk adjustment are changed to references to "approval" and "re-approval."

c. General Oversight Requirements for State-Operated Risk Adjustment Programs (§ 153.365)

To enable HHS to re-approve States to operate risk adjustment pursuant to 45 CFR 153.310(d), HHS proposed in § 153.365 that a State operating a risk adjustment program keep an accounting of all receipts and expenditures related to risk adjustment payments and charges and the administration of risk adjustment-related functions and activities for each benefit year. This accounting would be kept in accordance with GAAP, and would apply

consistently to all risk adjustment-related activities. This standard is similar to the standard proposed at § 153.260(a), which applies to the reinsurance program when operated by a State. We received no comment on this proposed provision.

Summary of Regulatory Changes

We are finalizing this provision as proposed.

4. Risk Adjustment Methodology

a. Modification to the Transfer Formula in the HHS Risk Adjustment Methodology (78 FR at 15430–34)

In the 2014 Payment Notice (78 FR at 15430–34), we noted our intent to modify the risk adjustment payment transfer formula in order to accommodate community rated States that utilize family tiering rating factors. In non-family tiering States, family policy premiums must be developed by adding up the applicable rates of each individual covered under the policy, as required under 45 CFR 147.102(c)(1). In the case of families with more than three children in non-family tiering States, only the applicable rates of the three oldest covered children under age 21 are counted towards the family policy premium rate (for example, for a family with four children under age 21, only the applicable individual rates of the three oldest children would count towards the family policy premium). These family rating requirements do not apply to States that use family tiering rating factors. In family tiering States, family tiering rating factors are not required to yield premiums that are equal to the sum of the individual policy members' applicable rates, nor must they be set in a way that counts only the rates of the oldest three children under age 21 within a family policy. For example, a family tiering State could establish a family tiering rating factor of 1.0 for an adult policy, 1.8 for a policy covering one adult and one or more children, 2.0 for a policy covering two adults, and 2.8 for a policy covering two adults and one or more children.

In order to account for the differences in family rating practices between family tiering States and non-family tiering States, we proposed two changes to the risk adjustment payment transfer formula that HHS will use when operating risk adjustment on behalf of a State. These changes would only apply to States that are using family tiering rating structures. In the 2014 Payment Notice, we stated that billable members exclude children who do not count towards family rates (that is, children

who do not count toward family policy premiums are excluded) (78 FR at 15432, 15434). We proposed to clarify that in the case of family tiering States, billable members would be based on the number of children that implicitly count towards the premium under a State's family rating factors. For example, assume a State has the following four family tiers: One adult; one adult plus one or more children; two adults; and two adults plus one or more children. Under this tiering structure, only one child would be counted as a billable member in the payment transfer formula, because additional children covered under a family policy would not affect the policy's premium.

Additionally, we proposed a modification to the allowable rating factor (ARF) formula that would be used for family tiering States. In the 2014 Payment Notice (78 FR at 15433), the ARF is calculated as the member month weighted average of the age factor applied to each billable enrollee. In non-family tiering States, the ARF is intended to measure the extent to which plans are increasing or decreasing their premiums based on allowable age rating factors. In the case of family tiering States, premium revenue will not vary by age-specific rating factors. Rather, policy level premiums will vary only based on the family tiering factors. In order to capture the impact of the family tiering factors on plans' premium revenue we proposed that the ARF formula for family tiering States be based on the family tiering factors instead of age rating factors.

Specifically, under our proposal, the ARF for family tiering States would be calculated at the level of the subscriber, as follows:

$$ARF_i = \frac{\sum (ARF_s - M_s)}{\sum (M_s)}$$

Where:

ARF_s is the rating factor for the subscriber(s) (based on family size/composition), and M_s is the number of billed person-months that are counted in determining the subscriber(s) premium.

We noted that, apart from the changes to the billable member months definition and the ARF formula discussed above, payment transfers in family tiering States will be calculated using the formulas provided in the 2014 Payment Notice (78 FR at 15431–34). The changes to the billable member month definition and the ARF formula would not apply to States that do not implement family tiering rating factors.

Comment: Several commenters supported the proposed modification to the payment transfer formula for a

family tiering State, agreeing with the proposal to base billable members on the number of children that implicitly count towards the premium under the State's family rating factors. These commenters also supported modifying the ARF formula to address rating limitations based on the family tiering factors instead of the age rating factors. However, these commenters asked that the ARF formula be modified to make the numerator a summation over all subscribers of the product of the family tiering factor and the subscriber member months, and the denominator the sum of billable member months.

Response: We agree with the commenters that the ARF formula should be modified so that the numerator is a summation over all subscribers of the product of the family tiering factor and the subscriber member months, and the denominator the sum of billable member months. We are making this technical correction so that the ARF formula accurately reflects a member month weighted average of the family tiering factor, as described in the preamble to the proposed rule (78 FR at 37039–040). Because of a typographical error, the formula did not align with this proposal. We are correcting the formula to align with our proposal, which we are finalizing in this final rule. Therefore, the ARF for family tiering States would be calculated at the level of the subscriber, as follows:

$$ARF_i = \frac{\sum (ARF_s \cdot M_s)}{\sum (M_s)}$$

Where:

ARF_s is the rating factor for the subscriber(s) (based on family size/composition), and M_s is the number of billed person-months that are counted in determining the premium(s) for the subscriber(s).

Summary of Regulatory Changes

We are finalizing the two proposed modifications to the risk adjustment payment transfer formula as proposed, with one technical correction. We are modifying the ARF formula by making the numerator a summation over all subscribers of the product of the family tiering factor and the subscriber member months, and the denominator the sum of billable member months.

5. Subpart E—Health Insurance Issuer and Group Health Plan Standards Related to the Reinsurance Program

a. Reinsurance Contribution Funds (§ 153.400)

In some health coverage arrangements, an insured group health plan may provide benefits through more than one policy to the same covered

lives, where each policy standing alone does not constitute major medical coverage, but the total benefits do.¹⁵ To clarify the application of the rules (solely for the purpose of reinsurance contributions), we proposed to amend paragraph (a)(1)(i) of 45 CFR 153.400(a) and add a new paragraph (a)(3) that would address liability for reinsurance contributions in the foregoing fact pattern. This paragraph (a)(3) would be an exception to the rule under paragraph (a)(1)(i), which provides that an issuer of health insurance coverage is not required to make reinsurance contributions for coverage to the extent the coverage is not major medical coverage.

Under the proposed paragraph (a)(3), a health insurance issuer providing coverage under a group health plan would make reinsurance contributions for lives under its health insurance coverage even if the insurance coverage does not constitute major medical coverage, if: (i) The group health plan provides health insurance coverage for the same covered lives through more than one insurance policy that in combination constitute major medical coverage but individually do not; (ii) the lives are not covered by self-insured coverage of the group health plan (except for self-insured coverage limited to excepted benefits); and (iii) the health insurance coverage under the policy offered by the health insurance issuer represents a percentage of the total health insurance coverage offered in combination by the group health plan greater than the percentage offered under any of the other policies. We further proposed that for purposes of paragraph (a)(3), the percentage of coverage offered under various policies would be determined based on the average premium per covered life for these policies. In the event that the percentage of coverage is equal, the issuer of the policy that provides the greatest portion of in-network hospitalization benefits would be responsible for reinsurance contributions.

Because an issuer of group health insurance coverage that does not, by itself, constitute major medical coverage may not be aware of the existence of, or premium for, other health insurance coverage obtained by a plan sponsor covering the same lives under a group health plan, we sought comment on whether and in what circumstances an

¹⁵ We note that, after 2014, such arrangements generally would only be permissible in the large employer group context, because issuers of small employer group market insurance coverage are required to provide all EHB under any policy they offer that does not qualify as "excepted benefits."

issuer should be entitled to rely upon representations from a plan sponsor regarding the relative percentage of coverage offered by the issuer. We also sought comment on what other means we should consider for ensuring that the relevant issuer knows of its obligation to make the reinsurance contributions, including any role that the employer should have in ensuring that issuers have the information necessary to determine which issuer is responsible for reinsurance contributions, as well as alternative approaches that should be considered for determining responsibility for reinsurance contributions in such circumstances.

Finally, we addressed in the proposed rule certain inquiries as to how reinsurance contribution obligations would be allocated in the case of a group health plan under which some benefit options for employees are insured by an issuer, and some options offer benefits without the involvement of an issuer in insuring the benefits (because either the group health plan or some non-issuer entity assumes the risk for that coverage option). We proposed that in such a case, if a coverage option is insured by an issuer, the issuer would be responsible for the reinsurance contribution associated with that coverage option. If an employee coverage option under such a group health plan is not insured (because either the group health plan or other non-issuer assumes the risk), we proposed that the group health plan would be responsible for the reinsurance contribution associated with that coverage option. After considering the comments received, we are modifying the proposed provisions by amending the “percentage of benefits” provision to state that the issuer of the plan that provides the greatest portion of the inpatient hospitalization benefits would be responsible for reinsurance contributions. We also are making two minor revisions to the language in proposed paragraph (a)(3) to clarify its scope.

Comment: Several commenters suggested that the “higher percentage of benefits” approach in proposed § 153.400(a)(3) is administratively burdensome and presents significant operational problems. A number of commenters suggested an alternative approach that would require the issuer that covers hospitalizations to be responsible for reinsurance contributions.

One commenter agreed with HHS’s statement in the preamble to the proposed rule that issuers may not know about other coverage purchased

by a plan sponsor, so directing issuers to seek representations from plan sponsors concerning the relative percentage of coverage offered by the issuer was reasonable. The commenter suggested that issuers be able to rely on employer representations regarding other coverage, and that issuers be held harmless from compliance actions if they do not receive such information from employers, or if the information is inaccurate. However, another commenter stated that plans or plan sponsors should not be required to provide information to issuers and that a rule that “looks to the types of coverage provided” is appropriate. One commenter requested clarification on which entity would be liable for reinsurance contributions where a group health plan has two insured major medical components offered by different issuers. The commenter stated that some States prohibit HMOs from providing out-of-network coverage for non-emergency services. HMOs in those States package their in-network coverage with out-of-network coverage issued by a non-HMO health insurance issuer, so that enrollees in the HMO have simultaneous coverage under both products. The commenter suggested that the rule should provide the issuer of the in-network coverage (the HMO, which would be expected to account for the majority of the total health coverage under the group health plan) is responsible for reinsurance contributions.

Response: We are revising proposed § 153.400(a)(3) to state that the issuer of the plan that provides the greatest portion of inpatient hospitalization coverage will be responsible for reinsurance contributions, and note that the issuer should be the issuer that provides the majority of the dollar value of the benefits in most situations. We believe this option will mitigate the operational difficulties discussed by the commenters, and will significantly reduce the need for plan sponsors to provide information to issuers. Because we recognize that there may be circumstances in which an issuer is unsure whether its coverage provides the greatest portion of inpatient hospitalization benefits, we intend to hold an issuer harmless from non-compliance actions for failure to pay reinsurance contributions if the issuer relies in good faith upon a written representation by the plan sponsor that the issuer’s coverage does not provide the greatest portion of inpatient hospitalization benefits.

Comment: One commenter asked HHS to clarify the type of group health plan coverage intended to be addressed by

the proposed addition of paragraph (a)(3) to § 153.400.

Response: Section 153.400(a)(3) applies to fully insured group health plans that offer health insurance coverage through more than one policy. For example, a fully insured group health plan with two insurance policies, one of which covers inpatient hospitalization and another that covers doctors’ office visits, prescriptions, vision and dental benefits, or other similar arrangements, would be covered by this paragraph.

Comment: One commenter requested a clarification on the proposed approach to allocating responsibility for reinsurance contributions, in the case of a group health plan where some options offered under a plan are insured and some options offer benefits without the involvement of an issuer (because either the group health plan or a non-issuer entity assumes the risk for that coverage option). The commenter requested that HHS clarify that the reinsurance contribution will not be imposed with respect to the same covered life more than once.

Response: Under the proposed approach, in such a group health plan, the issuer would be liable for reinsurance contributions with respect to an insured coverage option, and the group health plan would be liable for reinsurance contributions with respect to a coverage option that is not insured. Consequently, reinsurance contributions would not be required more than once for the same covered life.

In general, it is our intent not to require payment of reinsurance contributions more than once for the same covered life. We recognize that certain complex group health plan arrangements can lead to situations in which lives are covered multiple arrangements and where it is unclear whether more than one health plan or issuer must make reinsurance contributions on the same covered life.

To provide clarity on the matter, we intend to clarify in future rulemaking the principle that reinsurance contributions are required only once with respect to the same covered life. We also intend to propose that no reinsurance contributions are required under a group health plan where the group health plan coverage applies to lives that are also covered by individual market health insurance coverage for which reinsurance contributions are required, or where the coverage is supplemental or secondary to group health coverage for which reinsurance contributions must be made for the same covered lives.

Summary of Regulatory Changes

We are finalizing the reinsurance contribution provision discussed above as proposed, with the following modifications. We are modifying the “percentage of benefits” provision to state that the issuer of the plan that provides the greatest portion of the inpatient hospitalization benefits will be responsible for reinsurance contributions. We also are making two minor revisions to language in proposed paragraph (a)(3) to clarify its scope.

b. Maintenance of Records (§ 153.405(h) and § 153.410(c))

To meet our obligation to safeguard Federal funds, we proposed to amend § 153.405 by adding paragraph (h), which would require a contributing entity to maintain documents and records, whether paper, electronic, or in other media, that are sufficient to substantiate the enrollment count submitted under § 153.405 for at least 10 years, and would direct the contributing entity to make that evidence available upon request from HHS, the OIG, the Comptroller General, or their designees, for the purpose of verifying reinsurance contribution amounts. We also proposed to amend § 153.410 by adding paragraph (c), which would direct an issuer of a reinsurance-eligible plan in a State where HHS operates reinsurance to maintain documents and records, whether paper, electronic, or in other media, sufficient to substantiate the requests for reinsurance payments made pursuant to § 153.410 for at least 10 years, and would require the issuer to make that evidence available upon request from HHS, the OIG, the Comptroller General, or their designees, (or, in a State where the State is operating reinsurance, the State or its designee) for the purpose of verifying reinsurance payment requests. We note that these standards could be satisfied if the contributing entity or issuer of a reinsurance-eligible plan archived the documents and records and ensured that they were accessible in the event of an investigation, audit, or other review. We note that the 10-year obligation to retain records begins when the record is created.

We addressed the comments received on the proposed maintenance of records provisions in the preamble discussion related to § 153.240(c) above.

Summary of Regulatory Changes

We are finalizing these provisions as proposed, with one clarification in each provision to conform with the other record retention standards in this rule. We are clarifying that in each provision

it is the “documents and records” that must be made available upon request.

6. Subpart F—Health Insurance Issuer Standards Related to the Risk Corridors Program

a. Definitions (§ 153.500 and § 153.510)

Section 1342(a) of the Affordable Care Act provides that “a qualified health plan offered in the individual or small group market” is to participate in the risk corridors program. In the Exchange Establishment Rule, we stated that a stand-alone dental plan is “a type of qualified health plan.” However, we did not intend for all requirements applicable to a QHP to apply to stand-alone dental plans. For example, under 45 CFR 155.1065(a)(3), certain QHP standards are not applicable to a stand-alone dental plan if they cannot be met, given the limited benefit package offered by the plan. We believe that it would not be appropriate to subject stand-alone dental plans to the risk corridors program because such plans are considered excepted benefits plans under section 2791(c) of the PHS Act, and are therefore not subject to the rating rules—that is, the Federal prohibition on underwriting premiums, the requirement to base premium rating using the single risk pool, and the fair health insurance premiums limitations. Thus, although States have the option to prohibit underwriting for excepted benefits plans, and issuers of stand-alone dental plans may voluntarily choose not to underwrite these plans, we believe that, in general, an issuer of a stand-alone dental plan will not be subject to the same rate-setting uncertainty in 2014 as the issuer of a major medical plan, and will not need the risk-sharing protections of risk corridors.¹⁶ In the proposed rule, we noted that stand-alone dental plans are similarly excluded from participation in the two other premium stabilization programs—reinsurance and risk adjustment. We also noted that, consistent with the exclusion of excepted benefits plans from the medical loss ratio (MLR) requirements, stand-alone dental claims would not be pooled along with an issuer’s other claims for the purposes of determining “allowable costs” in the risk corridors

¹⁶ In the preamble to the Exchange Establishment Rule, we note that each Exchange has the authority to require, as a condition of certification, comprehensive medical QHPs to offer and price the pediatric dental EHB (if covered) separately, if doing so would be in the best interest of consumers. For the 2014 benefit year, an FFE will not require comprehensive medical QHP issuers that provide pediatric dental coverage to do so. We have provided this guidance in Chapter 4 of the 2014 Letter to Issuers on Federal and Partnership Marketplaces (April 5, 2013).

calculation, as defined at 45 CFR 153.500. We received several comments, all of which were supportive of this approach.

Summary of Regulatory Changes

We are finalizing this policy as proposed, and are adding a new paragraph (e) to § 153.510, which provides that a QHP issuer is not subject to the provisions under subpart F of part 153 with respect to a stand-alone dental plan.

b. Calculation of Allowable Costs, Attribution and Allocation of Revenue and Expense Items, and Risk Corridors Data Requirements (§ 153.500, § 153.520, and § 153.530)

In the interim final rule (78 FR 15541), we noted that, consistent with the single risk pool provision at 45 CFR 156.80, which directs an issuer to pool claims costs across all of its non-grandfathered health plans in a market within a State, a QHP issuer must pool allowable costs across all its non-grandfathered plans in the relevant market for the purposes of risk corridors calculation. We therefore amended the regulatory definition of “allowable costs” for purposes of the risk corridors program so that allowable costs for a QHP are equal to the pro rata portion of the QHP issuer’s incurred claims. We also modified the provision related to attribution and allocation of revenue and expense items in 45 CFR 153.520 to conform to the changes for the risk corridors calculation described above.

We are finalizing the policy set forth in the interim final rule with respect to the definition of “allowable costs,” and are making a number of modifications to maintain consistency with this policy in response to comment, as described below.

Comment: Several commenters recommended that we exclude the experience of non-QHPs from the risk corridors calculation, and include only the experience of an issuer’s QHPs in our definition of allowable costs. These commenters were concerned that tying allowable costs to the experience of all of a QHP issuer’s non-grandfathered health plans would have the effect of diluting the pricing protections afforded to QHPs through the risk corridors program. One commenter believed that it would be inconsistent to disconnect the premiums used for the risk corridors target amount from the claims used to develop the allowable costs, and suggested an alternate approach that would direct issuers to aggregate incurred claims for all QHPs and then allocate these incurred claims to each QHP pro rata based on the earned

premium of each QHP as a percentage of total earned premium for all QHPs. The commenter believed that, while this proposal would not affect the risk corridors calculation, it would require issuers to separate QHP and non-QHP claims and risk adjustment payments and charges.

Response: We are finalizing the definition of allowable costs as set forth in the interim final rule without change. As discussed in the preamble to the interim final rule, this approach is consistent with how issuers will determine premiums pursuant to the single risk pool requirement at 45 CFR 156.80. As stated in the interim final rule, allowable costs will be calculated based on an issuer's experience for all non-grandfathered plans in a State market, such that the actual risk corridors payment or charge will be calculated based on a QHP's pro rata share (based on premiums) of the QHP issuer's market-wide allowable costs and premiums. This approach ensures that the incurred claims used to develop the allowable costs in the numerator of the risk corridors calculation are consistent with the projected claims used to develop the premiums used to calculate the target amount in the denominator of the risk corridors calculation. We also note that this approach aligns with existing processes for the MLR program, and helps to maintain overall consistency between the MLR and risk corridors programs.

We agree with the comment that it is inconsistent to disconnect the projected claims used to develop premiums used to calculate the risk corridor target amount from the incurred claims used to develop the allowable costs, and are therefore modifying our risk corridors expense allocation rules at 45 CFR 153.520 to ensure that the numerator and the denominator of the risk corridors calculation are calculated in a fully consistent manner. We are revising the risk corridors allocation rules in § 153.520 to clarify that administrative expenses in the target amount, like allowable costs, should be calculated based on expenses across all non-grandfathered health plans in the market, and allocated pro rata to a QHP based on the QHP's premiums. Because certain administrative expenses, such as Exchange user fees are, like incurred claims costs, required to be spread across the relevant risk pool, their treatment should conform with the market-wide risk corridors calculation for allowable costs and premiums. Thus, we are clarifying that administrative expenses should be similarly allocated. We note that this change is consistent with our intention to align the risk

corridors calculation with the single risk pool provision, will further align the calculations for the MLR and risk corridors programs, and will reduce the burden on issuers of allocating expenses on a plan-by-plan basis.

Finally, we are also making conforming corrections to the risk corridors data requirements in § 153.530(b) and (c) to specify that issuers must submit risk corridors data in a manner that is consistent with the calculation of allowable costs and allowable administrative costs, as defined at § 153.500. We provide that a QHP issuer must submit to HHS data on allowable costs and allowable administrative costs incurred for all of its non-grandfathered plans in a market within a State. Without these corrections, issuers would be required to make plan-specific allocations and submit plan-specific amounts that are not necessary for the risk corridors calculation, while not providing the QHP aggregate premium data required for the risk corridors calculation as amended. We believe that these corrections will alleviate potential confusion among issuers with regard to submission of pooled risk corridors data.

Comment: One commenter noted that the risk corridors calculation compares allowable costs for QHPs and non-QHPs in the numerator of the calculation to target amounts for only QHPs in the denominator. The commenter recommended that the numerator of the calculation should only pool incurred claims across an issuer's QHPs to ensure a consistent comparison. One commenter noted that the single risk pool provision at 45 CFR 156.80 permits specific plan level premium adjustments, such that QHP premiums would reflect certain factors that relate particularly to QHPs, in addition to market-wide factors. Consequently, the commenter believed that an approach that limited the risk corridors calculation to the experience of only an issuer's QHPs would still be consistent with the single risk pool provision. However, another commenter supported the modification to the calculation of allowable costs that was set forth in the interim final rule, and believed that our policy was consistent with the single risk pool provision.

Response: Because a QHP's target amount is based on the QHP's premiums, which are principally set based on the index rate for QHPs and non-QHPs in the relevant market, we believe it is more consistent to set allowable costs based on the pooled claims costs of both QHPs and non-QHPs. We believe the allocation of the

allowable costs by plan premiums addresses the plan-specific premium variation.

Comment: All commenters supported the modification to the risk corridors formula to calculate allowable costs based on incurred claims at an aggregate level, rather than using incurred claims specific to each QHP.

Response: We are finalizing our definition of allowable costs to calculate allowable costs based on aggregate incurred claims as set forth in the interim final rule.

Summary of Regulatory Changes

We are finalizing the definition of "allowable costs" in § 153.500 without change. We are modifying § 153.520(a) and (b) to provide that expenses in the target amount of the risk corridors calculation should be based on market-wide expenses, and must be allocated across a QHP issuer's plans in proportion to the plans' premiums. Finally, we are making conforming modifications to the risk corridors data requirements in § 153.530(b) and (c) to require a QHP issuer to submit data on allowable costs and allowable administrative costs for its non-grandfathered health plans in a market within a State.

7. Subpart G—Health Insurance Issuer Standards Related to the Risk Adjustment Program

We proposed to amend § 153.620(b) to add a standard that would direct an issuer that offers risk adjustment covered plans to maintain documents and records, whether paper, electronic, or in other media, sufficient to enable the evaluation of the issuer's compliance with applicable risk adjustment standards, and to make that evidence available upon request from HHS, the OIG, the Comptroller General, or their designees (or in a State where the State is operating risk adjustment, the State or its designee), to any such entity. This standard, which is consistent with other records maintenance standards in this rule, would direct an issuer of a risk adjustment covered plan to retain additional records—not only those pertaining to data validation—to substantiate its compliance with risk adjustment standards, whether risk adjustment is operated by HHS or a State.

We addressed the comments received on the proposed maintenance of records provisions in the preamble discussion of § 153.240(c) above.

Comment: Several commenters asked HHS to clarify the record retention timeframe for this proposed provision.

Response: We are amending this proposed provision to specify the record retention timeframe for this proposed provision. We clarify that an issuer that offers risk adjustment covered plans must maintain documents and records, whether paper, electronic, or in other media, sufficient to enable the evaluation of the issuer's compliance with applicable risk adjustment standards for each benefit year, for at least 10 years, and make those documents and records available upon request from HHS, the OIG, the Comptroller General, or their designees (or in a State where the State is operating risk adjustment, the State or its designee), to any such entity. We note that the 10-year obligation to retain records begins when the record is created.

Comment: One commenter encouraged HHS to prohibit QHP issuers from demanding documentation or paperwork from physician practices or independently auditing physician practices in order to comply with HHS's proposed oversight requirements.

Response: This regulation does not seek to regulate the relationships between issuers of risk adjustment covered plans and health care providers. Rather, we expect that risk adjustment covered plans will make appropriate arrangements with providers to ensure compliance with this regulation.

Comment: One commenter asked HHS to amend this standard to provide that these documents and records be made available to the issuer's data validation auditor as well as HHS, the OIG, the Comptroller General, or their designees.

Response: We are not extending this provision to require an issuer of a risk adjustment covered plan to make available its documents and records to its data validation auditor. A data validation auditor's authority to review an issuer's relevant documents will be addressed under the risk adjustment data validation regulations in 45 CFR 153.630.

Summary of Regulatory Changes

We are making two corrections to this provision, to conform with our other record retention provisions throughout this rule. We are clarifying that it is the "documents and records" that must be made available upon request. We are also clarifying that documents and records must be maintained for each benefit year, for at least 10 years.

8. Subpart H—Distributed Data Collection for HHS-Operated Programs

a. Failure To Comply With HHS-Operated Risk Adjustment and Reinsurance Data Requirements (§ 153.740(a))

In § 153.740(a), we proposed that HHS may pursue an enforcement action for CMPs against an issuer in a State where HHS operates the reinsurance or risk adjustment program, if the issuer fails to: (a) Establish a secure, dedicated distributed data environment pursuant to 45 CFR 153.700(a); (b) provide HHS with access to enrollee-level plan enrollment information, enrollee claims data, or enrollee encounter data through its dedicated distributed data environment pursuant to 45 CFR 153.710(a); (c) otherwise comply with the requirements of 45 CFR 153.700 through 153.730; (d) adhere to the reinsurance data submission requirements set forth in 45 CFR 153.420; or (e) adhere to the risk adjustment data submission and data storage requirements set forth in 45 CFR 153.610 through 153.630. As discussed above, under the data collection approach that we are implementing when we operate risk adjustment or reinsurance on behalf of a State, an issuer must use masked enrollee identification numbers when making data accessible through the dedicated distributed data environment. In addition, we will not store any personally identifiable enrollee information or individual claim-level information from the data that issuers make accessible to HHS through the dedicated distributed data environment except when conducting data validation or audits.

Risk Adjustment: Risk adjustment covered plans must provide access to the risk adjustment enrollee-level plan enrollment information, enrollee claims data, or enrollee encounter data from the issuer by April 30 of the year following the applicable benefit year in order for HHS to calculate payment transfers based on claims experience and premiums as set forth in 45 CFR 153.730. In order to enforce risk adjustment standards when operating risk adjustment on behalf of a State pursuant to our authority under section 1321(c)(2) of the Affordable Care Act, we proposed establishing HHS authority to impose CMPs, and applying the related enforcement standards set forth in § 156.805 to non-compliant issuers. If a risk adjustment covered plan does not comply with the requirements set forth in 45 CFR 153.610 through 153.630 and 45 CFR 153.700 through 153.730, we proposed to apply a sanction so that the

level of the enforcement action would be proportional to the level of the violation. While we would reserve the right to impose penalties up to the maximum amounts set forth in § 156.805(c), as a general principle, we stated our intent to work collaboratively with issuers to address problems in establishing dedicated distributed data environments in 2014. We noted that HHS would reserve the right to impose, or not impose, CMPs as appropriate. We proposed that in our application of CMPs, we would take into account the totality of the issuer's circumstances, including such factors as an issuer's previous record of non-compliance (if any), the frequency and level of the violation, and any aggravating or mitigating circumstances. Our intent is to encourage issuers to address non-compliance and not to severely affect their financial condition, especially where the issuer demonstrates good faith in monitoring compliance with applicable standards, identifies any suspected occurrences of non-compliance, and attempts to remedy any non-compliance. For instance, if an issuer of a risk adjustment covered plan did not establish a dedicated distributed data environment or provide access to the necessary risk adjustment data to permit HHS to timely calculate the applicable risk adjustment transfer amounts, HHS would assess a default risk adjustment charge as described below. HHS might also elect to impose CMPs in conjunction with the imposition of the default risk adjustment charge if an issuer failed to comply with applicable data security or privacy standards placing the interests of third-parties at risk.

Reinsurance: We proposed that an issuer of a reinsurance-eligible plan may be subject to CMPs for failure to comply with 45 CFR 153.420, or 45 CFR 153.700 through 153.730. Under this proposal, HHS would take into account the totality of the issuer's circumstances, including such factors as an issuer's previous record of non-compliance (if any), the frequency and level of the violation, and any aggravating or mitigating circumstances when determining how to apply CMPs. In the proposed rule, we indicated that we might not impose CMPs in certain cases. For example, HHS might not impose CMPs on an issuer of a reinsurance-eligible plan if it fails to set up a dedicated distributed data environment or meet certain data requirements stated above if, as a consequence, HHS simply does not have the necessary claims data from the dedicated distributed data environment to calculate or distribute

reinsurance payments for the reinsurance-eligible plan, and as a result, the reinsurance-eligible plan would forgo significant reinsurance payments that it otherwise might have received. Regardless, HHS reserves the right to impose CMPs irrespective of whether an issuer becomes ineligible for reinsurance payments as a result of failing to comply with 45 CFR 153.420, or 45 CFR 153.700 through 153.730. After considering the comments received, we are finalizing § 153.740(a) with one modification. We are including a compliance standard, parallel to that set forth in 45 CFR 156.800(c), providing that CMPs will not be imposed under this provision during the 2014 calendar year, if the issuer has made good faith efforts to comply with the applicable requirements.

Comment: Several commenters supported HHS's proposed flexibility and cooperation with issuers when imposing CMPs on issuers that fail to establish a dedicated distributed data environment or provide HHS access to all necessary data. Commenters supported taking into account an issuer's good faith attempts to comply with the data requirements. One commenter suggested that HHS provide standards that would allow issuers to demonstrate that they have complied with the data requirements. Another commenter asked HHS to adopt a "safe harbor" that would defer the imposition of any CMPs for two years, and to require only good faith compliance. One commenter specifically suggested that issuers be subject to CMPs if they are out of compliance with risk adjustment and reinsurance data requirements for two or more consecutive benefit years, or if they fail to correct significant deficiencies discovered during the risk adjustment initial and secondary validation audit processes that result in substantially inaccurate data or produce upcoding trends significantly greater than those found among other issuers in the State.

Response: As we described in the proposed rule, HHS will take into account the totality of an issuer's circumstances, including such factors as the issuer's previous record of non-compliance (if any), the frequency and level of the violation, and any aggravating or mitigating circumstances, including the issuer's good faith in monitoring compliance with applicable standards and attempts to remedy any non-compliance. In addition, consistent with our policy and standards with respect to sanctions for non-compliance with FFE standards set forth in 45 CFR 156.800, 45 CFR 156.805, and 45 CFR 156.810, we are clarifying that if HHS is

able to determine that an issuer of a risk adjustment covered plan or reinsurance-eligible plan, as applicable, is making good faith efforts to comply with the standards set forth in § 153.740(a), we will not seek to impose CMPs for non-compliance with those standards during 2014. Based on the comments received in connection with the proposed rule, in 45 CFR 156.800(c), we provided that for 2014, sanctions under that subpart will not be imposed if the QHP issuer has made good faith efforts to comply with applicable requirements. We are adopting a similar CMP enforcement strategy here. However, we note that nothing in this provision prohibits HHS from imposing CMPs in 2015 for non-compliance that occurred in 2014. At the appropriate time, we will consider extending this good faith compliance policy through 2015. We also note that this good faith compliance policy does not apply to the imposition of the default risk adjustment charge described in § 153.740(b), which is intended as an administrative measure to ensure that HHS may properly calculate risk adjustment payments and charges for the entire market. Finally, we note that HHS's determination of good faith may require issuers of risk adjustment covered plans and reinsurance-eligible plans to allow HHS to conduct reviews of the issuer's risk adjustment and reinsurance materials and to review the issuer's good faith efforts to comply with corrective action plans.

Comment: One commenter asked whether the enforcement authority proposed in § 153.740 will apply to issuers in States where HHS operates reinsurance but the State operates the risk adjustment program.

Response: The enforcement actions set forth in § 153.740 apply to issuers that fail to comply with HHS-operated risk adjustment and reinsurance data requirements. As such, in States where HHS operates reinsurance but the State operates the risk adjustment program, the enforcement authority proposed in § 153.740 would apply with respect to non-compliance with reinsurance-related standards to issuers of reinsurance-eligible plans, but not to non-compliance with respect to risk adjustment-related standards to issuers of risk adjustment covered plans.

Comment: One commenter asked that HHS permit issuers to appeal any HHS enforcement actions.

Response: As noted in the proposed rule, HHS may impose CMPs in accordance with the procedures set forth in § 156.805 of this subchapter. Sections 156.805(d) and (e) provide a process for issuers that are assessed a CMP to request a hearing. We intend to

propose an administrative process in the HHS Notice of Benefit and Payment Parameters for 2015 through which an issuer may appeal the assessment of a default risk adjustment charge.

Summary of Regulatory Changes

To clarify our 2014 policy of nonenforcement of CMPs for good faith, we are adding a new sentence to § 153.740(a).

b. Default Risk Adjustment Charge (§ 153.740(b))

As described in the Premium Stabilization Rule (77 FR 17220) and the 2014 Payment Notice (78 FR 15410), HHS will employ a distributed data collection approach when it operates a risk adjustment program on behalf of a State. Under this approach, issuers in States where HHS operates a risk adjustment program will be required to establish dedicated, secure data environments, and provide HHS with access to "masked"¹⁷ enrollee-level plan enrollment information, enrollee claims data, and enrollee encounter data pursuant to 45 CFR 153.710 and 45 CFR 153.720. Pursuant to 45 CFR 153.730, issuers must provide access to required risk adjustment data by April 30 of the year following the applicable benefit year in order for HHS to calculate risk adjustment payment transfer amounts. As discussed above, under the data collection approach we are implementing when we operate risk adjustment or reinsurance on behalf of a State, we will not store any personally identifiable enrollee information or individual claim-level information from the data that issuers make accessible to HHS through the dedicated distributed data environment except for purposes of data validation and audit.

As discussed in the proposed rule, if an issuer does not set up a dedicated distributed data environment or submits inadequate risk adjustment data, HHS would not have the required risk adjustment data from the issuer to calculate risk scores or payment transfers. This data is necessary to properly calculate risk adjustment payments and charges for the entire applicable market for the State. If HHS cannot perform this calculation for a particular issuer, risk adjustment payment transfers would be affected for all other issuers in the State market because payment transfers are determined within a market within a State such that they will net to zero. In the proposed rule, we invoked our

¹⁷ As described at 45 CFR 153.720(b), masked data means data associated with a unique identifier, where the unique identifier does not include the enrollee's personally identifiable information.

authority pursuant to section 1343(b) of the Affordable Care Act to develop and apply criteria and methods for carrying out risk adjustment activities to apply a default risk adjustment charge to issuers in the individual or small group market that fail to provide the risk adjustment data necessary for HHS to calculate payments and charges for the market in the State.

In § 153.740(b), we proposed that if an issuer of a risk adjustment covered plan fails to establish a dedicated distributed data environment or fails to provide HHS with access to risk adjustment data in such environment by April 30 of the year following the applicable benefit year in accordance with §§ 153.610(a), 153.700, 153.710, or 153.730, such that HHS cannot apply its Federally certified risk adjustment methodology to calculate the plan's risk adjustment payment transfer amount in a timely fashion, HHS would assess a default risk adjustment charge.

We proposed two different methods for determining the per member per month amount used to calculate the default risk adjustment charge. One option would be to use the highest per member per month charge among risk adjustment covered plans in a risk pool in the market in the plan's geographic rating area. A second option would be to use a per member per month amount that is two standard deviations above the mean charge in the market in the plan's geographic rating area.

We noted in the proposed rule that in order to calculate a plan's risk adjustment default charge, we must multiply the per member per month amount by an enrollment count. We proposed to base the default charge on the average enrollment in the State market. If enrollment data is provided, we proposed that the default charge would be based on average annual enrollment for the plan in a risk pool in the State market. We sought comment on these methods, other appropriate methods for calculating a default risk adjustment charge, and other sources of data HHS could use to determine enrollment data for the issuers in question. We also sought comment on whether to allocate an issuer's default charge to other issuers in the market as part of payments and charges in the concurrent benefit year, during a subsequent benefit year, or sometime between annual payments and charges processes.

We received a number of comments strongly supporting our proposal to impose a default risk adjustment charge if an issuer of a risk adjustment covered plan fails to establish a dedicated distributed data environment or fails to

provide HHS with access to the required data. We are finalizing that regulation text as proposed.

Comment: Several commenters suggested that we tie the default charge to the issuer's actual enrollment based on an appropriate public filing by the issuer, such as MLR or NAIC filings, or information supplied by a State Department of Insurance (DOI), rather than average enrollment in the State.

Response: We agree with the comments, and are finalizing an approach based on the issuer's actual enrollment. Because the total risk adjustment default charge is a function of both a per member per month amount as well as a total enrollment amount, we recognize that actual enrollment would better align the risk adjustment default charge with the overall goal of market stabilization. Thus, if an issuer of a risk adjustment covered plan does not provide access to required risk adjustment data by April 30 of the year following the applicable benefit year, then we will seek from the issuer an attestation of total billable member months, which we would use to calculate the total risk adjustment default charge. That attestation would be subject to later HHS validation processes, which we will describe in future rulemaking and guidance, along with compliance with other risk adjustment-related requirements. If an issuer does not submit enrollment data, HHS will seek enrollment data from the issuer's MLR and risk corridors filings for the applicable benefit year, or, if unavailable, other reliable data sources, such as the State DOI.

Comment: We received several comments suggesting that HHS allocate an issuer's default charge to other issuers in the market as part of the payments and charges calculation in the concurrent benefit year.

Response: We agree that the default risk adjustment charge should be part of the concurrent benefit year payment and charges calculation. However, our ability to apply that charge to the current year will depend upon when we are able to obtain the enrollment data for the plan in question. As discussed above, HHS will assess the risk adjustment default charge once HHS receives actual enrollment data. Once calculated, we would transfer the risk adjustment default charge on a per member per month basis to all compliant risk adjustment covered plans in the plan's risk pool in the market in the State in the earliest possible payment and charges cycle. We further note that we would not include the non-compliant risk adjustment covered plan in the risk adjustment

transfer formula calculations because of the complexity of doing so. We intend to establish a methodology for allocating the default risk adjustment charge among plans in the risk pool in future rulemaking.

Comment: A number of commenters made suggestions on the specific methodology to be used to determine the per member per month amount for calculating the default risk adjustment charge. One commenter supported the second option for calculating the per member per month amount—assessing a per member per month amount two standard deviations above the mean per member per month charge. One commenter supported the use of the second option for calculating the per member per month amount for the first occurrence of non-compliance, but stated that setting a higher amount, such as the highest per member per month charge among risk adjustment covered plans in the market, would be appropriate for repeated violations. Other commenters asked that HHS adopt a third methodology for calculating the per member per month amount—specifically, a fixed percentage of State-wide average premium. They stated that this methodology could be more appropriate if a market has a limited number of issuers that submit risk adjustment data.

Response: In light of the comments received, we will not finalize a methodology to calculate the per member per month amount used in the default risk adjustment charge. We intend to establish that methodology in future rulemaking.

Summary of Regulatory Changes

We are finalizing our regulation text providing the authority to impose a default risk adjustment charge as proposed. We are finalizing aspects of the methodology for calculating the default risk adjustment charge—our use of the plan's actual enrollment and our application of the default risk charge to adjust payments to other plans in the market in the State on a per member per month basis in the earliest available payment and charges cycle. We are not finalizing our approach to determining the per member per month amount used to calculate the default risk charge at this time, and will propose that methodology in future rulemaking.

D. Part 155—Exchange Establishment Standards and Other Related Standards Under the Affordable Care Act

1. Subpart D—Exchange Functions in the Individual Market: Eligibility Determinations for Exchange Participation and Insurance Affordability Programs

a. Administration of Advance Payments of the Premium Tax Credit and Cost-Sharing Reductions (§ 155.340)

We proposed to amend § 155.340 by adding paragraph (h), which sets forth additional requirements applicable when an Exchange is facilitating the collection and payment of premiums to QHP issuers and stand-alone dental plans. Specifically, we proposed that if the Exchange did not reduce an enrollee's premium by the amount of the advance payment of the premium tax credit in accordance with 45 CFR 155.340(g), the Exchange would be required to refund to the enrollee any excess premium paid by or for the enrollee. The Exchange would also be required to notify the enrollee of the improper application of the advance payment of the premium tax credit no later than 30 calendar days after the Exchange discovers the error. We noted that an Exchange may provide the refund to the enrollee by reducing the enrollee's portion of the premium in the following month, as long as the reduction is provided no later than 30 calendar days after the Exchange discovers the improper application of the advance payment of the premium tax credit. We proposed that if the Exchange elects to provide the refund by reducing the enrollee's portion of the premium for following month, and the refund exceeds the enrollee's portion of the premium for the following month, then the Exchange would need to refund to the enrollee the excess, no later than 30 calendar days after the Exchange discovers the improper application of the advance payment of the premium tax credit. These provisions are similar to the policy we proposed in § 156.460, when a QHP issuer is collecting premiums directly from enrollees. We also noted that we were considering requiring the Exchange to provide to HHS for each quarter, a report detailing the occurrence of any improper application of the advance payments of the premium tax credit beginning in the 2015 benefit year. We sought comment on whether HHS should establish a minimum error rate or threshold before an Exchange is required to inform HHS of such improper applications of the advance payment of the premium tax credit in a quarterly report, as well as

what an appropriate error rate or threshold should be. For example, we noted that we were considering requiring issuers to report the number of enrollees for whom the Exchange improperly applied the advance payment of the premium tax credit compared to the total number of enrollees in the Exchange receiving Federal premium subsidies. We also sought comment on whether such reports should be provided to HHS less frequently than quarterly.

Comment: Several commenters supported the proposed policy and some commenters suggested that the enrollee should have the option of receiving the refund directly, especially upon termination of coverage. One commenter expressed concern that Exchanges would not have money to refund enrollees, since premiums and subsidies are paid to issuers, and asked HHS to clarify that plans are not responsible for sending the Exchange or consumers money to correct mistakes made by the Exchange.

Response: In § 156.460 of the proposed rule we sought comment on the timeframe for QHP issuers to refund any excess premiums to enrollees. We also noted that the policy proposed in § 155.340(h) is similar to the policy proposed in § 156.460(c), when a QHP issuer is collecting premiums directly from enrollees and fails to apply the advance payment of the premium tax credit to the enrollee's portion of the premiums, and that these parallel requirements are designed to ensure that all enrollees, regardless of whether a QHP issuer or the Exchange is collecting premiums, are afforded the same level of protection. As discussed further in section II.E.4.d, we received a number of comments to the policy proposed in § 156.460(c) requesting that the timeframe for QHP issuers to refund any excess premiums to enrollees be extended. In response to comments to the policies proposed in this section and § 156.460(c), and in order to align with parallel modifications in this final rule in § 156.460(c), we are modifying the proposed policy. We are finalizing a policy such that if an Exchange discovers that it did not reduce an enrollee's premium by the amount of the advance payment of the premium tax credit, then, if requested by or for the enrollee, the Exchange must refund any excess premium paid by or for the enrollee within 45 calendar days of the request. However, if the enrollee does not request a refund, the Exchange may refund the excess premium paid by applying the excess to the enrollee's portion of the premium each month for the remainder of the period of

enrollment or benefit year until the excess premium is fully refunded. Any excess amounts not refunded at the end of the period of enrollment or benefit year would have to be refunded within 45 days of the end of such period.

As discussed above, this provision applies when an Exchange facilitates collection and payment of the premiums to QHP issuers and stand-alone dental plans on behalf of an enrollee and collects a greater premium from the enrollee than required by the issuer, taking into account the advance payment of the premium tax credit. As an intermediary in this process, if the Exchange collects excess premiums from the enrollee on behalf of the issuer, it should be responsible for recouping the overpayments from the issuer and returning the funds to the enrollee. This standard would not prevent an Exchange for recouping excess funds, in the event the Exchange reduced the enrollee's portion of the premium by more than the advance payment of the premium tax credit. We also note that State Exchanges may not use funding for States establishing an Exchange provided under Section 1311 of the Affordable Care Act for such refunds.

Comment: One commenter asked HHS to limit Exchange errors that must be refunded to the current tax year, since income tax reconciliation should resolve any errors from the previous tax year. Another commenter asked that the enrollee be able to reduce the advance payment of the premium tax credit portion of premium for the remainder of the year, if the refund would result in the enrollee owing \$600 more than would otherwise be available to the enrollee in premium tax credits.

Response: This provision is intended to remedy instances when an Exchange overbills an enrollee for his or her portion of the monthly premium based on the eligibility determination that was made by the Exchange. This standard does not address the reconciliation of the tax credit, eligibility redeterminations, or Exchange errors regarding eligibility and enrollment.

Comment: Several commenters supported a requirement for quarterly reporting. One commenter suggested that such reports should be publicly available and required for all Exchanges, including an FFE, and that Exchanges should have the ability to refute and correct these reports. Another commenter asked HHS to set a minimum threshold for reporting errors, while another commenter opposed a minimum threshold.

Response: We believe that it is important to monitor the appropriate application of these advance payments

of the premium tax credits, regardless of whether an Exchange or the QHP issuer is facilitating the collection and payment of premiums. However, following review of the comments, we are no longer considering a quarterly reporting requirement. In parallel with the standards being finalized under § 156.480 of this final rule applicable to QHP issuers, when a State Exchange is facilitating the collection of premiums, the Exchange will be required to report on an *annual* basis if it did not reduce an enrollee's premium by the amount of the advance payment of the premium tax credit in accordance with 45 CFR 155.340(g)(1)–(2). We have modified § 155.1200 to incorporate this provision because § 155.1200 includes other annual reporting requirements applicable to State Exchanges (see section II.D.1.a below). We note that since issuers in an FFE are responsible for collecting premiums directly from enrollees, such errors will be reported to HHS by the QHP issuers.

Summary of Regulatory Changes

We are finalizing the proposed provisions with the following modifications. We are increasing the time period for notifying the enrollee of the improper application of the advance payment of the premium tax credit and issuing refunds from 30 days to 45 days. We are also providing that the Exchange may issue the refund by applying the total excess premium paid by or for the enrollee to the enrollee's portion of the premium each month for the remainder of the period of enrollment or benefit year until the excess premium is fully refunded, except that the Exchange must refund any remaining excess premium, within 45 days of a request by or for the enrollee for the refund or within 45 days of the end of the period of enrollment or benefit year.

2. Subpart E—Exchange Functions in the Individual Market: Enrollment in Qualified Health Plans

a. Special Enrollment Periods (§ 155.420)

In § 155.420 we proposed to amend § 155.420(d) to provide that a special enrollment period will be available when the Exchange determines that a consumer has been incorrectly or inappropriately enrolled in coverage due to misconduct on the part of a non-Exchange entity. Specifically we proposed to add a new paragraph § 155.420(d)(10) to create this new special enrollment period for qualified individuals. This amendment would extend a special enrollment period to a qualified individual when, in the

determination of the Exchange, misconduct on the part of a non-Exchange entity has caused the qualified individual to be enrolled incorrectly or inappropriately in coverage such that they are not enrolled in QHP coverage as desired, are not enrolled in their selected QHP, or have been determined eligible for but are not receiving advance payments of the premium tax credit or cost-sharing reductions. We proposed to limit this special enrollment opportunity to the individual market Exchange and not extend it to the SHOPS.

We proposed that a non-Exchange entity providing enrollment assistance or conducting enrollment activities would include, but not be limited to, those individuals and entities that are authorized by the Exchange to assist with enrollment in QHP, such as a Navigator, as described in § 155.210; non-Navigator assistance personnel, as authorized by § 155.205(d) and (e); a certified application counselor, as described in § 155.225; an agent or broker assisting consumers in an Exchange under § 155.220; issuer application assisters under § 155.415; or a QHP conducting direct enrollment under § 156.1230.

Comment: We received several comments supporting this proposed amendment to § 155.420(d) to ensure that consumers have an available remedy if misconduct on the part of a non-Exchange entity results in harm.

Response: We are finalizing the rule as proposed to ensure that consumers will have a special enrollment period if harmed by misconduct on the part of non-Exchange entities. We further clarify here that for purposes of § 155.420(d)(10) only, a non-Exchange entity includes an individual or entity fraudulently claiming to be an authorized entity approved by an Exchange, such as a Navigator, non-Navigator assister, or Exchange-approved agent or broker.

Comment: We received a comment recommending that the special enrollment period be available to consumers if a non-Exchange entity provides erroneous information to a consumer, regardless of whether the consumer can demonstrate harm.

Response: We believe that creating a special enrollment period for consumers who have been harmed by non-Exchange entity misconduct will help ensure that consumers have a remedy to address enrollment harms while limiting uncertainty for QHP issuers. We believe that this remedy is necessary for consumers who have been harmed, to allow them to mitigate the harm caused. However, we do not believe this

remedy would be necessary for consumers who have not suffered any harm resulting from misconduct. In addition, as stated in the preamble to the proposed rule, a qualified individual may also seek to demonstrate the existence of exceptional circumstances to the Exchange under § 155.420(d)(9) if the qualified individual is harmed due to error or inaction on the part of a non-Exchange entity. We intend to provide future guidance on the process for demonstrating harm as necessary.

Comment: We received several comments recommending that this special enrollment period be extended to the SHOPS, stating that SHOP consumers may be exposed to the same risk as consumers purchasing coverage in an Exchange.

Response: We believe that it is less likely for an employee enrolled in coverage through a SHOP to be harmed in the ways the new special enrollment period is intended to address than is the case for a qualified individual enrolled in coverage through the individual market Exchange. For example, advance payments of the premium tax credit and cost-sharing reductions are not available to employees enrolled in coverage through a SHOP, such that it would not be possible for them to be determined eligible for but not receive advance payments of the premium tax credit or cost-sharing reductions, one of the harms the special enrollment period was specifically designed to address. However, we are persuaded by the comments that some risk of harm does exist for employees enrolled in coverage through a SHOP, and are therefore extending the special enrollment period to SHOPS. We intend to monitor whether employees avail themselves of the special enrollment period and the circumstances surrounding each such election. We are making minor changes to the proposed rule text to clarify that the special enrollment period would be extended to employees enrolled in coverage through a SHOP and their dependents, and are also making a conforming change to 45 CFR 155.725(j) to clarify that this special enrollment period applies in the SHOPS.

Comment: We received several comments recommending that misconduct on the part of a non-Exchange entity should also result in a special enrollment period for enrollment into public programs the consumer may otherwise be eligible for, such as Medicaid or CHIP.

Response: Medicaid and CHIP have year round enrollment, so individuals eligible for these programs do not need a special enrollment period to enroll in these programs if they have been

incorrectly enrolled in private health insurance coverage.

Comment: We received one comment requesting clarification about what actions might be considered misconduct.

Response: As stated in the preamble of the proposed rule, misconduct includes the failure of a non-Exchange entity to comply with applicable requirements set forth in Exchange regulations, or other applicable Federal or State laws. For example, this might include a Navigator's failure to comply with the requirements set forth in 45 CFR 155.210.

Comment: We received comments stating that the special enrollment period, as proposed, might result in adverse selection or gaming by consumers. One commenter requested that this provision not be codified to eliminate the risk of adverse selection and another commenter requested that the duration of this special enrollment period be limited to 30-days, rather than the 60-days from the date of the triggering event, as proposed.

Response: We believe that any risk that this special enrollment period might result in adverse selection is mitigated by the fact that consumers will need to demonstrate to the Exchange that they have been harmed in order to receive this special enrollment period. We believe that this special enrollment period is important to protect consumers from certain kinds of misconduct on the part of non-Exchange entities. In addition, the 60-day time period for the new special enrollment period in the individual market Exchanges is consistent with special enrollment periods otherwise available to Exchange consumers in the individual market and we believe provides consumers with adequate time to review available plan options and make informed decisions to correct the harm. Consistent with other special enrollment periods available in the SHOPS, this special enrollment period will be for 30 days, not 60 days, in the SHOPS.

Summary of Regulatory Changes

We are finalizing the provision proposed in § 155.420(d)(10) with amendments reflecting our decision to extend the special enrollment period to SHOPS, and with a minor correction to remove "of this subchapter" following "part 156" from the proposed regulation text.

3. Subpart H—Exchange Functions: Small Business Health Options Program (SHOP)

a. Enrollment Periods Under SHOP (§ 155.725)

In section II.D.2 of this final rule, we describe our decision, made in response to comment, to extend to SHOPS the new special enrollment period that will be available when the Exchange determines that a consumer has been incorrectly or inappropriately enrolled in coverage due to misconduct on the part of a non-Exchange entity. Accordingly, we are making a conforming amendment to § 155.725(j)(2)(i) to add a cross-reference to § 155.420(d)(10), the new special enrollment period.

4. Subpart M—Oversight and Program Integrity Standards for State Exchanges

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

We proposed that the State Exchange maintain an accounting of all its receipts and expenditures, in accordance with GAAP. We also proposed that the State Exchange develop and implement a process for monitoring all Exchange-related activities for effectiveness, efficiency, integrity, transparency, and accountability. We stated our belief that these activities would help to ensure State Exchange compliance with Federal requirements as set forth in Part 155 and ensure the appropriate administration of Federal funds, including advance payment of the premium tax credit and cost-sharing reductions.

In § 155.1200(b), we proposed that the State Exchange submit several types of reports to HHS. The State Exchange would submit at least annually a report to allow for transparency of State Exchange activities. The report must include a financial statement presented in accordance with GAAP. The report is due to HHS by April 1 of each year. Additionally, the State Exchange must submit reports in a form and manner to be specified by HHS regarding eligibility and enrollment. These reports will focus on eligibility determination errors, non-discrimination safeguards, accessibility of information, and fraud and abuse incidences. The State Exchange must also submit performance monitoring data that includes financial sustainability, operational efficiency, and consumer satisfaction. We sought comments on our approach, including comments on the content, format, and timing of such reports.

In § 155.1200(c) we proposed that the State Exchange engage an independent qualified auditing entity, whether

governmental or private, which meets accepted professional and business standards and follows generally accepted governmental auditing standards (GAGAS) to perform an independent external financial and programmatic audit of the State Exchange. This entity should be selected to avoid any real or potential perception of conflict of interest, including being free from personal, external and organizational impairments to independence or the appearance of such impairments of independence. We stated that an external audit will help ensure the consistency and accuracy of State Exchange financial reporting and program activities. We proposed that this requirement may be satisfied through an audit by an independent State-government entity. We proposed that the State Exchange will submit to HHS, concurrent with the annual report, the results on the audit along with proposals on how it will remedy any material weakness or significant deficiency (the terms "material weakness" and "significant deficiency" are defined in OMB Circular A-133, Audits of States, Local Governments and Non-Profit Organizations).

In § 155.1200(d) we proposed that independent audits address specific processes and activities of State Exchanges including financial and programmatic activities and those related to the verification and determination of applicants' eligibility for enrollment in the State Exchanges and the subsequent enrollments. We also proposed that the external audit address whether the Exchange is complying with § 155.1200(a)(1) by keeping an accurate accounting of Exchange receipts and expenditures in accordance with generally accepted accounting principles (GAAP). We also proposed that external audits and annual reports required under paragraphs (b) and (c) address State Exchange processes and procedures to comply with the standards for Exchanges under Part 155 related to advance payments of the premium tax credits and cost-sharing reductions. These standards include the requirements under subpart D regarding eligibility determinations, including the requirements regarding the confidentiality, disclosure, maintenance, and use of information as set forth in 45 CFR 155.302(d)(3); subpart E regarding individual market enrollment in QHPs; and subpart K regarding QHP certification. We also proposed that such audits and annual reports assess whether a State Exchange has processes and procedures in place

to prevent improper eligibility determinations and enrollment transactions. We sought comment on the proposed annual audits, and other activities that State Exchanges should specifically be required to audit annually or on an interim basis.

Comment: We received comments on the timing of the annual financial statement. We also received comments requesting additional reporting requirements including reporting for fraud and abuse incidences and suggesting that we specify in regulation text the types of reporting requirements we described in the preamble.

Additionally, commenters suggested that we make reports publicly available.

Response: We do not believe any additional reporting requirements are needed because the financial statement is intended to ensure the transparency of State Exchange activity and the eligibility and enrollment reporting is intended to ensure that processes and procedures are appropriately in place to ensure that Federal requirements are being met.

The performance monitoring data provide insight into the performance and impact of State Exchanges, including the cost of insurance, the scope of coverage, and access issues. This limited set of standardized metrics also ensures basic transparency and allows consistent cross-state comparisons of the impacts of varying approaches to State Exchange implementation. We anticipate providing further guidance on the format and timing of the reports, as well as, whether the public will have access to them.

Comment: One commenter suggested that we make these independent annual audits available to the public and increase the scope of the independent audit.

Response: We accept the commenter's suggestion regarding public availability and we will require the State to make public a summary of the results of the independent annual audit. Publicizing the audit summary will increase the transparency and accountability of State Exchange activities. We are finalizing our proposal that the independent audit address the elements in § 155.1200(d) as described above, as well as all subparts of Part 155. While we are not accepting the commenter's suggestion that independent audits include incomplete applications or application questions most commonly left unanswered, we believe that the criteria in Part 155 and in § 155.1200(d) adequately address areas of compliance including eligibility denials and information to improve the eligibility process. We anticipate issuing

further guidance on the elements of financial and programmatic activities that should be included in the external financial audit.

Summary of Regulatory Changes

We are finalizing the provisions proposed in § 155.1200 with the following modification. As discussed in II.D.1.a of this final rule, if the Exchange is collecting premiums under 45 CFR 155.240, we are adding subparagraph (b)(4) to require the Exchange to annually report if it did not reduce an enrollee's premium by the amount of the advance payment of the premium tax credit in accordance with 45 CFR 155.340(g)(1)–(2). In paragraph (c) we are adding a requirement that the State make public a summary of the results of external financial audit.

b. Maintenance of Records (§ 155.1210)

We proposed that State Exchanges and its contractors, subcontractors, and agents maintain records for 10 years, including documents and records (whether paper, electronic, or other media) and other evidence of accounting procedures and practices of the State Exchanges to prepare for targeted audits. We stated that these records must be sufficient and appropriate to respond to any periodic auditing, inspection, or investigation of the State Exchange's financial records or to enable HHS or its designee to appropriately evaluate the State Exchange's compliance with Federal requirements. We anticipate that targeted audits will be conducted based on information from the external audit, annual report, prospective measurement programs of improper payments, consumer complaints, or other data sources. In addition, we proposed that the State Exchange must make all records of this section available to HHS, the OIG, the Comptroller General, or their designees, upon request.

Comment: Commenters suggested that the proposed maintenance of records requirements for State Exchanges and their contractors, subcontractors, and agents should specifically outline additional records to be kept, which could include data related not only to appeals but to the outcome of the appeals. In addition, commenters suggested that the requirement apply only to those eligible entities contracted with the State Exchanges to carry out one or more responsibilities of the Exchange (see 45 CFR 155.110), and should not apply to QHP issuers.

Response: The maintenance of records provision we are finalizing in § 155.1210 (b) sufficiently addresses the minimum types of records that we

would require State Exchanges to retain. The maintenance of records provision in § 155.1210 only applies to entities that are carrying out one or more responsibilities of the Exchange in the capacity of a contractor, subcontractor, or agent, and does not apply to QHP issuers because these entities do not provide services or carry out one or more responsibilities of the Exchange. Furthermore, the oversight standards with respect to cost-sharing reductions and advance payments of the premium tax credit finalized in 45 CFR 156.480 of this final rule ensure that CMS can sufficiently monitor compliance with federal standards with respect to the federal funds distributed to QHP issuers through these programs. Therefore, requiring QHP issuers to maintain records is not necessary.

Comment: One commenter suggested that HHS articulate how consumers, advocates, Navigators, and other entities will be able to file complaints with HHS in a meaningful way such as triggering a targeted audit.

Response: We expect that the consumer satisfaction section of the performance monitoring data will include reporting on consumer complaints that will be used in determining whether we will conduct a targeted audit.

Summary of Regulatory Changes

We are finalizing the provisions proposed in § 155.1210, and note that the 10 year record retention requirement begins when the record is created.

E. Part 156—Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related To Exchanges

1. Subpart A—General Provisions

a. Definitions (§ 156.20)

We proposed amending 45 CFR 156.20 by adding the definition for “Enrollee satisfaction survey vendor” and “Registered user of the enrollee satisfaction survey data warehouse.”

We are making a technical correction to our regulation text, which inadvertently left out the word “that” from the definition. The definition for “enrollee satisfaction survey vendor” should begin, “an organization that has . . .”

We received no comments in regards to these definitions, and finalize these definitions as proposed, but with the technical corrections as mentioned above.

Summary of Regulatory Changes

We are finalizing this provision as proposed.

b. Single Risk Pool (§ 156.80)

To ensure consistency with rate setting schedules in the Exchanges and thus reduce the risk of adverse selection, we proposed in § 156.80 to add paragraph (d)(3) to clarify when issuers may establish and update premium rates under the single risk pool requirements. Specifically, in paragraph (d)(3)(i), we proposed that issuers in the individual market or in a market in which the individual and small group risk pools were merged by the State would be permitted to make changes to their market-wide adjusted index rate and plan-specific pricing on an annual basis. In paragraph (d)(3)(ii), we proposed that issuers in the small group market would be permitted to make such changes on a quarterly basis once the Federally-Facilitated Small Business Health Options Program's (FF-SHOP) capability to process quarterly rate updates is established. Until that time, we proposed that issuers in the small group market may make changes to rates no more frequently than annually.

Comment: Commenters generally acknowledged the reasons for the proposal to prohibit quarterly index rate and plan-level adjustments for issuers in FF-SHOPs until the issues are resolved, but asserted this policy should not apply in States with SHOPs that have the capability to accept quarterly rate adjustments, nor should they apply to issuers offering coverage in the small group market solely outside of the SHOPs.

Response: HHS, in operating both the FF-SHOPs as well as the market-wide rate review program under section 2794 of the PHS Act, cannot accept quarterly rate changes at this time. Accordingly, we are finalizing our proposal that issuers offering coverage in the small group market through the SHOPs or outside of the SHOPs must refrain from making index rate and plan-level adjustments more frequently than annually, until notified of the system capability to process quarterly rate changes. We expect to establish this capability by the third quarter of 2014.

Comment: One commenter requested clarification as to whether States could require less frequent index rate and plan-level adjustments in the small group market than those specified in the regulation.

Response: Nothing in this final rule prevents a State from requiring less frequent rate changes in the small group market than the quarterly changes permitted under this final rule. At a minimum, however, an issuer in small group or individual market must

establish an index rate each calendar year with an effective date of January 1, and, in the small group market, ensure that any rate changes at other times during the year are effective only on April 1, July 1, or October 1, the only dates for which Federal systems will be in place for processing rate updates. We believe § 156.80(d)(1) already provides for the establishment of an index rate by January 1 of each calendar year, and that the proposed rule contemplates small group market rate changes that correspond to the calendar quarters. Nonetheless, for precision and clarity, we are revising the regulation text to include these clarifications. We note that any new rates set by an issuer would apply for new or renewing coverage on or after the rate effective date, and would apply for the entire the plan year.

Comment: Some commenters sought assurance that the single risk pool requirements would not prevent issuers from filing new products for sale outside of Exchanges nor prevent issuers from entering a market until January 1 of each year.

Response: As described above, under the guaranteed availability standard, all non-grandfathered plans in the individual or merged market must be offered on a calendar year basis starting January 1, 2014. Furthermore, under the single risk pool standard, an index rate must be established and adjusted only once annually in the individual and merged markets. The interaction of these provisions is such that an issuer cannot introduce new products throughout the year without affecting the pricing of all of the issuer's other products in the risk pool, in violation of the single risk pool provision. We note that issuers will have greater flexibility to introduce new products in the small group market, where coverage may be issued on a rolling basis throughout the year and rates generally will be able to be updated on a quarterly basis.

Summary of Regulatory Changes

We are finalizing the provisions proposed in § 156.80 of the proposed rule with the following modifications. We are revising existing paragraph (d)(1) to provide that an index rate must be established and effective for a State market (individual, small group, or merged market) by January 1 of each calendar year. We are also restructuring proposed paragraph (d)(3) to clearly state that an issuer is prohibited for making index rate and plan-level adjustments on any basis other than annually, except in the small group market once quarterly rate changes are permitted. We also now clearly state the

effective dates of quarterly rate updates in the small group market.

2. Subpart B—Standards for Essential Health Benefits, Actuarial Value, and Cost Sharing

a. Enrollment in Catastrophic Plans (§ 156.155)

We are making a technical correction to our regulation text in § 156.155, which inadvertently omitted the statutory language in section 1302(e) of the Affordable Care Act indicating that a catastrophic plan provides “no benefits” for any plan year (except for providing coverage for at least 3 primary care visits and preventive health services in accordance with section 2713 of the PHS Act) until the individual has incurred cost-sharing expenses in an amount equal to the annual limitation on cost sharing in effect under section 1302(c)(1) of the Affordable Care Act. Although this provision was not addressed in the proposed rule, it is part of the law governing benefits under catastrophic plans, and we believe it is appropriate to revise the regulation text in this final rule to reflect this fact.

3. Subpart D—Qualified Health Plan Minimum Certification Standards

a. Changes of Ownership of Issuers of Qualified Health Plans in Federally-Facilitated Exchanges (§ 156.330)

In § 156.330, we proposed that when a QHP issuer in the FFE undergoes a change in ownership, it notify HHS of the change at least 30 days prior to the date of the change and provide the legal name and taxpayer identification number (TIN) of the new owner, as well as the effective date of the change. We also proposed that the new owner must agree to adhere to applicable statutes and regulations.

Comment: One commenter expressed support for the proposed standard and urged HHS to examine any relevant compliance and other issues impacted by the change of ownership at the time notified, such as accreditation status.

Response: HHS intends to examine possible compliance issues related to the change of ownership, including impact on accreditation status, as part of its overall oversight framework.

Comment: One commenter urged flexibility in assessing what constitutes a change in ownership and expressed concern that the standard in § 156.330 could be triggered when transferring blocks of business from one affiliated entity to another.

Response: HHS believes that the notice requirement is minimally burdensome. Further, we believe that it

will be apparent to issuers when the standard is triggered—if recognized by the applicable State, then an issuer would need to comply with § 156.330.

Comment: One commenter asked HHS to exempt changes of ownership within the same holding company from the notice provision and requested additional flexibility in implementing this provision for the 2014 plan year.

Response: We believe that the standard, which would only require notification if the change of ownership is recognized at the State level, is clear. If a change of ownership within the same holding company is required by a State at the State level, then the issuer would need to report it pursuant to § 156.330. We believe that the notice standard is the most minimally burdensome way for HHS to be aware of these important changes, particularly as compared to standards that may be required under State law. Therefore, we do not believe that a transition period is necessary.

Summary of Regulatory Changes

We are finalizing this section as proposed.

4. Subpart E—Health Insurance Issuer Responsibilities With Respect to Advance Payments of the Premium Tax Credit and Cost-Sharing Reductions

a. Definitions (§ 156.400)

Section 156.400 of this subpart includes definitions of a “most generous,” and a “more generous,” plan variation. We proposed to supplement those definitions by clarifying that the definitions of a “least generous,” and a “less generous,” plan variation have the opposite meanings of the existing definitions of a “most generous,” or a “more generous” plan variation. Specifically, we proposed that, as between two plan variations (or a plan variation and a standard plan without cost-sharing reductions), the plan variation or standard plan without cost-sharing reductions designed for the category of individuals first listed in 45 CFR 155.305(g)(3) would be deemed the less generous one. The term less generous was used in the proposed rule to address circumstances in which a QHP issuer would reassign an enrollee from a more generous plan variation to a less generous plan variation (or standard plan without cost-sharing reductions), as discussed in greater detail below. We also proposed a technical modification to change “QHP or plan variation” to “standard plan or plan variation” to clarify that a plan variation is not distinct from a QHP. We received no comments on these

proposed provisions and are finalizing these provisions as proposed.

b. Improper Plan Assignment and Application of Cost-Sharing Reductions (§ 156.410(c) Through (d))

In § 156.410, we proposed to add new paragraphs (c) and (d) to specify the actions a QHP issuer would take if it does not provide the appropriate cost-sharing reductions to an individual, or if it does not assign an individual to the appropriate plan variation (or standard plan without cost-sharing reductions) in accordance with § 156.410(a) through (b) or § 156.425(a) through (b) of this subpart.

Specifically, in paragraph (c)(1), we proposed that if a QHP issuer fails to ensure that an individual assigned to a QHP plan variation receives the cost-sharing reductions required under the applicable plan variation (taking into account the requirement regarding cost sharing previously paid under other plan variations of the same QHP under § 156.425(b) if applicable), the QHP would notify the enrollee of the improper application of the cost-sharing reductions and refund any excess cost sharing paid by or for the enrollee during such period no later than 30 calendar days after discovery of the improper application of the cost-sharing reductions. This refund would be paid to the person or entity that paid the excess cost sharing, whether the enrollee or the provider.

In paragraph (c)(2), we proposed that if a QHP issuer provides an enrollee assigned to a plan variation with greater cost-sharing reductions than required under the applicable plan variation (taking into account § 156.425(b) concerning continuity of deductibles and out-of-pocket amounts if applicable) then the QHP issuer will not be eligible for reimbursement of any excess cost-sharing reductions provided to the enrollee, and may not seek reimbursement from the enrollee or the provider for any of the excess cost-sharing reductions. Because the QHP issuer is responsible for ensuring the cost-sharing reduction is provided appropriately, we noted that we do not believe that the QHP issuer should be able to recoup overpayments of cost-sharing reductions that resulted from the QHP issuer's own errors.

In paragraph (d), we proposed that if a QHP issuer improperly assigns an enrollee to a plan variation (or standard plan without cost-sharing reductions), or does not change the enrollee's assignment due to a change in eligibility in accordance with § 156.425(a), in each case, based on the eligibility and enrollment information or notification

provided by the Exchange, then the QHP issuer would, no later than 30 calendar days after discovery of the improper assignment, reassign the enrollee to the applicable plan variation (or standard plan without cost-sharing reductions) and notify the enrollee of the improper assignment.

Conversely, paragraph (d)(2) proposed that, if a QHP issuer reassigns an enrollee from a less generous plan variation (or a standard plan without cost-sharing reductions) to a more generous plan variation of a QHP to correct an improper assignment on the part of the issuer, the QHP issuer would recalculate the individual's liability for cost sharing paid between the effective date of eligibility required by the Exchange and the date on which the issuer effectuated the change. The QHP issuer would refund any excess cost sharing paid by or for the enrollee during such period, no later than 30 calendar days after discovery of the incorrect assignment. This refund would be paid to the person or entity that paid the excess cost sharing, whether the enrollee or the provider. We sought comment on the proposed approach, including the 30-calendar-day timeframe for QHP issuers to reassign an individual to the correct plan variation and refund any excess cost sharing paid by or for the enrollee. We also sought comment on whether the timeframe should depend on the point in the month the issuer discovers the improper assignment, considering the amount of time issuers may require to effectuate the reassignment, as well as the impact on enrollees due to a delay in reassignment. We noted that the date of the reassignment would not affect the initial effective date of eligibility, and that the enrollee would still be refunded any excess cost sharing paid by or for the enrollee between the effective date of eligibility and the date of the reassignment.

We also noted that we were considering requiring that, for each quarter, a QHP issuer provide to HHS and the Exchange a report beginning in the 2015 benefit year detailing the occurrence of any improper applications of cost-sharing reductions in violation of the standards finalized and proposed in § 156.410(a) and (c) and § 156.425(b), as well as instances when it did not refund any excess cost sharing paid by or for an enrollee in accordance with proposed § 156.410(c)(1) and § 156.410(d)(2), or was reimbursed for excess cost sharing provided in violation of proposed § 156.410(d)(1).

Comment: Several commenters supported holding enrollees harmless for issuer mistakes. A number of

commenters requested clarification that issuers will not be penalized for errors made by Exchanges or enrollee income misrepresentations, and asked HHS to institute policies or procedures that would make it easy for issuers to identify enrollment errors. One commenter suggested that restitution should only occur when the agencies can prove a pattern of willful misconduct, while another commenter suggested that HHS request compensation from an Exchange for errors by the Exchange.

Response: We are clarifying that QHP issuers may rely on the validity of an eligibility determination sent to the QHP issuer by the Exchange, and are not responsible for providing refunds under this provision resulting from an Exchange or enrollee error. However, as noted in the proposed rule, because of the reliance interests of an enrollee in the application of cost-sharing reductions when purchasing particular services, we believe that the QHP issuer should not be able to recover excess funds resulting from issuer error with respect to the application of cost-sharing reductions. We note that this is a different standard from the one we are finalizing for misapplications of the advance payments of the premium tax credit because we believe that an enrollee has lesser reliance interest in miscalculated premiums because the enrollee would have been clearly notified of both the monthly premium and advance payment of the premium tax credit when they enroll in the plan. In contrast, an enrollee may not be aware of the cost-sharing amount for a specific service and might not be able to determine whether the cost-sharing reduction was correctly applied for that particular service at the point the cost sharing is collected.

Comment: Several commenters noted that requiring issuers to provide refunds of cost-sharing reductions to enrollees is inconsistent with standard billing practices in which an issuer bills or credits the enrollee, noting that issuing refunds would require additional resources. Another commenter noted that consistent with current practices and procedures applicable to non-subsidized enrollees, issuers should be able to reprocess claims under the correct plan variation and recoup any excess payment.

Response: In consideration of standard issuer billing practices, the final rule provides that a QHP issuer may apply any excess cost sharing paid by or for an enrollee (except by a provider) to the enrollee's portion of the premium for the remainder of the period of enrollment or benefit year until the

excess is fully applied unless the enrollee requests the refund. (The issuer may also elect to directly refund the enrollee, regardless of whether the enrollee requests the refund.) However, if requested by the enrollee, the QHP issuer would be required to directly refund the enrollee any excess cost sharing paid by or for the enrollee within 45 calendar days of the request. The QHP issuer would refund the enrollee any remaining excess cost-sharing paid by the individual at the end of the period of enrollment or benefit year, and if the excess cost sharing amount was paid by the provider, the QHP issuer would refund to the provider any excess cost sharing paid by provider within 45 calendar days of discovery of the error. We believe that this standard will allow issuers to reimburse enrollees without incurring additional operational costs outside the standard billing practice, while still providing the option for direct refund to the enrollee.

Comment: One commenter asked HHS to clarify that consumer protections also apply to enrollees who are not eligible for a cost-sharing reduction but who are mistakenly enrolled in a silver plan variation by the issuer.

Response: We clarify that the standards in § 156.410(c) and (d) would apply when an enrollee should not be eligible for cost-sharing reductions but is erroneously assigned to a silver plan variation by the QHP issuer.

Comment: One commenter suggested HHS set a threshold date such that, if a QHP issuer discovers an enrollee was assigned to an incorrect plan variation before the 15th of a month, the enrollee would be reassigned to the proper plan variation by the 1st day of the following month, and errors discovered afterwards would be corrected in the following month. Another recommended that consumers be provided advance notice of plan reassignment, and that plans ensure that enrollees have full access to services while the errors are being corrected.

Response: In response to comments, we are modifying the proposed policy to align with existing Exchange regulations regarding the effective date of coverage with respect to special enrollment periods under 45 CFR 155.420(b)(i) and (ii). Section 156.410(d)(1) and (2) now provide that if the QHP issuer discovered the error between the first and fifteenth day of the month, the QHP issuer must reassign the enrollee to the correct plan variation (or standard plan without cost-sharing reductions) by the first day of the following month. If the QHP issuer discovers the error between the sixteen and the last day of the month,

the QHP issuer must reassign the individual to correct plan variation by the first day of the second following month. We note that as with reassignment, we expect issuers to notify enrollees prior to the effective date of the reassignment to prevent enrollee confusion.

Comment: While some commenters supported the 30-day timeframe for refunds, a number of commenters felt that this timeframe is not feasible, given enrollment reconciliation and payment discrepancy processes. One commenter suggested that the final rule adopt a 45-day timeframe, in line with Medicare Part D. Other commenters recommended increasing the timeframe to 60 or 90 days. One commenter suggested that issuers in State Exchanges have the flexibility to work with the Exchange to establish appropriate timelines.

Response: Because cost sharing-reductions are Federal outlays, we believe that it is appropriate to set uniform timeframes for correcting errors related to the underpayment of cost-sharing reductions, regardless of whether the individual receives coverage through a QHP issuer participating in a State Exchange or an FFE. However, taking into consideration current industry practice and the monthly enrollment reconciliation process, as well as the refunds standards specified under 42 CFR 423.800(e) and 42 CFR 423.466(a) with respect to the Medicare Part D low-income subsidy program, we are modifying the proposed policy and are requiring issuers to provide refunds to enrollees within 45 days of the discovery of the error. We believe that this will permit issuers to rectify errors in a timely manner consistent with their current monthly operational cycles, without significantly delaying the reimbursement to the enrollee or provider as applicable.

Comment: Some commenters suggested a de minimis threshold for required refunds, similar to the threshold for the medical loss ratio program.

Response: Unlike the minimum threshold for medical loss ratio rebates under 45 CFR 158.243, the standards proposed under this section were intended to ensure that Federal funds are being used to appropriately subsidize enrollee cost sharing, so that individuals receive the full cost-sharing reductions for which they were determined eligible. Because these refund standards are designed to protect low-income individuals from unforeseen costs, we do not believe there should be a de minimis threshold for refunds of cost-sharing reductions.

Comment: Several commenters supported a standard under which an issuer is not required to report on misapplication of cost-sharing reductions unless a minimum error rate occurs, while other commenters stated that all issuers should submit these reports without respect to such a threshold. Other commenters stated that a semi-annual or annual report should be required for the initial years. One commenter believed that such quarterly reports would duplicate the information provided via enrollment reconciliation and the payment discrepancy reporting process. The same commenter was also concerned about the implications of such self-reporting under Federal laws, and recommended a safe harbor from enforcement remedies for any good faith reporting. Another commenter suggested that HHS give State Exchanges flexibility to decide the timing of such reports.

Response: In response to comments, we are not establishing a quarterly reporting standard with respect to the improper application of cost-sharing reductions or improper assignments to plan variations (or standard plans without cost-sharing reductions). However, we require this reporting as part of the annual reporting requirement set forth under § 156.480(b). We believe that annual reporting of these errors will allow HHS to track the occurrence of these errors and identify any problems that affect multiple issuers without duplicating any existing interim reporting requirements. We do not intend to create a safe harbor for misreported information, and expect that issuers will make a good faith effort to accurately report these errors.¹⁸

Comment: One commenter asked how claims submitted for premium stabilization programs would be affected by erroneous cost-sharing reduction amounts.

Response: As noted in 45 CFR 156.430(d), HHS will perform periodic reconciliations of any advance payments of cost-sharing reductions provided to the QHP issuer with the actual amount of cost-sharing reductions provided to enrollees and reimbursed to providers by the QHP issuers. This calculation is not required for the risk adjustment or reinsurance programs, and will be completed prior to the deadline for the risk corridors program.

¹⁸ We note that many of the errors that will be the subject of the first annual report and to our 2014 policy of nonenforcement of CMPs for good faith, which we codified at 45 CFR 156.800(c).

Summary of Regulatory Changes

We are finalizing these provisions with the following modifications. We are amending paragraphs (c) and (d) to increase the time period for issuing refunds from 30 days to 45 days of discovery of the error. We are also modifying these paragraphs to provide that the QHP issuer may provide the refund by applying the total excess cost sharing paid by or for the enrollee to the enrollee's portion of the premium for the remainder of the period of enrollment or benefit year until the excess is fully applied, except that the QHP issuer must refund the enrollee the excess cost sharing within 45 days of the enrollee's request or the end of the period of enrollment or benefit year. (Any cost-sharing paid by the provider will still be refunded to the provider within 45 days of discovery of the error.) Additionally, we are re-designating subparagraphs (d)(1) and (d)(2) as (d)(3) and (4), and adding two new subparagraphs (d)(1) and (d)(2), which set forth a timeframe for effectuating a reassignment to the correct plan variation.

c. Payment for Cost-Sharing Reductions (§ 156.430)

In the 2014 Payment Notice, we established a payment approach under which monthly advance payments will be made to QHP issuers to cover projected cost-sharing reduction amounts, and then, after the close of the benefit year, the advance payments and the actual cost-sharing reduction amounts provided during the benefit year will be reconciled. In 45 CFR 156.430(c)(1), we established standards for QHP issuers to submit data to HHS detailing the amount of cost sharing the enrollees in each plan variation paid, as well as the amount of cost sharing the enrollees would have paid under the standard plan. The value of the cost-sharing reductions provided is the difference of these two amounts. We also finalized at 45 CFR 156.430(c)(2) a methodology (referred to as the "standard methodology") for calculating the amount of cost sharing that the enrollees would have paid under the standard plan, but for the cost-sharing reductions. Under the standard methodology, QHP issuers apply the cost-sharing requirements for the standard plan to the allowed costs for each plan variation policy; in effect, each claim would be processed twice: once using the cost-sharing structure that would have been in place if the individual were ineligible for cost-sharing reductions, and once using the reduced cost-sharing structure in the

applicable plan variation for which the individual is eligible.

In the Amendments to the HHS Notice of Benefit and Payment Parameters for 2014 interim final rule, we established in § 156.430(c)(4) an alternate methodology for calculating the amount of cost sharing that the enrollees would have paid under the standard plan for the purpose of reconciliation of the advance payments of the cost-sharing reductions. Under this alternate methodology (referred to as the "simplified methodology"), QHP issuers calculate the amount of cost sharing that the enrollees would have paid under the standard plan by using formulas based on certain summary cost-sharing parameters of the standard plan, applied to the total allowed costs for each policy. With this approach, we sought to balance the need to safeguard Federal funds with the goal of lessening the administrative burden on QHP issuers. We stated that we anticipated that after an appropriate transition period, all QHP issuers would be required to use the standard methodology, and sought comments on how long the transition period should be. We also noted that in later years, we would consider alternative approaches for reimbursing QHP issuers. For example, once more data is available, we could change to a capitated payment system as permitted in section 1402(c)(3)(B) of the Affordable Care Act. However, such a change would require access to data on the utilization and cost-sharing patterns of individuals eligible for cost-sharing reductions.

In § 156.430(c)(3)(i) of the interim final rule, we provided that a QHP issuer must notify HHS prior to the start of each benefit year whether or not it is selecting the simplified methodology for the benefit year. In paragraph (c)(3)(ii), we specified that if the QHP issuer selects the simplified methodology, it must apply the simplified methodology to all plan variations it offers on the Exchange for a benefit year. Since the simplified methodology is intended for issuers whose systems are not yet capable of implementing the standard methodology, in paragraph (c)(3)(iii) we specified that the QHP issuer may not select the simplified methodology if it did not select the simplified methodology for the prior benefit year. We also set forth standards governing the selection of a methodology if a QHP issuer merges with or acquires another QHP issuer on the Exchange, or acquires a QHP offered on the Exchange from another issuer. In paragraph (c)(3)(iv), we provided that if each of the affected parties had selected a different methodology for the benefit year, then

notwithstanding paragraphs (c)(3)(ii) and (iii), for the benefit year in which the merger or acquisition took place, the QHP issuer must continue to use the methodology selected prior to the start of the benefit year for each plan variation (whether or not the selection was made by that issuer), and for the next benefit year, the QHP issuer may select either methodology, subject to the requirement in paragraph (c)(3)(ii) that a QHP issuer select the same methodology for all plan variations it offers on the Exchange for the benefit year.

In this final rule, we are generally finalizing the standards related to the simplified methodology as established in the interim final rule, with minor clarifying edits to paragraph (c)(3)(iii) and (iv), and we are modifying paragraph (c)(3) to specify that QHP issuers may only choose to use the simplified methodology for benefit years 2014 through 2016. For the 2014 benefit year, HHS intends to contact each QHP offering individual market coverage through an Exchange in November, which will prompt the issuer to notify HHS prior to the start of the benefit year whether or not it selects the simplified methodology for the benefit year. We received a number of comments on the selection of the methodology and the transition period.

Comment: The majority of commenters supported the simplified methodology. Many noted that the simplified methodology will likely reduce QHP issuers' short-term costs and administrative burden. Two commenters argued that issuers should be permitted to choose between the simplified and standard methodologies indefinitely because of the many new functions that issuers will be performing in Exchanges and because the simplified methodology should produce results that are similar to the standard methodology. However, one commenter argued that the choice of methodologies could inflate Federal costs because QHP issuers will likely choose whichever methodology results in the largest payments. That commenter suggested that QHP issuers should only be permitted to choose between the simplified and standard methodologies for the first two years. Other commenters argued that the standards in § 156.430(c)(3) on selecting a methodology should adequately safeguard against potential gaming. In addition, commenters noted that it could take QHP issuers up to 18 months to develop the systems necessary to support the standard methodology, and that therefore HHS should provide at least one year's notice before requiring a transition to the standard

methodology. Several commenters also supported a shift to a capitated payment system in future years, though one noted that it will be important to require QHP issuers to use the standard methodology for at least two years so that adequate data can be collected on the value of the cost-sharing reductions, which may vary significantly between plan variations and enrollees. The same commenter suggested that HHS should ensure that QHP issuers are adequately compensated so that issuers provide cost-sharing reductions as required, including cost-sharing reductions for American Indians and Alaska Natives.

Response: To allow QHP issuers adequate time to develop their systems to support the standard methodology, we are establishing a three-year transition period during which QHP issuers may use the simplified methodology, provided that they choose the simplified methodology prior to the start of benefit year 2014. We are modifying § 156.430(c)(3) to specify that the option to use the simplified methodology will extend only through benefit year 2016. As a result, all QHP issuers offering coverage through the individual market of an Exchange must use the standard methodology to submit the data described in 45 CFR 156.430(c)(1) for cost-sharing reductions provided for benefit year 2017. We will continue to consider alternative approaches for reimbursing QHP issuers for the future, including a capitated payment system. We believe that both methods of calculating the value of cost-sharing reductions provided will be accurate so that QHP issuers are adequately compensated for providing cost-sharing reductions to all populations.

In § 156.430(c)(4) of the interim final rule we set forth a simplified methodology for calculating the amount of cost sharing that enrollees would have paid under the standard plan without cost-sharing reductions. We established that a QHP issuer selecting the simplified methodology must calculate the amount that the enrollees would have paid under the standard plan by applying four summary, or "effective cost-sharing parameters" for the standard plan—the effective deductible, the effective pre-deductible coinsurance rate, the effective post-deductible coinsurance rate, and the effective claims ceiling—to the total allowed costs paid for EHB under the policy (that is, the policy with cost-sharing reductions) for the benefit year. This simplified methodology allows QHP issuers to calculate enrollee liability under the standard plan using a standardized methodology that does

not require complex readjudication of claims. Specifically, in § 156.430(c)(4)(i), we detailed the process for calculating the amount that enrollees would have paid under the standard plan under the simplified methodology, depending on the utilization pattern under the policy. We described these calculations using Formulas A, B, and C, detailed in § 156.430(c)(4)(i)(A), (B) and (C). In § 156.430(c)(4)(ii) (renumbered as (c)(4)(iii) in this final rule), we defined the effective cost-sharing parameters for the standard plan, and established that these parameters must be calculated separately for self-only coverage and other than self-only coverage. We also noted that if a QHP issuer has entirely separate cost-sharing parameters for pharmaceutical and medical services, the QHP issuer may elect to develop separate sets of effective cost-sharing parameters for pharmaceutical and medical services.

We sought comments on these effective cost-sharing parameters and formulas for calculating the amount that enrollees would have paid under the standard plan, and whether this methodology appropriately categorizes policies based on utilization patterns. We also sought suggestions for alternative methodologies that might provide more accurate estimates of the amount that enrollees would have paid under the standard plan, while preserving the administrative efficiency of the simplified methodology. In response to comments, we are generally finalizing the simplified methodology as established in the interim final rule, with some modifications to address unique benefit structures and to reduce potential biases in the formulas identified by commenters. We are also clarifying how QHP issuers should calculate the effective cost-sharing parameters for self-only coverage, other than self-only coverage, medical coverage, and pharmaceutical coverage. Lastly, we are clarifying how the simplified methodology should apply when an enrollee is assigned to a different plan variation or is assigned from a plan variation to the standard plan (or vice versa) during the course of the benefit year.

Comment: In general, commenters supported the simplified methodology, and no commenters suggested any significantly different methodology. Some commenters stated that the simplified methodology will produce results that are not substantially different from the standard methodology, but others proposed certain modifications that they said would improve the accuracy of the

methodology, particularly when applied to certain types of plan designs.

Specifically, three commenters noted that the effective deductible and effective claims ceiling parameters, as established in the interim final rule, may result in the overestimation or underestimation of enrollee liability under a standard plan with certain benefit structures. For example, because the effective deductible was defined as the weighted average of the deductibles for the standard plan, excluding services not subject to the deductible, Formula B (described in § 156.430(c)(4)(i)(B)) may overestimate the cost sharing under the standard plan for those enrollees who incur claims costs greater than the effective deductible, because they receive services that are not subject to the deductible. In addition, because the effective claims ceiling was calculated based on the annual limitation on cost sharing, which may only apply to in-network benefits (as described in 45 CFR 156.130(c)), Formula C (described in § 156.430(c)(4)(i)(C)) may underestimate cost sharing under the standard plan for enrollees who incur large out-of-network claims. In light of these potential biases, one commenter suggested that in-network cost sharing should be calculated separately from out-of-network cost sharing. Other commenters suggested that the QHP issuer's actuary should be allowed greater flexibility in the calculation of an average deductible and an average claims ceiling, based on the actual claims experience of enrollees in the standard plan. One commenter suggested that the issuer's actuary should be required to submit an actuarial memorandum with a justification of any modifications to the effective cost-sharing parameters, demonstrating that the modifications were necessary due to the benefit design and result in a more accurate replication of the standard plan's cost sharing.

We also received a comment asking how mid-year changes in enrollee eligibility for cost-sharing reductions would affect the application of the simplified methodology.

Response: Overall, we believe the simplified methodology will yield results that are substantially similar to the results that would be produced using the standard methodology. In addition, we believe it is important that issuers choosing the simplified methodology use standard formulas and parameters to reduce the analytical burden on issuers, ensure the transparency of the calculations, and reduce the potential for gaming. Nevertheless, in response to these comments, we are finalizing several

modifications to the simplified methodology to improve the accuracy of the calculations.

First, we are making several minor edits to clarify the standards originally established. We are reordering some of the text in the definitions of the effective pre-deductible and effective post-deductible coinsurance rates to mirror the structure of the other definitions. Also, in response to the comment asking about mid-year changes in eligibility for cost-sharing reductions, we are clarifying in § 156.430(c)(4) that the effective cost-sharing parameters, or one minus the actuarial value of the standard plan, as appropriate, should be applied to the total allowed costs for EHB for the benefit year under each policy that was assigned to a plan variation for any portion of the benefit year. We note that a similar standard would apply to the standard methodology. This will ensure that QHP issuers are reimbursed for cost-sharing reductions provided to enrollees that are only assigned to a plan variation for a portion of the year. We are also clarifying in paragraphs (c)(4)(ii) and (iii) that the effective cost-sharing parameters should be calculated based on policies assigned to the standard plan without cost-sharing reductions for the entire benefit year. If a particular enrollee cancels his or her standard plan policy mid-year, or is re-assigned to a plan variation, the costs incurred by that enrollee should not be included in the calculation of the effective cost-sharing parameters for the standard plan because partial-year data could reduce the accuracy of the parameters. We also considered requiring QHP issuers to separate costs by month based on the assignment of an enrollee to a particular plan variation or standard plan, or requiring QHP issuers to annualize costs across the benefit year. However, these approaches would have significantly complicated the methodology and potentially reduced its accuracy.

Second, in response to comments that Formula B (described in § 156.430(c)(4)(i)(B)) may overestimate the cost sharing under the standard plan if the enrollees receive services that are not subject to a deductible, we are modifying several of the formulas and effective cost-sharing parameters to more accurately estimate cost sharing for services that are subject to a deductible and services that are not subject to a deductible. Specifically, in paragraph (c)(4)(iii)(A), we are defining the average deductible to be the weighted average deductible for the standard plan (weighted by allowed costs for EHB under the standard plan for the benefit year that are subject to

each separate deductible, and excluding services that are not subject to any deductible). Conversely, in paragraph (c)(4)(iii)(B), we are defining effective non-deductible cost sharing to be calculated based only on standard plan policies with total allowed costs for EHB for the benefit year that are above the effective deductible but for which associated cost sharing for EHB is less than the annual limitation on cost sharing, and equal to the average portion of total allowed costs for EHB that are *not* subject to any deductible for the standard plan for the benefit year incurred for standard plan enrollees and payable by the enrollees as cost sharing. We are also modifying the definition of effective deductible (which was initially set forth in paragraph (c)(4)(ii)(A), but has been renumbered in this final rule to be paragraph (c)(4)(iii)(C)), to be the sum of the average deductible and the average total allowed costs for EHB that are *not* subject to any deductible for the standard plan for the benefit year. The average total allowed costs for EHB that are not subject to any deductible for the standard plan for the benefit year must be calculated based only on standard plan policies with total allowed costs for EHB for the benefit year that are above the average deductible but for which associated cost sharing for EHB is less than the annual limitation on cost sharing. Lastly, we are making conforming modifications to the definition of effective claims ceiling (which was initially set forth in paragraph (c)(4)(ii)(D), but has been renumbered in this final rule to be paragraph (c)(4)(iii)(F)), to be calculated as follows:

$$ECC = ED + ((AL - AD - NDSCS) / \text{PostD})$$

Where,
 ECC = the effective claims ceiling;
 ED = the effective deductible;
 AL = the annual limitation on cost sharing;
 AD = the average deductible;
 NDSCS = the effective non-deductible cost sharing; and
 PostD = the effective post-deductible coinsurance rate.

Building off of these new definitions, we are modifying the definition of effective post-deductible coinsurance rate (initially set forth in paragraph (c)(4)(ii)(C), but renumbered as paragraph (c)(4)(iii)(E)) to be calculated as follows:

$$\text{PostD} = (\text{CSD}_p) / (\text{TACD}_p - \text{AD})$$

Where,
 PostD = the effective post-deductible coinsurance rate;
 CSD_p = the portion of average allowed costs for EHB subject to a deductible incurred for enrollees for the benefit year, and

payable by the enrollees as cost sharing other than through a deductible; AD = the average deductible; and $TACD_p$ = the average total allowed costs for EHB subject to a deductible incurred for those enrollees for the benefit year (we distinguish $TACD_p$ from the $TACD_i$; $TACD_p$ refers to *average* total allowed costs for EHB subject to a deductible for all the policies that are part of the calculation—which in this case, are standard plan policies with total allowed costs for EHB for the benefit year that are above the effective deductible but for which associated cost sharing for EHB is less than the annual limitation on cost sharing (that is, policies that do not incur enough cost sharing for the annual limitation on cost sharing to affect the cost sharing), while $TACD_i$ refers to the total allowed costs for EHB subject to a deductible for a particular policy).

These terms are then used in a modified Formula B (described in § 156.430(c)(4)(i)(B)), and detailed below, for plan variation policies with total allowed costs for EHB for the benefit year that are greater than the effective deductible but less than the effective claims ceiling, to calculate the amount that enrollees would have paid under the standard plan without cost-sharing reductions.

Formula B: $C = AD + NDCS + ((TACD_i - AD) * PostD)$

Where,

C = the amount that the enrollees in a particular policy would have paid under the standard plan without cost-sharing reductions;

AD = the average deductible;

NDCS = the effective non-deductible cost sharing;

$TACD_i$ = the total allowed costs under the policy for the benefit year for EHB that are subject to a deductible;

PostD = the effective post-deductible coinsurance rate; and

$((TACD_i - AD) * PostD)$ is calculated only if positive.

We believe this formula will more accurately capture cost sharing in plans that subject certain services to deductibles but exempt others (while imposing other forms of cost sharing).

In addition, we note that the new definition of effective deductible will likely cause some plan variation policies that previously would have been subject to calculation under Formula B to become subject to Formula A, which we are finalizing as established in the interim final rule. As described in paragraph (c)(4)(i)(A), Formula A applies to plan variation policies with total allowed costs for EHB for the benefit year that are less than or equal to the effective deductible, and calculates the amount that the enrollees would have paid under the standard plan as the total allowed costs

for EHB under the policy for the benefit year, multiplied by the effective pre-deductible coinsurance rate.

We are also adding a paragraph to clarify how the simplified methodology should be applied to HMO-like plans (or plans with HMO-like characteristics in certain subgroups) with no costs or few costs that are subject to a deductible. Specifically, in paragraph (c)(4)(vi) we provide that if more than eighty percent of the total allowed costs for EHB for the benefit year under a standard plan for a subgroup that requires a separate set of effective cost-sharing parameters pursuant to paragraph (c)(4)(ii) are not subject to a deductible, then (i) The average deductible, the effective non-deductible cost sharing, and the effective deductible for the subgroup equal zero; (ii) the effective pre-deductible coinsurance rate for the subgroup is equal to the effective post-deductible coinsurance rate for the subgroup, which is determined based on all standard plan policies for the applicable subgroup for which associated cost sharing for EHB is less than the annual limitation on cost sharing, and calculated for the applicable subgroup as the proportion of the total allowed costs for EHB under the standard plan for the benefit year incurred for standard plan enrollees and payable as cost sharing (including cost sharing payable through a deductible); and (iii) the amount that enrollees in the applicable subgroup in plan variation policies with total allowed costs for EHB for the benefit year that are less than the effective claims ceiling would have paid under the standard plan must be calculated using the formula in § 156.430(c)(4)(i)(A). In effect, we are merging Formulas A and B for these plans (or these subgroups), and are removing the distinction between the calculation of cost sharing for costs incurred before the deductible is met versus the calculation after the deductible is met. This modification should simplify calculations for issuers of these plans (or these subgroups), and improve the accuracy of the simplified methodology we are finalizing here for these plans (or these subgroups).

Lastly, in response to comments, we are modifying Formula C (described in § 156.430(c)(4)(i)(C)), which applies to plan variation policies with total allowed costs for EHB for the benefit year that are greater than or equal to the effective claims ceiling, and is used to calculate the amount of cost sharing that those enrollees would have paid under the standard plan. First, we are simplifying the formula established in the interim final rule. Second, because the annual limitation on cost sharing

may not apply to benefits provided out-of-network (as allowed under 45 CFR 156.130(c)), we are allowing issuers to elect to use, on a policy-by-policy basis, the standard methodology to calculate the amount of cost sharing that such enrollees would have paid under the standard plan. This modification will allow QHP issuers to capture the value of cost-sharing reductions for enrollees who incur large claim amounts for services from out-of-network providers.

Comment: Commenters noted that due to statistical aberrations under the simplified methodology, it is possible—though unlikely—that the calculated amount of cost sharing that enrollees would have paid under the standard plan could be less than what they actually paid under the plan variation. The commenter suggested that the amount that the enrollees would have paid in cost sharing under the standard plan be set at no less than what they paid under the plan variation.

Response: Although we acknowledge that in certain cases, the calculated amount of cost sharing that enrollees would have paid under the standard plan could be less than what the enrollees in a particular policy actually paid under the plan variation, any such results would likely be balanced by results for other policies that overestimate the cost sharing that the enrollees would have paid under the standard plan. As a result, we do not believe it is necessary to modify the simplified methodology. However, we note that we do not intend to charge a QHP issuer for cost-sharing reductions across all enrollees in a plan variation in the very unlikely event that the simplified methodology suggests that a negative amount of cost-sharing reductions were provided to all such enrollees in the aggregate during the benefit year.

Comment: We received comments on § 156.430(c)(4)(ii) of the interim final rule, which directs issuers to calculate the effective cost-sharing parameters separately for self-only coverage and other than self-only coverage, and provides the option to calculate separate parameters for pharmaceutical and medical services if the QHP has entirely separate cost-sharing parameters for each of these types of services. Two commenters suggested that issuers should be allowed to calculate a single set of effective cost-sharing parameters if the cost-sharing parameters of the other than self-only coverage are better replicated at the individual level (for example, for plan designs applying individual level deductibles first). The same commenters also suggested that issuers should be allowed to calculate

separate parameters for pharmaceutical and medical services even when the costs are not adjudicated by a separate vendor. Similarly, for QHPs in which a large portion of allowed charges are subject to co-pays but not deductibles, the commenters suggested that issuers should be allowed to calculate separate effective cost-sharing parameters for those services. Another commenter suggested that QHP issuers should calculate separate effective cost-sharing parameters for benefits provided in-network versus benefits provided out-of-network because enrollee liability often differs significantly for these benefits. The commenter also suggested that if the QHP issuer made no reductions in cost sharing for benefits provided out-of-network (that is, the out-of-network cost-sharing parameters for the standard plan match the out-of-network cost-sharing parameters for the plan variation), the QHP issuer should be able to exclude costs for benefits provided out-of-network and the applicable cost-sharing parameters from the simplified methodology calculations. Similarly, the QHP issuer should be allowed to exclude costs for benefits paid in full by the issuer for both the standard plan and plan variations, with no enrollee liability, since there are no cost-sharing reductions for these benefits. Lastly, one commenter requested clarification on whether the effective cost-sharing parameters for a QHP should be calculated separately for each rating area, or across an entire State.

Response: In response to comments, we are adding a new paragraph (c)(4)(ii) and making conforming edits to paragraphs (c)(4)(i) through (v) of this section to clarify which subgroups of costs require a unique set of effective cost-sharing parameters. In paragraph (c)(4)(ii)(A), we state that if the standard plan has separate cost-sharing parameters for self-only coverage and other than self-only coverage, but does not have separate cost-sharing parameters for pharmaceutical and medical services, the QHP issuer must calculate and apply separate sets of effective cost-sharing parameters based on the costs of enrollees in the standard plan with self-only coverage, and the costs of enrollees in the standard plan with other than self-only coverage. We clarify that if the cost-sharing parameters for other than self-only coverage accumulate at the enrollee-level and match the parameters for self-only coverage, then the standard plan would not be subject to subparagraph (c)(4)(ii)(A) or (C).

In paragraph (c)(4)(ii)(B), we clarify that if the standard plan has separate

cost-sharing parameters for pharmaceutical and medical services, but does not have separate cost-sharing parameters for self-only coverage and other than self-only coverage, the QHP issuer must calculate and apply separate sets of effective cost-sharing parameters based on the medical costs of the enrollees in the standard plan, and the pharmaceutical costs of the enrollees in the standard plan. This standard is not tied to whether or not the pharmaceutical costs are adjudicated separately by a vendor, but depends on whether or not the cost sharing accumulates to separate deductibles and annual limitations on cost sharing.

Lastly, in paragraph (c)(4)(ii)(C), we state that if the standard plan has separate cost-sharing parameters for self-only coverage and other than self-only coverage, and also has separate cost-sharing parameters for pharmaceutical and medical services, the QHP issuer must calculate and apply separate sets of effective cost-sharing parameters based on the medical costs of enrollees in the standard plan with self-only coverage, the pharmaceutical costs of enrollees in the standard plan with self-only coverage, the medical costs of enrollees in the standard plan with other than self-only coverage, and the pharmaceutical costs of enrollees in the standard plan with other than self-only coverage. While these new standards in paragraph (c)(4)(ii) may require additional calculations, enrollee liability can vary significantly between these subgroups, as noted by commenters, and as a result, we believe that separate effective cost-sharing parameters for each subgroup of costs will often lead to more accurate results.

For example, if a QHP is subject to the standards in paragraph (c)(4)(ii)(C), the QHP issuer must create four sets of effective cost-sharing parameters. One of the sets of effective cost-sharing parameters would be calculated based on self-only coverage of medical services (for example, the average deductible would be the medical deductible for self-only coverage). The effective cost-sharing parameters for the subgroup would then be applied to the total allowed medical costs for EHB of enrollees with self-only coverage under a plan variation policy, as described in paragraph (c)(4)(i). To determine the total amount that enrollees in the plan variation policy with self-only coverage would have paid under the standard plan without cost-sharing reductions, the QHP issuer would add the amounts calculated pursuant to paragraph (c)(4)(i) for each subgroup of costs (self-

only medical costs and self-only pharmaceutical costs).

In relation to in-network and out-of-network costs, we clarify that although QHP issuers are not required to reduce out-of-network cost sharing to meet the actuarial value requirements for the silver plan variations, as described on page 15481 of the 2014 Payment Notice, if a QHP issuer chooses to reduce out-of-network cost sharing, they will receive reimbursement for those reductions. In addition, QHP issuers must eliminate cost sharing for both in-network and out-of-network covered EHB for the zero cost sharing plan variation, as well as for the limited cost sharing plan variation when the service is furnished by the Indian Health Service, an Indian Tribe, Tribal Organization, or Urban Indian Organization, or through referral under contract health services, as described in 45 CFR 156.420(b). Nevertheless, we are not requiring, nor allowing, QHP issuers to calculate separate effective cost-sharing parameters for in-network and out-of-network costs. We believe that the modifications to Formula C should address much of the bias in the simplified methodology that could be caused by differences in cost-sharing parameters for in-network and out-of-network services. In addition, we hope to limit the number of plans that do not meet the minimum credibility standard, which as described below and in paragraph (c)(4)(v), requires QHP issuers to use an actuarial value methodology to calculate the amount that enrollees would have paid under the standard plan, if a standard plan has enrollment of fewer than 12,000 member months for a particular subgroup. We believe that it is possible that a large number of standard plans would not have 12,000 member months for enrollees with out-of-network claims costs above the applicable effective deductible. Therefore, we will not provide for separate calculations for in-network and out-of-network costs.

In response to the comments suggesting that QHP issuers should be allowed to exclude costs for benefits without cost-sharing reductions, we note that in many cases, these costs would accumulate towards certain cost-sharing parameters, such as a deductible or the annual limitation on cost sharing. Therefore, we are not finalizing any change permitting an issuer to exclude such claims. As discussed above, to address plans with cost-sharing structures where a large proportion of costs are not subject to a deductible, we have provided for a simplified, coinsurance-based calculation in paragraph (c)(4)(vi). Finally, we note

that QHP issuers cannot create separate effective cost-sharing parameters for each rating area.

In § 156.430(c)(4)(iii) of the interim final rule, we established reporting standards for QHP issuers that elect to use the simplified methodology. We specified that QHP issuers must submit to HHS, in the manner and timeframe established by HHS: The effective deductible; the effective pre-deductible coinsurance rate; the effective post-deductible coinsurance rate; the effective claims ceiling; and a memorandum developed by a member of the American Academy of Actuaries in accordance with generally accepted actuarial principles and methodologies that describes how the QHP issuer calculated the effective cost-sharing parameters for the standard plan. This information will allow HHS to ensure that QHP issuers are calculating the effective cost-sharing parameters correctly. We sought comments on whether HHS should require any other data submissions or establish any additional standards to oversee these provisions.

Comment: One commenter recommended that HHS put in place robust processes to monitor QHP issuers using the simplified methodology to limit the potential for overpayments. The commenter suggested that HHS reserve the authority to review and approve all QHP issuer submissions for the simplified methodology and the resulting reconciliation amount—particularly if such amounts are substantially different from the advance payment amounts. Another commenter suggested that HHS collect detailed data on the payments made by QHP issuers to providers to ensure that providers are reimbursed, particularly providers associated with the Indian Health Service, an Indian Tribe, Tribal Organization, or Urban Indian Organization.

Response: To ensure that QHP issuers using either the standard or simplified methodology submit accurate information for cost-sharing reduction payment reconciliation, we are finalizing cost-sharing reduction oversight standards in § 156.480 of this final rule. Specifically, § 156.480(c) provides HHS with the authority to audit an issuer to assess compliance with the cost-sharing reduction standards, including standards related to reconciliation and provider reimbursement, detailed in 45 CFR 156.430(c).

We are also clarifying in this final rule the standards for reporting information on the effective cost-sharing parameters. Specifically, we are renumbering the

paragraph on reporting as paragraph (c)(4)(iv), and specifying that a QHP issuer using the simplified methodology must submit to HHS, in the manner and timeframe established by HHS, the effective cost-sharing parameters, calculated pursuant to paragraph (c)(4)(iii), for each standard plan offered by the QHP issuer in the individual market through the Exchange for each set of circumstances described in paragraph (c)(4)(ii). Therefore, if a QHP issuer must calculate multiple sets of effective cost-sharing parameters as described in paragraph (c)(4)(ii), the QHP issuer must submit each set of parameters to HHS. A QHP issuer may submit one actuarial memorandum as long as it describes how the QHP issuer calculated each set of effective cost-sharing parameters for each standard plan. We will provide guidance on the manner and timeframe of this submission in the future.

As discussed in the interim final rule, we recognize that because the effective pre- and post-deductible coinsurance rates are calculated based on the average experience of the enrollees in the standard plan, low enrollment in the standard plan could lead to inaccurate effective coinsurance rates. Therefore, we provided additional standards related to the simplified methodology in § 156.430(c)(4)(iv) to address credibility concerns that may result from low enrollment in the standard plan. We established that if a standard plan has an enrollment during the benefit year of fewer than 12,000 member months (that is, the sum of the months that each enrollee is covered by the plan) in any of four subgroups, and the QHP issuer has selected the simplified methodology, then the QHP issuer must calculate the amount that all enrollees in the plan variation (in all subgroups) would have paid under the standard plan by applying the standard plan's actuarial value, as calculated under § 156.135, to the allowed costs for EHB for the enrollees for the benefit year. The credibility standard of 12,000 member months aligns with a similar standard used by the Medicare Part D program; however, we sought comments on the appropriate number of member months to achieve credible use of the simplified methodology. We also sought comments on whether the standard plan's actuarial value applied to the allowed costs for EHB for enrollees for the benefit year would provide an appropriate estimate of the amount of cost sharing that enrollees would have paid under the standard plan without cost-sharing reductions, or whether an alternative approach would be more

appropriate. Last, we requested comments on the composition of the subgroups, whether they appropriately divide enrollees based on their utilization patterns, whether any subgroups are required, and whether low enrollment in one subgroup should prompt the QHP issuer to use the actuarial value for enrollees in all subgroups or just the subgroup with low enrollment.

Comment: We received one comment on this section, suggesting that the credibility standard should apply to both the standard plan and the plan variations because even if the effective cost-sharing parameters are based on at least 12,000 member months, applying them to a small number of plan variation policies could produce unusual results. The same commenter noted that because actuarial value is a measure of the issuer's liability, one minus the actuarial value should be applied to the total allowed costs for EHB for each policy offered under the plan variation for the benefit year in order to determine the cost sharing that enrollees would have paid under the standard plan.

Response: In response to these comments, we are correcting the instructions for calculating enrollee cost sharing based on actuarial value in the renumbered paragraph (c)(4)(v). We are not expanding the credibility standard to apply to enrollment in each plan variation since this would likely require many more QHP issuers to use the standard or actuarial value methodology, rather than the simplified methodology. However, we are adding a "cap" to the actuarial methodology, such that QHP issuers whose standard plan does not meet the credibility standard must calculate the amount that enrollees would have paid under the standard plan as the lesser of the annual limitation on cost sharing for the standard plan or the amount derived through the actuarial value methodology. This approach will reduce the likelihood that plan variations with small enrollment will report amounts that are materially inaccurate.

We are also modifying paragraph (c)(4)(v) to align with the standards established in paragraph (c)(4)(ii) and to clarify how the minimum credibility standard should be applied to each subgroup. In addition, we are removing the minimum credibility standard described in the interim final rule in subparagraphs (c)(4)(iv)(A) and (C), related to enrollees with total allowed costs for EHB for the benefit year that are less than or equal to the effective deductible. This change should simplify the credibility analysis, with little

impact on the ultimate credibility of the effective cost-sharing parameters because it is unlikely that a standard plan would have adequate enrollment with costs above the effective deductible, but low enrollment with costs below the effective deductible. As discussed in the interim final rule, a subgroup is not necessary for enrollees with cost sharing for EHB above the annual limitation on cost sharing because the experience of this population is not used to calculate the effective cost-sharing parameters.

Therefore, in § 156.430(c)(4)(v) of this final rule, we establish that if a QHP issuer's standard plan meets certain criteria, and the QHP issuer has selected the simplified methodology described in this paragraph (c)(4), then the QHP issuer must calculate the amount that enrollees in the plan variation would have paid under the standard plan without cost-sharing reductions as the lesser of the annual limitation on cost sharing for the standard plan or the amount equal to the product of, (x) one minus the standard plan's actuarial value, as calculated under 45 CFR 156.135, and (y) the total allowed costs for EHB for the benefit year under each policy that was assigned to a plan variation for any portion of the benefit year.

In subparagraphs (A) through (D) of § 156.430(c)(4)(v), we detail the minimum credibility criteria that prompt a QHP issuer to use the actuarial value methodology:

(A) The standard plan has separate cost-sharing parameters for self-only coverage and other than self-only coverage, does not have separate cost-sharing parameters for pharmaceutical and medical services, and has an enrollment during the benefit year of fewer than 12,000 member months for coverage with total allowed costs for EHB for the benefit year that are greater than the effective deductible, but for which associated cost sharing for EHB is less than the annual limitation on cost sharing, in either of the following categories: (i) Self-only coverage, or (ii) other than self-only coverage.

(B) The standard plan has separate cost-sharing parameters for pharmaceutical and medical services, does not have separate cost-sharing parameters for self-only coverage and other than self-only coverage, and has an enrollment during the benefit year of fewer than 12,000 member months for coverage with total allowed costs for EHB for the benefit year that are greater than the effective deductible, but for which associated cost sharing for EHB is less than the annual limitation on cost sharing, in either of the following

categories: (i) Coverage of medical services, or (ii) coverage of pharmaceutical services.

(C) The standard plan has separate cost-sharing parameters for self-only coverage and other than self-only coverage, has separate cost-sharing parameters for pharmaceutical and medical services, and has an enrollment during the benefit year of fewer than 12,000 member months for coverage with total allowed costs for EHB for the benefit year that are greater than the effective deductible, but for which associated cost sharing for EHB is less than the annual limitation on cost sharing, in any of the following categories: (i) Self-only coverage of medical services, (ii) self-only coverage of pharmaceutical services, (iii) other than self-only coverage of medical services, or (iv) other than self-only coverage of pharmaceutical services.

(D) The standard plan does not have separate cost-sharing parameters for pharmaceutical and medical services, does not have separate cost-sharing parameters for self-only coverage and other than self-only coverage, and has an enrollment during the benefit year of fewer than 12,000 member months with total allowed costs for EHB for the benefit year that are greater than the effective deductible, but for which associated cost sharing for EHB is less than the annual limitation on cost sharing.

In the interim final rule, we noted the possibility that for a very small number of plans with unique cost-sharing structures, the amounts that enrollees would have been paid under the plan might not be fairly estimated using the simplified methodology. We considered a process in which a QHP issuer of such a plan may notify HHS if it believes that this is the case for one or more of its plans. We considered requiring such a notification within ninety days of the beginning of the applicable benefit year, and we considered requiring the QHP issuer to provide information on the unique plan design supporting the QHP issuer's assessment.

Under this approach, if HHS were to agree with the assessment, we considered requiring the QHP issuer to calculate the amount that enrollees would have paid under the standard plan without cost-sharing reductions by applying the standard plan's actuarial value, as calculated pursuant to 45 CFR 156.135, to the allowed costs for EHB for the enrollees for the benefit year. If HHS were to disagree with the issuer's assessment, the QHP issuer would calculate such amounts using the effective cost-sharing parameters under the approach described in paragraphs

(4)(i) through (4)(iii) of the interim final rule (or paragraph (4)(iv), if applicable).

We sought comments on whether we should adopt such an approach, and on the specifics outlined above. In particular, we sought comments on the types of plans, if any, for which it would be difficult to fairly calculate the amount that enrollees would have paid under the standard plan without cost-sharing reductions using the simplified methodology, and their prevalence. We sought comments on the standard that should apply for determining whether the plan will be exempted from using the simplified methodology, and how HHS should make that determination. Finally, we requested comments on what estimation methodology should be used if the plan is determined to be exempt, and if it is not.

We did not receive any specific comments on this proposal, though as noted above, some commenters suggested that for certain plan designs, the simplified methodology may result in the overestimation or underestimation of enrollee liability, and as a result, the QHP issuer's actuary should be allowed greater flexibility in the calculation of an average deductible and an average claims ceiling, as long as the calculations are justified in the actuarial memorandum.

Because we did not receive any comments supporting this proposal, or any examples of plans for which the simplified methodology would not adequately approximate cost sharing, we are not finalizing this approach.

Comment: We received a comment that relates generally to the reconciliation of cost-sharing reduction payments. The commenter asked whether a QHP issuer that is using the standard methodology must re-adjudicate the claims sequentially as if the enrollees were in the standard plan.

Response: QHP issuers using the standard methodology should adjudicate the claims in a manner that will yield an accurate calculation of the amount of cost sharing that enrollees would have paid under the standard plan. If sequential adjudication of claims is not necessary to do so, the issuer is not required to engage in sequential adjudication.

Summary of Regulatory Changes

We are modifying § 156.430(c)(3) to specify that QHP issuers may only choose the simplified methodology for calculating the amounts that would have been paid under the standard plan without cost-sharing reductions for benefit years 2014 through 2016. We also are modifying § 156.430(c)(4) to address unique benefit structures and

reduce potential biases in the formulas. We are clarifying how QHP issuers should calculate the effective cost-sharing parameters for self-only coverage, other than self-only coverage, medical services, and pharmaceutical services.

d. Failure To Reduce an Enrollee's Premium To Account for Advance Payments of the Premium Tax Credit (§ 156.460(c))

We also proposed to add new paragraph (c) to § 156.460, providing that if a QHP issuer discovers that it did not reduce the portion of the premium charged to or for the enrollee for the applicable month(s) by the amount of the advance payment of the premium tax credit as required in § 156.460(a)(1), the QHP issuer would be required to refund to the enrollee any excess premium paid by or for the enrollee and notify the enrollee of the improper application no later than 30 calendar days after the QHP issuer discovers the error. We noted that a QHP issuer may provide the refund to the enrollee by reducing the enrollee's portion of the premium in the following month, as long as the reduction is provided no later than 30 calendar days after the QHP issuer discovers the improper reduction. If the QHP issuer elects to provide the refund by reducing the enrollee's portion of the premium for the following month, and the refund exceeds the enrollee's portion of the premium for the following month, then the QHP issuer would need to refund to the enrollee the excess no later than 30 calendar days after the QHP issuer discovers the improper reduction. We also noted that we were also considering that for each quarter beginning in 2015, a QHP issuer would be required to provide a report to HHS and the Exchange, in a manner and timeframe specified by HHS, detailing the occurrence of instances of improper applications of the requirements of § 156.460.

Comment: Several commenters supported a 30-day timeframe for issuers to refund excess advance payment of the premium tax credit to enrollees, while other commenters stated that a 60-day timeframe is more realistic. Another recommended a 90-day timeframe given the challenges of enrollment reconciliation and resolution of discrepancies. One commenter noted that associated refunds are commonly performed through batch processing which could take more than 30 calendar days to correct, and suggested that HHS allow a longer timeframe to account for such administrative processes.

Response: In consideration of the timeframes for enrollment reconciliation and resolution processes we are extending the timeframe for QHP issuers to provide refunds in such cases to within 45 days of discovery of the error. This timeframe aligns with the timeframe established under § 156.410 with respect to misapplication of cost-sharing reductions.

Comment: Several commenters suggested that issuers be allowed to apply such refundable amounts to the premium due in subsequent months through the end of the benefit year, and that a refund be provided only at the request of the enrollee. One commenter noted that issuing a partial refund and partial credit in a given month may be confusing to consumers, and does not align with standard practice today. Another commenter recommended that consumers should have the option of receiving a refund directly.

Response: In response to comments, we are modifying the proposed policy in this final rule. In particular, if a QHP issuer discovers that it did not reduce an enrollee's premium by the amount of the advance payment of the premium tax credit, then, upon request by or for the enrollee, the QHP issuer must refund to the enrollee any excess premium paid by or for the enrollee within 45 calendar days of discovery of the improper reduction. However, if a direct refund is not requested, the QHP issuer may apply the total remaining excess premium paid by or for the enrollee to the enrollee's portion of the premium each month for the remainder of the period of enrollment or benefit year, until the excess is fully applied. If any excess premium paid by or for the enrollee remains at the end of the period of enrollment or benefit year, the QHP issuer would be required to refund the excess within 45 calendar days of discovery or the error.

Additionally, we clarify that this provision would not prevent a QHP issuer from recouping excess funds from the enrollee, if the QHP reduced the enrollee's portion of the premium by more than the advance payment of the premium tax credit.

Comment: Two commenters supported a standard requiring quarterly error reports, although one suggested that such reports be delayed until 2016. One commenter recommended a semi-annual report. Another commenter stated that such reports duplicate information in the monthly enrollment reconciliation reports.

Response: Taking into consideration the comments received and to align with the policy finalized in § 156.410, we are not establishing a quarterly

reporting standard. We require issuers to report if they did not reduce the portion of the premium charged to or for the enrollee for the applicable month(s) by the amount of the advance payment of the premium tax credit as part of the annual reporting requirements set forth in § 156.480(b) of this final rule.

Summary of Regulatory Changes

We are finalizing these provisions as proposed with the following modifications. We are increasing the time period for issuing refunds from 30 to 45 days. We are also permitting the QHP issuer to apply the total excess premium paid by or for the enrollee to the enrollee's portion of the premium each month for the remainder of the period of enrollment or benefit year, except that the QHP issuer must refund the excess premium within 45 days of a request for the refund by or for the enrollee or within 45 days following the end of the period of enrollment or benefit year.

e. Oversight of the Administration of Cost-Sharing Reductions and Advance Payments of the Premium Tax Credit Programs (§ 156.480)

In § 156.480, we proposed general provisions related to the oversight of QHP issuers in relation to cost-sharing reductions and advance payments of the premium tax credit. We proposed to apply certain standards proposed in Part 156, subpart H for QHP issuers participating in FFEs to QHP issuers participating in the individual market on a State Exchange. In paragraph (a), we proposed to extend the standards set forth in proposed § 156.705 concerning maintenance of records to a QHP issuer in the individual market on a State Exchange in relation to cost-sharing reductions and advance payments of the premium tax credit. We also proposed that QHP issuers ensure that any delegated and downstream entities adhere to these requirements. We noted that a QHP issuer and its delegated and downstream entities may satisfy this standard by maintaining the relevant records for a period of 10 years and ensuring that they are accessible if needed in the event of an investigation or audit.

We also proposed that QHP issuers participating in State Exchanges and FFEs be subject to reporting and oversight requirements. In particular, in paragraph (b), we proposed that an issuer that offers a QHP in the individual market through a State Exchange or an FFE report to HHS annually, in a timeframe and manner required by HHS, summary statistics with respect to administration of cost-

sharing reductions and advance payments of the premium tax credit. Additionally, in paragraph (c) we proposed that HHS or its designee may audit an issuer that offers a QHP in the individual market through a State Exchange or an FFE to assess compliance with the requirements of this subpart and ensure appropriate use of Federal funds.

Comment: In response to proposed § 156.480(b), several commenters stated that the annual reports will be critical to protecting consumer rights, while others argued that this information will already be in HHS's possession. Another commenter recommended that HHS rely on market conduct examinations to conduct oversight. One commenter asked for more information on the rationale for and content of these reports.

Response: As discussed in the proposed rule, the annual reports will permit HHS to obtain summary information regarding cost-sharing reductions and advance payments of the premium tax credit across a broad range of issuers and identify any systemic issues and errors, without requiring annual audits. These reports will contain information not available to HHS through other channels, such as data on misapplications of cost-sharing reductions and advance payments of the premium tax credit. We believe that a consolidated report from all applicable issuers with respect to these programs will assist HHS in effectively targeting oversight activities and identifying problems that affect multiple issuers.

Comment: One commenter asked HHS to clarify the meaning of "delegated entities" and "downstream entities" that are subject to the requirement, and noted that the requirement should only apply to entities responsible for keeping records associated with advance payments of the premium tax credit or cost-sharing reductions.

Response: The terms "delegated entity" and "downstream entity" are defined at § 156.20. Furthermore, as noted in § 156.480(a), the maintenance of records standard applies to relevant delegated entities and downstream entities only in connection with cost-sharing reductions and advance payments of the premium tax credit.

Comment: We received a comment asking for further guidance on how Navigators, consumers, and other entities can report instances of non-compliance to HHS.

Response: We note that consumers, Navigators, and other entities can report issuer non-compliance to HHS through communication channels offered to consumers, such as the Health

Insurance Marketplace Call Center, where such reports will be entered into the casework tracking system and addressed by CMS.

Comment: One commenter asked HHS to clarify that any self-reported error rates will not be used as a basis for civil money penalties or decertification, since both penalties may be imposed for non-compliance with cost-sharing reduction and advance payment of the premium tax credit requirements. Another commenter asked HHS to provide guidance on how it will collect and respond to reports of non-compliance by QHP issuers and others.

Response: HHS will collect information from QHP issuers on the administration of cost-sharing reductions and advance payments of the premium tax credit, including error rates, through the annual reports described in § 156.480(b). We anticipate that this information will be used to inform an oversight and audit strategy with respect to these programs, and will be provided to the State Exchanges and utilized by the FFE as applicable for oversight and enforcement activities such as decertification and CMPs. We note that the 2014 policy of nonenforcement of CMPs in instances of good faith established in § 156.800 would apply in 2014 with respect to such errors.

Comment: One commenter suggested limiting the record retention requirement to 6 years, while another supported the proposed timeframe.

Response: As previously noted in this final rule, we are finalizing the maintenance of records provisions retention standard as proposed, in alignment with the statute of limitations for the False Claims Act and existing Exchange regulations.

Comment: One commenter requested that HHS provide further information on the timeframe and procedure of proposed audits, suggested that audits should be limited to three years after the completion of a benefit year, and recommended that HHS specify a mechanism by which issuers can challenge the audit findings.

Response: We intend to provide detailed guidance in the future and will seek comment on our audit process prior to finalization in order to ensure a transparent program and consistent audits. We are considering conducting audits in a manner that is coordinated across all programs and FFE compliance reviews to limit the number of potential audits that an organization would experience.

Summary of Regulatory Changes

We are finalizing these provisions and modifying paragraph (b) to specify that the annual reports must contain summary statistics with respect to the application of cost-sharing reductions and advance payments of the premium tax credit, including any failure to adhere to the standards set forth under § 156.410(a) through (d), § 156.425(a) through (b), and § 156.460(a) through (c) of this Part.

5. Subpart H—Oversight & Financial Integrity Requirements for Issuers of Qualified Health Plans in Federally-Facilitated Exchanges

a. Maintenance of Records for Federally-Facilitated Exchanges (§ 156.705)

We proposed in § 156.705(a) that issuers offering QHPs in an FFE maintain all documents and records (whether paper, electronic, or other media) and other evidence of accounting procedures and practices, which are critical for HHS to conduct activities necessary to safeguard the financial and programmatic integrity of the FFEs. We proposed that such activities include: (1) Periodic auditing of the QHP issuer's financial records related to the QHP issuer's participation in an FFE, and to evaluate the ability of the QHP issuer to bear the risk of potential financial losses; and (2) compliance reviews and other monitoring of a QHP issuer's compliance with all Exchange standards applicable to issuers offering QHPs in the FFE listed in part 156. We proposed limiting the scope of this requirement to Exchange-specific records as applicable to the FFEs. In § 156.705(b), we proposed that the records described in proposed paragraph (a) of this section include the sources listed in proposed § 155.1210(b)(2), (b)(3), and (b)(5) in order to align the record maintenance standards of the FFEs and State Exchanges to the extent possible. In § 156.705(c), we proposed that issuers offering QHPs in an FFE must maintain the records described in this section, as well as records required by § 155.710 (to determine SHOP eligibility), for 10 years. Proposed § 156.705(d) explained that the records referenced in paragraph (a) must be made available to HHS, the OIG, the Comptroller General, or their designees, upon request. We stated that the proposed standards pertain only to Exchange-specific areas of concern (for example, matters pertaining to advance payments of premium tax credits or cost-sharing reductions) within the FFEs, as HHS would expect the State DOI to oversee the maintenance of records pertaining to other aspects of

QHP issuer operations as required under State law.

Comment: Several commenters requested that HHS require maintenance and review of records related to particular standards in part 156, including QHP provider network adequacy, and the availability of essential community providers. Commenters also requested that HHS review documentation related to wellness programs, rating rules, essential health benefit requirements, and other applicable market reforms included in the Affordable Care Act, particularly in direct enforcement States.

Response: Under § 156.715, which we are finalizing in this final rule, HHS will be conducting compliance reviews to ensure that issuers offering QHPs in the FFE comply with Exchange standards as applicable to them. These include the standards related to network adequacy under § 156.230 and the standards related to essential community providers under § 156.235. Section 156.705 only applies to maintenance of records pertaining to FFEs, as we expect that QHP issuers will also have to comply with other aspects of issuer operations as required under state law.

Comment: Several commenters recommended the 10-year record maintenance standards be reduced to 6 or 7 years.

Response: We are finalizing the maintenance of records provisions as proposed, in alignment with the statute of limitations for the False Claims Act and existing related regulations. A civil action may be brought under the False Claims Act “no more than 10 years after the date on which the violation is committed.” Additionally, similar 10-year record retention standards were previously finalized in the Exchange Establishment Rule and the Premium Stabilization Rule. We believe that maintaining consistency in our record retention standards will help ensure that entities maintain records across programs in a consistent manner, allowing HHS and States to coordinate oversight efforts across those program areas and reduce the burden on stakeholders. QHP issuers have the choice to maintain records in either paper or electronic format. We note that the 10-year obligation to retain records begins when the record is created.

Summary of Regulatory Changes

We are finalizing the provisions proposed in § 156.705 without modification.

b. Compliance Reviews of QHP Issuers in Federally-Facilitated Exchanges (§ 156.715)

In § 156.715 we proposed that QHP issuers will be subject to compliance review by HHS to ensure ongoing compliance with Exchange standards applicable to issuers offering QHPs in FFEs. We proposed the scope of the compliance reviews and the window of time that such compliance reviews could be conducted.

Comment: We received comments supporting HHS’s authority to conduct compliance reviews of QHP issuers in the FFEs and no comments opposing this provision.

Response: We are finalizing our policy as proposed.

Summary of Regulatory Changes

We are finalizing this provision with the correction of a typographical error in paragraph (c).

6. Subpart J—Administrative Review of QHP Issuer Sanctions in a Federally-Facilitated Exchange

a. Administrative Review in a Federally-Facilitated Exchange (§§ 156.901 Through 156.963)

In Subpart J, we proposed the administrative hearing process for issuers of QHPs in an FFE against which an enforcement action has been taken. The process is intended to provide the issuer an opportunity to submit evidence to be considered by the administrative law judge (ALJ) in determining whether a basis exists to assess a CMP against or decertify a QHP offered by the respondent, and whether the amount of the assessed CMP is reasonable, if applicable. Our proposed process is modeled after the appeals process for individuals and entities against which a CMP has been imposed in the individual and group health coverage markets. We did not receive any comments on our proposed regulations in this Subpart J.

In § 156.805(d), we proposed that, if HHS proposes to assess a CMP under subpart I, HHS will send written notice of intent to issue a CMP to the QHP issuer concerned. Similarly, in § 156.810(c) and (d), we proposed that, for standard and expedited decertifications, HHS will notify the QHP issuer, enrollees in the QHP, and the State DOI in the State in which the QHP is being decertified of HHS’s intent decertify a QHP offered by the issuer. We note that the notice under 45 CFR 156.805(d) and 156.810(c) and (d) is different from, and in addition to, the notice required under 45 CFR 155.1080. In § 156.805 and § 156.810, we set forth

the process by which QHP issuers will be notified formally of HHS’s intent to issue a CMP or decertify one or more of their QHPs, the grounds for the enforcement action, and other specified information, including information about the process for requesting an appeal. The 30-day clock for requesting an appeal under 45 CFR 156.905(a) starts on the date of issuance of HHS’s notice of intent to issue a CMP under § 156.805 or notice of decertification of a QHP under § 156.810(c) or (d). By contrast, 45 CFR 155.1080 requires that notice be sent to the QHP issuer, enrollees in the QHP, and the State DOI when the decertification is final and no longer appealable. Furthermore, 45 CFR 155.1080 does not apply in the case of a CMP. We are finalizing 45 CFR part 156, subpart J as proposed, except for a minor change to § 156.963, described below.

Summary of Regulatory Changes

We are finalizing these provisions of 45 CFR part 156, subpart J as proposed, with two exceptions. We are not finalizing § 156.949, and we are making a minor change to correct the reference to the “final order” in § 156.963. We are replacing “the final order described in § 156.945” with “the final order imposing a civil money penalty.”

7. Subpart L—Quality Standards

a. Establishment of Standards for HHS-Approved Enrollee Satisfaction Survey Vendors for Use by QHP Issuers in Exchanges (§ 156.1105)

In § 156.1105, we proposed processes by which HHS would approve and oversee enrollee satisfaction survey vendors that will administer enrollee satisfaction surveys on behalf of QHP issuers. We proposed that enrollee satisfaction survey vendors be approved for one year terms and would be required to submit an annual application demonstrating that they meet all of the application and approval standards. We also proposed listing HHS-approved enrollee satisfaction survey vendors on an HHS Web site. We received several comments and our responses to § 156.1105 are set forth below.

Comment: Commenters generally supported the proposal to establish an application and review process for enrollee satisfaction survey vendors. Commenters supported the proposed requirements that will ensure that enrollee satisfaction survey vendors abide by standards for integrity, including privacy and security standards. Commenters also supported establishing standards for QHP issuers

to use only HHS-approved vendors to ensure consistency and integrity in enrollee satisfaction survey administration.

Response: We are adopting the regulation as proposed to have HHS approve and oversee enrollee satisfaction survey vendors that meet certain standards. As stated in the proposed rule, we intend to promulgate future rulemaking requiring QHP issuers to contract with HHS-approved survey vendors to administer enrollee satisfaction surveys. By finalizing as proposed, we are ensuring that enrollee satisfaction survey vendors will be approved by mid-2014. We believe that this will allow QHP issuers adequate time to contract with these vendors by late 2014, prior to the implementation of any relevant quality reporting standards.

Comment: Commenters suggested that HHS utilize one enrollee satisfaction survey vendor on behalf of all QHPs. Commenters also suggested that issuers have a role in the survey vendor application process.

Response: We believe that allowing multiple enrollee satisfaction survey vendors the opportunity to apply for approval will encourage a competitive market of qualified enrollee satisfaction survey vendors. Therefore, HHS is finalizing the proposal to establish a standardized process to review and approve multiple enrollee satisfaction survey vendors. We intend for QHP issuers, along with the public, to have an opportunity to provide comments on other draft documents related to the enrollee satisfaction survey vendor application and approval process. Further, while QHP issuers will not have a direct role in HHS review and approval of enrollee satisfaction survey vendors, QHP issuers are expected to have a choice of enrollee satisfaction survey vendors with which to contract, including those with which the issuers may already have a business relationship, for example, to administer other surveys like the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) survey on behalf of the issuer. Additionally, QHP issuers will have the opportunity to provide to HHS comment and feedback related to the work of approved enrollee satisfaction survey vendors.

Comment: Commenters requested affirmation that enrollee satisfaction survey vendors would be required to adhere to non-discrimination standards.

Response: Enrollee satisfaction survey vendors, as “delegated entities” of QHP issuers defined in 45 CFR 156.20 and set forth in 45 CFR 156.340, would be required to meet any non-discrimination

standards required of QHP issuers, as specified in 45 CFR 156.200(e).

Comment: Commenters requested that enrollee satisfaction survey vendors translate the enrollee satisfaction survey into different languages for populations representing a certain enrollment threshold, for example any language for which a QHP issuer’s enrollment meets a threshold of 5 percent or 1000 primary speakers.

Response: Enrollee satisfaction survey vendors will not be responsible for translating the enrollee satisfaction survey. HHS is developing the enrollee satisfaction survey system as required by section 1311(c)(4) of the Affordable Care Act and will provide translated versions of the survey to ensure consistency across all surveys. HHS will provide enrollee satisfaction survey vendors with versions in English, Spanish, and Chinese, which align with current translation standards for the Medicare Advantage CAHPS® Health Plan surveys.

Comment: Commenters supported the recommendation that HHS utilize the CAHPS® Health Plan survey as a model for the enrollee satisfaction survey to assess patient experience with QHP issuers. Another commenter suggested using the existing CAHPS® Health Plan survey without modification.

Response: As stated in the proposed rule, we intend to establish in future rulemaking that the enrollee satisfaction survey will be modeled on the CAHPS® 5.0 Health Plan survey, which assesses patients’ satisfaction and experience with their health care, personal doctors, and health plans. In a **Federal Register** Notice published June 28, 2013,¹⁹ we sought public comment on the Enrollee Satisfaction Survey Data Collection, including the draft surveys. Commenters may wish to review the draft enrollee satisfaction surveys.

Comment: Commenters requested that CMS articulate detailed implementation standards for the enrollee satisfaction survey. Commenters also requested that results of the survey be shared with State Exchanges.

Response: As indicated in the proposed rule, we are planning to issue future regulations that will include detailed implementation standards for the enrollee satisfaction surveys as they relate to QHP issuers and Exchanges. Further, 45 CFR 155.205(a)(iv) requires Exchanges to display the enrollee satisfaction results on their Web sites.

Comment: Several commenters made remarks about the content of the

enrollee satisfaction survey, including requests that the survey assess: Provider satisfaction with QHP issuers and the experience of families and pediatricians that interact with the Exchange for their children’s coverage, and satisfaction with Exchanges overall, including the eligibility determination processes, plan selection, and in-person and telephonic assistance. Other commenters requested that HHS ensure experience of the Exchange is not attributed to QHP issuer performance. Finally, commenters cited their previously submitted comments in response to an HHS solicitation for comments on enrollee satisfaction measures and asked that their comments be considered.²⁰

Response: Comments with regard to the content of the surveys are outside the scope of this final rule, which includes standards for the application and approval process for enrollee satisfaction survey vendors. However, as previously mentioned, commenters can review the draft surveys as part of the Enrollee Satisfaction Survey Data Collection, including the QHP Survey and the Marketplace Survey. Comments submitted in response to the June 21, 2013 call for measures will be considered in the development of the enrollee satisfaction survey.

Summary of Regulatory Changes

We are finalizing the provisions proposed in § 156.1105 without modification.

8. Subpart M—Qualified Health Plan Issuer Responsibilities

a. Confirmation of HHS Payment and Collections Reports (§ 156.1210)

We noted in the proposed rule that we anticipate sending each applicable issuer a monthly payment and collections report. This report will show, with respect to certain provisions under Title I of the Affordable Care Act, payments the Federal government owes to the issuer, as well as those the issuer owes the Federal government. For the 2014 benefit year, we anticipate issuing a detailed monthly report, also known as the HIX 820, that will describe the advance payments of the premium tax credit and advance payments of cost-sharing reductions that the Federal government is paying to the issuer for each policy listed on the payment report, any amounts owed by the issuer for FFE user fees, as well as any adjustments from previous payments

¹⁹ Agency Information Collection Activities: Proposed Collection; Comment Request, 78 FR 38986 (June 28, 2013).

²⁰ Request for Domains, Instruments, and Measures for Development of a Standardized Instrument for Use in Public Reporting of Enrollee Satisfaction With Their Qualified Health Plan and Exchange 77 FR 37409 (June 21, 2012).

under those programs. The issuer will need to review this detailed payment and collections report against the payments it expects for each policy based on the eligibility and enrollment information transmitted by the Exchange, and any amounts it expects the Federal government to collect for FFE user fees.²¹ In § 156.1210 we proposed that, within 15 calendar days of the date of a payment and collections report, the issuer would either confirm to HHS that the payment and collections report accurately lists payments owed by and to the issuer for the timeframe specified in the payment and collections report, or would describe to HHS any inaccuracy it identifies in these amounts (including incorrect payment amounts, or extra or missing policies in the report). These notifications would be provided in a format specified by HHS. We stated that HHS will work with issuers to resolve any discrepancies between the amounts listed in the HIX 820 payment and collections report and the amounts the issuer believes it should receive for the time period specified in the report. This proposed provision's verification timeframe helps align enrollment and eligibility data transmitted by the Exchange, payments provided by and collected by the Federal government, and the issuer's own records of payments due. This provision will also help ensure that the correct amounts of advance payments of the premium tax credit and cost-sharing reductions are paid to issuers on behalf of eligible individuals in a timely manner. The ability of HHS to identify and correct these errors promptly protects enrollees from unanticipated tax liability that could result if the advance payments of the premium tax credit they receive are greater than the amounts of premium tax credit authorized by the Exchange and accepted by the enrollee.

Comment: We received several comments seeking further information about the HIX 820 payment and collections report.

Response: In the fall of 2013, HHS intends to publish a Companion Guide to the HIX 820 payment and collections report. HHS offered related issuer training in September.

Comment: Some commenters suggested that issuers would need at least 30 days to analyze and respond to the HIX 820 payment and collections report. Another commenter suggested

that there should be at least a 60-day lag between the dates covered by the payment and collections report and the date it is sent to issuers.

Response: We are aware that in some cases, particularly in this first year of operations, issuers may find it difficult to perform a full analysis of the payment and collections report and provide a response. However, it is largely due to the challenges of the first year of operations that we proposed a 15-day verification period—this short time lag will help HHS adjust any discrepancies as soon as possible. As we discuss below, if an issuer is unable to meet the 15-day timeline, it will have later opportunities to note discrepancies.

Comment: Several commenters expressed concern about the potential consequences of failing to report a discrepancy. Other commenters suggested that there should be a retroactive payment correction process, or an appeals process, to update eligibility and enrollment determinations based upon information received late.

Response: We recognize that there are legitimate circumstances in which an issuer might not discover an inaccuracy within the 15-day timeline set forth in § 156.1210, and we do not wish to penalize an issuer in such circumstances. Therefore, we are adding a new paragraph (b) to § 156.1210 stating that HHS will work with issuers to resolve discrepancies reported by an issuer after the 15-day deadline, as long as the late discovery of the discrepancy was not due to misconduct on the part of the issuer. We are also considering establishing in future rulemaking a final deadline after which discrepancies cannot be reported, as well as an administrative appeals process that would be available to issuers that are not satisfied with the result of that process.

Summary of Regulatory Changes

We are finalizing § 156.1210, with the following modifications. We are redesignating paragraphs (a) and (b) as paragraphs (a)(1) and (a)(2) and are adding a new paragraph (b) to state that if an issuer reports a discrepancy in a payment and collections report later than 15 calendar days after the date of the report, HHS will work with the issuer to resolve the discrepancy as long as the late reporting by the issuer was not due to misconduct on the part of the issuer. And because HHS's payments will technically be made by the U.S. Treasury, we are modifying § 155.1210(a)(1) to clarify that the payments owed by and to the issuer listed on the payment and collections

report are payments to and from the Federal government.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

The following sections of this document contain estimates of burden imposed by the associated information collection requirements (ICRs); however, not all of these estimates are subject to the ICRs under the PRA for the reasons noted. Estimated salaries for the positions cited were mainly taken from the Bureau of Labor Statistics (BLS) Web site (http://www.bls.gov/oco/oooh_index.htm). The estimated salaries for the health policy analyst and the senior manager were taken from the Office of Personnel Management Web site. Fringe Benefits estimates were taken from the BLS March 2013 Employer Costs for Employee Compensation Report.²²

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

A. ICRs Regarding Program Integrity Provisions Related to State Operation of the Reinsurance Program (§ 153.260)

In § 153.260, we direct a State-operated reinsurance program to: (1) Keep an accurate accounting of reinsurance contributions, payments, and administrative expenses; (2) submit to HHS and make public a summary report on program operations; and (3) engage an independent qualified auditing entity to perform a financial

²¹ We note that in order to provide issuers with more lead time to review the payment and collections report, HHS also anticipates providing an initial statement listing anticipated payments and charges. Issuers will not be under any obligation to respond to this initial statement.

²² BLS March 2013 Employer Costs for Employee Compensation Report (March 12, 2013). Available at: <http://www.bls.gov/news.release/eecc.toc.htm>.

and programmatic audit for each benefit year, provide the audit results to HHS, and make public a summary of the audit results. Fewer than 10 States have informed HHS that they will operate reinsurance for the 2014 benefit year. While these reinsurance records requirements are subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.3(c)(4) and 44 U.S.C. 3502(3)(A)(i), since fewer than 10 entities would be affected. Therefore, we are not seeking approval from OMB for these information collection requirements.

B. ICRs Regarding Program Integrity Provisions Related to State Operation of the Risk Adjustment Program (§ 153.310(c)(4) and § 153.310(d)(3)–(4), and § 153.365)

In § 153.310(c)(4), § 153.310(d)(3)–(4), and § 153.365, we require a State operating risk adjustment to: (1) Retain records for a 10-year period; (2) submit an interim report in its first year of operation; (3) submit to HHS and make public a summary report on program operations for each benefit year; and (4) keep an accurate accounting for each benefit year of all receipts and expenditures related to risk adjustment payments, charges, and administrative expenses. Fewer than 10 States have informed HHS that they will operate risk adjustment for the 2014 benefit year. Since the burden associated with collections from fewer than 10 entities is exempt from the PRA under 5 CFR 1320.3(c)(4) and 44 U.S.C. 3502(3)(A)(i), we are not seeking approval from OMB for the risk adjustment information collection requirements. However, if more than nine States elect to operate risk adjustment in the future, we will seek approval from OMB for these information collections.

C. ICRs Regarding Maintenance of Records for Contributing Entities and Issuers of Reinsurance-Eligible Plans (§ 153.405(h) and § 153.410(c))

In § 153.405(h) and § 153.410(c), we included record retention standards for contributing entities and issuers of reinsurance-eligible plans. In § 153.405(h), we require contributing entities to maintain documents and records, whether paper, electronic, or in other media, sufficient to substantiate the enrollment count submitted pursuant to § 153.405(b) for a period of at least 10 years, and to make those documents and records available upon request to HHS, the OIG, the Comptroller General, or their designees, for purposes of verification of reinsurance contribution amounts. This requirement may be satisfied if the

contributing entity archives the documents and records and ensures that they are accessible if needed in the event of an investigation or audit.

We estimate that 26,200 contributing entities will be subject to this requirement, based on the Department of Labor's (DOL) estimated count of self-insured plans and the number of fully insured issuers that we estimate will make reinsurance contributions.²³ We believe that most of these contributing entities will already have the systems in place for record maintenance, and that the additional burden associated with this requirement is the time, effort, and additional labor cost required to maintain the records. On average, we estimate that it will take each contributing entity approximately 5 hours annually to maintain records. We estimate that it will take an insurance operations analyst 5 hours (at \$38.49 per hour) to meet the requirements in § 153.405(h). On average, the cost for each contributing entity would be approximately \$192.45 annually. Therefore, for 26,200 contributing entities, we estimate an aggregate burden of \$5,042,190.00 and 131,000 hours as a result of this requirement.

In § 153.410(c), we require issuers of reinsurance-eligible plans to maintain documents and records, whether paper, electronic, or in other media, sufficient to substantiate the requests for reinsurance payments made pursuant to § 153.410(a) for a period of at least 10 years, and must make that evidence available upon request to HHS, the OIG, the Comptroller General, or their designees, (or, in the case of a State operating reinsurance, the State or its designees), for purposes of verification of reinsurance payment requests. We estimate that 1,900 issuers of reinsurance-eligible plans will be subject to this requirement, based on HHS's most recent estimate of the number of fully insured issuers that will submit requests for reinsurance payments. On average, we estimate that it will take each issuer of a reinsurance-eligible plan approximately 10 hours annually to maintain the records. We estimate that it will take an insurance operations analyst 10 hours (at \$38.49 per hour) to meet these requirements. On average, the cost estimate for each issuer is approximately \$384.90 annually. Therefore, for 1,900 issuers,

we estimate an aggregate burden of \$731,310.00 and 19,000 hours as a result of this requirement.

The burden estimates for these two recordkeeping requirements are broad estimates that include not only the maintenance of data, but all records and documents that may be necessary to substantiate the enrollment count and requests for reinsurance payments made pursuant to 45 CFR 153.405 and 153.410, respectively. Because the scope of these requirements is substantially narrower than the scope of the recordkeeping requirement applicable to a State operating reinsurance, these estimates are lower than those that were set forth for the State-operated reinsurance programs record maintenance requirement (45 CFR 153.240(c)) in the Premium Stabilization Rule published March 23, 2012 (77 FR 17220), and the associated information collection request approved under OMB Control Number 0938–1155. We note that we will account for the additional burden associated with submitting this information to HHS in a future information collection request that will go through the requisite notice and comment period and subsequent OMB review and approval process.

D. ICRs Related to Oversight and Financial Integrity Standards for State Exchanges (§ 155.1200 to § 155.1210)

In subpart M of part 155, we describe the information collection and third-party disclosure standards related to the oversight and financial integrity of State Exchanges.

Section 155.1200(a)(1) through (3) requires the State Exchange to follow GAAP and to monitor and report to HHS all Exchange-related activities. This includes keeping an accurate accounting of all Exchange receipts and expenditures. The burden associated with this reporting requirement is the time and effort needed to develop and submit reports of Exchange-related activities to HHS. The State Exchanges will electronically maintain the information as a result of normal business practices; therefore, the burden does not include the time and effort needed to maintain the Exchange-related activity information. State Exchanges most likely will already have accounting systems in place to store accounting information. The burden associated with this requirement includes a computer programmer taking 8 hours (at \$48.61 an hour) to modify the system to maintain and monitor the information required under § 155.1200(a)(1) through (3), an analyst taking 8 hours (at \$58.05 an hour) to pull the necessary data under

²³ We use an estimate of self-insured entities published by the DOL in the March 2013 "Report to Congress: Annual Report of Self-insured Group Health Plans," which reflects only those self-insured health plans (including 19,800 self-insured plans and 4,000 plans that mixed self-insurance and insurance) that are required to file a Form 5500 with the DOL.

§ 155.1200(a)(1) through (3) in the State Exchange accounting system, and a senior manager taking 2 hours (at \$77.00 an hour) to oversee the development and transmission of the reported data. We estimate that it will take 18 total hours at a cost of \$1,007.28 for each State Exchange. Therefore, for the 18 State Exchanges, we estimate an aggregate burden of \$18,131.04 and 324 hours as a result of this requirement.

Section 155.1200(b)(1) requires the State Exchange to submit a financial statement, in accordance with GAAP to HHS. The information under § 155.1200(b) must be submitted at least annually by April 1 to HHS and must also be publicly displayed. The burden associated with this reporting requirement is the time and effort needed to develop and submit the financial statement to HHS. The State Exchanges will electronically submit the information. Therefore, the burden is the time and effort needed to develop and publicly display the financial statement. The State Exchanges will electronically maintain the information as a result of normal business practices, therefore the burden does not include the time and effort needed to develop and maintain the financial information. The burden associated with this requirement includes a computer programmer taking 40 hours (at \$48.61 an hour) to design the financial statement report, an analyst taking 8 hours (at \$58.05 an hour) pulling the necessary data and inputting it into the financial statement report, and a senior manager taking 2 hours (at \$77.00 an hour) overseeing the development and transmission of the reported data. We estimate a burden of 50 total hours for each State Exchange at a cost of \$2,562.80. Therefore, for the 18 State Exchanges, we estimate an aggregate burden of \$45,410.40 and 900 hours as a result of this requirement.

Section 155.1200(b)(2) requires the State Exchange to submit eligibility and enrollment reports to HHS. The State Exchanges will electronically maintain the information as a result of normal business practices, therefore the burden does not include the time and effort required to develop and maintain the source information. The burden associated with this reporting requirement includes the time and effort necessary for a computer programmer taking 40 hours (at \$48.61 an hour) to design the report template, an analyst taking 8 hours (at \$58.05 an hour) to compile the statistics for the report for submission to HHS, a privacy officer taking 8 hours (at \$64.98 an hour) and senior manager taking 2 hours (at \$77.00 an hour) overseeing the development

and submission of the reported data. The burden also includes the time and effort necessary to post the data on the State Exchange Web site. We estimate an initial year burden of 58 hours at a cost of \$3,082.64 to each State Exchange. Therefore, for the 18 State Exchanges, we estimate an aggregate burden of \$55,487.52 and 1,044 hours as a result of this requirement.

As discussed in § 155.1200(b)(3), the State Exchange will report performance monitoring data to HHS. The performance monitoring data includes information on financial sustainability, operational efficiency, and consumer satisfaction which will be reported on an annual basis. The State Exchanges will electronically maintain the information as a result of normal business practices developed under Establishment Grants from HHS for this purpose. Therefore the burden does not include the time and effort needed to develop and maintain the performance data. The burden associated with meeting the reporting requirement includes the time and effort necessary for a computer programmer taking 40 hours (at \$48.61 an hour) to design the report, for an analyst taking 12 hours (at \$58.05 an hour) to pull data into the report and prepare for submission to HHS and for a senior manager taking 2 hours (at \$77.00 an hour) to oversee the development and transmission of the reported data. Section 155.1200(b) requires the State Exchange to submit to HHS and to display publicly financial, eligibility and enrollment reports and performance data at least annually. For those measures reported annually, we estimate that in the initial year a burden of 54 hours at a cost of \$2,795.00 for each State Exchange. Therefore, for the 18 State Exchanges, we estimate an aggregate burden of \$50,031.00 and 972 hours as a result of this requirement. For subsequent years, when the Establishment Grant project period ends we estimate an additional burden of 208 hours necessary for the computer programmer (at \$48.61 an hour) to maintain the performance data. For the first year, the burden for maintaining the data was already accounted for in the PRA package for the Exchange Establishment Grants (OMB Control Number 0938–1119); therefore, we are only including subsequent years in the ICR. We estimate that the total burden from year 1 will decrease to \$25,016.00 assuming a decreased effort and an additional burden of \$18,199.00 for maintaining the data, yielding a total burden of \$44,012.00 for subsequent years.

Section 155.1200(b)(4) requires the State Exchange to make public a

summary of the results of the external financial audit. The burden associated with this requirement is the time and effort for a computer programmer taking 1 hour (at \$48.61 an hour) to design the summary and for an analyst to take 1 hour (at \$58.05 an hour) to pull data into the summary and prepare for public display. For this requirement we estimate in the initial year a burden of 2 hours for the State Exchanges at a cost of \$107.00 each and a total burden of \$1926.00. Therefore, for the 18 State Exchanges, we estimate an aggregate burden of \$1926.00 and 36 hours as a result of this requirement.

Section 155.1200(c)(1) through (3) directs the State Exchange to engage an independent audit/review organization to perform an external financial and programmatic audit of the State Exchange. The State Exchange must provide the results of the audit and identify any material weakness or significant deficiency and any intended corrective action. The State Exchange must also make public a summary of the audit results. The burden associated with meeting this third party disclosure requirement includes the burden for an analyst level employee taking 3 hours (at \$48.61 an hour) to pull data into a report, the time and effort necessary for a health policy analyst taking 2 hours (at \$58.05 an hour) to prepare the report of the audit results, and the time for senior management taking 1 hour (at \$77.00 an hour) to review and submit to HHS. We estimate a burden of 6 hours at a cost of \$338.93 for each State Exchange. Therefore, for the 18 State Exchanges, we estimate an aggregate burden of \$6,100.74 and 108 hours as a result of this requirement.

As stated in § 155.1210(a), the State Exchange and its contractors, subcontractors, and agents must maintain for 10 years, books, records, documents, and other evidence of accounting procedures and practices. Section 155.1210(b) specifies that the records include information concerning management and operation of the State Exchange's financial and other record keeping systems. The records must also include financial statements, including cash flow statements, and accounts receivable and matters pertaining to the costs of operation. Additionally, the records must contain any financial report filed with other Federal programs or State authorities. Finally, the records must contain data and records relating to the State Exchange's eligibility verifications and determinations, enrollment transactions, appeals, plan variation certifications, QHP contracting data, consumer outreach, and Navigator grant oversight information. State

Exchanges most likely already have systems in place to store records. The burden associated with this record keeping requirement includes the time and effort necessary for a network administrator taking 16 hours (at \$46.86 an hour) to modify the State systems to maintain the information required under § 155.1210(b), for a health policy analyst taking 8 hours (at \$58.05 an hour) to enter the data under § 155.1210(b) into the State Exchange record retention system, and for senior management taking 2 hours (at \$77.00 an hour) to oversee record collection and retention. We estimate that it will take 26 hours at a cost of \$1,368.16 for each State Exchange. Therefore, for the 18 State Exchanges, we estimate an aggregate burden of \$24,626.88 and 468 hours as a result of this requirement.

E. ICRs Related to Change of Ownership (§ 156.330)

The QHP issuer must notify HHS of the change in a manner to be specified by HHS and provide the legal name and tax identification number of the new owner of the QHP and the effective date of the change of ownership. The information must be submitted at least 30 days prior to the effective date of the change of ownership. We estimate fewer than 10 QHP issuers will report changes of ownership. While this reporting requirement is subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.3(c)(4) and 44 U.S.C. 3502(3)(A)(i), since fewer than 10 entities would be affected. Therefore, we are not seeking approval from OMB for these information collection requirements.

F. ICRs Related to Payment for Cost-Sharing Reductions (§ 156.430)

Several of the provisions established in the interim final rule and finalized in this final rule require the collection of information.

First, under paragraph (c)(3)(i) as established in the interim final rule, and finalized in this rule, a QHP issuer must notify HHS prior to the start of each benefit year whether or not it selects the simplified methodology for the benefit year. Pursuant to the Paperwork Reduction Act of 1995, we detailed this information collection in a notice requesting comment in the **Federal Register** (78 FR 38983), and estimated the total burden of this request to be \$3,600,000 for 2014 through 2016.

In § 156.430(c)(4) of the interim final rule, we established a simplified methodology for calculating the value of the amount that the enrollees would have paid under the standard plan without cost-sharing reductions. To

estimate the incremental effect of the simplified methodology, we compared the burden of the standard methodology to the simplified methodology for those issuers that we assumed would select the simplified methodology. As discussed in the Collection of Information section in the 2014 Payment Notice, we estimated that 1,200 issuers will participate in an Exchange nationally and will incur total costs of approximately \$138 million using the standard methodology. In contrast, in the interim final rule, we estimated that each issuer using the simplified methodology would incur labor costs of 40 hours of work by an actuary (at a wage rate of \$56.89) and 20 hours of work by an insurance manager (at a wage rate of \$67.44) to develop the effective cost-sharing parameters and actuarial memorandum, and calculate the amount of cost-sharing reductions provided, resulting in a cost of approximately \$3,624 per issuer.²⁴

Because we have modified the simplified methodology in this final rule, we are updating this estimate to require 42 hours of work by an actuary and 22 hours of work by an insurance manager, resulting in a cost of approximately \$3,873 per issuer. Although we cannot predict the precise number of issuers that will select either the standard or simplified methodology, we estimate that approximately half of QHP issuers (600 issuers) will implement the simplified methodology. Therefore, we estimate that the provisions of this rule will result in an incremental savings of approximately \$57,676,164 (\$60 million that would have been incurred by these issuers under the standard methodology, minus 600 multiplied by \$3,873) by reducing the overall administrative costs that issuers incur.

The information collections associated with these provisions are subject to the Paperwork Reduction Act; however, the information collection process and instruments are currently under development. We will seek OMB approval and solicit public comments upon their completion.

G. ICRs Related to Oversight of Cost-Sharing Reductions and Advance Payments of the Premium Tax Credit (§ 155.340, § 156.410, § 156.460 and § 156.480)

Section 156.460 requires a QHP issuer to notify the enrollee within 45 calendar days of the QHP issuer's discovery of

the error, when the QHP issuer improperly reduces the premium by the amount of the advance payment of the premium tax. A parallel provision is established under § 155.340 when the Exchange is facilitating the collection of premiums. Additionally, in § 156.410(c) and (d) a QHP issuer must notify the enrollee within 45 calendar days of the QHP issuer's discovery of the error of a misapplication of the cost-sharing reduction or the improper assignment to a plan variation (or standard plan without cost-sharing reductions) and subsequent reassignment. We believe that these notifications will be effectuated as part of standard billing practices and therefore will not create an additional burden on the Exchange or QHP issuers. Therefore, we do not estimate a burden for this notification.

In § 156.480(a), we extend the standards set forth in proposed § 156.705 concerning maintenance of records to a QHP issuer in the individual market on State Exchange with respect to cost-sharing reductions and advance payments of the premium tax credit. We believe that the burden of maintaining records related to cost-sharing reductions and advance payments of the premium tax credit for QHP issuers in an FFE is already accounted for in the burden for finalized § 156.705, described elsewhere in the Collection of Information section of this final rule. In § 156.480(b), we establish that, for each benefit year, an issuer that offers a QHP in the individual market through a State Exchange or an FFE report to HHS annually, in a timeframe and manner required by HHS, summary statistics with respect to cost-sharing reductions and advance payments of the premium tax credit. In the proposed rule we stated that we believed that QHP issuers would already have the information and data systems in place necessary to generate a summary report, and that there would only be a small additional burden as a result of this submission requirement. We estimated that it would take an insurance operations analyst 16 hours (at \$38.49 an hour) annually and one senior manager 2 hours (at \$77.00 an hour) to gather summary information and prepare a report for submission to HHS. Therefore, we estimated an additional burden of 21,600 hours and total costs of approximately \$923,808 for 1,200 QHP issuers (\$769.84, on average, for each QHP issuer) as a result of this requirement. However, in this final rule, we are adding a requirement that these summary reports include information on misapplication of cost-sharing reductions and advance payments of the

²⁴ HHS relied on the Bureau of Labor Statistics, U.S. Department of Labor, *National Compensation Survey Occupational Earnings in the United States, 2011*, for estimates of job descriptions and wages.

premium tax credit. We estimate that will take an insurance operations analyst 3 hours (at \$38.49 an hour) annually and one senior manager 1 hour (at \$77.00 an hour) to gather and prepare this additional information for the summary report, resulting in an additional burden of 4,800 hours and total costs of approximately \$230,964 for 1,200 QHP issuers (\$192.84, on average, for each issuer). This would increase the total burden for the summary reports to 26,400 hours and total costs to approximately \$1,154,772.

H. ICRs Related to Oversight and Financial Integrity Standards for Issuers of Qualified Health Plans in Federally-facilitated Exchanges (§ 156.705 to § 156.715)

The burden estimates for the collections of information in Part 156, Subpart H, of the regulation reflect the assumption that the FFEs will include 475 QHP issuers. We update the number of issuers in the FFEs from the estimated number in the proposed rule to reflect more current information on the number of issuers expected to participate in the FFEs. The labor categories and salary estimates used to calculate the cost burden of these collections on issuers are derived from the Bureau of Labor Statistics' (BLS) May 2012 Occupational Employment Statistics data for selected occupations. These burden estimates generally reflect burden for the first year.

Section 156.705 provides that issuers offering QHPs in an FFE must maintain all documents and records (whether paper, electronic or other media), and other evidence of accounting procedures and practices necessary for HHS to conduct activities necessary to safeguard the financial and programmatic integrity of the FFEs. Such activities include: (1) periodic auditing of the QHP issuer's financial records, including data related to the QHP issuer's ability to bear the risk of potential financial losses; and (2) compliance reviews and other monitoring of a QHP issuer's compliance with all Exchange standards applicable to issuers offering QHPs in the FFEs listed in part 156. These standards are limited to Exchange-specific records as applicable to the FFEs, and are not enforced by States as primary regulators. This standard mirrors the maintenance of records standard applicable to State Exchanges and set forth in § 155.1210. The burden includes utilizing existing technology and systems to process and maintain this information. This reflects 60 hours of work by an actuary (at \$56.89 an hour), 15 hours by a network

administrator (at \$46.86 an hour), 15 hours by a compliance officer (at \$53.75 an hour), and 10 hours for a senior manager to review (at \$77.00 an hour). We estimate that it will take 100 hours total at a cost of \$5,693.00 for a QHP issuer to maintain these records for an aggregate burden of 47,500 hours and \$2,704,175 for all 475 QHP issuers.

Section 156.705(d) provides that QHP issuers must make all records described in paragraph (a) of this section available to HHS, the OIG, the Comptroller General, or their designees, upon request. In estimating the annual hour and cost burden on QHP issuers of making these records available to such authorities upon request, we assumed that such requests would normally be made in connection with a formal audit or compliance review or a similar process. Our burden estimates for this section address the hour and cost burden of making records available to HHS, the OIG, the Comptroller General, or their designees, for audit. Our estimates reflect our assumptions that about 47 QHP issuers would be subject to a formal audit in a given year and that the burden on issuers of making the records available would include the time, effort, and associated cost of compiling the information, reviewing it for completeness, submitting it to the auditor(s), and participating in telephone or in-person interviews. We anticipate using a risk-based approach to selection of the majority of QHP issuers for compliance review so that burdens to the issuer community would generally be linked to the QHP issuers' risk. This reflects 75 hours of work by an actuary (at \$56.89 an hour), 10 hours by a compliance officer (at \$53.75 an hour), and 5 hours for a senior manager to review (at \$77.00 an hour). We estimate it will take 90 hours at a cost of \$5,189.25 for an issuer to make its records available for an audit for a total of 4,230 hours and \$243,894.75 across all QHP issuers subject to this requirement, which we estimate at an upper end as 100 issuers.

Section 156.715 establishes the general standard that QHP issuers are subject to compliance reviews. Our burden estimates for § 156.715 address the estimated annual hour and cost burden on QHP issuers of complying with the records disclosure requirements associated with compliance reviews conducted by an FFE.

Section 156.715 provides standards for compliance reviews in the FFEs, stating that QHP issuers offering QHPs in the FFEs may be subject to compliance reviews. This section also describes the categories of records and

information issuers must make available to an FFE in conducting such reviews.

Compliance reviews evaluate a QHP issuer's compliance with the Affordable Care Act and applicable regulations. Compliance reviews will target high-risk QHP issuers and not every issuer will be reviewed each year. The results of compliance reviews will also provide insight into trends across the compliance statuses of QHP issuers, enabling HHS to prioritize areas of oversight and technical assistance.

We assume that HHS will conduct desk reviews of 31 QHP issuers each year. For each QHP issuer desk review we estimate an average of 40 hours of administrative work to assemble the requested information by a health policy analyst (at \$58.05 an hour), 19.5 hours to review the information for completeness and an additional 30 minutes for a compliance officer to submit the information to HHS (at \$53.75 an hour). There will also be an additional 10 hours to spend on phone interviews conducted by the compliance reviewer and 2 hours to spend speaking through processes with the compliance reviewer (at \$53.75 an hour). We estimate it will take 72 hours at a cost of \$4,042.00 for an issuer to make information available to HHS for a desk review for a total of 2,232 hours and \$125,302.00 across all issuers that may be subject to this information collection requirement.

We assume that HHS will conduct onsite reviews of 16 QHP issuers each year. For each onsite review we estimate it will take an average of 40 hours for a health policy analyst (at \$58.05 an hour) to assemble the requested information, and 19.5 hours for a compliance officer (at \$53.75 an hour) to review the information for completeness and 30 minutes to submit the information to HHS in preparation for an onsite review. An onsite review requires an additional 2 hours to schedule the onsite activities with the compliance officer (at \$53.75 an hour), 4 hours for introductory meeting, 8 hours to tour reviewers onsite, 10 hours of interview time, 2 hours to walk through processes with the reviewer, and 4 hours for concluding meetings. This is a total of approximately 60 hours of preparation time and an additional 30 hours for onsite time for each QHP. We estimate it will take 90 hours at a cost of \$5,009.50 for an issuer to make information available to HHS for an onsite review. We estimate that the burden for all respondents that may be subject to this information collection will be 1,440 hours at a cost of \$80,152.00

In cases in which HHS could potentially require clarification around submitted information, HHS may need to contact QHP issuers within 30 days of information submission. This would be the case for approximately 20 issuers. We estimate it will take an issuer 2 hours (at \$53.75 an hour) to respond to questions for a total of 40 hours and \$1,075.00.

I. ICRs Regarding Administrative Review of QHP Issuer Sanctions in a Federally-facilitated Exchange (§ 156.901 to § 156.963)

Subpart J of Part 156 sets forth the administrative process for issuers subject to a CMP or decertification of a QHP offered by the issuer to appeal the enforcement action. In this process, an ALJ decides whether there is a basis for HHS to assess a CMP against the issuer and whether the amount of an assessed penalty is reasonable, or whether there is a basis for decertifying a QHP offered by the issuer, as applicable. Section 156.905 (intended to parallel 45 CFR 150.405) provides that a party has a right to a hearing before an ALJ if it files a valid request for a hearing within 30 days after the date of issuance of HHS's notice of proposed assessment or decertification. An issuer's request for a hearing must include the information listed in § 156.907. Under § 156.907, the request for a hearing must identify any factual or legal bases for the assessment or decertification with which the issuer disagrees. It must also describe with reasonable specificity the basis for the disagreement, including any affirmative facts or legal arguments on which the respondent is relying. The request must also identify the relevant notice of assessment or decertification by date and attach a copy of the notice.

The burden associated with this request includes the time and effort needed by the issuer to create the written request and submit it to the appropriate entity. The associated costs are labor costs for gathering the necessary background information described under § 156.907 and then preparing and submitting the written statement.

We base our burden estimate on the assumptions that one issuer will be subject to a CMP and that one issuer will have a QHP that it offers in an FFE decertified. We assume that the issuer in each case will choose to exercise its right to a hearing and will submit a valid request for hearing. The hours involved in preparing this request may vary; for the purpose of this burden estimate we estimate an average of 24 hours will be needed: 10 hours for the compliance officer to gather and

assemble the necessary background materials described under § 156.907, and prepare the written request (at \$53.75 an hour), 12 hours for an attorney (at \$90.14 an hour) to review the background materials and written request and provide recommendations to the senior manager, and 2 hours for the senior manager (at \$77.00 an hour) to discuss and act upon the attorney's recommendations and submit the written request. We estimate that it will take 24 hours at a cost of \$1,773.18 for an issuer to prepare and submit a request for a hearing for a total of 48 hours and \$3546.36 for each issuer subject to an enforcement action under this scenario. This estimate includes any statement of good cause under § 156.805(e)(3) or request for extension under § 156.905(b), if applicable. Because we only estimate that one issuer per year would appeal a CMP and one issuer will have its QHP offered in an FFE decertified, we do not include this burden estimate in our overall calculation of burden for this rule.

J. ICRs Related to Quality Standards (§ 156.1105)

In subpart L of part 156, we describe the information collection and disclosure requirements that pertain to the approval of enrollee satisfaction survey vendors. The burden estimate associated with these disclosure requirements includes the time and effort required for enrollee satisfaction survey vendors to develop, compile, and submit the application information and any documentation necessary to support oversight in the form and manner required by HHS. HHS is developing a model enrollee satisfaction survey vendor application that will include data elements necessary for HHS review and approval. In the near future, HHS will publish the model application and will solicit public comment. At that time, and per the requirements outlined in the PRA, we will estimate the burden on survey vendors for complying with this provision of the regulation. We solicit comment on the burden for the application and review process for these entities.

K. ICRs Related to Confirmation of Payment and Collection Reports (§ 156.1210)

In § 156.1210, we establish that, within 15 calendar days of the date of a HIX 820 payment and collections report from HHS, the issuer must, in a format specified by HHS, either confirm to HHS that the HIX 820 payment and collections report accurately lists, for the timeframe specified in the report, applicable payments owed by the

Federal government and the issuer; or describe to HHS any inaccuracy it identifies in the payment and collections report. We believe that issuers will generally be able to perform this confirmation automatically, and that there will only be a small additional burden as a result of this requirement. We estimate that it will take an insurance operations analyst 1 hour (at \$38.49 an hour) monthly to make the comparison and note any discrepancies to HHS (approximately \$461.88 for each issuer annually). Based on our most recent estimates, we believe that 2,400 issuers will be affected by this requirement, resulting in aggregate burden of approximately \$1,108,512.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this rule; or
2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, [CMS-9957-F2], Fax: (202) 395-6974; or Email: OIRA_submission@omb.eop.gov.

IV. Regulatory Impact Analysis

In accordance with the provisions of Executive Order 12866, this rule was reviewed by the OMB.

A. Summary

This final rule sets financial integrity and oversight standards with respect to Exchanges; QHP issuers in an FFE; and States in regards to the operation of the risk adjustment and reinsurance programs. It also provides additional standards for special enrollment periods; survey vendors that may conduct enrollee satisfaction surveys on behalf of QHP issuers in Exchanges; and issuer participation in an FFE. In addition, this final rule amends and adopts as final interim provisions related to risk corridors and cost-sharing reduction reconciliation. Finally, it provides additional standards for guaranteed availability and renewability and makes certain amendments to the definitions and standards related to the market reform rules.

HHS has crafted this final rule to implement the protections intended by Congress in an economically efficient manner. We have examined the effects of this final rule as required by Executive Order 12866 (58 FR 51735, September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social

Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804(2)). In accordance with OMB Circular A–4, HHS has quantified the benefits and costs where possible, and has also provided a qualitative discussion of some of the benefits and costs that may stem from this final rule.

B. Executive Orders 13563 and 12866

Executive Order 12866 (58 FR 51735) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 (76 FR 3821, January 21, 2011) is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866.

Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a final rule—(1) Having an annual effect on the economy of \$100 million or more in any one 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 major rules with economically significant effects (\$100 million or more in any 1 year), and a “significant” regulatory action is subject to review by the OMB. OMB has designated this final rule as a “significant regulatory action.” Even though it is not certain whether it will have economic impacts of \$100 million or more in any one year, HHS has provided an assessment of the potential costs and benefits associated with this final regulation.

1. Need for Regulatory Action

Starting in 2014, qualified individuals and qualified employers will be able to use coverage provided by QHPs—private health insurance that has been certified as meeting certain standards—through Exchanges. The premium stabilization programs—the reinsurance, risk corridors and risk adjustment programs—will be in place to ensure premium stability for health insurance issuers as enrollment increases and issuers enroll high-risk individuals. This final rule establishes general oversight requirements for State-operated reinsurance and risk adjustment programs; establishes oversight of issuers inside and outside of the Exchange when HHS operates risk adjustment or reinsurance on behalf of a State; and establishes oversight and monitoring of State Exchanges, FFEs, SHOPs (both State Exchanges and FFEs) and issuers of QHPs, specifically with respect to financial integrity, and maintenance of records. This final rule

also restricts the use of funds for administrative expenses generated for State Exchanges and State-operated reinsurance programs; specifies procedures for oversight of advance payments of the premium tax credit and cost-sharing reductions; provides procedures to ensure the accuracy of data collection, calculations, and submissions; establishes requirements for enrollee satisfaction survey vendors; establishes standards related to risk corridors and cost-sharing reduction reconciliation; and provides additional standards for special enrollment periods.

2. Summary of Impacts

In accordance with OMB Circular A–4, Table IV.1 below depicts an accounting statement summarizing HHS’s assessment of the benefits and costs associated with this regulatory action. The period covered by the RIA is 2014–2017.

HHS anticipates that the provisions of this final rule will ensure smooth operation of Exchanges, integrity of the reinsurance, risk adjustment and risk corridors programs, safeguard the use of Federal funds, prevent fraud and abuse, and increase access to healthcare coverage. Affected entities such as States and QHP issuers will incur costs to maintain records, submit reports to HHS and Exchanges, and provide records for compliance reviews. In addition, QHP issuers that adopt the simplified methodology for calculating cost sharing reductions will incur lower administrative costs during a transitional period. In accordance with Executive Order 12866, HHS believes that the benefits of this regulatory action justify the costs.

TABLE IV.1—ACCOUNTING TABLE

Benefits:				
Qualitative:				
<ul style="list-style-type: none"> * Ensure integrity of the reinsurance and risk adjustment programs, smooth functioning of State Exchanges and FFEs * Prevent fraud and abuse * Ensure prompt refund of any excess premium or cost-sharing paid * Safeguard the use of Federal funds provided as cost-sharing reductions and advance payments of the premium tax credit and provide value for taxpayers’ dollars 				
Costs:	Estimate	Year dollar	Discount rate percent	Period covered
Annualized Monetized (\$/year)	\$15.4 million ¹	2013	7	2014–2017
	\$15.3 million ¹	2013	3	2014–2017

Annual costs related to financial oversight, maintenance of records and reporting requirements for State Exchanges and State-operated reinsurance and risk-adjustment programs; record retention requirements for contributing entities and issuers of reinsurance-eligible plans; audit costs for State Exchanges and State-operated risk adjustment and reinsurance programs; costs for QHP issuers related to reporting requirements, record maintenance, audits, and training for customer service representatives.

Qualitative:

* Costs incurred by enrollee satisfaction survey vendors related to annual application and meeting HHS standards

TABLE IV.1—ACCOUNTING TABLE—Continued

- * Reduce administrative costs for QHP issuers by allowing the use of a simplified methodology to calculate cost-sharing reductions during a transitional period
- * Reduce compliance costs for issuers by allowing a State operating a SHOP-only Exchange to establish and operate risk adjustment programs for both the small group and individual markets

Note: 1. Approximately \$2.7 million of these costs are estimated below in the RIA, including the audit costs in Table IV.2 and the rest of these costs are estimated in section III.

3. Anticipated Benefits and Costs

Starting in 2014, individuals and small businesses will be able to use health insurance coverage purchased through Exchanges. The Congressional Budget Office estimated that the number of people enrolled in coverage through Exchanges will increase from 7 million in 2014 to 24 million in 2017.²⁵ Exchanges will create competitive marketplaces where qualified individuals and qualified employers can shop for insurance coverage, and are expected to reduce the unit price of quality insurance for the average consumer by pooling risk and promoting competition.

The final rule specifies the standards and processes for the oversight and accountability of entities responsible for operations of the Exchanges and reinsurance and risk adjustment programs. Affected entities include States that establish and operate Exchanges and administer reinsurance and risk adjustment programs; FFEs; issuers of QHPs; health insurance issuers offering coverage both through and outside of an Exchange when HHS operates risk adjustment or reinsurance on behalf of the State; and contractors of these organizations.

a. Benefits

This final rule implements oversight, record maintenance, and enforcement provisions that will ensure integrity of the reinsurance and risk adjustment programs, State Exchanges and FFE functions, and prevent fraud and abuse.

This final rule includes provisions that will create a system of oversight, financial integrity and program integrity in the Exchanges and the premium stabilization programs. The oversight requirements for the reinsurance and risk-adjustment programs will ensure that these programs are effective and efficient, and use program funds appropriately. The provisions of this final rule will also ensure that Federal funds are used appropriately by State Exchanges. By monitoring financial reports and overseeing State Exchange activities, HHS will safeguard the use of

Federal funds provided as cost-sharing reductions and advance payments of the premium tax credit, and provide value for taxpayers' dollars.

The provisions of this final rule also ensure that enrollees are promptly refunded any excess premium paid or any excess cost sharing they should not have paid. Individuals harmed by misconduct on the part of non-Exchange entities will also be eligible for a special enrollment period. A QHP is also required to promptly reassign an enrollee improperly assigned to a plan variation (or standard plan without cost-sharing reductions), minimizing consumer harm.

The annual application requirement for enrollee satisfaction survey vendors allows HHS to ensure that these entities participate in relevant training and post-training certification, follow protocols related to quality assurance and the use of HHS data, and adhere to privacy and security standards when handling data. This will help to ensure that ultimately the enrollee satisfaction survey data are reliable and valid and that the information is sufficiently protected.

b. Costs

Affected entities will incur costs to comply with the provisions of this final rule. Costs related to information collection requirements subject to PRA are discussed in detail in section III and include administrative costs incurred by States and issuers related to record maintenance and reporting requirements; and oversight and financial integrity standards. In this section we discuss other costs related to the provisions in this final rule.

States operating reinsurance programs are required to keep an accurate accounting for each benefit year, of all reinsurance funds received from HHS for reinsurance payments and for administrative expenses, as well as all claims for reinsurance payments from issuers of reinsurance-eligible plans, all payments made to those issuers, and all administrative expenses incurred. State-operated reinsurance programs will already have a system in place to track reinsurance funds received from HHS, claims from and payments to issuers, and expenses incurred to operate the reinsurance program. The cost for States

operating reinsurance programs to maintain any records associated with the reinsurance program was previously estimated in the RIA of the 2014 Payment Notice as being part of State administrative costs associated with operating the reinsurance program and are not included in this RIA.

State-operated reinsurance programs will submit to HHS annually and make public a summary report of their program operations, which will include a summary of the accounting kept pursuant to § 153.260(a). We assume that the data already collected and used to report to issuers and HHS will be the same used to prepare this annual report. Therefore, the cost associated with this requirement is the incremental time and cost to prepare an annual report to HHS and the public on program operations. We estimate it will take an insurance management analyst 16 hours (at \$51 per hour) and a senior manager 2 hours (at \$77 per hour) to prepare the report. Therefore, we estimate it will cost each State that operates reinsurance approximately \$970 to submit this report to HHS. Because two States will operate reinsurance programs in the 2014 benefit year, we estimate that an aggregate cost of \$1,940 as a result of this requirement in the first year. We note that HHS will provide a portion of the reinsurance contributions it collects to States operating reinsurance programs to support State administration of reinsurance payments, which will likely cover the costs associated with this requirement.

A State operating a risk adjustment program is required to maintain documents and records relating to the risk adjustment program, whether paper, electronic or in other media, for each benefit year for at least 10 years, and make them available upon request from HHS, the OIG, the Comptroller General, or their designees, to any such entity. The documents and records must be sufficient to enable the evaluation of a State-operated risk adjustment program's compliance with Federal standards. States are also directed to ensure that their contractors, subcontractors, and agents maintain and make those documents and records available upon request from HHS, the OIG, the Comptroller General, or their

²⁵ "Effects on Health Insurance and the Federal Budget for the Insurance Coverage Provisions in the Affordable Care Act—May 2013 Baseline," Congressional Budget Office, May 14, 2013.

designees. States operating risk adjustment programs should already have the documents and records of accounting procedures needed for periodic audits. Therefore, we estimate that the additional burden associated with this requirement is the time, effort, and additional labor cost required to maintain and archive the records. We assume that it will take an insurance operations analyst 10 hours (at \$38.49 an hour) to maintain records. Therefore, the average cost for each State will be approximately \$385. Because one State will operate risk adjustment for the 2014 benefit year, we estimate an aggregate cost of \$385 to comply with this requirement in the first year.

A State operating a risk adjustment program is required to submit by December 31st of the first benefit year of operation an interim summary report on the first 10 months of risk adjustment activities, in order to obtain re-certification for the third benefit year. The cost of complying with this provision is the time and effort to write the interim report and submit it to HHS. We estimate it will take an insurance management analyst 16 hours (at \$51 per hour) and a senior manager 2 hours (at \$77 per hour) to prepare the interim summary report. Therefore, we estimate that it will cost each State operating risk adjustment \$970 to submit this report to HHS (an aggregate cost of \$970 in the 2014 benefit year). A State operating a risk adjustment program will submit and make public, a summary report of its risk adjustment program operations for each benefit year after the first benefit year for which the State operates

the program. This summary report will include the results of a programmatic and financial audit for each benefit year conducted by an independent qualified auditing entity. We believe the cost of this annual report will be the same as the cost of producing the interim first-year report described above, except for the cost of independent external audits required in subsequent years. The costs related to the annual external audit are estimated later in this RIA. These estimates also include the administrative costs related to the requirement for State-operated risk adjustment programs to keep accurate accounting for each benefit year of all receipts and expenditures related to risk adjustment payments, charges, and administration of the program.

States face a variety of costs due to the monitoring requirements in this final rule. Conducting oversight of the Exchanges, State-operated risk adjustment and reinsurance programs, administration of the advance payments of the premium tax credit or cost-sharing reductions, and other activities require independent external audits, investigations, rectification of errors, and the development of summary reports which will be submitted to HHS. The estimated total costs for independent external audits for State-operated reinsurance, risk adjustment and Exchange programs are presented in Table IV.2. It is expected that 18 States will establish State Exchanges in 2014 and, without further information; we assume that number will stay the same during the period covered by the RIA. We also assume that each State will

conduct a financial audit and a programmatic audit annually, which will encompass the reinsurance and risk adjustment programs if the State operates these programs. Financial audit costs are estimated based on prices among the big four audit firms for governmental entities of similar size to those of the anticipated State Exchanges for a financial statement audit and Yellowbook Report (report on internal controls) that reflects different levels of cost for small, medium, and large entities, for entities with low, medium, and high risk. Programmatic audit estimates reflect the experience of Federal entitlement programs similar to Medicaid, audited under an A-133 program compliance supplement, and vary only by the size of the program (small, medium and large). For example, a small Exchange judged to have low risk is estimated to have a combined financial and programmatic audit cost of \$90,000; a large Exchange, in a State that also administers a reinsurance program (which implies a more complex, high risk operation) is estimated to have combined financial and programmatic audit costs of \$360,000. Audit prices are based on 2012 pricing and reflect an annual increase of 3 percent each year, based on recent industry experience. It is expected that there will be four small State Exchanges, 12 medium size State Exchanges and two large State Exchanges. The lower bound of the range in Table IV.2 below assumes that all State Exchanges have low risk and the upper bound is calculated assuming that all State Exchanges have high risk.

TABLE IV.2—ESTIMATED AUDIT COSTS FOR STATE PROGRAMS: EXCHANGES, RISK ADJUSTMENT AND REINSURANCE

	2014	2015	2016	2017
Mid-range point estimate	\$2,572,000	\$2,649,160	\$2,728,635	\$2,810,494
Range	\$2,320,000–\$2,820,000	\$2,389,600–\$2,904,600	\$2,461,288–\$2,991,738	\$2,535,127–\$3,081,490

A State operating a SHOP-only Exchange will be able to establish and operate a risk adjustment program for both the small group and individual markets starting in 2015, which will allow it to minimize costs by achieving economies of scale and reduce compliance costs for issuers. The approach to allowable costs will be operationally simpler for issuers to implement and thus minimize related costs.

The final rule permits QHP issuers to use the simplified methodology to calculate cost-sharing reductions during a transitional period and postpone a more costly IT implementation that

would be required for the standard methodology. The costs related to the administration of cost-sharing reductions using the standard methodology are accounted for in the 2014 Payment Notice and are not included here. However, as explained in section III, the provisions of this final rule allowing the use of a simplified methodology during the transitional period are likely to result in a reduction in costs estimated to be approximately \$57.7 million.²⁶

²⁶ These cost savings have not been accounted for in the RIA since they are mostly due to a postponement of IT implementation necessary for using the standard methodology. QHP issuers will

The final rule requires the enrollee satisfaction survey vendors engaged by issuers to meet HHS standards. Survey vendors will apply for approval annually in order to administer enrollee satisfaction surveys to QHP enrollees on behalf of a QHP issuer. Survey vendors will incur costs to submit the annual applications to HHS and to meet the requirements necessary to meet approval.

C. Regulatory Alternatives

Under the Executive Order, HHS is required to consider alternatives to incur those costs at the end of the transitional period.

issuing rules and alternative regulatory approaches. HHS considered the following alternatives while developing this final rule:

1. Increased Uniformity of FFE and State Exchange Standards

Under this alternative, HHS would have required a single standard for Exchanges across the nation regardless of whether the Exchange was established and operated by a State or was Federally-facilitated. The final rule defers to State discretion in oversight of QHPs. This element of State flexibility would have been precluded if greater uniformity in operations and standards were to be imposed. Greater standardization would have had an uncertain impact on Federal oversight activities but would have likely imposed greater costs of compliance on State operations and issuers of QHPs in those States.

2. Place More Responsibility on the States To Oversee Standards, Including Those for FFEs

Under this alternative, HHS would have placed more responsibility on States and State Exchanges to interpret and meet statutory requirements. This approach could have created a number of problems. If every State developed its own monitoring standards, oversight of different Exchanges could be quite uneven, as States across the country have varying levels of fiscal resources with which to monitor activities. States currently have certain levels of responsibility under the Affordable Care Act to oversee standards for Exchanges, QHPs, and other programs. State Exchanges also have latitude in the number, type, and standardization of plans they certify and accept into the Exchange as QHPs.

There are a number of provisions in the Affordable Care Act that devolve responsibilities from the Federal government to States. Increased devolution could have decreased the need of Federal oversight, while granting States increased flexibility to regulate Exchanges within their borders. There would also have been a decrease in oversight-related activities for the Federal government such as HHS investigations or audits. On the other hand, States would have likely faced an increase in their own oversight activities and related costs.

3. Require QHP Issuers To Use the Standard Methodology To Reconcile Cost-Sharing Reductions.

HHS considered not promulgating the simplified methodology during a transition period. However, doing so

could have imposed costly IT system build requirements on many issuers at a time when QHP issuers are required to make many significant IT and operational changes.

HHS believes that the options adopted in this final rule strike the best balance of ensuring efficient operation and integrity of Exchanges and the premium stabilization programs while providing flexibility to the States and minimizing the burden on States.

D. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires agencies that issue a rule to analyze options for regulatory relief of small businesses if a rule has a significant 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 nonprofit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000 (States and individuals are not included in the definition of “small entity”). HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 percent to 5 percent. HHS anticipates that this final rule will not have a significant economic impact on a substantial number of small entities.

As discussed in the Web Portal interim final rule with comment period published on May 5, 2010 (75 FR 24481), HHS examined the health insurance industry in depth in the RIA we prepared for the proposed rule on the establishment of the Medicare Advantage program (69 FR 46866, August 3, 2004). In that analysis it was determined that there were few, if any, insurance firms underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) that fell below the size thresholds for “small” business established by the SBA (currently \$35.5 million in annual receipts for health insurance issuers).²⁷ In addition, HHS used the data from Medical Loss Ratio (MLR) annual report submissions for the 2012 MLR reporting year to develop an estimate of the number of small entities that offer comprehensive major medical coverage. These estimates may overstate the actual number of small health insurance issuers that will be affected,

since they do not include receipts from these companies’ other lines of business. It is estimated that out of 510 issuers nationwide, there are 58 small entities each with less than \$35.5 million in earned premiums that offer individual or group health insurance coverage and will therefore be subject to the requirements of this final regulation. Forty three percent of these small issuers belong to larger holding groups, and many if not all of these small issuers are likely to have other lines of business that will result in their revenues exceeding \$35.5 million. It is uncertain how many of these 510 issuers will offer QHPs and be subject to the provisions of this final rule. Based on this analysis, however, HHS expects that this final rule will not affect small issuers.

E. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act (UMRA) of 1995 requires that agencies assess anticipated costs and benefits before issuing any final rule that includes a Federal mandate that could result in expenditure in any one year by State, local or tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. In 2013, that threshold level is approximately \$141 million.

UMRA does not address the total cost of a final rule. Rather, it focuses on certain categories of cost, mainly those “Federal mandate” costs resulting from—(1) imposing enforceable duties on State, local, or tribal governments, or on the private sector; or (2) increasing the stringency of conditions in, or decreasing the funding of, State, local, or tribal governments under entitlement programs.

The final rule directs States to undertake oversight activities for State Exchanges, State-operated reinsurance and risk adjustment programs. The costs related to oversight activities, recordkeeping, reporting and audits are estimated to be approximately \$2.8 million in 2014. There are no mandates on local or tribal governments. The private sector, for example, QHP issuers and agents and brokers, will incur costs to comply with the record maintenance and reporting requirements set forth in this final rule. The related costs are estimated to be approximately \$14.2 million in 2014. However, QHP issuers are also expected to experience a cost savings of approximately \$57.7 million by adopting the simplified methodology to calculate cost sharing reductions during a transitional period and postponing costly IT implementation.

²⁷ “Table of Small Business Size Standards Matched To North American Industry Classification System Codes,” effective July 23, 2013, U.S. Small Business Administration, available at <http://www.sba.gov>.

Consistent with the policy embodied in UMRA, this final rule has been designed to be a low-burden alternative for State, local and tribal governments, and the private sector while achieving the objectives of the Affordable Care Act.

F. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.

States are the primary regulators of health insurance coverage. States will continue to apply State laws regarding health insurance coverage. However, if any State law or requirement prevents the application of a Federal standard, then that particular State law or requirement would be preempted. State requirements that are more stringent than the Federal requirements would be not be preempted by this final rule. Accordingly, States have significant latitude to impose requirements with respect to health insurance coverage that are more restrictive than the Federal law.

The State Exchange oversight program builds on State oversight efforts, where possible, by coordinating with State authorities to address compliance issues and concerns. Because QHPs are one of several commercial market insurance products operating in State markets, HHS will not seek to inappropriately duplicate or interfere with the traditional regulatory roles played by the State DOIs. HHS will generally confine its QHP oversight to Exchange-specific requirements and attributes. HHS will also seek to work collaboratively with State DOIs on topics of mutual concern, in the interest of efficiently deploying oversight resources and avoiding needlessly duplicative regulatory roles. QHP issuers are expected to comply with standards established by State law and regulation for cases forwarded to an issuer by a State in which it offers QHPs.

The requirements specified in this final rule will impose direct costs on State and local governments and HHS has attempted to minimize those costs. State Exchanges and State-operated reinsurance and risk adjustment programs are required to undertake oversight, record maintenance and reporting activities.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have Federalism implications or limit the policymaking discretion of the

States, HHS has engaged in efforts to consult with and work cooperatively with affected States. Throughout the process of developing this final rule, HHS has attempted to balance the States' interests in regulating health insurance issuers, and the Congress' intent to provide uniform protections to consumers in every State. By doing so, it is HHS's view that it has complied with the requirements of Executive Order 13132. Under the requirements set forth in section 8(a) of Executive Order 13132, and by the signatures affixed to this rule, HHS certifies that the CMS Center for Consumer Information and Insurance Oversight has complied with the requirements of Executive Order 13132 for the attached final rule in a meaningful and timely manner.

G. Congressional Review Act

This final rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.), which specifies that before a rule can take effect, the Federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report containing a copy of the rule along with other specified information, and has been transmitted to the Congress and the Comptroller General for review.

List of Subjects

45 CFR Part 144

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 146

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, and State regulation of health insurance.

45 CFR Part 153

Administrative practice and procedure, Adverse selection, Health care, Health insurance, Health records, Organization and functions (Government agencies), Premium stabilization, Reporting and recordkeeping requirements, Reinsurance, Risk adjustment, Risk corridors, Risk mitigation, State and local governments.

45 CFR Part 155

Administrative practice and procedure, Health care access, Health

insurance, Reporting and recordkeeping requirements, State and local governments, Cost-sharing reductions, Advance payments of premium tax credit, Administration and calculation of advance payments of the premium tax credit, Plan variations, Actuarial value.

45 CFR Part 156

Administrative practice and procedure, Advertising, Advisory Committees, Brokers, Conflict of interest, Consumer protection, Cost-sharing reductions, Cost-sharing reduction reconciliation, Administration and calculation of advance payments of the premium tax credit, Payment and Collection Reports, Grant programs—health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, American Indian/Alaska Natives, Individuals with disabilities, Loan programs—health, Organization and functions (Government agencies), Medicaid, Public assistance programs, Reporting and recordkeeping requirements, State and local governments, Sunshine Act, Technical assistance, Women, and Youth.

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR parts 144, 146, 147, 153, 155, and 156 as set forth below:

PART 144—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

■ 1. The authority citation for part 144 continues to read as follows:

Authority: Secs. 2701 through 2763, 2791, and 2792 of the Public Health Service Act 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92.

■ 2. Section 144.102 is amended by revising the second sentence of paragraph (c) to read as follows:

§ 144.102 Scope and applicability.

* * * * *

(c) * * * If the coverage is offered to an association member other than in connection with a group health plan, the coverage is considered individual health insurance coverage for purposes of 45 CFR parts 144 through 148.

* * * * *

■ 3. Section 144.103 is amended by revising the introductory text and the definitions of “Group market,” “Individual market,” “Large employer,” “Policy year,” and “Small employer” to read as follows:

§ 144.103 Definitions.

For purposes of parts 146 (group market), 147 (group and individual market), 148 (individual market), and 150 (enforcement) of this subchapter, the following definitions apply unless otherwise provided:

* * * * *

Group market means the market for health insurance coverage offered in connection with a group health plan.

* * * * *

Individual market means the market for health insurance coverage offered to individuals other than in connection with a group health plan.

* * * * *

Large employer means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 101 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year. In the case of plan years beginning before January 1, 2016, a State may elect to define large employer by substituting “51 employees” for “101 employees.”

* * * * *

Policy year means, with respect to—

(1) A grandfathered health plan offered in the individual health insurance market, the 12-month period that is designated as the policy year in the policy documents of the individual health insurance coverage. If there is no designation of a policy year in the policy document (or no such policy document is available), then the policy year is the deductible or limit year used under the coverage. If deductibles or other limits are not imposed on a yearly basis, the policy year is the calendar year.

(2) A non-grandfathered health plan offered in the individual health insurance market, or in a market in which the State has merged the individual and small group risk pools, for coverage issued or renewed beginning January 1, 2014, a calendar year for which health insurance coverage provides coverage for health benefits.

* * * * *

Small employer means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 1 but not more than 100 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year. In the case of plan years beginning before January 1, 2016, a State may elect to define small

employer by substituting “50 employees” for “100 employees.”

* * * * *

PART 146—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 4. The authority citation for part 146 continues to read as follows:

Authority: Secs. 2702 through 2705, 2711 through 2723, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg–1 through 300gg–5, 300gg–11 through 300gg–23, 200gg–91, and 300gg–92) (1996).

Section 146.145 also issued under secs. 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended (2010).

§ 146.145 [Amended]

■ 5. Section 146.145 is amended by—

- A. Removing paragraph (b).
- B. Redesignating paragraphs (c) through (e) as paragraphs (b) through (d).
- C. In redesignated paragraph (b), removing references to “paragraph (c)” and adding in their place “paragraph (b)” wherever they appear in the following places:
 - i. Paragraph (b)(1).
 - ii. Paragraph (b)(3)(i).
 - iii. Paragraph (b)(3)(ii).
 - iv. Paragraph (b)(4)(i).
 - v. Paragraph (b)(4)(ii).
 - vi. Paragraph (b)(4)(iii) and Conclusion.
 - vii. Paragraph (b)(5)(ii) and Conclusion.
- D. In redesignated paragraph (c), removing references to “paragraph (d)” and adding in their place “paragraph (c)” wherever they appear in the following places:
 - i. Paragraph (c)(1).
 - ii. Paragraph (c)(3).

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 6. The authority citation for part 147 continues to read as follows:

Authority: Secs. 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

■ 7. Section 147.104 is amended by revising paragraph (a), adding a sentence at the end of paragraph (b)(2), and revising paragraphs (c)(2), (d)(1)(ii), and (d)(2) introductory text to read as follows:

§ 147.104 Guaranteed availability of coverage.

(a) *Guaranteed availability of coverage in the individual and group market.* Subject to paragraphs (b) through (d) of this section, a health insurance issuer that offers health insurance coverage in the individual, small group, or large group market in a State must offer to any individual or employer in the State all products that are approved for sale in the applicable market, and must accept any individual or employer that applies for any of those products.

* * * * *

(b) * * *

(2) * * * Health insurance coverage in the individual market or in a market in which the State has merged the individual and small group risk pools must be offered on a calendar year basis.

* * * * *

(c) * * *

(2) An issuer that denies health insurance coverage to an individual or an employer in any service area, in accordance with paragraph (c)(1)(ii) of this section, may not offer coverage in the individual, small group, or large group market, as applicable, for a period of 180 calendar days after the date the coverage is denied. This paragraph (c)(2) does not limit the issuer’s ability to renew coverage already in force or relieve the issuer of the responsibility to renew that coverage.

* * * * *

(d) * * *

(1) * * *

(ii) It is applying this paragraph (d)(1) uniformly to all employers or individual in the large group, small group, or individual market, as applicable, in the State consistent with applicable State law and without regard to the claims experience of those individuals, employers and their employees (and their dependents) or any health status-related factor relating to such individuals, employees, and dependents.

(2) An issuer that denies health insurance coverage to any employer or individual in a state under paragraph (d)(1) of this section may not offer coverage in the large group, small group, or individual market, as applicable, in the State before the later of either of the following dates:

* * * * *

■ 8. Section 147.106 is amended by revising paragraphs (a) and (d)(1) introductory text to read as follows:

§ 147.106 Guaranteed renewability of coverage.

(a) *General rule.* Subject to paragraphs (b) through (d) of this section, a health insurance issuer offering health insurance coverage in the individual, small group, or large group market is required to renew or continue in force the coverage at the option of the plan sponsor or the individual, as applicable.

* * * * *

(d) * * *

(1) An issuer may elect to discontinue offering all health insurance coverage in the individual, small group, or large group market, or all markets, in a State in accordance with applicable State law only if—

* * * * *

PART 153—STANDARDS RELATED TO REINSURANCE, RISK CORRIDORS, AND RISK ADJUSTMENT UNDER THE AFFORDABLE CARE ACT

■ 9. The authority citation for part 153 is revised to read as follows:

Authority: Secs. 1311, 1321, 1341–1343, Pub. L. 111–148, 24 Stat. 119.

■ 10. Section 153.20 is amended by revising the definition of “contributing entity” to read as follows:

§ 153.20 Definitions.

* * * * *

Contributing entity means a health insurance issuer or a self-insured group health plan (including a group health plan that is partially self-insured and partially insured, where the health insurance coverage does not constitute major medical coverage). A self-insured group health plan is responsible for the reinsurance contributions, although it may elect to use a third party administrator or administrative services-only contractor for transfer of the reinsurance contributions.

* * * * *

■ 11. Section 153.240 is amended by revising paragraph (c) to read as follows:

§ 153.240 Disbursement of reinsurance payments.

* * * * *

(c) *Maintenance of records.* If a State establishes a reinsurance program, the State must maintain documents and records relating to the reinsurance program, whether paper, electronic, or in other media, for each benefit year for at least 10 years, and make them available upon request from HHS, the OIG, the Comptroller General, or their designees, to any such entity. The documents and records must be sufficient to enable the evaluation of the State-operated reinsurance program’s

compliance with Federal standards. The State must also ensure that its contractors, subcontractors, and agents similarly maintain and make relevant documents and records available upon request from HHS, the OIG, the Comptroller General, or their designees, to any such entity.

* * * * *

■ 12. Section 153.260 is added to subpart C to read as follows:

§ 153.260 General oversight requirements for State-operated reinsurance programs.

(a) *Accounting requirements.* A State that establishes a reinsurance program must ensure that its applicable reinsurance entity keeps an accounting for each benefit year of:

(1) All reinsurance contributions received from HHS for reinsurance payments and for administrative expenses;

(2) All claims for reinsurance payments received from issuers of reinsurance-eligible plans;

(3) All reinsurance payments made to issuers of reinsurance-eligible plans; and

(4) All administrative expenses incurred for the reinsurance program.

(b) *State summary report.* A State that establishes a reinsurance program must submit to HHS and make public a report on its reinsurance program operations for each benefit year in the manner and timeframe specified by HHS. The report must summarize the accounting for the benefit year kept pursuant to paragraph (a) of this section.

(c) *Independent external audit.* A State that establishes a reinsurance program must engage an independent qualified auditing entity to perform a financial and programmatic audit for each benefit year of its State-operated reinsurance program in accordance with generally accepted auditing standards (GAAS). The State must:

(1) Provide to HHS the results of the audit, in the manner and timeframe to be specified by HHS;

(2) Ensure that the audit addresses the prohibitions set forth in § 153.265;

(3) Identify to HHS any material weakness or significant deficiency identified in the audit, and address in writing to HHS how the State intends to correct any such material weakness or significant deficiency; and

(4) Make public a summary of the results of the audit, including any material weakness or significant deficiency and how the State intends to correct the material weakness or significant deficiency, in the manner and timeframe to be specified by HHS.

■ 13. Section 153.265 is added to subpart C to read as follows:

§ 153.265 Restrictions on use of reinsurance funds for administrative expenses.

A State that establishes a reinsurance program must ensure that its applicable reinsurance entity does not use any funds for the support of reinsurance operations, including any reinsurance contributions provided under the national contribution rate for administrative expenses, for any of the following purposes:

(a) Staff retreats;

(b) Promotional giveaways;

(c) Excessive executive compensation; or

(d) Promotion of Federal or State legislative or regulatory modifications.

■ 14. Section 153.310 is amended by:

A. Adding paragraph (c)(4).

B. Revising the paragraph (d) subject heading and adding paragraphs (d)(3) and (4).

C. Removing paragraph (f).

The additions and revision read as follows:

§ 153.310 Risk adjustment administration.

* * * * *

(c) * * *

(4) *Maintenance of records.* A State operating a risk adjustment program must maintain documents and records relating to the risk adjustment program, whether paper, electronic, or in other media, for each benefit year for at least 10 years, and make them available upon request from HHS, the OIG, the Comptroller General, or their designees, to any such entity. The documents and records must be sufficient to enable the evaluation of the State-operated risk adjustment program’s compliance with Federal standards. A State operating a risk adjustment program must also ensure that its contractors, subcontractors, and agents similarly maintain and make relevant documents and records available upon request from HHS, the OIG, the Comptroller General, or their designees, to any such entity.

(d) *Approval for a State to operate risk adjustment.* * * *

(3) In addition to requirements set forth in paragraphs (d)(1) and (2) of this section, to obtain re-approval from HHS to operate risk adjustment for a third benefit year, the State must, in the first benefit year for which it operates risk adjustment, provide to HHS an interim report, in a manner specified by HHS, including a detailed summary of its risk adjustment activities in the first 10 months of the benefit year, no later than December 31 of the applicable benefit year.

(4) To obtain re-approval from HHS to operate risk adjustment for each benefit year after the third benefit year, each

State operating a risk adjustment program must submit to HHS and make public a detailed summary of its risk adjustment program operations for the most recent benefit year for which risk adjustment operations have been completed, in the manner and timeframe specified by HHS.

(i) The summary must include the results of a programmatic and financial audit for each benefit year of the State-operated risk adjustment program conducted by an independent qualified auditing entity in accordance with generally accepted auditing standards (GAAS).

(ii) The summary must identify any material weakness or significant deficiency identified in the audit and address how the State intends to correct any such material weakness or significant deficiency.

■ 15. Section 153.365 is added to subpart D to read as follows:

§ 153.365 General oversight requirements for State-operated risk adjustment programs.

If a State is operating a risk adjustment program, it must keep an accounting of all receipts and expenditures related to risk adjustment payments and charges and the administration of risk adjustment-related functions and activities for each benefit year.

■ 16. Section 153.400 is amended by revising paragraph (a)(1)(i) and adding paragraph (a)(3) to read as follows:

§ 153.400 Reinsurance contribution funds.

- (a) * * *
- (1) * * *

(i) Such plan or coverage is not major medical coverage, subject to paragraph (a)(3) of this section.

* * * * *

(3) Notwithstanding paragraph (a)(1)(i) of this section, a health insurance issuer must make reinsurance contributions for lives covered by its group health insurance coverage whether or not the insurance coverage constitutes major medical coverage, if—

(i) The group health plan provides health insurance coverage for those covered lives through more than one insurance policy that in combination constitute major medical coverage;

(ii) The lives are not covered by self-insured coverage of the group health plan (except for self-insured coverage limited to excepted benefits); and

(iii) The health insurance coverage under the policy offered by the health insurance issuer constitutes the greatest portion of inpatient hospitalization benefits under the group health plan.

* * * * *

■ 17. Section 153.405 is amended by adding paragraph (h) to read as follows:

§ 153.405 Calculation of reinsurance contributions.

* * * * *

(h) *Maintenance of records.* A contributing entity must maintain documents and records, whether paper, electronic, or in other media, sufficient to substantiate the enrollment count submitted pursuant to this section for a period of at least 10 years, and must make those documents and records available upon request from HHS, the OIG, the Comptroller General, or their designees, to any such entity, for purposes of verification, investigation, audit, or other review of reinsurance contribution amounts.

■ 18. Section 153.410 is amended by adding paragraph (c) to read as follows:

§ 153.410 Requests for reinsurance payment.

* * * * *

(c) *Maintenance of records.* An issuer of a reinsurance-eligible plan must maintain documents and records, whether paper, electronic, or in other media, sufficient to substantiate the requests for reinsurance payments made pursuant to this section for a period of at least 10 years, and must make those documents and records available upon request from HHS, the OIG, the Comptroller General, or their designees, or, in a State where the State is operating reinsurance, the State or its designee, to any such entity, for purposes of verification, investigation, audit, or other review of reinsurance payment requests.

■ 19. Section 153.510 is amended by adding paragraph (e)

§ 153.510 Risk corridors establishment and payment methodology

* * * * *

(e) A QHP issuer is not subject to the provisions of this subpart with respect to a stand-alone dental plan.

■ 20. Section 153.520 is amended by revising paragraphs (a), (b), and (e) to read as follows:

§ 153.520 Attribution and allocation of revenue and expense items.

(a) *Attribution to plans.* Each item of expense in the target amount with respect to a QHP must be reasonably attributable to the operation of the QHP issuer's non-grandfathered health plans in a market within a State, with the attribution based on a generally accepted accounting method, consistently applied. To the extent that a QHP issuer utilizes a specific method for allocating expenses for purposes of

§ 158.170 of this subchapter, the method used for purposes of this paragraph must be consistent.

(b) *Allocation across plans.* Each item of expense in the target amount must reflect an amount equal to the pro rata portion of the aggregate amount of such expense across all of the QHP issuer's non-grandfathered health plans in a market within a State, allocated to the QHP based on premiums earned.

* * * * *

(e) *Maintenance of records.* A QHP issuer must maintain documents and records, whether paper, electronic, or in other media, sufficient to enable the evaluation of the issuer's compliance with applicable risk corridors standards, for each benefit year for at least 10 years, and must make those documents and records available upon request from HHS, the OIG, the Comptroller General, or their designees, to any such entity, for purposes of verification, investigation, audit or other review.

■ 21. Section 153.530 is amended by revising paragraphs (b) and (c) to read as follows:

§ 153.530 Risk corridors data requirements.

* * * * *

(b) *Allowable costs.* A QHP issuer must submit to HHS data on the allowable costs incurred with respect to the QHP issuer's non-grandfathered health plans in a market within a State in a manner specified by HHS. For purposes of this subpart, allowable costs must be —

(1) Increased by any risk adjustment charges paid by the issuer for the non-grandfathered health plans under the risk adjustment program established under subpart D of this part.

(i) Any risk adjustment charges paid by the issuer for the non-grandfathered health plans under the risk adjustment program established pursuant to subpart D of this part; and

(ii) Any reinsurance contributions made by the issuer for the non-grandfathered health plans under the transitional reinsurance program established pursuant to subpart C of this part.

(2) Reduced by —

(i) Any risk adjustment payments received by the issuer for the non-grandfathered health plans under the risk adjustment program established pursuant to subpart D of this part;

(ii) Any reinsurance payments received by the issuer for the non-grandfathered health plans under the transitional reinsurance program established pursuant to subpart C of this part; and

(iii) Any cost-sharing reduction payments received by the issuer for the QHP issuer's QHPs in a market within a State to the extent not reimbursed to the provider furnishing the item or service.

(c) *Allowable administrative costs.* A QHP issuer must submit to HHS data on the allowable administrative costs incurred with respect to the QHP issuer's non-grandfathered health plans in a market within a State in a manner specified by HHS.

* * * * *

■ 22. Section 153.620 is amended by revising paragraph (b) to read as follows:

§ 153.620 Compliance with risk adjustment standards.

* * * * *

(b) *Issuer records maintenance requirements.* An issuer that offers risk adjustment covered plans must also maintain documents and records, whether paper, electronic, or in other media, sufficient to enable the evaluation of the issuer's compliance with applicable risk adjustment standards, for each benefit year for at least 10 years, and must make those documents and records available upon request to HHS, the OIG, the Comptroller General, or their designees, or in a State where the State is operating risk adjustment, the State or its designee to any such entity, for purposes of verification, investigation, audit or other review.

■ 23. Section 153.740 is added to subpart H to read as follows:

§ 153.740 Failure to comply with HHS-operated risk adjustment and reinsurance data requirements.

(a) *Enforcement actions.* If an issuer of a risk adjustment covered plan or reinsurance-eligible plan fails to establish a dedicated distributed data environment in a manner and timeframe specified by HHS; fails to provide HHS with access to the required data in such environment in accordance with § 153.700(a) or otherwise fails to comply with the requirements of §§ 153.700 through 153.730; fails to adhere to the reinsurance data submission requirements set forth in § 153.420; or fails to adhere to the risk adjustment data submission and data storage requirements set forth in §§ 153.610 through 153.630, HHS may impose civil money penalties in accordance with the procedures set forth in § 156.805 of this subchapter. Civil monetary penalties will not be imposed for non-compliance with these requirements during 2014 pursuant to this paragraph (a) if the issuer has made good faith efforts to comply with these requirements.

(b) *Default risk adjustment charge.* If an issuer of a risk adjustment covered plan fails to establish a dedicated distributed data environment or fails to provide HHS with access to the required data in such environment in accordance with § 153.610(a), § 153.700, § 153.710, or § 153.730 such that HHS cannot apply the applicable Federally certified risk adjustment methodology to calculate the risk adjustment payment transfer amount for the risk adjustment covered plan in a timely fashion, HHS will assess a default risk adjustment charge.

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

■ 24. The authority citation for part 155 is revised to read as follows:

Authority: Title I of the Affordable Care Act, sections 1301, 1302, 1303, 1304, 1311, 1312, 1313, 1321, 1322, 1331, 1332, 1334, 1402, 1411, 1412, 1413, Pub. L. 111-148, 124 Stat. 119 (42 U.S.C. 18021-18024, 18031-18033, 18041-18042, 18051, 18054, 18071, and 18081-18083).

■ 25. Section 155.340 is amended by adding paragraph (h) to read as follows:

§ 155.340 Administration of advance payments of the premium tax credit and cost-sharing reductions.

* * * * *

(h) *Failure to reduce enrollee's premiums to account for advance payments of the premium tax credit.* If the Exchange discovers that it did not reduce an enrollee's premium by the amount of the advance payment of the premium tax credit, then the Exchange must notify the enrollee of the improper reduction within 45 calendar days of discovery of the improper reduction and refund the enrollee any excess premium paid by or for the enrollee as follows:

(1) Unless a refund is requested by or for the enrollee, the Exchange must, within 45 calendar days of discovery of the error, apply the excess premium paid by or for the enrollee to the enrollee's portion of the premium (or refund the amount directly). If any excess premium remains, the Exchange must then apply the excess premium to the enrollee's portion of the premium for each subsequent month for the remainder of the period of enrollment or benefit year until the excess premium is fully refunded (or refund the remaining amount directly). If any excess premium remains at the end of the period of enrollment or benefit year, the Exchange must refund any excess premium within 45 calendar days of the end of the

period of enrollment or benefit year, whichever comes first.

(2) If a refund is requested by or for the enrollee, the refund must be provided within 45 calendar days of the date of the request.

■ 26. Section 155.420 is amended by adding paragraph (d)(10) to read as follows:

§ 155.420 Special enrollment periods.

* * * * *

(d) * * *

(10) It has been determined by the Exchange that a qualified individual or enrollee, or his or her dependents, was not enrolled in QHP coverage; was not enrolled in the QHP selected by the qualified individual or enrollee; or is eligible for but is not receiving advance payments of the premium tax credit or cost-sharing reductions as a result of misconduct on the part of a non-Exchange entity providing enrollment assistance or conducting enrollment activities. For purposes of this provision, misconduct includes, but is not limited to, the failure of the non-Exchange entity to comply with applicable standards under this part, part 156 of this subchapter, or other applicable Federal or State laws, as determined by the Exchange.

* * * * *

§ 155.725 [Amended]

■ 27. Section 155.725(j)(2)(i) is revised to read as follows:

* * * * *

(j) * * *
(2) * * *

(i) Experiences an event described in § 155.420(d)(1), (2), (4), (5), (7), (8), (9), or (10);

* * * * *

■ 28. Subpart M is added to read as follows:

Subpart M—Oversight and Program Integrity Standards for State Exchanges

- Sec.
155.1200 General program integrity and oversight requirements.
155.1210 Maintenance of records.

Subpart M—Oversight and Program Integrity Standards for State Exchanges

§ 155.1200 General program integrity and oversight requirements.

(a) *General requirement.* A State Exchange must:

- (1) Keep an accurate accounting of Exchange receipts and expenditures in accordance with generally accepted accounting principles (GAAP).
- (2) Monitor and report to HHS on Exchange related activities.

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

- (1) A financial statement presented in accordance with GAAP by April 1 of each year,
- (2) Eligibility and enrollment reports,
- (3) Performance monitoring data, and
- (4) If the Exchange is collecting premiums under § 155.240, a report on instances in which it did not reduce an enrollee's premium by the amount of the advance payment of the premium tax credit in accordance with § 155.340(g)(1) and (2).

(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 must:

- (1) Provide to HHS the results of the annual external audit; and
- (2) Inform HHS of any material weakness or significant deficiency identified in the audit and must develop and inform HHS of a corrective action plan for such material weakness or significant deficiency;
- (3) Make public a summary of the results of the external audit.

(d) *External audit standard.* The State Exchange must ensure that independent audits of State Exchange financial statements and program activities in paragraph (c) of this section address:

- (1) Compliance with paragraph (a)(1) of this section;
- (2) Compliance with requirements under this part;
- (3) Processes and procedures designed to prevent improper eligibility determinations and enrollment transactions; and
- (4) Identification of errors that have resulted in incorrect eligibility determinations.

§ 155.1210 Maintenance of records.

(a) *General.* The State Exchange must maintain and must ensure its contractors, subcontractors, and agents maintain for 10 years, documents and records (whether paper, electronic, or other media) and other evidence of accounting procedures and practices, which are sufficient to do the following:

- (1) Accommodate periodic auditing of the State Exchange's financial records; and
- (2) Enable HHS or its designee(s) to inspect facilities, or otherwise evaluate the State-Exchange's compliance with Federal standards.

(b) *Records.* The State Exchange and its contractors, subcontractors, and agents must ensure that the records specified in paragraph (a) of this section include, at a minimum, the following:

- (1) Information concerning management and operation of the State Exchange's financial and other record keeping systems;
 - (2) Financial statements, including cash flow statements, and accounts receivable and matters pertaining to the costs of operations;
 - (3) Any financial reports filed with other Federal programs or State authorities;
 - (4) Data and records relating to the State Exchange's eligibility verifications and determinations, enrollment transactions, appeals, and plan variation certifications; and
 - (5) Qualified health plan contracting (including benefit review) data and consumer outreach and Navigator grant oversight information.
- (c) *Availability.* A State Exchange must make all records and must ensure its contractors, subcontractors, and agents must make all records in paragraph (a) of this section available to HHS, the OIG, the Comptroller General, or their designees, upon request.

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

■ 29. The authority citation for part 156 continues to read as follows:

Authority: Title I of the Affordable Care Act, sections 1301–1304, 1311–1313, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, Pub. L. 111–148, 124 Stat. 119 42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

■ 30. Section 156.20 is amended by adding definitions in alphabetical order for “Enrollee satisfaction survey vendor” and “Registered user of the enrollee satisfaction survey data warehouse” to read as follows:

§ 156.20 Definitions

* * * * *
Enrollee satisfaction survey vendor means an organization that has relevant survey administration experience (for example, CAHPS® surveys), organizational survey capacity, and quality control procedures for survey administration.
* * * * *

Registered user of the enrollee satisfaction survey data warehouse means enrollee satisfaction survey vendors, QHP issuers, and Exchanges

authorized to access CMS's secure data warehouse to submit survey data and to preview survey results prior to public reporting.

■ 31. Section 156.80 is amended by revising the first sentence of paragraph (d)(1) and adding paragraph (d)(3) to read as follows:

§ 156.80 Single risk pool.

* * * * *

(d) * * *

(1) *In general.* A health insurance issuer must establish an index rate that is effective January 1 of each calendar year for a state market described in paragraphs (a) through (c) of this section based on the total combined claims costs for providing essential health benefits within the single risk pool of that state market. * * *

* * * * *

(3) *Frequency of index rate and plan-level adjustments.* (i) A health insurance issuer may not establish an index rate and make the market-wide adjustments pursuant to paragraph (d)(1) of this section, or make the plan-level adjustments pursuant to paragraph (d)(2) of this section, more or less frequently than annually, except as provided in paragraph (d)(3)(ii) of this section.

(ii) Beginning the quarter after HHS issues notification that the FF-SHOP can process quarterly rate updates, a health insurance issuer in the small group market (not including a merged market) may establish index rates and make the market-wide adjustments pursuant to paragraph (d)(1) of this section, and make the plan-level adjustments pursuant to paragraph (d)(2) of this section, no more frequently than quarterly, provided that any changes to rates must have effective dates of January 1, April 1, July 1, or October 1.

* * * * *

■ 32. Section 156.155 is amended by revising paragraph (a)(3) to read as follows:

§ 156.155 Enrollment in catastrophic plans.

(a) * * *

(3) Provides coverage of the essential health benefits under section 1302(b) of the Affordable Care Act, except that the plan provides no benefits for any plan year (except as provided in paragraphs (a)(4) and (b) of this section) until the annual limitation on cost sharing in section 1302(c)(1) of the act is reached.

* * * * *

■ 33. Section 156.330 is added to subpart D to read follows:

§ 156.330 Changes of Ownership of Issuers of Qualified Health Plans in Federally-facilitated Exchanges.

When a QHP issuer that offers one or more QHPs in a Federally-facilitated Exchange undergoes a change of ownership as recognized by the State in which the issuer offers the QHP, the QHP issuer must notify HHS of the change in a manner to be specified by HHS, and provide the legal name and Taxpayer Identification Number (TIN) of the new owner and the effective date of the change at least 30 days prior to the effective date of the change of ownership. The new owner must agree to adhere to all applicable statutes and regulations.

■ 34. Section 156.400 is amended by revising the definition of “*Most generous or more generous*” to read as follows:

§ 156.400 Definitions.

* * * * *

Most generous or more generous means, as between a QHP (including a standard silver plan) or plan variation and one or more other plan variations of the same QHP, the standard plan or plan variation designed for the category of individuals last listed in § 155.305(g)(3) of this subchapter. *Least generous or less generous* has the opposite meaning.

* * * * *

■ 35. Section 156.410 is amended by adding paragraphs (c) and (d) to read as follows:

§ 156.410 Cost-sharing reductions for enrollees.

* * * * *

(c) *Improper cost-sharing reductions.*

(1) If a QHP issuer fails to ensure that an individual assigned to a plan variation receives the cost-sharing reductions required under the applicable plan variation, taking into account § 156.425(b) concerning continuity of deductibles and out-of-pocket amounts (if applicable), then the QHP issuer must notify the enrollee of the improper application of any cost-sharing reduction within 45 calendar days of discovery of such improper application, and refund any resulting excess cost sharing paid by or for the enrollee as follows:

(i) If the excess cost sharing was paid by the provider, the QHP issuer must refund the excess cost sharing to the provider within 45 calendar days of discovery of the improper application.

(ii) If the excess cost sharing was not paid by the provider and is not requested by the enrollee as a refund, the QHP issuer must, within 45 calendar days of discovery of the error, apply the excess cost sharing paid by or for the

enrollee to the enrollee's portion of the premium (or refund the amount directly). If any excess premium remains, the QHP issuer must apply the excess premium to the enrollee's portion of the premium for each subsequent month for the remainder of the period of enrollment or benefit year until the excess is fully applied (or refund any remaining amount directly). If any excess premium remains at the end of the period of enrollment or benefit year, the QHP issuer must refund the enrollee any remaining excess cost sharing paid by or for the enrollee within 45 calendar days of the end of the period of enrollment or benefit year, whichever comes first.

(iii) If the excess cost sharing was not paid by the provider, and if a refund is requested by the enrollee, the refund must be provided to the enrollee within 45 calendar days of the date of the request.

(2) If a QHP issuer provides an individual assigned to a plan variation greater cost-sharing reductions than required under the applicable plan variation, taking into account § 156.425(b) concerning continuity of deductibles and out-of-pocket amounts (if applicable), then the QHP issuer will not be eligible for reimbursement of any excess cost-sharing reductions provided to the enrollee, and may not seek reimbursement from the enrollee or the applicable provider for any of the excess cost-sharing reductions.

(d) *Improper assignment.* If a QHP issuer does not assign an individual to the applicable plan variation (or standard plan without cost-sharing reductions) in accordance with § 156.410(b) and § 156.425(a) based on the eligibility and enrollment information or notification provided by the Exchange, then the QHP issuer must reassign the enrollee to the applicable plan variation (or standard plan without cost-sharing reductions) and notify the enrollee of the improper assignment such that:

(1) If the QHP issuer discovers the improper assignment between the first and fifteenth day of the month, the QHP issuer must reassign the enrollee to the correct plan variation (or standard plan without cost-sharing reductions) by the first day of the following month.

(2) If the QHP issuer discovers the improper assignment between the sixteen and the last day of the month, the QHP issuer must reassign the individual to the correct plan variation (or standard plan without cost-sharing reductions) by the first day of the second following month.

(3) If, pursuant to a reassignment under this paragraph (d), a QHP issuer

reassigns an enrollee from a more generous plan variation to a less generous plan variation of a QHP (or a standard plan without cost-sharing reductions), the QHP issuer will not be eligible for reimbursement for any of the excess cost-sharing reductions provided to the enrollee following the effective date of eligibility required by the Exchange, and may not seek reimbursement from the enrollee or the applicable provider for any of the excess cost-sharing reductions.

(4) If, pursuant to a reassignment under this paragraph (d), a QHP issuer reassigns an enrollee from a less generous plan variation (or a standard plan without cost-sharing reductions) to a more generous plan variation of a QHP, the QHP issuer must recalculate the enrollee's liability for cost sharing paid between the effective date of eligibility required by the Exchange and the date on which the issuer effectuated the change, and must refund any excess cost sharing paid by or for the enrollee during such period as follows:

(i) If the excess cost sharing was paid by the provider, the QHP issuer must refund the excess cost sharing to the provider within 45 calendar days of discovery of the improper assignment.

(ii) If the excess cost sharing was not paid by the provider and is not requested by the enrollee as a refund, the QHP issuer must, within 45 calendar days of discovery of the improper assignment, apply the excess cost sharing paid by or for the enrollee to the enrollee's portion of the premium (or refund the amount directly). If any excess premium remains, the QHP issuer must apply the excess premium to the enrollee's portion of the premium for each subsequent month for the remainder of the period of enrollment or benefit year until the excess is fully applied (or refund the remaining amount directly). If any excess premium remains at the end of the period of enrollment or benefit year, the QHP issuer must refund the enrollee any remaining excess cost sharing paid by or for the enrollee within 45 calendar days of the end of the period of enrollment or benefit year, whichever comes first.

(ii) If the excess cost sharing was not paid by the provider, then, if the enrollee requests a refund, the refund must be provided to the enrollee within 45 calendar days of the date of the request.

■ 36. Section 156.430 is amended by revising paragraphs (c)(3) introductory text, (c)(3)(iii) through (iv), and (c)(4) to read as follows:

§ 156.430 Payment for cost-sharing reductions.

* * * * *

(c) * * *

(3) *Selection of methodology.* For benefit years 2014 through 2016, notwithstanding paragraph (c)(2) of this section, a QHP issuer may choose to calculate the amounts that would have been paid under the standard plan without cost-sharing reductions using the simplified methodology described in paragraph (c)(4) of this section.

* * * * *

(iii) The QHP issuer may not select the simplified methodology for a benefit year if the QHP issuer did not select the simplified methodology for the prior benefit year.

(iv) Notwithstanding paragraphs (c)(3)(ii) and (iii) of this section, if a QHP issuer merges with or acquires another issuer of a QHP on the Exchange, or acquires a QHP offered on the Exchange from another QHP issuer, and if one, but not all, of the merging, acquiring, or acquired parties had selected the simplified methodology for the benefit year, then for the benefit year in which the merger or acquisition took place, the QHP issuer must calculate the amounts that would have been paid using the methodology (whether the standard methodology described in paragraph (c)(2) of this section or the simplified methodology described in paragraph (c)(4) of this section) selected with respect to the plan variation prior to the start of the benefit year (even if the selection was not made by that QHP issuer). For the next benefit year (if such benefit year is 2015 or 2016), the QHP issuer may select the simplified methodology (subject to paragraph (c)(3)(ii) of this section but, for that benefit year, not paragraph (c)(3)(iii) of this section) or the standard methodology.

(4) *Simplified methodology.* Subject to paragraph (c)(4)(v) of this section, a QHP issuer that selects the simplified methodology described in this paragraph (c)(4) must calculate the amount that the enrollees would have paid under the standard plan without cost-sharing reductions for each policy that was assigned to a plan variation for any portion of the benefit year by applying each set of the standard plan's effective cost-sharing parameters (as calculated under paragraphs (c)(3)(ii) and (iii) of this section) to the corresponding subgroup of total allowed costs for EHB for the policy (as described in paragraph (c)(4)(i) of this section).

(i) For plan variation policies with total allowed costs for EHB for the benefit year that are:

(A) Less than or equal to the effective deductible, the amount that the enrollees would have paid under the standard plan is equal to the total allowed costs for EHB under the policy for the benefit year multiplied by the effective pre-deductible coinsurance rate.

(B) Greater than the effective deductible but less than the effective claims ceiling, the amount that the enrollees would have paid under the standard plan is equal to the sum of (x) the average deductible, plus (y) the effective non-deductible cost sharing, plus (z) the difference, if positive, between the total allowed costs under the policy for the benefit year for EHB that are subject to a deductible and the average deductible, multiplied by the effective post-deductible coinsurance rate.

(C) Greater than or equal to the effective claims ceiling, the amount that the enrollees would have paid under the standard plan is equal to the annual limitation on cost sharing for the standard plan (as defined at 45 CFR 156.400), or, at the QHP issuer's election on a policy-by-policy basis, the amount calculated pursuant to the standard methodology described in paragraph (c)(2) of this section,

(ii) The QHP issuer must calculate one or more sets of effective cost-sharing parameters, as described in paragraph (c)(4)(iii) of this section, based on policies assigned to the standard plan without cost-sharing reductions for the entire benefit year and must separately apply each set of effective cost-sharing parameters to the corresponding subgroup of total allowed costs for EHB for each plan variation policy, as described in paragraph (c)(4)(i) of this section, as follows:

(A) If the standard plan has separate cost-sharing parameters for self-only coverage and other than self-only coverage, but does not have separate cost-sharing parameters for pharmaceutical and medical services, the QHP issuer must calculate and apply separate sets of effective cost-sharing parameters based on the costs of enrollees in the standard plan with self-only coverage, and based on the costs of enrollees in the standard plan with other than self-only coverage.

(B) If the standard plan has separate cost-sharing parameters for pharmaceutical and medical services, but does not have separate cost-sharing parameters for self-only coverage and other than self-only coverage, the QHP issuer must calculate and apply separate sets of effective cost-sharing parameters based on the medical costs of the enrollees in the standard plan, and

based on the pharmaceutical costs of the enrollees in the standard plan.

(C) If the standard plan has separate cost-sharing parameters for self-only coverage and other than self-only coverage, and also has separate cost-sharing parameters for pharmaceutical and medical services, the QHP issuer must calculate and apply separate sets of effective cost-sharing parameters based on the medical costs of enrollees in the standard plan with self-only coverage, based on the pharmaceutical costs of enrollees in the standard plan with self-only coverage, based on the medical costs of enrollees in the standard plan with other than self-only coverage, and based on the pharmaceutical costs of enrollees in the standard plan with other than self-only coverage.

(iii) The effective cost-sharing parameters for the standard plan without cost-sharing reductions must be calculated based on policies assigned to the standard plan for the entire benefit year for each of the required subgroups under paragraph (c)(4)(ii) of this section as follows:

(A) If the standard plan has only one deductible (for the applicable subgroup), the average deductible of the standard plan is that deductible amount. If the standard plan has more than one deductible (for the applicable subgroup), the average deductible is the weighted average of the deductibles, weighted by allowed costs for EHB under the standard plan for the benefit year that are subject to each separate deductible. Services that are not subject to any deductible (including services subject to copayments or coinsurance but not any deductible) are not to be incorporated into the calculation of the average deductible.

(B) The effective non-deductible cost sharing for the applicable subgroup is the average portion of total allowed costs for EHB that are not subject to any deductible for the standard plan for the benefit year incurred for standard plan enrollees and payable by the enrollees as cost sharing. The effective non-deductible cost sharing must be calculated based only on standard plan policies with total allowed costs for EHB for the benefit year that are above the effective deductible but for which associated cost sharing for EHB is less than the annual limitation on cost sharing.

(C) The effective deductible for the applicable subgroup is equal to the sum of the average deductible and the average total allowed costs for EHB that are not subject to any deductible for the standard plan for the benefit year. The average total allowed costs for EHB that

are not subject to any deductible for the standard plan for the benefit year must be calculated based only on standard plan policies with total allowed costs for EHB for the benefit year that are above the average deductible but for which associated cost sharing for EHB is less than the annual limitation on cost sharing.

(D) The effective pre-deductible coinsurance rate for the applicable subgroup is the proportion of the total allowed costs for EHB under the standard plan for the benefit year incurred for standard plan enrollees and payable as cost sharing. The effective pre-deductible coinsurance rate must be calculated based only on standard plan policies with total allowed costs for EHB for the benefit year that are less than or equal to the effective deductible.

(E) The effective post-deductible coinsurance rate for the applicable subgroup is the quotient of (x) the portion of average allowed costs for EHB subject to a deductible incurred for enrollees for the benefit year, and payable by the enrollees as cost sharing other than through a deductible, over the difference of (y) the average allowed costs for EHB subject to a deductible incurred for enrollees for the benefit year, and (z) the average deductible. The effective post-deductible coinsurance rate must be calculated based only on standard plan policies with total allowed costs for EHB for the benefit year that are above the effective deductible but for which associated cost sharing for EHB is less than the annual limitation on cost sharing.

(F) The effective claims ceiling for the applicable subgroup is calculated as the effective deductible plus the quotient of (x) the difference between the annual limitation on cost sharing and the sum of the average deductible and the effective non-deductible cost sharing, divided by (y) the effective post-deductible coinsurance rate.

(iv) If a QHP issuer uses the simplified methodology described in this paragraph (c)(4), and the QHP issuer's standard plan does not meet any of the criteria in paragraphs (c)(4)(v)(A) through (D) of this section, the QHP issuer must also submit to HHS, in the manner and timeframe established by HHS, the following information for each standard plan offered by the QHP issuer in the individual market through the Exchange for each of the required subgroups described in paragraph (c)(4)(ii) of this section:

(A) The average deductible for each applicable subgroup;

(B) The effective deductible for each applicable subgroup;

(C) The effective non-deductible cost sharing amount for each applicable subgroup;

(D) The effective pre-deductible coinsurance rate for each applicable subgroup;

(E) The effective post-deductible coinsurance rate for each applicable subgroup;

(F) The effective claims ceiling for each applicable subgroup; and

(G) A memorandum developed by a member of the American Academy of Actuaries in accordance with generally accepted actuarial principles and methodologies that describes how the QHP issuer calculated the effective cost-sharing parameters for each applicable subgroup for the standard plan.

(v) Notwithstanding paragraphs (c)(4)(i) through (iii) of this section, if a QHP issuer's standard plan meets the criteria in any of the following subparagraphs, and the QHP issuer has selected the simplified methodology described in this paragraph (c)(4), then the QHP issuer must calculate the amount that the enrollees in the plan variation would have paid under the standard plan without cost-sharing reductions as the lesser of the annual limitation on cost sharing for the standard plan or the amount equal to the product of, (x) one minus the standard plan's actuarial value, as calculated under 45 CFR 156.135, and (y) the total allowed costs for EHB for the benefit year under each policy that was assigned to a plan variation for any portion of the benefit year.

(A) The standard plan has separate cost-sharing parameters for self-only coverage and other than self-only coverage, does not have separate cost-sharing parameters for pharmaceutical and medical services, and has an enrollment during the benefit year of fewer than 12,000 member months for coverage with total allowed costs for EHB for the benefit year that are greater than the effective deductible, but for which associated cost sharing for EHB is less than the annual limitation on cost sharing, in either of the following categories –

- (1) Self-only coverage; or
- (2) Other than self-only coverage.

(B) The standard plan has separate cost-sharing parameters for pharmaceutical and medical services, does not have separate cost-sharing parameters for self-only coverage and other than self-only coverage, and has an enrollment during the benefit year of fewer than 12,000 member months for coverage with total allowed costs for EHB for the benefit year that are greater than the effective deductible, but for which associated cost sharing for EHB is

less than the annual limitation on cost sharing, in either of the following categories:

- (1) Coverage of medical services; or
- (2) Coverage of pharmaceutical services.

(C) The standard plan has separate cost-sharing parameters for self-only coverage and other than self-only coverage and for pharmaceutical and medical services, and has an enrollment during the benefit year of fewer than 12,000 member months for coverage with total allowed costs for EHB for the benefit year that are greater than the effective deductible, but for which associated cost sharing for EHB is less than the annual limitation on cost sharing, in any of the following categories:

- (1) Self-only coverage of medical services;
- (2) Self-only coverage of pharmaceutical services;
- (3) Other than self-only coverage of medical services; or
- (4) Other than self-only coverage of pharmaceutical services.

(D) The standard plan does not have separate cost-sharing parameters for pharmaceutical and medical services, or for self-only coverage and other than self-only coverage, and has an enrollment during the benefit year of fewer than 12,000 member months with total allowed costs for EHB for the benefit year that are greater than the effective deductible, but for which associated cost sharing for EHB is less than the annual limitation on cost sharing.

(vi) Notwithstanding paragraphs (c)(4)(i)(A) and (B) of this section, and paragraphs (c)(4)(iii)(A) through (E) of this section, if more than eighty percent of the total allowed costs for EHB for the benefit year under a standard plan for a subgroup that requires a separate set of effective cost-sharing parameters pursuant to paragraph (c)(4)(ii) are not subject to a deductible, then:

(A) The average deductible, the effective non-deductible cost sharing, and the effective deductible for the subgroup equal zero;

(B) The effective pre-deductible coinsurance rate for the subgroup is equal to the effective post-deductible coinsurance rate for the subgroup, which is determined based on all standard plan policies for the applicable subgroup for which associated cost sharing for EHB is less than the annual limitation on cost sharing, and calculated for the applicable subgroup as the proportion of the total allowed costs for EHB under the standard plan for the benefit year incurred for standard plan enrollees and payable as

cost sharing (including cost sharing payable through a deductible); and

(C) The amount that enrollees in the applicable subgroup in plan variation policies with total allowed costs for EHB for the benefit year that are less than the effective claims ceiling would have paid under the standard plan must be calculated using the formula in paragraph (c)(4)(i)(A).

* * * * *

■ 37. Section 156.460 is amended by adding paragraph (c) to read as follows:

§ 156.460 Reduction of enrollee's share of premium to account for advance payments of the premium tax credit.

* * * * *

(c) *Refunds to enrollees for improper reduction of enrollee's share of premium to account for advance payments of the premium tax credit.* If a QHP issuer discovers that it did not reduce the portion of the premium charged to or for an enrollee for the applicable month(s) by the amount of the advance payment of the premium tax credit in accordance with paragraph (a)(1) of this section, the QHP issuer must notify the enrollee of the improper reduction within 45 calendar days of the QHP issuer's discovery of the improper reduction and refund any excess premium paid by or for the enrollee, as follows:

(1) Unless a refund is requested by or for the enrollee, the QHP issuer must, within 45 calendar days of discovery of the error, apply the excess premium paid by or for the enrollee to the enrollee's portion of the premium (or refund the amount directly). If any excess premium remains, the QHP issuer must apply the excess premium to the enrollee's portion of the premium for each subsequent month for the remainder of the period of enrollment or benefit year until the excess is fully applied (or refund the remaining amount directly). If any excess premium remains at the end of the period of enrollment or benefit year, the QHP issuer must refund any excess premium within 45 calendar days of the end of the period of enrollment or benefit year, whichever comes first.

(2) If a refund is requested by or for the enrollee, the refund must be provided within 45 calendar days of the date of the request.

■ 38. Section 156.480 is added to subpart E to read as follows:

§ 156.480 Oversight of the administration of the cost-sharing reductions and advance payments of the premium tax credit programs.

(a) *Maintenance of records.* An issuer that offers a QHP in the individual

market through a State Exchange must adhere to, and ensure that any relevant delegated entities and downstream entities adhere to, the standards set forth in § 156.705 concerning maintenance of documents and records, whether paper, electronic, or in other media, by issuers offering QHPs in a Federally-facilitated Exchange, in connection with cost-sharing reductions and advance payments of the premium tax credit.

(b) *Annual reporting requirements.* For each benefit year, an issuer that offers a QHP in the individual market through an Exchange must report to HHS, in the manner and timeframe required by HHS, summary statistics specified by HHS with respect to administration of cost-sharing reduction and advance payments of the premium tax credit programs, including any failure to adhere to the standards set forth under § 156.410(a) through (d), § 156.425(a) through (b), and § 156.460(a) through (c) of this Part.

(c) *Audits.* HHS or its designee may audit an issuer that offers a QHP in the individual market through an Exchange to assess compliance with the requirements of this subpart.

■ 39. Subpart H is added to read as follows:

Subpart H—Oversight and Financial Integrity Standards for Issuers of Qualified Health Plans in Federally-Facilitated Exchanges

Sec.

156.705 Maintenance of records for Federally-facilitated Exchange.

156.715 Investigations and compliance reviews in Federally-facilitated Exchanges.

Subpart H—Oversight and Financial Integrity Standards for Issuers of Qualified Health Plans in Federally-Facilitated Exchanges

§ 156.705 Maintenance of records for Federally-facilitated Exchanges.

(a) *General standard.* Issuers offering QHPs in a Federally-facilitated Exchange must maintain all documents and records (whether paper, electronic, or other media) and other evidence of accounting procedures and practices, necessary for HHS to do the following:

(1) Periodically audit financial records related to QHP issuers' participation in a Federally-facilitated Exchange, and evaluate the ability of QHP issuers to bear the risk of potential financial losses; and

(2) Conduct compliance reviews or otherwise monitor QHP issuers' compliance with all Exchange standards applicable to issuers offering QHPs in a

federally-facilitated Exchange as listed in this part.

(b) *Records.* The records described in paragraph (a) of this section include the sources listed in § 155.1210(b)(2), (3), and (5) of this subchapter.

(c) *Record retention timeframe.* Issuers offering QHPs in a Federally-facilitated Exchange must maintain all records referenced in paragraph (a) of this section for 10 years.

(d) *Record availability.* Issuers offering QHPs in a Federally-facilitated Exchange must make all records in paragraph (a) of this section available to HHS, the OIG, the Comptroller General, or their designees, upon request.

§ 156.715 Compliance Reviews of QHP Issuers in Federally-facilitated Exchanges.

(a) *General standard.* Issuers offering QHPs in a Federally-facilitated Exchange may be subject to compliance reviews to ensure ongoing compliance with Exchange standards applicable to issuers offering QHPs in a Federally-facilitated Exchange.

(b) *Records.* In preparation for or in the course of the compliance review, a QHP issuer must make available for HHS to review the records of the QHP issuer that pertain to its activities within a Federally-facilitated Exchange. Such records may include, but are not limited to the following:

(1) The QHP issuer's books and contracts, including the QHP issuer's policy manuals and other QHP plan benefit information provided to the QHP issuer's enrollees;

(2) The QHP issuer's policies and procedures, protocols, standard operating procedures, or other similar manuals related to the QHP issuer's activities in a Federally-facilitated Exchange;

(3) Any other information reasonably necessary for HHS to—

(i) Evaluate the QHP issuer's compliance with QHP certification standards and other Exchange standards applicable to issuers offering QHPs in a Federally-facilitated Exchange;

(ii) Evaluate the QHP's performance, including its adherence to an effective compliance plan, within a Federally-facilitated Exchange;

(iii) Verify that the QHP issuer has performed the duties attested to as part of the QHP certification process; and

(iv) Assess the likelihood of fraud or abuse.

(c) *Interest of Qualified Individuals and Qualified Employers.* HHS's findings from the compliance reviews under this section may be in conjunction with other findings related to the QHP issuers' compliance with certification standards, used to confirm

that permitting the issuer's QHPs to be available through a Federally-facilitated Exchange is in the interest of the qualified individuals and qualified employers as provided under § 155.1000(c)(2) of this subchapter.

(d) *Onsite and desk reviews.* The QHP issuer will make available, for the purposes listed in paragraph (c) of this section, its premises, physical facilities and equipment (including computer and other electronic systems), for HHS to conduct a compliance review as provided under this section.

(1) A compliance review under this section will be carried out as an onsite or desk review based on the specific circumstances.

(2) Unless otherwise specified, nothing in this section is intended to preempt Federal laws and regulations related to information privacy and security.

(e) *Compliance review timeframe.* A QHP issuer may be subject to a compliance review up to 10 years from the last day of that plan benefit year, or 10 years from the last day that the QHP certification is effective if the QHP is no longer available through a Federally-facilitated Exchange; provided, however, that if the 10 year review period falls during an ongoing compliance review, the review period would be extended until the compliance review is completed.

■ 40. Subpart J is added to read as follows:

Subpart J—Administrative Review of QHP Issuer Sanctions in Federally-Facilitated Exchanges

Sec.

- 156.901 Definitions.
- 156.903 Scope of Administrative Law Judge's (ALJ) authority.
- 156.905 Filing of request for hearing.
- 156.907 Form and content of request for hearing.
- 156.909 Amendment of notice of assessment or decertification request for hearing.
- 156.911 Dismissal of request for hearing.
- 156.913 Settlement.
- 156.915 Intervention.
- 156.917 Issues to be heard and decided by ALJ.
- 156.919 Forms of hearing.
- 156.921 Appearance of counsel.
- 156.923 Communications with the ALJ.
- 156.925 Motions.
- 156.927 Form and service of submissions.
- 156.929 Computation of time and extensions of time.
- 156.929 Computation of time and extensions of time.
- 156.931 Acknowledgment of request for hearing.
- 156.935 Discovery.
- 156.937 Submission of briefs and proposed hearing exhibits.

- 156.939 Effect of submission of proposed hearing exhibits.
- 156.941 Prehearing conferences.
- 156.943 Standard of proof.
- 156.945 Evidence.
- 156.947 The record.
- 156.951 Posthearing briefs.
- 156.953 ALJ decision.
- 156.955 Sanctions.
- 156.957 Review by Administrator.
- 156.959 Judicial review.
- 156.961 Failure to pay assessment.
- 156.963 Final order not subject to review.

Subpart J—Administrative Review of QHP Issuer Sanctions in Federally-Facilitated Exchanges

§ 156.901 Definitions.

In this subpart, unless the context indicates otherwise:

ALJ means administrative law judge of the Departmental Appeals Board of HHS.

Filing date means the date postmarked by the U.S. Postal Service, deposited with a carrier for commercial delivery, or hand delivered.

Hearing includes a hearing on a written record as well as an in-person or telephone hearing.

Party means HHS or the respondent.

Receipt date means five days after the date of a document, unless there is a showing that it was in fact received later.

Respondent means an entity that received a notice of proposed assessment of a civil money penalty issued pursuant to § 156.805 or a notice of decertification pursuant to § 156.810(c) or (d).

§ 156.903 Scope of Administrative Law Judge's (ALJ) authority.

(a) The ALJ has the authority, including all of the authority conferred by the Administrative Procedure Act (5 U.S.C. 554a), to adopt whatever procedures may be necessary or proper to carry out in an efficient and effective manner the ALJ's duty to provide a fair and impartial hearing on the record and to issue an initial decision concerning the imposition of a civil money penalty or the decertification of a QHP offered in a Federally-facilitated Exchange.

(b) The ALJ's authority includes the authority to modify, consistent with the Administrative Procedures Act (5 U.S.C. 552a), any hearing procedures set out in this subpart.

(c) The ALJ does not have the authority to find invalid or refuse to follow Federal statutes or regulations.

§ 156.905 Filing of request for hearing.

(a) A respondent has a right to a hearing before an ALJ if it files a request for hearing that complies with § 156.907(a), within 30 days after the

date of issuance of either HHS' notice of proposed assessment under § 156.805, notice of decertification of a QHP under § 156.810(c) or § 156.810(d). The request for hearing should be addressed as instructed in the notice of proposed determination. "date of issuance" is five (5) days after the filing date, unless there is a showing that the document was received earlier.

(b) The ALJ may extend the time for filing a request for hearing only if the ALJ finds that the respondent was prevented by events or circumstances beyond its control from filing its request within the time specified above. Any request for an extension of time must be made promptly by written motion.

§ 156.907 Form and content of request for hearing.

(a) The request for hearing must do the following:

(1) Identify any factual or legal bases for the assessment or decertifications with which the respondent disagrees.

(2) Describe with reasonable specificity the basis for the disagreement, including any affirmative facts or legal arguments on which the respondent is relying.

(b) Identify the relevant notice of assessment or decertification by date and attach a copy of the notice.

§ 156.909 Amendment of notice of assessment or decertification request for hearing.

The ALJ may permit CMS to amend its notice of assessment or decertification, or permit the respondent to amend a request for hearing that complies with § 156.907(a), if the ALJ finds that no undue prejudice to either party will result.

§ 156.911 Dismissal of request for hearing.

An ALJ will order a request for hearing dismissed if the ALJ determines that:

(a) The request for hearing was not filed within 30 days as specified by § 156.905(a) or any extension of time granted by the ALJ pursuant to § 156.905(b).

(b) The request for hearing fails to meet the requirements of § 156.907.

(c) The entity that filed the request for hearing is not a respondent under § 156.901.

(d) The respondent has abandoned its request.

(e) The respondent withdraws its request for hearing.

§ 156.913 Settlement.

HHS has exclusive authority to settle any issue or any case, without the consent of the ALJ at any time before or after the ALJ's decision.

§ 156.915 Intervention.

(a) The ALJ may grant the request of an entity, other than the respondent, to intervene if all of the following occur:

(1) The entity has a significant interest relating to the subject matter of the case.

(2) Disposition of the case will, as a practical matter, likely impair or impede the entity's ability to protect that interest.

(3) The entity's interest is not adequately represented by the existing parties.

(4) The intervention will not unduly delay or prejudice the adjudication of the rights of the existing parties.

(b) A request for intervention must specify the grounds for intervention and the manner in which the entity seeks to participate in the proceedings. Any participation by an intervenor must be in the manner and by any deadline set by the ALJ.

(c) The Department of Labor (DOL) or the Internal Revenue Service (IRS) may intervene without regard to paragraphs (a)(1) through (3) of this section.

§ 156.917 Issues to be heard and decided by ALJ.

(a) The ALJ has the authority to hear and decide the following issues:

(1) Whether a basis exists to assess a civil money penalty against the respondent.

(2) Whether the amount of the assessed civil money penalty is reasonable.

(3) Whether a basis exists to decertify a QHP offered by the respondent in a Federally-facilitated Exchange.

(b) In deciding whether the amount of a civil money penalty is reasonable, the ALJ—

(1) Will apply the factors that are identified in § 156.805 for civil money penalties.

(2) May consider evidence of record relating to any factor that HHS did not apply in making its initial determination, so long as that factor is identified in this subpart.

(c) If the ALJ finds that a basis exists to assess a civil money penalty, the ALJ may sustain, reduce, or increase the penalty that HHS assessed.

§ 156.919 Forms of hearing.

(a) All hearings before an ALJ are on the record. The ALJ may receive argument or testimony in writing, in person, or by telephone. The ALJ may receive testimony by telephone only if the ALJ determines that doing so is in the interest of justice and economy and that no party will be unduly prejudiced. The ALJ may require submission of a witness' direct testimony in writing only if the witness is available for cross-examination.

(b) The ALJ may decide a case based solely on the written record where there is no disputed issue of material fact the resolution of which requires the receipt of oral testimony.

§ 156.921 Appearance of counsel.

Any attorney who is to appear on behalf of a party must promptly file, with the ALJ, a notice of appearance.

§ 156.923 Communications with the ALJ.

No party or person (except employees of the ALJ's office) may communicate in any way with the ALJ on any matter at issue in a case, unless on notice and opportunity for both parties to participate. This provision does not prohibit a party or person from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

§ 156.925 Motions.

(a) Any request to the ALJ for an order or ruling must be by motion, stating the relief sought, the authority relied upon, and the facts alleged. All motions must be in writing, with a copy served on the opposing party, except in either of the following situations:

(1) The motion is presented during an oral proceeding before an ALJ at which both parties have the opportunity to be present.

(2) An extension of time is being requested by agreement of the parties or with waiver of objections by the opposing party.

(b) Unless otherwise specified in this subpart, any response or opposition to a motion must be filed within 20 days of the party's receipt of the motion. The ALJ does not rule on a motion before the time for filing a response to the motion has expired except where the response is filed at an earlier date, where the opposing party consents to the motion being granted, or where the ALJ determines that the motion should be denied.

§ 156.927 Form and service of submissions.

(a) Every submission filed with the ALJ must be filed in triplicate, including one original of any signed documents, and include:

(1) A caption on the first page, setting forth the title of the case, the docket number (if known), and a description of the submission (such as "Motion for Discovery").

(2) The signatory's name, address, and telephone number.

(3) A signed certificate of service, specifying each address to which a copy of the submission is sent, the date on which it is sent, and the method of service.

(b) A party filing a submission with the ALJ must, at the time of filing, serve a copy of such submission on the opposing party. An intervenor filing a submission with the ALJ must, at the time of filing, serve a copy of the submission on all parties. Service must be made by mailing or hand delivering a copy of the submission to the opposing party. If a party is represented by an attorney, service must be made on the attorney.

§ 156.929 Computation of time and extensions of time.

(a) For purposes of this subpart, in computing any period of time, the time begins with the day following the act, event, or default and includes the last day of the period unless it is a Saturday, Sunday, or legal holiday observed by the Federal government, in which event it includes the next business day. When the period of time allowed is less than seven days, intermediate Saturdays, Sundays, and legal holidays observed by the Federal government are excluded from the computation.

(b) The period of time for filing any responsive pleading or papers is determined by the date of receipt (as defined in § 156.901) of the submission to which a response is being made.

(c) The ALJ may grant extensions of the filing deadlines specified in these regulations or set by the ALJ for good cause shown (except that requests for extensions of time to file a request for hearing may be granted only on the grounds specified in § 156.905(b)).

§ 156.931 Acknowledgment of request for hearing.

After receipt of the request for hearing, the ALJ assigned to the case or someone acting on behalf of the ALJ will send a letter to the parties that acknowledges receipt of the request for hearing, identifies the docket number assigned to the case, provides instructions for filing submissions and other general information concerning procedures, and sets out the next steps in the case.

§ 156.935 Discovery.

(a) The parties must identify any need for discovery from the opposing party as soon as possible, but no later than the time for the reply specified in § 156.937(c). Upon request of a party, the ALJ may stay proceedings for a reasonable period pending completion of discovery if the ALJ determines that a party would not be able to make the submissions required by § 156.937 without discovery. The parties should attempt to resolve any discovery issues informally before seeking an order from the ALJ.

(b) Discovery devices may include requests for production of documents, requests for admission, interrogatories, depositions, and stipulations. The ALJ orders interrogatories or depositions only if these are the only means to develop the record adequately on an issue that the ALJ must resolve to decide the case.

(c) Each discovery request must be responded to within 30 days of receipt, unless that period of time is extended for good cause by the ALJ.

(d) A party to whom a discovery request is directed may object in writing for any of the following reasons:

(1) Compliance with the request is unduly burdensome or expensive.

(2) Compliance with the request will unduly delay the proceedings.

(3) The request seeks information that is wholly outside of any matter in dispute.

(4) The request seeks privileged information. Any party asserting a claim of privilege must sufficiently describe the information or document being withheld to show that the privilege applies. If an asserted privilege applies to only part of a document, a party withholding the entire document must state why the nonprivileged part is not segregable.

(5) The disclosure of information responsive to the discovery request is prohibited by law.

(e) Any motion to compel discovery must be filed within 10 days after receipt of objections to the party's discovery request, within 10 days after the time for response to the discovery request has elapsed if no response is received, or within 10 days after receipt of an incomplete response to the discovery request. The motion must be reasonably specific as to the information or document sought and must state its relevance to the issues in the case.

§ 156.937 Submission of briefs and proposed hearing exhibits.

(a) Within 60 days of its receipt of the acknowledgment provided for in § 156.931, the respondent must file the following with the ALJ:

(1) A statement of its arguments concerning CMS's notice of assessment or decertification (respondent's brief), including citations to the respondent's hearing exhibits provided in accordance with paragraph (a)(2) of this section. The brief may not address factual or legal bases for the assessment or decertification that the respondent did not identify as disputed in its request for hearing or in an amendment to that request permitted by the ALJ.

(2) All documents (including any affidavits) supporting its arguments,

tabbed and organized chronologically and accompanied by an indexed list identifying each document.

(3) A statement regarding whether there is a need for an in-person hearing and, if so, a list of proposed witnesses and a summary of their expected testimony that refers to any factual dispute to which the testimony will relate.

(4) Any stipulations or admissions.

(b) Within 30 days of its receipt of the respondent's submission required by paragraph (a) of this section, CMS will file the following with the ALJ:

(1) A statement responding to the respondent's brief, including the respondent's proposed hearing exhibits, if appropriate. The statement may include citations to CMS's proposed hearing exhibits submitted in accordance with paragraph (b)(2) of this section.

(2) Any documents supporting CMS's response not already submitted as part of the respondent's proposed hearing exhibits, organized and indexed as indicated in paragraph (a)(2) of this section (CMS's proposed hearing exhibits).

(3) A statement regarding whether there is a need for an in-person hearing and, if so, a list of proposed witnesses and a summary of their expected testimony that refers to any factual dispute to which the testimony will relate.

(4) Any admissions or stipulations.

(c) Within 15 days of its receipt of CMS's submission required by paragraph (b) of this section, the respondent may file with the ALJ a reply to CMS's submission.

§ 156.939 Effect of submission of proposed hearing exhibits.

(a) Any proposed hearing exhibit submitted by a party in accordance with § 156.937 is deemed part of the record unless the opposing party raises an objection to that exhibit and the ALJ rules to exclude it from the record. An objection must be raised either in writing prior to the prehearing conference provided for in § 156.941 or at the prehearing conference. The ALJ may require a party to submit the original hearing exhibit on his or her own motion or in response to a challenge to the authenticity of a proposed hearing exhibit.

(b) A party may introduce a proposed hearing exhibit following the times for submission specified in § 156.937 only if the party establishes to the satisfaction of the ALJ that it could not have produced the exhibit earlier and that the opposing party will not be prejudiced.

§ 156.941 Prehearing conferences.

An ALJ may schedule one or more prehearing conferences (generally conducted by telephone) on the ALJ's own motion or at the request of either party for the purpose of any of the following:

(a) Hearing argument on any outstanding discovery request.

(b) Establishing a schedule for any supplements to the submissions required by § 156.937 because of information obtained through discovery.

(c) Hearing argument on a motion.

(d) Discussing whether the parties can agree to submission of the case on a stipulated record.

(e) Establishing a schedule for an in-person hearing, including setting deadlines for the submission of written direct testimony or for the written reports of experts.

(f) Discussing whether the issues for a hearing can be simplified or narrowed.

(g) Discussing potential settlement of the case.

(h) Discussing any other procedural or substantive issues.

§ 156.943 Standard of proof.

(a) In all cases before an ALJ—

(1) CMS has the burden of coming forward with evidence sufficient to establish a prima facie case;

(2) The respondent has the burden of coming forward with evidence in response, once CMS has established a prima facie case; and

(3) CMS has the burden of persuasion regarding facts material to the assessment or decertification; and

(4) The respondent has the burden of persuasion regarding facts relating to an affirmative defense.

(b) The preponderance of the evidence standard applies to all cases before the ALJ.

§ 156.945 Evidence.

(a) The ALJ will determine the admissibility of evidence.

(b) Except as provided in this part, the ALJ will not be bound by the Federal Rules of Evidence. However, the ALJ may apply the Federal Rules of Evidence where appropriate; for example, to exclude unreliable evidence.

(c) The ALJ excludes irrelevant or immaterial evidence.

(d) Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence.

(e) Although relevant, evidence is excluded if it is privileged under Federal law.

(f) Evidence concerning offers of compromise or settlement made in this action will be inadmissible to the extent provided in the Federal Rules of Evidence.

(g) Evidence of acts other than those at issue in the instant case is admissible in determining the amount of any civil money penalty if those acts are used under § 156.805 of this part to consider the entity's prior record of compliance, or to show motive, opportunity, intent, knowledge, preparation, identity, or lack of mistake. This evidence is admissible regardless of whether the acts occurred during the statute of limitations period applicable to the acts that constitute the basis for liability in the case and regardless of whether HHS' notice sent in accordance with § 156.805 referred to them.

(h) The ALJ will permit the parties to introduce rebuttal witnesses and evidence.

(i) All documents and other evidence offered or taken for the record will be open to examination by all parties, unless the ALJ orders otherwise for good cause shown.

(j) The ALJ may not consider evidence regarding the willingness and ability to enter into and successfully complete a corrective action plan when that evidence pertains to matters occurring after HHS' notice under § 156.805(d) or § 156.810(c) or § 156.810(d).

§ 156.947 The record.

(a) Any testimony that is taken in-person or by telephone is recorded and transcribed. The ALJ may order that other proceedings in a case, such as a prehearing conference or oral argument of a motion, be recorded and transcribed.

(b) The transcript of any testimony, exhibits and other evidence that is admitted, and all pleadings and other documents that are filed in the case constitute the record for purposes of an ALJ decision.

(c) For good cause, the ALJ may order appropriate redactions made to the record.

§ 156.951 Posthearing briefs.

Each party is entitled to file proposed findings and conclusions, and supporting reasons, in a posthearing brief. The ALJ will establish the schedule by which such briefs must be filed. The ALJ may direct the parties to brief specific questions in a case and may impose page limits on posthearing briefs. Additionally, the ALJ may allow the parties to file posthearing reply briefs.

§ 156.953 ALJ decision.

The ALJ will issue an initial agency decision based only on the record and on applicable law; the decision will contain findings of fact and conclusions of law. The ALJ's decision is final and appealable after 30 days unless it is modified or vacated under § 156.957.

§ 156.955 Sanctions.

(a) The ALJ may sanction a party or an attorney for failing to comply with an order or other directive or with a requirement of a regulation, for abandonment of a case, or for other actions that interfere with the speedy, orderly or fair conduct of the hearing. Any sanction that is imposed will relate reasonably to the severity and nature of the failure or action.

(b) A sanction may include any of the following actions:

(1) In the case of failure or refusal to provide or permit discovery, drawing negative fact inferences or treating such failure or refusal as an admission by deeming the matter, or certain facts, to be established.

(2) Prohibiting a party from introducing certain evidence or otherwise advocating a particular claim or defense.

(3) Striking pleadings, in whole or in part.

(4) Staying the case.

(5) Dismissing the case.

(6) Entering a decision by default.

(7) Refusing to consider any motion or other document that is not filed in a timely manner.

(8) Taking other appropriate action.

§ 156.957 Review by Administrator.

(a) The Administrator of CMS (which for purposes of this section may include his or her delegate), at his or her discretion, may review in whole or in part any initial agency decision issued under § 156.953.

(b) The Administrator may decide to review an initial agency decision if it appears from a preliminary review of the decision (or from a preliminary review of the record on which the initial agency decision was based, if available at the time) that:

(1) The ALJ made an erroneous interpretation of law or regulation.

(2) The initial agency decision is not supported by substantial evidence.

(3) The ALJ has incorrectly assumed or denied jurisdiction or extended his or her authority to a degree not provided for by statute or regulation.

(4) The ALJ decision requires clarification, amplification, or an alternative legal basis for the decision.

(5) The ALJ decision otherwise requires modification, reversal, or remand.

(c) Within 30 days of the date of the initial agency decision, the Administrator will mail a notice advising the respondent of any intent to review the decision in whole or in part.

(d) Within 30 days of receipt of a notice that the Administrator intends to review an initial agency decision, the respondent may submit, in writing, to the Administrator any arguments in support of, or exceptions to, the initial agency decision.

(e) This submission of the information indicated in paragraph (d) of this section must be limited to issues the Administrator has identified in his or her notice of intent to review, if the Administrator has given notice of an intent to review the initial agency decision only in part. A copy of this submission must be sent to the other party.

(f) After receipt of any submissions made pursuant to paragraph (d) of this section and any additional submissions for which the Administrator may provide, the Administrator will affirm, reverse, modify, or remand the initial agency decision. The Administrator will mail a copy of his or her decision to the respondent.

(g) The Administrator's decision will be based on the record on which the initial agency decision was based (as forwarded by the ALJ to the Administrator) and any materials submitted pursuant to paragraphs (b), (d), and (f) of this section.

(h) The Administrator's decision may rely on decisions of any courts and other applicable law, whether or not cited in the initial agency decision.

§ 156.959 Judicial review.

(a) *Filing of an action for review.* Any responsible entity against whom a final order imposing a civil money penalty or decertification of a QHP is entered may obtain review in the United States District Court for any district in which the entity is located or in the United States District Court for the District of Columbia by doing the following:

(1) Filing a notice of appeal in that court within 30 days from the date of a final order.

(2) Simultaneously sending a copy of the notice of appeal by registered mail to HHS.

(b) *Certification of administrative record.* HHS promptly certifies and files with the court the record upon which the penalty was assessed.

(c) *Standard of review.* The findings of HHS and the ALJ may not be set aside unless they are found to be unsupported by substantial evidence, as provided by 5 U.S.C. 706(2)(E).

§ 156.961 Failure to pay assessment.

If any entity fails to pay an assessment after it becomes a final order, or after the court has entered final judgment in favor of CMS, CMS refers the matter to the Attorney General, who brings an action against the entity in the appropriate United States district court to recover the amount assessed.

§ 156.963 Final order not subject to review.

In an action brought under § 156.961, the validity and appropriateness of the final order imposing a civil money penalty is not subject to review.

■ 41. Subpart L is added to read as follows:

Subpart L—Quality Standards**§ 156.1105 Establishment of standards for HHS-approved enrollee satisfaction survey vendors for use by QHP issuers in Exchanges.**

(a) *Application for approval.* An enrollee satisfaction survey vendor must be approved by HHS, in a form and manner to be determined by HHS, to administer, on behalf of a QHP issuer, enrollee satisfaction surveys to QHP enrollees. HHS will approve enrollee satisfaction survey vendors on an annual basis, and each enrollee satisfaction survey vendor must submit an application for each year that approval is sought.

(b) *Standards.* To be approved by HHS, an enrollee satisfaction survey vendor must meet each of the following standards:

(1) Sign and submit an application form for approval in accordance with paragraph (a) of this section;

(2) Ensure, on an annual basis, that appropriate staff participate in enrollee satisfaction survey vendor training and successfully complete a post-training certification exercise as established by HHS;

(3) Ensure the accuracy of their data collection, calculation and submission processes and attest to HHS the veracity of the data and these processes;

(4) Sign and execute a standard HHS data use agreement, in a form and manner to be determined by HHS, that establishes protocols related to the disclosure, use, and reuse of HHS data;

(5) Adhere to the enrollee satisfaction survey protocols and technical specifications in a manner and form required by HHS;

(6) Develop and submit to HHS a quality assurance plan and any supporting documentation as determined to be relevant by HHS. The plan must describe in adequate detail the implementation of and compliance with all required protocols and technical specifications described in paragraph (b)(5) of this section;

(7) Adhere to privacy and security standards established and implemented under § 155.260 of this subchapter by the Exchange with which they are associated;

(8) Comply with all applicable State and Federal laws;

(9) Become a registered user of the enrollee satisfaction survey data warehouse to submit files to HHS on behalf of its authorized QHP contracts;

(10) Participate in and cooperate with HHS oversight for quality-related activities, including, but not limited to: review of the enrollee satisfaction survey vendor's quality assurance plan and other supporting documentation; analysis of the vendor's submitted data and sampling procedures; and site visits and conference calls; and,

(11) Comply with minimum business criteria as established by HHS.

(c) *Approved list.* A list of approved enrollee satisfaction survey vendors will be published on an HHS Web site.

■ 42. Section 156.1210 is added to subpart M to read as follows:

§ 156.1210 Confirmation of HHS payment and collections reports.

(a) *Responses to reports.* Within 15 calendar days of the date of a payment and collections report from HHS, the issuer must, in a format specified by HHS, either:

(1) Confirm to HHS that the amounts identified in the payment and collections report for the timeframe specified in the report accurately reflect applicable payments owed by the issuer to the Federal government and the payments owed to the issuer by the Federal government; or

(2) Describe to HHS any inaccuracy it identifies in the payment and collections report.

(b) *Late discovery of a discrepancy.* If an issuer reports a discrepancy in a payment and collections report later than 15 calendar days after the date of the report, HHS will work with the issuer to resolve the discrepancy as long as the late reporting was not due to misconduct on the part of the issuer.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 27, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Dated: Approved: October 18, 2013

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

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