

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

[CMS-9954-F]

RIN 0938-AR89

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2015**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Final rule.

SUMMARY: This final rule sets forth payment parameters and oversight provisions related to the risk adjustment, reinsurance, and risk corridors programs; cost sharing parameters and cost-sharing reductions; and user fees for Federally-facilitated Exchanges. It also provides additional standards with respect to composite premiums, privacy and security of personally identifiable information, the annual open enrollment period for 2015, the actuarial value calculator, the annual limitation in cost sharing for stand-alone dental plans, the meaningful difference standard for qualified health plans offered through a Federally-facilitated Exchange, patient safety standards for issuers of qualified health plans, and the Small Business Health Options Program.

DATES: These regulations are effective on May 12, 2014.

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Acronyms

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

AV Actuarial Value

CFR Code of Federal Regulations

CMS Centers for Medicare & Medicaid Services

EHB Essential Health Benefits

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

FFE Federally-facilitated Exchange

FF–SHOP Federally-facilitated Small Business Health Options Program

FPL Federal poverty level

HCC Hierarchical condition category

HHS United States Department of Health and Human Services

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

IRS Internal Revenue Service

MLR Medical Loss Ratio

OMB Office of Management and Budget

OPM United States Office of Personnel Management

PHS Act Public Health Service Act

PII Personally identifiable information

PSO Patient Safety Organization

PRA Paperwork Reduction Act of 1995

PSES Patient safety evaluation system

QHP Qualified health plan

SADP Stand-alone Dental Plan

SHOP Small Business Health Options Program

The Code Internal Revenue Code of 1986

TPA Third party administrator

I. Executive Summary

Qualified individuals and qualified employers are now able to purchase private health insurance coverage through competitive marketplaces called Affordable Insurance Exchanges, or “Exchanges” (also called Health Insurance Marketplaces, or “Marketplaces”).¹ Individuals who enroll in qualified health plans (QHPs) through individual market Exchanges may be eligible to receive premium tax credits to make health insurance more affordable and reductions in cost-sharing payments to reduce out-of-pocket expenses for health care services. In 2014, HHS began operationalizing the premium stabilization programs established by the Affordable Care Act. These programs—the risk adjustment, reinsurance, and risk corridors programs—are intended to mitigate the potential impact of adverse selection and stabilize the price of health insurance in the individual and small

group markets. We believe that these programs, together with other reforms of the Affordable Care Act, will make high-quality health insurance affordable and accessible to millions of Americans.

HHS has previously outlined the major provisions and parameters related to the advance payments of the premium tax credit, cost-sharing reductions, and premium stabilization programs. This rule finalizes additional provisions related to the implementation of these programs, including certain oversight provisions for the premium stabilization programs, as well as key payment parameters for the 2015 benefit year.

The HHS Notice of Benefit and Payment Parameters for 2014 final rule (78 FR 15410) (2014 Payment Notice) finalized the risk adjustment methodology that HHS will use when it operates risk adjustment on behalf of a State. This final rule establishes updates to the risk adjustment methodology for 2014 to account for certain private market Medicaid expansion alternative plans. It also establishes the counting methods for determining small group size for participation in the risk adjustment and risk corridors programs.

Using the methodology set forth in the 2014 Payment Notice, we establish a 2015 uniform reinsurance contribution rate of \$44 annually per capita, and the 2015 uniform reinsurance payment parameters—a \$70,000 attachment point, a \$250,000 reinsurance cap, and a 50 percent coinsurance rate. We are also finalizing our proposal to decrease the attachment point for 2014 from \$60,000 to \$45,000. Additionally, in order to maximize the financial effect of the transitional reinsurance program, we provide that if reinsurance contributions collected for a benefit year exceed total requests for reinsurance payments for the benefit year, we will increase the coinsurance rate on our reinsurance payments for that benefit year up to 100 percent, rolling over any remaining funds for use as reinsurance payments for the subsequent benefit year.

We also finalize several provisions related to cost sharing. First, we establish a methodology, with certain modifications described below, for estimating average per capita premium and for calculating the premium adjustment percentage for 2015, which is used to set the rate of increase for several parameters detailed in the Affordable Care Act, including the maximum annual limitation on cost sharing and the maximum annual limitation on deductibles for health plans in the small group market for 2015. We are establishing the reduced maximum annual limitations on cost

sharing for the 2015 benefit year for cost-sharing reduction plan variations. We are relaxing the requirement that a QHP and its plan variations have the same out-of-pocket spending for non-EHBs. We are finalizing our proposal to modify the methodology for calculating advance payments for cost-sharing reductions for the 2015 benefit year. We are also finalizing parameters for updating the AV Calculator.

For 2015, we are finalizing the FFE user fee rate of 3.5 percent of premium. Additionally, with respect to the FFE user fee adjustment set forth under the Coverage of Certain Preventive Services Under the Affordable Care Act final rule, published in the July 2, 2013 **Federal Register** (78 FR 39870) (Preventive Services Rule), we are finalizing an allowance for administrative costs and margin associated with the payment for contraceptive services. We are also finalizing proposed modifications to the risk corridors program for the 2014 benefit year.

The success of the premium stabilization programs depends on a robust oversight program. This final rule expands on the provisions of the Premium Stabilization Rule (77 FR 17220), the 2014 Payment Notice (78 FR 15410), and the first and second final Program Integrity Rules (78 FR 54070 and 78 FR 65046). We are finalizing HHS’s authority to audit State-operated reinsurance programs, contributing entities, and issuers of risk adjustment covered plans and reinsurance eligible plans. We also finalize participation standards for the risk corridors program, and outline a process for validating risk corridors data submissions and enforcing compliance with the provisions of the risk corridors program.

We also finalize several aspects of our methodology for the HHS-operated risk adjustment data validation process. On June 22, 2013, we issued “The Affordable Care Act HHS-operated Risk Adjustment Data Validation Process White Paper”² and on June 25, 2013, we held a public meeting to discuss how to best ensure the accuracy and consistency of the data we will use when operating the risk adjustment program on behalf of a State. In this final rule, we establish certain standards for risk adjustment data validation, including a sampling methodology for the initial validation audit and detailed audit standards. These standards will be used and evaluated for 2 years before

¹ The word “Exchanges” refers to both State Exchanges, also called State-based Exchanges, and Federally-facilitated Exchanges (FFEs). In this rule, we use the terms “State Exchange” or “FFE” when we are referring to a particular type of Exchange. When we refer to “FFEs,” we are also referring to State Partnership Exchanges, which are a form of FFE.

² Available at: https://www.regtap.info/uploads/library/ACA_HHS_OperatedRADVWhitePaper_062213_5CR_062213.pdf.

they are used as a basis for payment adjustments.

This rule also includes a reduction in the time period for which a State electing to operate an Exchange after 2014 must have in effect an approved, or conditionally approved, Exchange Blueprint and operational readiness assessment from at least 12 months to 6.5 months prior to the Exchange's first effective date of coverage. We also finalize certain provisions related to the privacy and security of personally identifiable information (PII) in the Exchange, the Exchange annual open enrollment period for 2015, the annual limitation on cost sharing for stand-alone dental plans, the meaningful difference standards for QHPs offered through an FFE, the SHOP, patient safety standards for QHP issuers, and composite premiums in the small group market.

II. Background

A. Legislative and Regulatory Overview

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

Section 1201 of the Affordable Care Act added section 2701 of the Public Health Service Act (PHS Act) regarding fair health insurance premiums. Section 2701(a)(1) limits the variation in premium rates charged by a health insurance issuer for non-grandfathered health insurance coverage (including QHPs) in the individual or small group market to four factors: Family size; rating area; age; and tobacco use. Section 2701(a)(4) of the PHS Act requires that any family premium using age or tobacco rating may only apply those rates to the portion of the premium that is attributable to each family member.

Section 1302 of the Affordable Care Act directs the Secretary of Health and Human Services (referred to throughout this rule as the Secretary) to define essential health benefits (EHBs) and provides for cost-sharing limits and actuarial value (AV) requirements. Section 1302(d) of the Affordable Care Act describes the various levels of coverage based on AV. Consistent with section 1302(d)(2)(A) of the Affordable Care Act, AV is calculated based on the provision of EHB to a standard population. Section 1302(d)(3) of the Affordable Care Act directs the

Secretary to develop guidelines that allow for *de minimis* variation in AV calculations.

Section 1311(b)(1)(B) of the Affordable Care Act directs that the SHOP assist qualified small employers in facilitating the enrollment of their employees in QHPs offered in the small group market. Under section 1312(f)(2)(B) of the Affordable Care Act, beginning in 2017, States will have the option to allow issuers to offer QHPs in the large group market through the SHOP.³

Section 1311(c)(6)(B) of the Affordable Care Act states that the Secretary is to set annual open enrollment periods for Exchanges for calendar years after the initial enrollment period.

Section 1311(h)(1) of the Affordable Care Act specifies that a QHP may contract with health care providers and hospitals with more than 50 beds only if they meet certain patient safety standards. For hospitals with more than 50 beds, this includes the use of a patient safety evaluation system and a comprehensive hospital discharge program. Section 1311(h)(2) of the Affordable Care Act also provides the Secretary flexibility to establish reasonable exceptions to these patient safety requirements, and section 1311(h)(3) of the Affordable Care Act allows the Secretary flexibility to issue regulations to modify the number of beds described in section 1311(h)(1)(A) of the Affordable Care Act.

Sections 1313 and 1321 of the Affordable Care Act provide the Secretary with the authority to oversee the financial integrity of State Exchanges, their compliance with HHS standards, and the efficient and non-discriminatory administration of State Exchange activities. Section 1321(a) of the Affordable Care Act provides general authority for the Secretary to establish standards and regulations to implement the statutory requirements related to Exchanges, QHPs, and other components of Title I of the Affordable Care Act.

When operating an FFE under section 1321(c)(1) of the Affordable Care Act, HHS has the authority under sections 1321(c)(1) and 1311(d)(5)(A) of the Affordable Care Act to collect and spend user fees. In addition, 31 U.S.C. 9701 permits a Federal agency to establish a charge for a service provided by the agency. Office of Management and

Budget (OMB) Circular A-25 Revised establishes Federal policy regarding user fees and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public.

Section 1341 of the Affordable Care Act requires the establishment of a transitional reinsurance program in each State to help pay the cost of treating high-cost enrollees in the individual market from 2014 through 2016. Section 1342 of the Affordable Care Act directs the Secretary to establish a temporary risk corridors program that provides for the sharing in gains or losses resulting from inaccurate rate setting from 2014 through 2016 between the Federal government and certain participating health plans. Section 1343 of the Affordable Care Act establishes a permanent risk adjustment program that is intended to provide increased payments to health insurance issuers that attract higher-risk populations, such as those with chronic conditions, and thereby reduce incentives for issuers to avoid higher-risk enrollees. Sections 1402 and 1412 of the Affordable Care Act establish a program for reducing cost sharing for qualified individuals with lower household income and Indians.

Section 1411(g) of the Affordable Care Act requires that any person who receives information specified in section 1411(b) from an applicant or information specified in section 1411(c), (d), or (e) from a Federal agency must use the information only for the purpose of and to the extent necessary to ensure the efficient operation of the Exchange, and may not disclose the information to any other person except as provided in that section. Section 6103(l)(21)(C) of the Code additionally provides that return information disclosed under section 6103(l)(21)(A) or (B) may be used only for the purpose of and to the extent necessary in establishing eligibility for participation in the Exchange, verifying the appropriate amount of any premium tax credit or cost-sharing reduction, or determining eligibility for participation in a health insurance affordability program as described in that section.

Section 1560(c) of the Affordable Care Act provides that nothing in title I of the Affordable Care Act (or an amendment made by Title I of the Affordable Care Act) shall be construed to prohibit an institution of higher education (as such term is defined for purposes of the Higher Education Act of 1965) from offering a student health insurance plan, to the extent that such requirement is

³ If a State elects this option, the rating rules in section 2701 of the PHS Act and its implementing regulations will apply to all coverage offered in such State's large group market (except for self-insured group health plans) pursuant to section 2701(a)(5) of the PHS Act.

otherwise permitted under applicable Federal, State or local law.

1. Premium Stabilization Programs

In the July 15, 2011 **Federal Register** (76 FR 41930), we published a proposed rule outlining the premium stabilization programs. We implemented the premium stabilization programs in a final rule, published in the March 23, 2012 **Federal Register** (77 FR 17220) (Premium Stabilization Rule). In the December 7, 2012 **Federal Register** (77 FR 73118) (proposed 2014 Payment Notice), we published a proposed rule outlining the benefit and payment parameters for the 2014 benefit year to expand the provisions related to the premium stabilization programs and set forth payment parameters in those programs. We published the final rule in the March 11, 2013 **Federal Register** (78 FR 153410) (2014 Payment Notice).

As discussed above, we published a white paper on risk adjustment data validation on June 22, 2013, and hosted a public meeting on June 25, 2013, to discuss the white paper.

2. Program Integrity

In the June 19, 2013 **Federal Register** (78 FR 37032), we published a proposed rule that proposed certain program integrity standards related to Exchanges and the premium stabilization programs (proposed Program Integrity Rule). The provisions of that proposed rule were finalized in two rules, the “first final Program Integrity Rule” published in the August 30, 2013 **Federal Register** (78 FR 54070) and the “second final Program Integrity Rule” published in the October 30, 2013 **Federal Register** (78 FR 65046).

3. Exchanges, Essential Health Benefits, Actuarial Value

A proposed rule relating to EHBs and AV was published in the November 26, 2012 **Federal Register** (77 FR 70644). We finalized standards related to the premium adjustment percentage and AV in the Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation Final Rule, published in the February 25, 2013 **Federal Register** (78 FR 12834) (EHB Rule). We established standards for the administration and payment of cost-sharing reductions and the SHOP in the 2014 Payment Notice and in the Amendments to the HHS Notice of Benefit and Payment Parameters for 2014 interim final rule, published in the March 11, 2013 **Federal Register** (78 FR 15541). The provisions established in the interim final rule were finalized in the second final Program Integrity Rule.

We established standards related to Exchange user fees in the 2014 Payment Notice. We also established an adjustment to the FFE user fee in the Preventive Services Rule.

A Request for Comment relating to Exchanges was published in the August 3, 2010 **Federal Register** (75 FR 45584). An Initial Guidance to States on Exchanges was issued on November 18, 2010. A proposed rule was published in the July 15, 2011 **Federal Register** (76 FR 41866) to implement components of the Exchange. A proposed rule regarding Exchange functions in the individual market, eligibility determinations, and Exchange standards for employers was published in the August 17, 2011 **Federal Register** (76 FR 51202). A final rule implementing components of the Exchanges and setting forth standards for eligibility for Exchanges was published in the March 27, 2012 **Federal Register** (77 FR 18310) (Exchange Establishment Rule).

4. Market Rules

We published a proposed rule relating to the 2014 market reforms in the November 26, 2012 **Federal Register** (77 FR 70584), and a final rule implementing these provisions in the February 27, 2013 **Federal Register** (78 FR 13406) (Market Reform Rule).

5. Medical Loss Ratio

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

B. Stakeholder Consultation and Input

In addition to seeking advice from the public on risk adjustment data validation, HHS has consulted with stakeholders on policies related to the operation of Exchanges, including the SHOP and the premium stabilization programs. HHS has held a number of listening sessions with consumers, providers, employers, health plans, the actuarial community, and State representatives to gather public input. HHS consulted with stakeholders through regular meetings with the National Association of Insurance Commissioners, regular contact with States through the Exchange Establishment grant and Exchange Blueprint approval processes, and meetings with Tribal leaders and representatives, health insurance

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

C. Intended Future Rulemaking

Some of the public input suggested changes for 2015 that require additional rulemaking. In the interest of transparency, we describe here the potential policies that we intend to include in such future rulemaking for public comment.

Eligibility & Enrollment: We intend to propose in future rulemaking a limited number of revisions to our rules on eligibility, enrollment, and eligibility appeals. For example, we intend to propose that an appeals entity be required to dismiss an appeal if the employer or employee withdraws the request in writing or by telephone. In future rulemaking, we also intend to propose that an Exchange may establish one or more standard processes for prorating premiums for partial month enrollment, and that the FFE will establish one consistent with the methodology finalized in this rule for the FF-SHOPS.

Index of Premium Growth and Income Growth: To implement section 5000A(e)(1)(D) of the Code, we intend to propose a methodology for determining the excess of the rate of premium growth over the rate of income growth for years after 2014. We are also considering modifying our rounding rules to always round certain cost-sharing parameters down to the next lower multiple of \$50.

Plan Management: In future rulemaking, we intend to propose technical amendments to standards for issuing civil money penalties against QHP issuers and for decertifying QHPs, as currently set forth in 45 CFR 156.805 and 156.810.

Plan Changes: We intend to outline in future guidance the distinction between when a plan is being modified and when it is being terminated for purposes of plan renewal. For example, if an issuer makes changes to a plan that cause it to be in a different metal level, it would in fact be considered to be a new plan. We also intend to propose that issuers utilize standard notices in a format designated by the Secretary when discontinuing a product.

HIPAA Opt-Out for Self-Funded, Non-Federal Governmental Plans: Prior to enactment of the Affordable Care Act, sponsors of self-funded, non-Federal governmental plans were permitted to elect to exempt those plans from certain provisions of title XXVII of the PHS Act. We intend to propose amendments to

the non-Federal governmental plan regulations (45 CFR 146.180) to reflect the amendments made by the Affordable Care Act to these provisions, consistent with previously released guidance.⁴

Fixed Indemnity Insurance in the Individual Market: As indicated in previously released guidance, we intend to propose to amend the criteria for fixed indemnity insurance to be treated as an excepted benefit in the individual health insurance market.⁵

Minimum Essential Coverage: On October 31, 2013, we published guidance indicating that certain types of foreign group coverage are recognized as minimum essential coverage.⁶ We intend to propose amendments to in future rulemaking that would codify the treatment of foreign group coverage as described in the October 31, 2013 guidance. We also intend to clarify that entities other than plan sponsors (for example, issuers) can apply for their coverage to be recognized as minimum essential coverage, pursuant to the process outlined in 45 CFR 156.604 and guidance thereunder.⁷

Navigator, Non-Navigator Assistance Personnel, and Certified Application Counselor Program Standards: We also intend to specify in future rulemaking certain types of State laws applicable to Navigators, non-Navigator assistance personnel, and certified application counselors that HHS would consider to prevent the application of the provisions of title I of the Affordable Care Act. We intend to propose through future rulemaking to update the standards applicable to Navigators and non-Navigator assistance personnel. In addition, we intend to propose standards specific to certified application counselors and certified application counselor designated organizations that would prohibit them

from receiving consideration, directly or indirectly, from health insurance issuers or stop loss insurance issuers in connection with the enrollment of consumers in QHPs or non-QHPs, and that would require certified application counselors to be recertified on at least an annual basis. We further intend to propose that, in specific circumstances, certified application counselor designated organizations may serve targeted populations without violating the broad non-discrimination requirement related to Exchange functions.

Civil Money Penalties for Consumer Assistance Entities: In future rulemaking, we intend to propose that HHS may impose civil money penalties against Navigators, non-Navigator assistance personnel, certified application counselor designated organizations, and certified application counselors in Federally-facilitated and State Partnership Exchanges, if these entities or individuals violate Federal requirements.

Quality: In future rulemaking, we intend to propose quality reporting requirements for Exchanges and QHP issuers, including standards related to the implementation of the quality rating system (QRS), enrollee satisfaction survey (ESS), and a monitoring and appeals process for survey vendors. We intend to propose a beta testing period of the QRS and ESS in 2015 to provide early feedback to Exchanges and QHP issuers and begin public reporting of quality rating information in 2016.

Risk Corridors: In response to our proposed adjustments to the risk corridors program to account for the transitional policy, we received comments urging us to raise the ceiling on allowable administrative costs for QHP issuers in all States. We are carefully analyzing it to consider proposing for the 2015 benefit year, considering its policy and budgetary implications, and would consider making corresponding changes to the risk corridors profit floor and to the MLR regulations at that time. We would implement this policy up to the point of budget neutrality, and may make downward adjustments to parameters if necessary.

SHOP: In future rulemaking, we intend to propose amendments to align the dates for the annual election periods for qualified employers in all SHOPS with the start of open enrollment in the corresponding individual market Exchange for the 2015 benefit year. We also plan to propose to remove the required minimum lengths of both the employer election period and the employee open enrollment period to

provide additional flexibility to SHOPS and qualified employers, which would permit SHOPS to complete the entire election and enrollment processes in fewer than 45 days.

We are considering proposing through future rulemaking specific circumstances under which States could recommend that a SHOP modify the employee choice provision in 2015 if doing so would preserve and promote affordable insurance for employees and small businesses.

Medical Loss Ratio: We intend to propose several amendments to the MLR regulations (45 CFR Part 158). We intend to propose standardized methodologies to take into account the special circumstances of issuers associated with the initial open enrollment and other changes to the market in 2014, including incurred costs due to technical problems during the launch of the State and Federal Exchanges. We also intend to propose amendments that would improve the consistency of MLR and rebate calculations in States that require the individual and small group markets to be merged. In addition, we intend to propose an extension to the period during which issuers may include ICD-10 conversion costs in the MLR numerator and a clarification to the rules for distribution of *de minimis* rebates.

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

A proposed rule, titled “Patient Protection and Affordable Care Act: HHS Notice of Benefit and Payment Parameters for 2015” was published in the December 2, 2013 **Federal Register** (78 FR 72322) with a comment period ending on December 26, 2013. In total, we received 129 comments from various stakeholders, including States, health insurance issuers, consumer groups, labor entities, industry groups, provider groups, patient safety groups, national interest groups, and other stakeholders. The comments ranged from general support or opposition to the proposed provisions to very specific questions or comments regarding proposed changes. We received a number of comments and suggestions that were outside the scope of the proposed rule and therefore will not be addressed in this final rule.

Another proposed rule, entitled “Patient Protection and Affordable Care Act; Program Integrity: Exchange, SHOP, and Eligibility Appeals” (78 FR 37032), was published in the **Federal Register** on June 19, 2013 with a comment period ending on July 19, 2013. We received a total of 99

⁴ Amendments to the HIPAA opt-out provision (formerly section 2721(b)(2) of the Public Health Service Act) made by the Affordable Care Act (September 21, 2010). Available at: http://www.cms.gov/CCIIO/Resources/Files/Downloads/opt_out_memo.pdf.

⁵ FAQs about Affordable Care Act Implementation (Part XVIII) and Mental Health Parity Implementation, Q11 (January 9, 2014). Available at: http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs18.html and <http://www.dol.gov/ebsa/faqs/faq-aca18.html>.

⁶ See CCIIO Sub-Regulatory Guidance: Process for Obtaining Recognition as Minimum Essential Coverage (October 31, 2013). Available at: <http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/mec-guidance-10-31-2013.pdf>.

⁷ See CCIIO Sub-Regulatory Guidance: Process for Obtaining Recognition as Minimum Essential Coverage (October 31, 2013). Available at: <http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/mec-guidance-10-31-2013.pdf>.

comments from various stakeholders, including States, health insurance issuers, consumer groups, agents and brokers, provider groups, Members of Congress, individuals, Tribal organizations, and other stakeholders. In this final rule, we are only finalizing from that proposed rule provisions related to standards for the SHOP to require all QHP issuers to make any change to rates at a uniform time.⁸ In this final rule, we are finalizing language proposed at § 155.705(b)(6)(ii) at § 155.705(b)(6)(i)(A) instead of at (b)(6)(ii), to make clear that we never intended for this proposal to supersede the language at current § 155.705(b)(6)(ii), and are making a minor change to replace the word FF-SHOP with the term “Federally-facilitated SHOP.”

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the provisions we are finalizing. We note that nothing in these regulations limits the authority of the Office of the Inspector General (OIG) as set forth by the Inspector General Act of 1978 or other applicable law.

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

Response: While we are sympathetic to these concerns, we received numerous detailed, substantive submissions on the contents of the rule. Additionally, the timeline for publication of this final rule accommodates issuer deadlines applicable for the 2015 benefit year.

A. Part 144—Requirements Relating to Health Insurance Coverage

In 45 CFR 144.103, we proposed to amend the definition of “policy year” for student health insurance coverage to mean generally the 12-month period that is designated as the policy year in the policy documents of the student health insurance coverage (rather than a calendar year). This amendment takes into account that student health insurance coverage is traditionally offered on an academic year basis with a policy year other than the calendar year. It is also consistent with our proposal in § 147.145 to exempt student health insurance coverage, a type of individual coverage, from certain calendar year requirements that apply to individual health insurance coverage.

⁸ Other provisions of that proposed rule were finalized in two rules, the “first final Program Integrity Rule” published in the August 30, 2013 *Federal Register* (78 FR 54070) and the “second final Program Integrity Rule” published in the October 30, 2013 *Federal Register* (78 FR 65046).

We received comments supporting this proposal. We are finalizing the amendment to the definition of “policy year” with the following minor modification. We remove the word “individual” from the reference to “individual health insurance coverage” so that the terminology is appropriate for both grandfathered individual market and student health insurance coverage. Accordingly, the definition of “policy year” with respect to grandfathered individual health insurance coverage and student health insurance coverage generally now reads as “the 12-month period that is designated as the policy year in the policy documents of the health insurance coverage.”

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

1. Composite Premiums

Section 2701(a)(1) of the PHS Act restricts the variation in premium rating for a particular plan or coverage to four factors: family size, geography, age, and tobacco use (within limits). Section 2701(a)(4) of the PHS Act further requires that any rating variation for age and tobacco use must be applied based on the portion of the premium attributable to each family member covered under a group health plan or health insurance coverage. These rules generally apply to health insurance issuers offering non-grandfathered individual market and small group market coverage, both through and outside an Exchange, for plan or policy years beginning on or after January 1, 2014.⁹

Consistent with the rating rules of section 2701 of the PHS Act, we established in 45 CFR 147.102(c) of the Market Reform Rule that the total premium charged by an issuer to a group health plan (in the small group market) or family (in the individual market) is generally determined by summing the premiums of each individual enrolled in the plan or coverage based on their age and tobacco use. This rating practice is known as per-member rating (also referred to as “list billing”).

In the small group market, section 2701 of the PHS Act regulates the premium “rate” that may be charged by an issuer for a group health plan based on the age and tobacco use of each

⁹ Section 2701(a)(5) of the PHS Act provides that if a State exercises the option of offering large group market QHPs in the SHOP, the rating rules in section 2701 that apply to the small group market will also apply to all coverage offered in that State’s large group market, except for self-insured group health plans.

enrollee; however the statute does not preclude the possibility that the group could be charged an amount for enrollees based on the average premium per member of the group, rather than their own specific per-member amount. We codified this interpretation in § 147.102(c)(3) of the Market Reform rule, which provides that nothing prevents an issuer in the small group market from dividing the total group premium by the total number of enrollees covered under the plan to develop an average premium amount per enrollee. The preamble to the proposed rule referred to this practice as “composite rating.” However, to avoid unintended confusion with the traditional industry use of that term, we use only the terms “composite premiums” or “average enrollee premium amounts” when referring to average per-enrollee premium amounts in this final rule.¹⁰ An issuer may offer composite premiums in connection with a small group health plan as long as the total group premium calculated at the time of applicable enrollment at the beginning of the plan year equals the amount that is derived from per-member rating.¹¹

In the proposed rule, we proposed to amend § 147.102(c)(3) to specify that if an issuer offers a composite premium in connection with a group health plan in the small group market, the composite premium that was calculated based on applicable enrollment at the beginning of the plan year cannot vary during the plan year. For example, if a new hire enrolls in the plan in the middle of the plan year, the issuer would not adjust the average enrollee premium amount

¹⁰ The term “composite rating” has historically referred to an issuer rating practice that used the rating characteristics of a group as a whole—average employee health risk, average employee age, group size, and industrial code, among others—to determine an average rate per employee and corresponding average rates for different coverage tiers (for example, employee only, employee plus spouse, employee plus one or more children, and family coverage). This rating practice is no longer permitted under section 2701 of the PHS Act.

¹¹ Under 45 CFR 147.102(c)(2), States that do not permit rating for age or tobacco use may require health insurance issuers in the individual and small group markets to use uniform family tiers and corresponding multipliers established by the State. In States that elect this approach, a small group market issuer may offer composite premiums in connection with a group health plan, as long as the total group premium equals the amount that is derived from family-tier rating. For ease of reference, we do not discuss this alternative each time we refer to a total group premium equaling the sum of per-member premiums. However, we note that references in this preamble to the total group premium equaling the sum of per-member premiums also include references to the total group premium equaling the sum of family-tier premiums in States with community rating that have established uniform family tiers.

for the group based on the addition of the new enrollee. Rather, the amount that would be charged to the group for the new hire would be the same average enrollee premium amount that was established at the beginning of the plan year, and that amount would be added to the total group premium. The issuer would recalculate the average enrollee premium amount for the group only upon renewal.

We proposed this policy to ensure that composite premiums for small group coverage—and thus employer contributions to coverage—could remain stable during the plan year even if the composition of the group changes (for example, due to employees adding or dropping coverage). Additionally, we indicated that we were considering establishing a “tiered-composite” premium structure under which a separate composite premium could be calculated for different tiers or categories of enrollees covered under a group health plan (such as employees, adult dependents, and child dependents). We described several possible alternatives for implementing tiered-composite premiums and sought comment on whether and how to establish such approach.

We are finalizing our composite premium proposals with the addition of a tiered-composite premium structure based on one of the alternatives discussed in the preamble to the proposed rule. Specifically, we provide that a composite premium charged to a small group health plan must be based on enrollment of “participants and beneficiaries” at the beginning of the plan year, and may not vary until renewal. We also provide that any rating for tobacco use cannot be included in the composite premium for all enrollees but instead must be applied on a per-member basis. Finally, we specify that an issuer offering composite premiums with respect to a particular product offered in the small group market in a State must do so uniformly for all group health plans enrolling in that product, giving those group health plans the option to pay premiums based on a composite premium methodology (to the extent permitted by applicable State law and except as provided in § 156.285(a)(4) of this final rule when employee choice is offered in the FF–SHOPS).

Comment: In response to the composite premium proposals, we received a few comments that suggested some concern and confusion that per-member rating would no longer be required.

Response: We have not changed the basic per-member rating requirement

under section 2701 of the PHS Act, or the policy that in the small group market, an issuer may convert a group’s per-member premiums into average enrollee premium amounts as long as the total premium owed by the plan to the issuer is the same total produced by per-member rating. The proposed rule and this final rule simply provide clarity about when the per-member rating requirement is satisfied. Specifically, we recognize that, where an issuer offers a composite premium in connection with a group health plan, requiring strict adherence to a per-member buildup at all times throughout the plan year may impose undue administrative burden on issuers and create premium instability for employers and employees. Given that the statute can reasonably be read to support either interpretation, we are finalizing amendments to § 147.102(c)(3) which make clear that the requirement that the sum of composite premiums must equal the sum of per-member premiums is determined at the time of applicable enrollment at the beginning of the plan year.

Comment: Some commenters urged HHS to make compositing premiums mandatory for all small group market issuers. Other commenters emphasized that the decision to offer composite premiums should continue to be voluntary at the option of the issuer (or as required by applicable State law). One commenter noted that issuers historically have offered composite rates to some group health plans but not others (for example, groups with more than ten employees) and requested clarification of whether this practice could continue.

Response: This final rule neither requires nor prohibits the compositing of premiums in connection with a small group health plan (except with respect to employee choice in the FF–SHOPS as discussed below). This decision is within the discretion of the issuer unless applicable State law requires composite premiums. However, in response to comments, we are clarifying that if an issuer elects to offer composite premiums with respect to a particular product offered in the small group market in a State, the issuer cannot do so for only certain group health plans; the issuer must make the option to composite premiums uniformly available to all group health plans enrolling in that product, to the extent permitted by applicable State law and subject to § 156.285(a)(4) of this final rule (prohibiting QHP issuers from offering composite premiums when employers offer employee choice in the

FF–SHOPS). Plan sponsors selecting a product that offers composite premiums may then decide whether to pay premiums based on a per-member or composite premium methodology. This does not affect what portion of the group premium will be paid by the employer or the employee.¹²

Comment: One commenter stated that requiring issuers to accept a premium based on a group’s composite premium at the beginning of the plan year as the standard rate for the entire plan year could affect the premium charged to the group health plan.

Response: Depending on whether a new enrollee added to the plan mid-year is above or below the average age of the group, the composite premium might be higher or lower than the per-member premium that would otherwise be charged for that individual. Consequently, the total group premium would at that point no longer precisely equal the sum of the per-member premiums for each enrollee until the next renewal. Although this policy may thus create some variation from the result that would be produced by calculating premiums based on a strict per-member approach, we do not believe it will result in any material under-rating or over-rating in the market generally, because rates on average should balance out over the issuer’s single risk pool for the small group market. Additionally, as described above, we believe this method of calculating premiums is still based on a per-member rating methodology that is consistent with the statute. However, we will monitor the effects of this policy on the small group market and assess whether future changes may be necessary.

Comment: In response to the request for comment regarding a uniform tiered-composite premium structure, we received comments that both supported and opposed the tiered-composite approach under consideration. Commenters who opposed the suggested alternatives for implementing tiered-composite premiums emphasized the differences between the suggested alternatives and current standard industry practice, which commonly

¹² This separate pricing decision is governed by section 2705(b) of the PHS Act, as amended by the Affordable Care Act and incorporated into ERISA and the Code (providing that a group health plan, and a health insurance issuer offering group or individual health insurance coverage, generally may not require any individual (as a condition of enrollment or continued enrollment under the plan or coverage) to pay a premium or contribution which is greater than the premium or contribution for a similarly situated individual enrolled in the plan or coverage based on any health factor of the individual or a dependent of the individual).

establishes four or five coverage tiers and corresponding premiums that do not vary based on the number of children covered. Some commenters opposed the use of composite premiums altogether, suggested alternative tiered-composite approaches using coverage tiers and corresponding multipliers, or advocated for a “pure” composite that averages the per-member rates of all enrollees in a plan, including the rates of both adults and children. Commenters who supported a tiered-composite methodology generally thought it would ensure that premiums for family coverage appropriately reflect the lower rates of children.

Response: We agree with commenters who suggested a tiered-composite premium approach would benefit families with children enrolled in plans using composite premiums. Based on our analysis, without a tiered approach, the composite premium charged for a family consisting of two adults (both age 24) and three children (all under age 21) would be about 35 to 55 percent higher than the composite premium charged for the same family under a tiered approach, depending on the average age of the group.¹³ Accordingly, this rule establishes a tiered-composite methodology based on one of the alternatives discussed in the preamble to the proposed rule.

The rule creates a two-tiered composite premium structure for small group market issuers that offer composite premiums, effective for plan years beginning on or after January 1, 2015. Under this approach, an issuer offering composite premiums will calculate a composite premium (or average enrollee premium amount) for each individual age 21 and older and a composite premium for each individual under age 21 covered under the plan. We note that an individual’s status as an employee or adult dependent is not relevant for this purpose. To determine the total premium charged by the issuer for a given family composition, the issuer sums the average enrollee premium amount for each covered family member age 21 and older and the average enrollee premium amount for each covered family member under age 21, as applicable, taking into account no more than three covered children under

age 21 and applying any applicable tobacco rating factor on a per-member basis (as discussed below).

For example, suppose the composite premium for a group health plan is \$200 for each covered individual age 21 and older and \$100 for each covered individual under age 21. Also suppose that none of the enrollees uses tobacco. In this example, the premium charged for a single employee (over age 21) would be \$200; the premium charged for an employee and spouse (both over age 21) would be \$400 (\$200 + \$200); and the premium charged for a family consisting of an employee and spouse (both over age 21) and four children (all under age 21) would be \$700 (\$200 + \$200 + \$100 + \$100 + \$0). An example of how a tobacco rating factor would be applied is provided below.

We discussed in the proposed rule that, under the approach we were considering, States could establish different tiered-composite premium standards with approval from HHS. We are finalizing this flexibility for States in this final rule. Thus, the tiered-composite premium methodology established in this rule will apply in the small group market in a State, both for coverage offered through a SHOP (subject to the amendments in § 156.285(a)(4) of this final rule that limit the availability of composite premiums in the FF–SHOPS when employee choice is offered) and for coverage outside of a SHOP, unless a State establishes and HHS approves an alternate tiered-composite methodology for the State.

Section 147.103 of the Market Reform Rule directs States to report certain information to HHS about State-specific rating requirements, including State-specific standards or requirements concerning average enrollee premium amounts. We interpret § 147.103(a)(5) to include a requirement that States report any State-proposed tiered-composite premium methodology that relates to average enrollee premium amounts. Accordingly, States seeking to adopt tiered-composite premium standards that differ from the Federal standards will submit information about such standards to HHS in accordance with the State reporting provisions set forth in § 147.103 and as further described in guidance. HHS will review a State’s composite premium standards to ensure (1) the State standards are at least as consumer protective as the Federal standards; and (2) the State methodology produces a total group premium that equals the amount that is derived through per-member rating established at the time of applicable

enrollment at the beginning of the plan year.

We believe these composite premium standards will guarantee minimum consumer protections in every State to assure that children are charged only child premium rates, while promoting administrative simplicity for issuers and employers and providing flexibility for States to establish alternative approaches for their health insurance market.

Comment: Tobacco rating is subject to the non-discrimination and wellness provisions under section 2705 of the PHS Act (providing that an issuer in the group market may vary the premium rate based on legal use of tobacco only in connection with a wellness program meeting the standards of section 2705(j) of the PHS Act and its implementing regulations).¹⁴ The preamble to the proposed rule indicates that this is true regardless of whether a tobacco rating factor is applied on a per-member or composite basis.¹⁵ One commenter suggested that including any surcharge for tobacco use in a composite premium was inconsistent with the rationale of ensuring that tobacco rating is applied only to portion of the premium attributable to each individual covered under the plan or coverage.

Response: To ensure that non-tobacco users do not have to pay any portion of a premium that is attributable to tobacco users enrolled in the plan, and to promote consistency with the wellness program requirements, this rule excludes any rating for tobacco use (as defined in § 147.102(a)(1)(iv)) from any enrollee’s composite premium. If an issuer offering composite premiums wishes to rate for tobacco use, consistent with applicable Federal and State law, the issuer must calculate the tobacco rating factor based on the applicable enrollee’s per-member premium, not the composite premium for all enrollees. The resulting tobacco rating factor is added to the composite premium for the enrollee who uses tobacco to create a premium specific to each tobacco user. For example, assume that the rate of a non-tobacco user is \$100 and the issuer does not rate based on age. The issuer imposes a 1.5:1 tobacco rating factor for individuals age 45 and older who use tobacco (that is, a \$50 tobacco surcharge) and a 1.3:1 tobacco rating factor for individuals under age 45 who use tobacco (that is, a \$30 tobacco surcharge). Further, assume that the composite premium for a group health plan is \$100 for each

¹³ For illustration, we assumed per-member premiums for family members of different ages enrolled in employer-group coverage and assumed various average ages for the group. For each average age, we calculated the total composite family premium that would be charged under a pure composite and two-tiered composite approach. The difference in the total composite premium for the family between the pure composite and two-tiered composite approach ranged from 35 to 55 percent, depending on the average age of the group.

¹⁴ 26 CFR 54.9802–1(f); 29 CFR 2590.702(f); and 45 CFR 146.121(f).

¹⁵ 78 FR at 72328, footnote 6.

covered individual age 21 and older. In this example, the premium charged for a single employee (over age 45) who uses tobacco would be \$150 (\$100 + \$50), and the premium charged for a single employee (under age 45) who uses tobacco would be \$130 (\$100 + \$30), subject to the non-discrimination and wellness provisions under section 2705 of the PHS Act.

Comment: Some commenters questioned how a composite premium would be established for adult and child dependents under a two-tiered or three-tiered composite approach if none were enrolled at the time of initial enrollment (or re-enrollment).

Response: This rule establishes a two-tiered rather than a three-tiered composite premium structure in response to these comments. The composite premium calculated at the beginning of the plan year for covered adults applies for all covered individuals age 21 and older regardless of whether they are an employee or adult dependent or when they enroll during the plan year. The composite premium calculated for covered individuals under age 21 is simply the per-member child age rate, which is a single rate for children ages 0 through 20 pursuant to § 147.102(d) and (e), regardless of the total number of children covered under the plan (taking into account no more than three covered children under age 21 with respect to a given family). For these reasons, and because a tobacco rating factor may be applied only on per-member basis, a composite premium will apply for both adult and child dependents who enroll after the start of the plan year (subject to the applicability of the tobacco rating factor).

Comment: Commenters suggested modifying the regulation text to clarify that a composite premium is calculated based on applicable employee “and dependent” enrollment at the beginning of the plan year.

Response: Because composite premiums will be generated for employees and dependents, as well as other types of group health plan enrollees (for example, retirees), we now refer to “participants” and “beneficiaries” in the regulation text for consistency with the terms generally used under the Employee Retirement Income Security Act of 1974 (ERISA).

Comment: The proposed rule provided that the new composite premium provisions would become applicable for plan years beginning on or after January 1, 2015. Some commenters noted that small group policies are issued on a rolling basis throughout the year and recommended

the requirements become effective prior to 2015.

Response: We recognize that issuers have developed the expertise and resources to comply with the per-member rating methodology generally required under the law and regulations and that some issuers might need time to adjust their systems to offer composite premiums in accordance with this rule. Therefore, the rule will take effect as a requirement for plan years beginning on or after January 1, 2015. However, as noted in the preamble to the proposed rule, we encourage issuers to voluntarily adopt the final rule’s composite premium standards for plan years beginning in 2014.

2. Student Health Insurance Coverage

Student health insurance coverage is traditionally offered on an academic year basis with a policy year other than a calendar year. Accordingly, we proposed in § 147.145 to exempt student health insurance from certain calendar year requirements that would otherwise apply to student health insurance coverage as a type of individual health insurance coverage. We proposed to exempt student health insurance coverage from the requirement to establish open enrollment periods and coverage effective dates based on a calendar policy year, and clarified that student health insurance coverage is not required to be offered as a calendar year plan.

We received comments supporting this proposal and are finalizing these provisions as proposed.

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

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

Section 1341 of the Affordable Care Act provides that States may elect to operate the transitional reinsurance program. Based on HHS’s communications with States, as of January 31, 2014, Connecticut is the only State that elected to operate a transitional reinsurance program. We indicated in the 2014 Payment Notice that Maryland had elected to operate reinsurance for 2014; however since the publication of the 2014 Payment Notice, Maryland has indicated that it wishes to defer the operation of the transitional reinsurance program to HHS. Because, at this time, taking on the operation of the reinsurance program on behalf of Maryland would not raise operational concerns, we are confirming that HHS

will operate reinsurance on Maryland’s behalf.

Section 153.100(c) provides that a State that operates or establishes a risk adjustment or reinsurance program, and is required to publish a State notice of benefit and payment parameters under § 153.100(a) or (b), must publish an annual State notice of benefit and payment parameters by March 1st of the calendar year prior to the benefit year for which the notice applies. However, because the 2014 Payment Notice was published after March 1, 2013, the 2014 Payment Notice extended this deadline to the 30th day following publication of that final rule. Similarly, we are extending the deadline for publication of a 2015 State notice of benefit and payment parameters until the 30th day following publication of this final rule. Consistent with this policy, we intend to propose in future rulemaking that for future benefit years, the publication deadline for the State notice of benefit and payment parameters be the later of March 1st of the calendar year prior to the applicable benefit year, or the 30th day following publication of the final HHS notice of benefit and payment parameters for the calendar year.

2. Provisions and Parameters for the Permanent Risk Adjustment Program

The risk adjustment program is a permanent program created by section 1343 of the Affordable Care Act that transfers funds from lower risk, non-grandfathered plans to higher risk, non-grandfathered plans in the individual and small group markets, inside and outside the Exchanges. A State that is approved or conditionally approved by the Secretary to operate an Exchange may establish a risk adjustment program, or have HHS do so on its behalf.

In the proposed rule, we proposed a risk adjustment user fee to support HHS operation of the risk adjustment program in 2015. We also considered two adjustments to our risk adjustment methodology: One concerning adjustments for Medicaid alternative plans and the other concerning adjustments relating to the geographic rating areas. We also proposed a default counting method for determining whether a plan is a small group plan for purposes of risk adjustment when a State’s counting method does not account for non-full-time employees. We proposed standards for risk adjustment data validation, including a sampling methodology, audit standards, internal consistency standards, a methodology to adjust risk scores, and actions upon noncompliance. We proposed that HHS have the authority to

conduct audits of issuers of risk adjustment covered plans.

a. Risk Adjustment User Fees

If a State is not approved to operate, or chooses to forgo operating, its own risk adjustment program, HHS will operate a risk adjustment program on the State's behalf. As described in the 2014 Payment Notice, HHS's operation of risk adjustment on behalf of States is funded through a risk adjustment user fee. Section 153.610(f)(2) provides that an issuer of a risk adjustment covered plan must remit a user fee to HHS for each month equal to the product of its monthly enrollment in the plan and the per-enrollee-per-month risk adjustment user fee specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year.

OMB Circular No. A-25R establishes Federal policy regarding user fees, and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public. The risk adjustment program will provide special benefits as defined in section 6(a)(1)(b) of Circular No. A-25R to an issuer of a risk adjustment covered plan because it will mitigate the financial instability associated with risk selection as other market reforms go into effect. The risk adjustment program also will contribute to consumer confidence in the health insurance industry by helping to stabilize premiums across the individual and small group health insurance markets.

For the 2015 benefit year, we proposed to use the same methodology that we used in the 2014 Payment Notice to estimate our administrative expenses to operate the risk adjustment program. That proposed methodology was based upon our contract costs in operating risk adjustment on behalf of States. The contract costs we considered cover development of the model and methodology, collections, payments, account management, data collection, data validation, program integrity and audit functions, operational and fraud analytics, stakeholder training, and operational support. We proposed not to set the user fee to cover costs associated with Federal personnel. We proposed to calculate the user fee by dividing HHS's projected total costs for administering the risk adjustment programs on behalf of States by the expected number of enrollees in risk adjustment covered plans in HHS-operated risk adjustment programs for the benefit year (other than plans not subject to market reforms and student health plans, which are not

subject to payments and charges under the risk adjustment methodology HHS uses when it operates risk adjustment on behalf of a State).

We estimated that the total cost for HHS to operate the risk adjustment program on behalf of States for 2015 would be approximately \$27.3 million, and that the per capita risk adjustment user fee would be no more than \$1.00 per enrollee per year. We are finalizing the proposed methodology for benefit year 2015, and are finalizing a per capita risk adjustment user fee of \$0.96 per enrollee per year, which we will apply as a per-enrollee-per-month risk adjustment user fee of \$0.08.

We received no comments on the risk adjustment user fee, and are therefore finalizing this proposal as proposed.

b. HHS Risk Adjustment Methodology Considerations

In the 2014 Payment Notice, we finalized the methodology that HHS will use when operating a risk adjustment program on behalf of a State in 2014. We proposed to use the same methodology in 2015, but proposed to amend the methodology by applying an adjustment for individuals enrolled in premium assistance Medicaid alternative plans. We proposed to apply the amended methodology beginning in 2014. We also sought comment on potential adjustments to the geographic cost factor to account for rating areas with low populations in the HHS risk adjustment methodology for future years.

We received a number of general comments regarding the HHS risk adjustment methodology.

Comment: Commenters requested that HHS provide additional guidance on the ICD-10 transition for risk adjustment, including the ICD-10 mappings, as soon as possible.

Response: We will publish updated ICD-9 instructions and software and then a combined set of ICD-9 and ICD-10 instructions and software on our Web site, as we did for the original ICD-9 software and instructions.¹⁶ Because ICD-10 codes will be accepted for risk adjustment beginning October 1, 2014, we intend to publish these documents shortly.

Comment: One commenter requested that the risk adjustment model be calibrated for 2015 using the most current data possible. Other commenters suggested that HHS incorporate

¹⁶ The HHS-Developed Risk Adjustment Model Algorithm Software is available at: <http://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/index.html> under "Regulations & Guidance" (posted under "Guidance" on May 7, 2013).

pharmacy utilization in the risk adjustment model. One commenter suggested that HHS include transitional plans' data in the risk adjustment model, but exclude them from payments and charges.

Response: We believe it is important to maintain model stability in implementing the risk adjustment methodology in the initial years of risk adjustment, and therefore do not intend to recalibrate the model in the initial years. Similarly, we do not intend to significantly change the model by including pharmacy utilization, though we continue to consider whether and how to include prescription drug data in future models. Finally, as we described in the 2014 Payment Notice (78 FR 15418), under our current methodology, plans not subject to the market reform rules are not subject to risk adjustment charges and do not receive risk adjustment payments. Because under the transitional policy, the Federal government will not consider certain health insurance coverage in the individual or small group market renewed after January 1, 2014, under certain conditions, to be out of compliance with specified 2014 market rules, and requested that States adopt a similar non-enforcement policy, transitional plans are able to set premiums and provide coverage as if they were not subject to market reform rules.¹⁷ For this reason, transitional plans are not subject to risk adjustment payments and charges under our methodology at this time.

Comment: One commenter sought clarification on the risk scoring process. The commenter sought clarification on whether an enrollee's risk score is calculated monthly and aggregated to reflect changes in the receipt of cost-sharing reductions. The commenter also sought clarification on whether diagnoses carry through to the new plan if a qualifying event results in a special enrollment period and an enrollee changes plans, but stays with the same issuer. One commenter questioned whether an issuer would receive credit for the diagnoses on risk adjustment eligible claims paid by the issuer during a grace period if the issuer later processes a retroactive termination because the individual does not pay the premium.

Response: For each enrollee, HHS will use all risk adjustment eligible claims or encounters submitted from across all of the issuer's risk adjustment covered

¹⁷ Letter to Insurance Commissioners, Center for Consumer Information and Insurance Oversight, November 14, 2013. Available at: <http://www.cms.gov/CCIIO/Resources/Letters/Downloads/commissioner-letter-11-14-2013.PDF>.

plans to calculate a risk score. The diagnoses would be associated with each of the issuer's plans in which the individual enrolls. This means that if the enrollee changes plans within the same issuer, then the claims data from all of the issuer's plans will be utilized to calculate the member's plan-specific risk scores for each of these plans. We note that in accordance with our methodology, the risk score value could change based on cost-sharing reductions received or plan AV. However, to align with our distributed data collection approach, which collects data by issuer, we will not link enrollee data across different issuers, even if the issuers are affiliated with the same insurance company. Diagnoses from risk adjustment eligible claims will only be accepted with dates of service that occur during active enrollment periods. Therefore, claims associated with months during a grace period will be counted toward risk adjustment, so long as the months are not later subject to a retroactive termination.

We are finalizing the use of the 2014 Federal risk adjustment methodology when HHS operates a risk adjustment program on behalf of a State, for 2015, with the modification for the treatment of Medicaid alternative plans discussed below, effective for 2014 risk adjustment.

(i) Incorporation of Premium Assistance Medicaid Alternative Plans in the HHS Risk Adjustment Methodology

Section 1343(c) of the Affordable Care Act provides that risk adjustment applies to non-grandfathered health insurance coverage offered in the individual and small group markets. In some States, expansion of Medicaid benefits under section 2001(a) of the Affordable Care Act may take the form of enrolling newly Medicaid-eligible enrollees into individual market plans. For example, these enrollees could be placed into silver plan variations—either the 94 percent silver plan variation or the zero cost sharing plan variation—with a portion of the

premiums and cost sharing paid for by Medicaid on their behalf. Because individuals in these types of Medicaid alternative plans receive significant cost-sharing assistance, they may utilize medical services at a higher rate. To address this induced utilization in the context of cost-sharing reduction plan variations in the HHS risk adjustment methodology, our methodology increases the risk score for individuals in plan variations by a certain factor. We proposed to use the same factor that we use to adjust for induced utilization for individuals enrolled in cost-sharing plan variations to adjust for induced utilization for individuals enrolled in the corresponding Medicaid alternative plan variations, and to implement these adjustments in 2014. Table 1 shows the cost-sharing adjustments for both 94 percent silver plan variation enrollees and zero cost-sharing plan variation enrollees for silver QHPs as finalized in the 2014 Payment Notice.

TABLE 1—COST-SHARING REDUCTION ADJUSTMENTS

Plan variation	Induced utilization factor
94 Percent Plan Variation	1.12
Zero Cost-Sharing Plan Variation of Silver QHP	1.12

We are finalizing the application of the cost-sharing reduction adjustments to corresponding Medicaid alternative expansion plans as proposed. We plan to evaluate these adjustments in the future, after data from the initial years of risk adjustment is available.

Comment: Commenters agreed with our approach for accounting for Medicaid alternative plans under risk adjustment, with one commenter recommending that we monitor utilization patterns and consider evaluating States' Medicaid alternative plans separately in 2015 and beyond.

Response: We intend to examine the utilization patterns of current Medicaid alternative plans and the benefit structure of future Medicaid alternative plans, and may make appropriate adjustments in the future.

(ii) Adjustment to the Geographic Cost Factor

As finalized in the 2014 Payment Notice, the geographic cost factor is an adjustment in the payment transfer formula to account for plan costs, such as input prices, that vary by geography and are likely to affect plan premiums. For the metal-level risk pool, it is calculated based on the observed

average silver plan premium in a geographic area relative to the Statewide average silver plan premium. It is separately calculated for catastrophic plans in a geographic area relative to the Statewide catastrophic pool. However, as we noted in the proposed rule, several States have defined a large number of rating areas, potentially leading to rating areas with low populations. Less populous rating areas raise concerns about the accuracy and stability of the calculation of the geographic cost factor, because in less populous rating areas, the geographic cost factor might be calculated based on a small number of plans. Inaccurate or unstable geographic cost factors could distort premiums and the stability of the risk adjustment model.

We sought comment in the proposed rule on how to best adjust the geographic cost factors or geographic rating areas in future years to address these potential premium distortions. We also sought comment on how this adjustment should be implemented for a separately risk adjusted pool of catastrophic plans. We stated that we did not intend to make this adjustment for 2014.

Based on comments received, we will continue to implement the geographic cost factor for each rating area established by the State under § 147.102(b) and calculated based on the observed average silver plan premium for the metal-level risk pool, as finalized in the 2014 Payment Notice (78 FR 15433).

Comment: Commenters did not support making additional adjustments to the geographic cost factor. Commenters stated that the time and resources needed to calculate and implement such an adjustment would be considerable, and that any such adjustment would be unlikely to have a material impact on final risk adjustment results.

Response: We will not adjust the geographic cost factors or geographic rating areas, but will monitor 2014 risk adjustment data for any potential premium distortions.

c. Small Group Determination for Risk Adjustment

For a plan to be subject to risk adjustment, according to section 1343(c) of the Affordable Care Act and the definition of a "risk adjustment covered plan" in § 153.20, a plan must be offered

in the “individual or small group market.” The definition of small group market in § 153.20 references the definition at section 1304(a)(3) of the Affordable Care Act.

Section 1304(a)(3) of the Affordable Care Act, in defining “small group market,” references the definition of a “small employer” in section 1304(b)(2) of the Affordable Care Act. That definition provides that an employer with an average of at least 1 but not more than 100 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year will be considered a “small employer.”

However, section 1304(b)(3) of the Affordable Care Act provides that, for plan years beginning before January 1, 2016, a State may elect to define “small employer” to mean an employer with at least 1 but not more than 50 employees.

In the 2014 Payment Notice, we stated that we believe that the Affordable Care Act requires the use of a counting method that accounts for non-full-time employees, and that the full-time equivalent method described in section 4980H(c)(2)(E) of the Code is a reasonable method to apply (78 FR 15503). We stated that we believe that the risk adjustment program must also use a counting method that takes employees that are not full-time into account when determining whether a group health plan must participate in that program.

However, we also recognize that, because risk adjustment is intended to stabilize premiums by mitigating pricing uncertainty associated with the rating rules, it is important that the program be available to plans that are subject to the rating rules, to the extent permissible under the Affordable Care Act. We recognize that a number of States, which have primary enforcement jurisdiction over the market rules, may use counting methods that do not take non-full-time employees into account.

Thus, we are finalizing our proposal, with one modification—we are changing the cross-reference to the Code so that it references section 4980H(c)(2). In determining which group health plans participate as small group plans in the risk adjustment program, we will apply the applicable State counting method, unless the State counting method does not take into account employees that are non-full-time. In that circumstance, we will apply the counting method described in section 4980H(c)(2) of the Code and any implementing regulations.¹⁸ We believe that this

approach defers to State counting methods and aligns with State enforcement of rating rules, within the bounds of what is legally permissible under the Affordable Care Act.

Comment: One commenter supported our proposed counting method when a State counting method does not account for non-full-time employees. Some commenters urged us to maintain consistency with other counting methods, noting the administrative burden of having inconsistent counting methods across different Affordable Care Act programs. One commenter suggesting that we codify the average number of employees during the preceding calendar year as the single counting method across Affordable Care Act programs. Some commenters recommended deferring to the State counting method in the transitional years while collaborating with other Federal agencies to issue a uniform counting method in future rulemaking. One commenter recommended that if a group is required to be rated as a small group based on rating rules or SHOP requirements and is part of the single risk pool pricing, it should be included in the small group risk adjustment pool.

Response: We agree that risk adjustment should apply to plans subject to the market reform rating rules, to the extent permissible under the Affordable Care Act. We also agree with commenters that consistency in counting methods across Affordable Care Act programs is important, and we plan to collaborate with other Federal agencies to streamline counting methods in future rulemaking. To better address commenters’ requests for consistency across Affordable Care Act programs, we have changed the Code reference from section 4980H(c)(2)(E) to 4980H(c)(2). This broader cross-reference will incorporate the limit in section 4980H(c)(2)(B) on how certain seasonal employees are counted, and will be consistent with the counting method used by the SHOP, as finalized in the 2014 Payment Notice (78 FR 15503). Prior to streamlining counting methods, because we interpret the employer size definitions in the Affordable Care Act to include non-full-time employees for purposes of determining small group status for purposes of risk adjustment, in States that do not account for non-full-time employees, we believe that requiring the large group counting method described in section 4980H(c)(2) of the Code (which accounts for non-full-time employees) is an appropriate standard

because it is used by other Affordable Care Act programs and will reduce administrative burden for issuers.

d. Risk Adjustment Data Validation

The 2014 Payment Notice established a risk adjustment data validation program that HHS will use when operating risk adjustment on behalf of a State. In the 2014 Payment Notice (78 FR 15436), we specified a framework for this program that includes six stages: (1) Sample selection; (2) initial validation audit; (3) second validation audit; (4) error estimation; (5) appeals; and (6) payment adjustments.

To develop the details of the program, we sought the input of issuers, consumer advocates, providers, and other stakeholders. We issued the “Affordable Care Act HHS-Operated Risk Adjustment Data Validation Process White Paper” on June 22, 2013 (the “white paper”).¹⁹ That white paper discussed and sought comments on a number of potential considerations for the development of the risk adjustment data validation methodology. We received submissions from 53 commenters, including issuers, issuer trade groups, advocacy groups, and consultants. As we noted in the white paper, our overall goals are to promote consistency and a level playing field by establishing uniform audit requirements, and to protect private information by limiting data transfers during the data validation process.

In the proposed rule, we proposed provisions for the risk adjustment data validation process and methodology that reflect our analysis of the white paper comments and our discussions with stakeholders. We again note that a State operating a risk adjustment program is not required to adopt these standards.

We received some general comments about our proposed risk adjustment data validation methodology and process.

Comment: We received comments supporting the risk adjustment data validation methodology and process, noting that data validation is critical to issuer confidence and to encouraging the enrollment of individuals with significant health needs. Another commenter suggested that we model the HHS risk adjustment data validation program after the Medicare Advantage risk adjustment data validation program to the extent possible.

Response: We agree that a robust risk adjustment data validation program is

¹⁸ We note that the IRS has published a final regulation that contains further details that would

apply to this calculation (§ 54.4980H–2(c) (79 FR 8544).

¹⁹ “Affordable Care Act HHS-Operated Risk Adjustment Data Validation Process White Paper.” 22 June 2013. https://www.regtap.info/uploads/library/ACA_HHS_OperatedRADVWhitePaper_062213_5CR_062213.pdf.

critical to ensuring that we effectively promote issuer confidence and the goals of the risk adjustment program. We note that many aspects of the HHS risk adjustment data validation program were modeled after the Medicare Advantage risk adjustment data validation program. For example, we have adopted a sampling strategy modeled on the one used in the Medicare Advantage risk adjustment program. Additionally, we have elected to adopt the medical record as the authoritative source to verify diagnoses, and have required that certified reviewers perform medical record reviews, as discussed below. Both of those program features are modeled on the Medicare Advantage risk adjustment data validation process. However, because our risk adjustment methodology uses a more comprehensive set of data elements, our data collection approach is more robust, and our data validation approach is broader.

(i) Sample Selection

The first stage in the HHS-operated risk adjustment data validation process is the selection of a sample of an issuer's enrollees whose risk adjustment data will be validated. In the final 2014 Payment Notice, we stated that HHS would choose a sample size of enrollees such that the estimated risk score errors would be statistically sound and the enrollee-level risk score distributions would reflect enrollee characteristics for each issuer. We stated that in determining the appropriate sample size for data validation, we recognized the importance of striking a balance between ensuring statistical soundness of the sample, and minimizing the operational burden on issuers, providers, and HHS. Additionally, we stated that we would ensure that the sample would cover critical subpopulations of enrollees for each risk adjustment covered plan, such as enrollees with and without hierarchical condition categories (HCCs). To develop a proposed sample size for the first year of the HHS risk adjustment data validation program, in the proposed rule we proposed to use the methodology outlined in the white paper. We stated in the proposed rule that our goal in determining the enrollee sample size for the initial 2 years of risk adjustment data validation is to use a sample large enough to inform us in a statistically valid manner of the dynamics of the risk adjustment data validation process in operation, and to permit statistically valid estimation of risk score accuracy. As we established in the 2014 Payment Notice, in order to permit HHS to

observe and optimize the risk adjustment data validation process, no payment adjustments will be made based on the risk adjustment data validation process for the initial 2 years of HHS-operated risk adjustment.

In the proposed rule, we proposed selecting the initial validation audit sample for a given benefit year by dividing the relevant population into a number of "strata," representing different demographic and risk score bands. For the initial 2 years of the risk adjustment data validation program, we proposed an initial validation audit sample of 200 enrollees from each issuer. We stated in the proposed 2014 Payment Notice and the proposed rule that the overall sample will reflect a disproportionate selection of enrollees with HCCs. In the proposed rule, we discussed in detail our sampling methodology, including our proposal to group enrollees to account for age characteristics and health status. Some commenters on the white paper suggested that we also consider sampling based on plan types and other characteristics. We will consider other sampling strategies in the future, but believe that we do not yet have enough experience with the risk adjustment process to determine the most appropriate sampling groups at this time. Therefore, we are finalizing a simple age and risk score stratification for the initial 2 years of the program. Following the division of the relevant population into strata, we will use the following formulas to calculate a proposed sample size for the initial validation audit each year. In general, the formula for the overall sample size for an issuer (n) is:

$$n = \frac{\left(\sum_{h=1}^H N_h S_h \right)^2}{\sum_{h=1}^H N_h S_h^2 + \left(\frac{Prec \times Y}{z - value} \right)^2}$$

Where:

H is the number of strata;

N_h is the population size of the h^{th} stratum;

Y is the average risk score of the population, adjusted based upon the estimated risk score error;

S_h represents the standard deviation of risk score error for the h^{th} stratum;

$Prec$ represents the desired precision level (for example, 10 percent, meaning a 10 percent margin of error in the estimated risk score); and

z -value is the z -value associated with the desired confidence level (for example, 1.96 for a two-sided 95 percent confidence level).

We are finalizing a sample size of 200 enrollees from each issuer for the initial 2 years of the program. The formula above will use real data from the HHS-operated risk adjustment program after this initial 2-year period to calculate a more precise, issuer-specific sample size for each issuer.

The formula for calculating the sample size for each stratum (n_h) is:

$$n_h = n \times \frac{N_h S_h}{\sum_{h=1}^H N_h S_h}$$

Where:

N_h is the population size of the h^{th} stratum; n is the overall sample size; and S_h represents the standard deviation of risk score error for the h^{th} stratum.

As we described in the proposed rule, for the 2014 benefit year, the parameters listed above were developed using data from two principal sources: Medicare Advantage risk adjustment data validation net error rates and variances; and expenditures data from the Truven Health Analytics 2010 MarketScan® Commercial Claims and Encounters database (MarketScan®). We chose to use Medicare Advantage error rates because Medicare Advantage utilizes an HCC-based methodology similar to the one used for HHS risk adjustment, and because it uses a similar risk adjustment data validation process to determine payment error rates.

We also chose to use the MarketScan® expenditure database because of the comprehensiveness of the database, which was the primary source for calibration for the HHS risk adjustment models. The database contains enrollee-specific claims utilization, expenditures, and enrollment across inpatient, outpatient, and prescription drug services from a selection of large employers and health plans. The database includes de-identified data from approximately 100 payers, and contains more than 500 million claims from insured employees, spouses, and dependents.

We used enrollee predicted expenditure results from our risk adjustment model calibration, which was based on the MarketScan® data, to stratify the population (by age group for enrollees with HCCs, and within a single group for enrollees with no HCCs), then calculated risk scores for the predicted expenditures to relate them to the average expenditures. To estimate a sample size for each issuer, an average issuer size was estimated based on the total expected insured population and the total expected number of issuers. The average issuer

population containing enrollees with and without HCCs was assumed to be split 20 percent with HCCs and 80 percent without HCCs, consistent with the MarketScan® data.

We will group each issuer's enrollee population into 10 strata based on age group, risk level, and presence of HCCs, as follows:

- Strata 1–3 will include low, medium, and high risk adults with the presence of at least one HCC.
- Strata 4–6 will include low, medium, and high risk children with the presence of at least one HCC.
- Strata 7–9 will include low, medium, and high risk infants with the presence of at least one HCC.
- Stratum 10 will include the No-HCC population, which will not be further stratified by age or risk level, because we assume this stratum has a uniformly low error rate.

We calculated a predicted risk score for each individual in each stratum by dividing the predicted expenditures for that individual by the average predicted expenditures for the entire population. Using these individual predicted risk scores, we calculated the overall average risk score for all individuals in each risk-based stratum. This calculation was performed nine times for the HCC population—once for each of the three risk-based strata within each of the three age groups. We set the minimum risk score for enrollees without HCCs in the tenth stratum.

This method of stratification is similar to that used in the Medicare Advantage risk adjustment data validation program, which divides enrollees into three strata, representing low, medium, and high risk expenditures. Error rates and variances are calculated for each of these strata. In the initial year, before error rate and standard deviation data for the population subject to the HHS-operated risk adjustment program are available, we will use the Medicare Advantage error rates and variances to calculate sample sizes. After the initial year, we will evaluate whether sufficient HHS-operated risk adjustment error rate and standard deviation data are available to calculate sample sizes.

We will use the lowest error rate across all HCC strata as the error rate for the stratum of enrollees without HCCs, and we will use the variance associated with that error rate to calculate the standard deviation of the error for the stratum of enrollees without HCCs. If error rates and variances are smaller than assumed for this stratum, the resulting sampling precision may increase.

Because the Medicare Advantage error rates and variances are not calculated

for different age bands, and therefore are available only for three risk-score differentiated subgroups, we will use the same risk score error rates and standard deviation for the age bands for a risk category. Thus, we will use the same risk score error rate and standard deviation assumptions for the adult, child, and infant strata associated with each risk score band. We do not anticipate the expected risk score error rate and variance to be uniform for all age groups; however, in the absence of data, we are making this simplifying assumption. In general, we believe the Medicare Advantage error rates and variances likely overstate the corresponding error rates and assumptions for the HHS risk adjusted population, and therefore, the estimated precision of our error estimates may be understated.

The formulas identified above require data on error rates and standard deviations for the strata, and also a target confidence interval and sampling precision level (or margin of error). For the initial year, as we proposed in the proposed rule, we are finalizing a 10 percent relative sampling precision at a two-sided 95 percent confidence level. That is, we wish to obtain a sample size such that 1.96^{20} multiplied by the standard error, divided by the estimated adjusted risk score, equals 10 percent or less. After actual data are collected from the initial year, we will test and evaluate the data for use in determining the sample size in future years.

Once the overall sample size is calculated, the enrollee count will be distributed among the population based on the second formula above for calculating the sample size of each stratum. Because strata with enrollees with HCCs have a higher standard deviation of risk score error, the overall sample will be disproportionately allocated to enrollees with HCCs (Strata 1–9), helping to ensure adequate coverage of the higher risk portion of the enrollee population.

When data becomes available from the program's first year, we expect to examine our sampling assumptions using actual enrollee data. We anticipate that in the initial 2 years of the risk adjustment data validation program, the stratification design will remain consistent with the design outlined above—nine HCC strata and one No-HCC stratum. However, the specific size and allocation of the sample to each stratum may be refined based on average issuer enrollee risk score distributions. For example, in future years, we are

²⁰Critical value for the two-sided 95 percent confidence level.

considering using larger sample sizes for larger issuers or issuers with higher variability in their enrollee risk scores, and smaller sample sizes for smaller issuers or issuers with lower variability in their enrollee risk scores. The sampling design may also consist of a minimum and maximum sample size per stratum for each average issuer (large, medium, small) to follow when selecting the sample.

We are finalizing our sampling approach as proposed for the initial 2 years of risk adjustment data validation.

Comment: Several commenters supported reducing the sample size from 300 to 200 enrollees for the initial years of data validation. Commenters supported using sampling experience from the initial years to improve the sampling methodology and target issuer-specific sample sizes in 2016. Other commenters requested that HHS increase the sample size for larger issuers and decrease the sample size for smaller issuers. One commenter requested that we use a nationwide sample to assess error rates for multi-State carriers, while another commenter requested that we combine the risk pools to minimize issuer burden for sample selection. Some commenters did not support the smaller sample size, noting that questionable enrollment data in the initial years may result in erroneous risk scores. One commenter recommended that HHS use a statistically sound method to ensure that there is a proportionate representation of plan metal levels in each issuer sample.

Response: We will use our sampling experience in the initial years of data validation to evaluate how and if we can appropriately establish issuer-specific sample sizes, and whether our sample size is adequate. We believe that lowering the sample size from 300 to 200 will yield a statistically valid sample, while minimizing the burden on all issuers. We also clarify that the enrollee sample totals 200 enrollees per issuer across all risk pools, and not per plan. Our sampling methodology does not separate risk pools within an issuer.

Comment: Commenters generally supported our proposed strata. One commenter suggested that fewer than ten strata are necessary, while another commenter suggested that because our risk adjustment model is calibrated for a standard population, it has significantly lower predictive power when applied to a pediatric-only population.

Response: We believe that the ten strata are appropriate for the initial years of data validation, in order to ensure that the sample targets enrollees

with HCCs of varying ages and health statuses. We intend to use real data as it becomes available to improve our precision in error rate and variance estimation by age and health status.

(ii) Initial Validation Audit

The second stage of the HHS-operated risk adjustment data validation process is the initial validation audit. In this section, we discuss standards and guidelines regarding the qualifications of the initial validation auditor, including conflict of interest standards, standards for the initial validation auditor consistency and reliability, and confirmation of risk adjustment errors. As discussed in the white paper and the proposed rule, we considered existing best practices and standards for independent auditors, such as those of Medicare Quality Improvement Organizations and the National Committee for Quality Assurance, when establishing our standards for initial validation auditors.

(1) Initial Validation Auditor

The 2014 Payment Notice established certain standards for the initial validation auditor. In § 153.630(b)(2) and (b)(3), we directed the issuer to ensure that the initial validation auditor is reasonably capable of performing an initial validation audit, and is reasonably free of conflicts of interest, such that it is able to conduct the initial validation audit in an impartial manner with its impartiality not reasonably open to question.

In the white paper, we elaborated on potential options for ensuring that an initial validation auditor meets these criteria, including standardized auditor certification processes and promulgation of best practices. Many commenters sought additional information and guidance regarding initial validation auditor selection and requested that HHS define conflicts of interest between an issuer and the initial validation auditor. In the proposed rule, we proposed the following criteria for assessing conflicts of interest between the issuer and the initial validation auditor:

- Neither the issuer nor any member of its management team (or any member of the immediate family of such a member) may have any material financial or ownership interest in the initial validation auditor, such that the financial success of the initial validation auditor could be seen as materially affecting the financial success of the issuer or management team member (or immediate family member) and the impartiality of the initial validation audit process could reasonably be called

into question, or such that the issuer or management team member (or immediate family member) could be reasonably seen as having the ability to influence the decision-making of the initial validation auditor;

- Neither the initial validation auditor nor any member of its management team or data validation audit team (or any member of the immediate family of such a member) may have any material financial or ownership interest in the issuer, such that the financial success of the issuer could be reasonably seen as materially affecting the financial success of the initial validation auditor or management team or audit team member (or immediate family member) and the impartiality of the initial validation audit process could reasonably be called into question, or such that the initial validation auditor or management or audit team member (or immediate family member) could be seen as having the ability to influence the decision-making of the issuer;

- Owners, directors and officers of the issuer may not be owners, directors or officers of the initial validation auditor, and vice versa;

- Members of the data validation audit team of the initial validation auditor may not be married to, in a domestic partnership with, or otherwise be in the same immediate family as an owner, director, officer, or employee of the issuer; and

- The initial validation auditor may not have had a role in establishing any relevant internal controls of the issuer related to the risk adjustment data validation process when HHS is operating risk adjustment on behalf of a State, or serve in any capacity as an advisor to the issuer regarding the initial validation audit.

In addition, we stated in the proposed rule that we were considering establishing standards under which issuers must verify that no key individuals involved in supervising or performing the initial validation audit have been excluded from working with either the Medicare or Medicaid program, are on the OIG exclusion list or, to its knowledge, are under investigation with respect to any HHS programs.

We noted in the proposed rule that we intend to review the initial validation auditor's qualifications and relationship to the issuer to verify that the initial validation auditor is qualified to perform the audit, and that the issuer and initial validation auditor are free of actual or apparent conflicts of interest, including those stated above. We noted that HHS could gather information

through external reporting to support that review. Although we remain confident that most issuers will exercise diligence in selecting an initial validation auditor that will be able to comply with HHS audit standards, we intend to monitor the performance of initial validation auditors to determine whether certification or additional safeguards are necessary.

In the proposed rule, we proposed to amend § 153.630(b)(1) to specify that the issuer of a risk adjustment covered plan must provide HHS with the identity of the initial validation auditor, and must attest to the absence of conflicts of interest between the initial validation auditor (or the members of its audit team, owners, directors, officers, or employees) and the issuer (or its owners, directors, officers, or employees). We stated that we considered any individual with a significant ownership stake in an entity such that the individual could reasonably be seen to have the ability to influence the decision making of the entity to be an "owner," and considered any individual that serves on the governing board of an entity to be a "director" of the entity. We stated that we were contemplating beginning the initial validation process at the end of the first quarter of the year following the benefit year, with the issuer's submission of the initial validation auditor's identity. We stated that we expected to identify the enrollee sample for the initial validation audit in the summer of the year following the benefit year, and that we were contemplating requiring delivery of the initial validation audit findings to HHS in the fourth quarter of that year. We included a proposed schedule of the risk adjustment data validation process.

Once the audit sample is selected by HHS, we stated that we expect issuers to ensure that the initial validation audit is conducted in the following manner:

- The issuer would provide the initial validation auditor with source enrollment and source medical record documentation to validate issuer-submitted risk adjustment data for each sampled enrollee;

- The issuer and initial validation auditor would determine a timeline and information-transfer methodology that satisfies the data security and privacy requirements at § 153.630(f)(2), and enables the initial validation auditor to meet HHS established timelines;

- The initial validation auditor would validate the status of each enrollee in the sample in accordance with the standards established by HHS; and

- The initial validation auditor would provide HHS with the final results from

the initial validation audit and all requested information for the second validation audit.

We noted in the proposed rule that we did not propose amending § 153.630(f)(2), and that the issuer would be required to ensure that its initial validation auditor comply with the security standards described at §§ 164.308, 164.310, and 164.312 in connection with the initial validation audit.

We are finalizing these standards as proposed, with certain modifications in response to comments to § 153.630(b)(1). Where we had proposed requiring an attestation from the issuer as to the absence of conflicts of interest with the initial validation auditor on the part of the issuer, we are modifying the conflict of interest attestation requirement in § 153.630(b)(1) so that the issuer must attest to the absence of conflicts of interest with the initial validation auditor to its knowledge, following reasonable investigation. Similarly, where we had proposed requiring an attestation from the issuer as to the absence of conflicts of interest on the part of the initial validation auditor, we are modifying the attestation requirement so that the issuer may attest that it has obtained a representation from the initial validation auditor that to its knowledge, following reasonable investigation, there are no conflicts of interest. We are also including a standard under which an issuer must verify that no key individual involved in supervising or performing the initial validation audit appears on the Office of the Inspector General List of Excluded Individuals and Entities or, to the issuer's knowledge, are under investigation with respect to any HHS program.

Comment: One commenter recommended that HHS provide a pre-certified list of auditors to make it easier for issuers to select an independent entity to perform the initial data validation audit. Another commenter suggested that HHS maintain adequate staff to monitor the performance of issuers and their auditors. Commenters suggested that the initial validation auditor, rather than the issuer, certify that the entity meets the conflict of interest standards, since the issuer may be unaware of all potential conflicts. The commenters suggested that the initial validation auditor attest to an absence of conflict to both HHS and the issuer, and that the issuer attest to the absence of conflicts only on the issuer's side. Several commenters recommended that HHS require attestation of an absence of conflict of interest only from senior management teams of the issuer

and the auditor, and permit members of the initial validation audit team to simply disclose any potential conflicts for issuer evaluation, rather than categorically excluding an initial validation auditor. One commenter requested that HHS prohibit vendors that provide risk adjustment services from serving as initial validation auditors.

Response: We believe that members of the initial validation audit team should be subject to the same conflict-of-interest requirements as owners and directors. However, we agree with the commenters that the issuer may not be able to provide the full attestation proposed, and are finalizing a change in our policy in § 153.630(b)(1) so that the issuer is required to attest to the absence of conflicts of interest between the initial validation auditor (or the members of the audit team, owners, directors, officers, or employees) and the issuer (or its owners, directors, officers, or employees), to its knowledge following reasonable investigation, and must attest that it has obtained an equivalent representation from the initial validation auditor.

We do not intend to pre-certify auditors at this time. However, as stated elsewhere in the preamble to this rule, we intend to monitor the performance of initial validation auditors to determine whether additional certification or safeguards are necessary.

Comment: Several commenters suggested that HHS require the initial validation auditor to provide issuers, as well as HHS, with the results of the initial validation audit.

Response: Nothing in our rules prevents the issuer from requiring that the initial validation auditor provide it with the results of the initial validation audit.

(2) Standards for the Initial Validation Audit

In the proposed rule, we proposed that an initial validation audit review of enrollee health status be conducted by medical coders certified after examination by a nationally recognized accrediting agency for medical coding, such as the American Health Information Management Association (AHIMA) or the American Academy of Professional Coders (AAPC). We are finalizing this provision as proposed.

Comment: Several commenters supported requiring nationally accredited medical coders to review an enrollee's health status during an initial validation audit. One commenter recommended that the Practice Management Institute be considered a nationally recognized accrediting

agency for medical coding. Another commenter suggested that reviewers receive certification in the specialty area in which they work and by the appropriate specialized accrediting agency. Another commenter supported coding education and clinical training for medical coders, but suggested that HHS should consider other standards, if available, to enhance consistency among auditors.

Response: We will not recognize certification by the Practice Management Institute as certification by a nationally recognized accrediting agency because we do not believe this organization is nationally recognized for the rigor of its coding training and accreditation practices. By contrast, AHIMA and AAPC certification is intended for a broad group of health providers, issuers, and associated industry groups. At this time, while our risk adjustment data validation standards are relatively new, we will not require specialty certification, but we will consider additional standards in the future.

(3) Validation of Enrollees' Risk Scores

An enrollee's risk score is derived from demographic and health status factors, which requires the use of enrollee identifiable information. Thus, in the proposed rule we proposed to add paragraph (b)(6) to § 153.630, to require an issuer to provide the initial validation auditor and the second validation auditor with all relevant information on each sampled enrollee, including source enrollment documentation, claims and encounter data, and medical record documentation from providers of services to enrollees in the applicable sample without unreasonable delay and in a manner that reasonably assures confidentiality and security of data in transmission. We noted that existing privacy and security standards, such as standards under HIPAA and those detailed at § 153.630(f)(2), will apply. This information would be used to validate the enrollment, demographic, and health status data of each enrollee. Only source documentation for encounters with dates of services within the applicable benefit year would be considered relevant. This would require issuers to collect the appropriate enrollment and claims information from their own systems, as well as from all relevant providers (particularly with respect to medical record documentation). We noted that only a very small percentage of an issuer's records containing personally identifiable information (PII) would be made available to auditors as part of the

risk adjustment data validation process, and that similar transmissions are required today for data validation for the Medicare Advantage program. We also proposed to add paragraph (b)(7) to § 153.630, to describe the standards for validating an enrollee's risk score. Under paragraph (b)(7)(i), we proposed that the initial validation auditor would validate information by reviewing plan source enrollment documentation, such as the 834 transaction,²¹ which is the HIPAA-standard form used for plan benefit enrollment and maintenance transactions. These enrollment transactions reflect the data the issuer captured for an enrollee's age, name, sex, plan of enrollment, and enrollment periods in the plan. We noted that certain identifying information from these enrollment transactions would be used to ensure that the appropriate medical documentation has been provided. We are finalizing these standards as proposed, with the modification to § 153.630(b)(7)(i) that an enrollee's risk score must be validated through enrollment and demographic data in a manner to be determined by HHS. We have made this change because we are exploring an approach under which we would use an automated data validation process for the enrollment and demographic data. We believe that such an approach could lessen the burden of the data validation process on issuers. We will provide further guidance on this topic in the future. We stated in the proposed rule that the sample audit pool would consist of enrollees with and without risk adjustment eligible diagnoses within eligible dates of service. For each enrollee in the sample with risk adjustment HCCs, the initial validation auditor would validate diagnoses through a review of the relevant risk adjustment eligible medical records. We stated we would consider medical record documentation generated with respect to dates of service that occurred during the benefit year at issue to be relevant for these purposes. For enrollees without risk adjustment HCCs for whom the issuer has submitted a risk adjustment eligible claim or encounter, we would require the initial validation auditor to review all medical record documentation for those risk adjustment eligible claims or encounters, as

provided by the issuer, to determine if HCC diagnoses should be assigned for risk score calculation, provided that the documentation meets the requirements for the risk adjustment data validation audits. Documents used to validate all components of the risk score would be required to reflect dates of service during the applicable benefit year. In the initial years of the data validation program, we plan to accept certain supplemental documentation, such as health assessments, to support the risk adjustment diagnosis. We expect to provide additional details on acceptable supplemental documentation in future guidance.²²

Therefore, we proposed in § 153.630(b)(7)(ii) to require that the validation of enrollee health status (that is, the medical diagnoses) occur through medical record review, that the validation of medical records include a check that the records originate from the provider of the medical services, that they align with the dates of service for the medical diagnosis, and that they reflect permitted providers and services. For purposes of § 153.630, "medical record documentation" would mean: "clinical documentation of hospital inpatient or outpatient treatment or professional medical treatment from which enrollee health status is documented and related to accepted risk adjustment services that occurred during a specified period of time." Medical record documentation would be required to be generated in the course of a face-to-face or telehealth visit documented and authenticated by a permitted provider. We expect to provide additional guidance on telehealth services in future guidance.

In § 153.630(b)(7)(iii), we proposed that medical record review and abstraction be performed in accordance with industry standards for coding and reporting. Current industry standards are set forth in the *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9)*, or the *International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, 4th Edition (ICD-10)* guidelines for coding and reporting.

We are finalizing these standards as proposed, with the modification to § 153.630(b)(7)(i) discussed above.

Comment: One commenter requested that HHS specify documents other than

the "834" plan benefit and enrollment form that could be used to validate demographic data and enrollment information for risk adjustment validation when a plan is not part of a State Exchange. One commenter recommended that HHS adjust its audit standards to rely on medical conditions as described and substantiated in medical claims forms rather than medical records. Several commenters supported our proposal that medical records generated in the course of telehealth encounters be deemed acceptable for risk adjustment data validation, and asked HHS for additional guidance. However, another commenter stated that limiting medical record documentation to face-to-face encounters and telehealth visits would be too restrictive, because of the difficulty in obtaining medical records from providers from prior insurance plans.

Response: HHS will provide further guidance on appropriate sources of plan enrollment data. We believe that the original medical record provides the most complete information on which to assess whether a claim is eligible for risk adjustment. With respect to the challenge of obtaining prior medical documentation when an enrollee changes issuers, we note that the data validation documentation request process for each issuer will be specific to periods during which the issuer reported plan enrollment for the sampled enrollees.

Comment: One commenter stated that the proposed process does not provide adequate recourse for issuers to identify and correct legitimate errors in the provider's medical records. One commenter asked that HHS allow initial validation auditors to use analytic tools to help providers locate overlooked risk adjustment eligible claims.

Response: As part of medical record review, HHS expects that the initial validation auditor will provide the issuer with adequate time to submit accurate medical records from providers. HHS expects that any amendments to medical records will be made in the normal course of business and according to practice protocols. Although we defer to auditors to determine the appropriate tools for their analyses, we encourage issuers to be proactive in identifying risk adjustment eligible claims during the data collection period and, at the same time, to correct for claims identified during data collection that should not be included.

Comment: Another commenter expressed concern that medical

²¹ Issuers and State Exchanges use the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Benefit Enrollment and Maintenance (834), August 2006, ASC X12N/005010X220, as referenced in § 162.1502, or "834 form" to transmit and update enrollment and eligibility to HHS as often as daily but at least monthly. In Federal operations, HHS and the issuer exchange and update data via this same form.

²² See "HHS-Operated Data Collection Policy FAQ" for a discussion of chart review as an acceptable source of supplemental diagnosis codes. Available at: https://www.regtap.info/uploads/library/HHS_OperatedDataCollectionPolicyFAQs_062613. Additional detail will be provided in future guidance.

providers may bear the financial burden of data validation audits.

Response: We appreciate that issuers may require more extensive access to provider medical documentation, and expect issuers and providers to negotiate suitable arrangements, as they do today under similar data validation processes.

(4) Confirmation of Risk Adjustment Errors

In the proposed rule, we noted that the data validation audit processes may identify various discrepancies, many of which will have no impact on an enrollee's risk score. For example, if a medical diagnosis underlying an enrollee's HCC was present on a claim but was not supported by medical record documentation, but the same HCC was supported by the medical record for a different diagnosis, no risk adjustment error would be assessed for the enrollee's HCC. However, if none of the medical record documentation supports a particular HCC diagnosis for an enrollee, we proposed that a risk adjustment error be assessed.

We stated that we consider a risk adjustment error to occur when a discrepancy uncovered in the data validation audit process results in a change to the enrollee's risk score. A risk adjustment error could result from incorrect demographic data, an unsupported HCC diagnosis, or a new HCC diagnosis identified during the medical record review. An unsupported HCC diagnosis could be the result of missing medical record documentation, medical record documentation that does not reflect the diagnosis, or invalid medical record documentation (such as an unauthenticated record or a record that does not meet risk adjustment data collection standards for the applicable benefit year).

We proposed in § 153.630(b)(7)(iv) that a senior reviewer be required to confirm any finding of a risk adjustment error. We proposed to define a senior reviewer as a medical coder certified by a nationally recognized accrediting agency who possesses at least 5 years of experience in medical coding.

Comment: Commenters supported requiring senior reviewers to confirm an enrollee risk adjustment error during the initial data validation audit. However, one commenter suggested increasing the experience required for a senior reviewer from 5 years to 7 years; a different commenter recommended that HHS require only 2 years of experience for the senior reviewer. The commenter said it may be difficult to find enough experienced coders. The commenter suggested permitting junior coders with

2 years of experience to act as senior reviewers for the first 2 years of auditing, after which they could obtain certification in their subject area.

Response: As we discussed in the proposed rule, we believe that once risk adjustment data validation is established, 5 years should be the minimum experience necessary for a senior coder, and that all coders should be certified. We believe that, in the long term, this standard appropriately balances the need to assure that senior coders are sufficiently experienced with the need to assure a reasonable supply of senior coders. However, we recognize that in the initial years of risk adjustment data validation, it may be difficult to find experienced coders. In recognition of this difficulty, and because we believe that by 2016, there will be a sufficient supply of coders with 5 years' experience, we are modifying this provision to permit coders who will have sufficient experience by 2016 to act as senior coders—thus, we provide that senior coders are required to have at least 3 years of experience for risk adjustment data validation for the 2014 and 2015 benefit years.

(5) Review Consistency and Reliability

Validation audits typically include methods of evaluating review consistency and reliability. We believe such processes help to ensure the integrity of the data validation process and strengthen the validity of audit results. In § 153.630(b)(8), we proposed that the initial validation auditor measure and report to the issuer and HHS its inter-rater reliability rates among its reviewers. Such processes measure the degree of agreement among reviewers. In the proposed rule, we set the threshold for the acceptable level of consistency among reviewers at 95 percent for both demographic and enrollment data review, and health status data review outcome. We proposed that reviews be performed using rater-to-standard procedures whereby reviews conducted by reviewers with extensive qualifications and credentials are used to establish testing thresholds or standards for consistency. We are amending § 153.630(b)(8) to provide that, for the initial years of risk adjustment data validation (the 2014 and 2015 benefit years), the initial validation auditor may meet an inter-rater reliability standard of 85 percent for validating review outcomes in accordance with the standards established by HHS.

(iii) Second Validation Audit

The initial validation audit will be followed by a second validation audit, which will be conducted by an auditor retained by HHS to verify the accuracy of the findings of the initial validation audit.

In the proposed rule, we proposed to select a subsample of the initial validation audit sample enrollees for review by the second validation auditor. The second validation auditor would perform the data validation audit of the enrollee subsample, adhering to the same audit standards applicable to the initial validation audit described above, but would only review enrollee information that was originally presented during the initial validation audit. In § 153.630(c), we established standards for issuers of risk adjustment covered plans related to HHS's second validation audit. In § 153.630(b)(4), we established that issuers must submit (or ensure that their initial validation auditor submits) data validation information, as specified by HHS, from their initial validation audit for each enrollee included in the initial validation sample. Issuers must transmit all information to HHS or its second validation auditor in a timeframe and manner to be determined by HHS. The second validation auditor would inform the issuer of error findings based on its review of enrollees in the second validation audit subsample. We will provide additional guidance on the manner and timeframe of these submissions in the future.

As discussed in the white paper and in the proposed rule, we would select the second validation audit small subsample using a sampling methodology that would allow for pair-wise means testing to establish a statistical difference between the initial and second validation audit results. If the pair-wise means test results were to suggest that the difference in enrollee results between the initial validation audit and second validation audit is not statistically significant, the initial validation audit error results would be used for error estimation and calculation of adjustments for plan average risk score. If the test results suggest a statistical difference, the second validation auditor would perform another validation audit on a larger subsample of the enrollees previously subject to the initial validation audit. The results from the second validation audit of the larger subsample would again be compared to the results of the initial validation audit using the pair-wise means test. Again, if no statistical difference were to be

found between the initial validation audit and the second validation audit conducted on the larger subsample, HHS would apply the initial validation audit error results for error estimation using all enrollees selected for the initial validation audit sample. However, if a statistical difference were to be found based on the second validation audit on the larger subsample, HHS would apply the second validation audit error results to modify the initial validation sample, which would be used for the error estimate and calculation of adjustments for the plan average risk score. We stated that we were considering using a 95 percent confidence interval for these pair-wise means tests.

As we discussed in the white paper and the proposed rule, we are considering ways to expedite the second validation audit and the subsequent appeals processes. One possibility would be to begin the second validation audit on those enrollees for which the initial validation audit is complete, even if the entire initial validation audit has not been completed.

We are finalizing the second validation audit approach as proposed.

Comment: Commenters stated that it is unclear how and when enrollees will be included in the expedited second validation audit. Commenters expressed concern that the expedited process would permit the initial validation auditor to review its simplest cases first, negating the benefit of additional time for discussion in an expedited second validation audit. One commenter suggested that it would not be realistic to begin the second validation audit in advance because of the time it would take for the health plan to gather the necessary medical documentation.

Response: We will take commenters' suggestions under consideration when we issue guidance on this process in the future.

(iv) Error Estimation

The fourth stage in the HHS risk adjustment data validation process is error estimation. Upon completion of the initial and second validation audits, HHS will derive an issuer-level risk score adjustment and confidence interval. This adjustment will be used to adjust the average risk score for each risk adjustment covered plan offered by the issuer. HHS intends to provide each

issuer with enrollee-level audit results and the error estimates.

In the proposed rule, we proposed to use a two-phase procedure to accept or correct the results of the initial validation audit based on the results of the second validation audit. In phase one, as described above, we would conduct a pair-wise statistical test for consistency between the initial validation and second validation audit results (as described above for second validation audits). In phase two, if we determine that the results of the two audits are inconsistent, we would adjust the initial validation audit results based on the second validation audit results. In the proposed rule, for phase two, we described two options for using second validation audit results to derive an estimate of an overall corrected risk score for each issuer.

Phase One: Consistency Test Between Initial and Second Validation Audit

In phase one, we proposed using a pair-wise statistical test to determine if the initial validation audit sample results should be adjusted using the results of the second validation audit. To illustrate the underlying statistical test, consider the following notations:

\tilde{x}_i is the i th initial validation audit risk score observation in the second validation audit

sample of n_{sva} observations;

\mathcal{Y}_i is the i th second validation audit risk score observation in the second validation audit

sample of n_{sva} observations;

d_i is the difference between \mathcal{Y}_i and \tilde{x}_i within the second validation audit sample;

\bar{d} is the mean of all d_i observations within the second validation audit sample; and

\mathcal{S}_d is the standard deviation of all d_i observations within the second validation audit

sample.

Assume an issuer submits enrollment and claims data to its dedicated distributed data environment that are used to compute a set of "original" risk

scores. As required by the risk adjustment data validation process, the issuer engages an independent validation auditor, who reviews n_{iva}

enrollee records, as sampled by HHS, and validates the original enrollee risk scores.

From the n_{iva} enrollees in the initial validation audit sample, HHS would select a small second validation audit subsample of n_{sva} enrollees. For each second validation audit selected record, HHS calculates the difference, $d_t = y_t - x_t$. HHS would then conduct a pair-wise means test to determine whether the mean difference, \bar{d} , is statistically significant (that is, unlikely to be zero). Specifically, HHS would conduct a statistical test to determine if zero (0) is contained within the range, $\bar{d} \pm 1.96 \left(\frac{s_d}{\sqrt{n_{iva}}} \right)$. If so, HHS would conclude that there is no statistically significant difference between risk scores determined by the initial and second validation audit processes, and would accept the results of the initial validation audit.

However, if zero (0) is not contained within this range (that is, the difference between \bar{d} and zero is statistically significant), HHS would expand the second validation audit subsample to select a larger subset of n_{iva} , have the second validation auditor review the enrollee files, and again conduct a pair-wise means test using this larger subsample. If the statistical test shows no statistically significant difference, HHS would accept the results of the initial validation audit. If the statistical test shows a statistically significant

difference between the initial validation audit and larger subsample second validation audit findings, HHS would conduct phase two to adjust the full initial validation audit sample based on the larger subsample second validation audit findings.

Phase Two: Adjustment to the Initial Validation Audit Sample

In phase two, if the difference between the initial and second validation audits is found to be statistically significant, HHS would utilize the risk score error rate

calculated from the larger second validation audit subsample to adjust the full initial validation audit sample, which could in turn be used to adjust the average risk scores for each plan. This approach would adjust the entire initial validation audit sample using a one-for-one replacement for the enrollees reviewed by the second validation audit, and a uniform adjustment for the enrollees that were not.

To illustrate this process, consider the following notations:

M is the total number of enrollees in the risk adjustment covered plans of the issuer;

n_{iva} is the initial validation audit sample size;

n_{sva} is the size of the larger second validation audit subsample;

$\bar{y}_{n_{iva}}$ is the mean of the initial validation audit-adjusted risk scores in the initial validation audit sample n_{iva} ;

$\bar{y}_{n_{sva}}$ is the mean of the second validation audit-adjusted risk scores in the second validation audit sample n_{sva} ;

$\bar{x}_{n_{iva}}$ is the mean of the original risk scores in the initial validation audit sample n_{iva} ;

$\bar{x}_{n_{sva}}$ is the mean of the original risk scores in the second validation audit sample n_{sva} ;

X_M is the original risk score total across all M records;

$\hat{Y}_{n_{iva}}$ is the projected correct risk score across all M records using the initial validation error rate; and

$$\hat{Y}_{n_{iva}} = \frac{\bar{y}_{n_{iva}}}{\bar{x}_{n_{iva}}} X_M$$

$\hat{Y}_{n_{sva}}$ is the projected correct risk score across all M records using the error rate from the

larger second validation audit subsample.

$$\hat{Y}_{n_{sva}} = \frac{\bar{Y}_{n_{sva}}}{\bar{X}_{n_{sva}}} X_M$$

We would undertake the following steps to adjust the risk scores in the initial validation audit samples:

(1) Replace the initial validation audit-adjusted risk scores with the second validation audit-adjusted risk scores in the n_{sva} records that were sampled from n_{iva} (one-for-one risk score adjustment).

(2) Apply a uniform adjustment factor, $\frac{\hat{Y}_{n_{sva}}}{\hat{Y}_{n_{iva}}}$ to the initial validation audit-adjusted risk

scores in the $(n_{iva}-n_{sva})$ records not reviewed by the second validation audit.

Comment: Commenters were supportive of using a pair-wise means test and a larger second validation audit subsample to adjust the initial validation audit sample. One commenter recommended that HHS clarify whether the larger second validation audit subsample will include the small second validation audit sample in the event the second validation audit includes the second, larger review.

Response: The larger subsample will not include the small second validation audit subsample if a larger second validation audit subsample is necessary. However, all enrollees in both the small second validation audit subsample and the larger second validation audit

subsample will be used for the pair-wise test and risk score adjustment, if applicable. We are finalizing this error estimation process as proposed.

Adjusted Risk Score Projections

The results of the initial or second validation audits will be used as the basis for projecting a corrected risk score for each issuer's population. The full initial validation audit sample of 200, whether the initial validation audit sample has been adjusted or not, will be used to calculate adjusted risk score projections. In the proposed rule, we proposed performing the projections described above on a stratum-by-stratum level, weighted to achieve an estimate of the corrected risk score for each issuer.

We proposed to use a stratified separate ratio estimator²³ to estimate the corrected average risk score for each issuer. To compute the stratified separate ratio estimator, HHS would first extrapolate the total correct risk score within each stratum, then sum the stratum-specific projected correct risk scores for all strata, with the total sum divided by the total enrollee count to arrive at the corrected average risk score. The projected risk score error would then be calculated as the difference between the recorded average risk score across the entire population and the point estimate.

The stratified separate ratio estimator of the total correct risk score would be calculated using the following equation:

²³ For a discussion of stratified separate ratio estimators, see Cochran, William G., *Sampling*

Techniques, third edition, John Wiley & Sons, 1977, at 164.

$$\hat{Y}_R = \sum_{h=1}^H \frac{\bar{y}_h}{\bar{x}_h} X_h$$

Where:

\hat{Y}_R is used to estimate the correct total risk score;

\bar{y}_h is the sample mean of the correct risk score in stratum h ;

\bar{x}_h is the sample mean of the original risk score in stratum h ;

X_h is the total sum of the original risk score in stratum h ; and

H is the total number of strata.

\hat{Y}_R would then be normalized by the enrollment count to derive a corrected average risk score for the issuer.

To estimate the variance of the point estimate, HHS would first estimate the variance within each stratum and then sum the stratum-specific variances for all strata. As noted above, the point estimate and variance of the point estimate would be calculated using the full initial validation audit sample of 200, whether the initial validation audit sample has been adjusted or not. The estimated variance of the stratified separate ratio estimate for the correct total risk score would be calculated as follows:

$$\text{Variance } (\hat{Y}_R) = \sum_{h=1}^H \left[\frac{N_h^2 \left(1 - \frac{n_h}{N_h}\right)}{n_h(n_h - 1)} \left(\sum_{i=1}^{n_h} y_{ih}^2 + \hat{R}_h^2 \sum_{i=1}^{n_h} x_{ih}^2 - 2\hat{R}_h \sum_{i=1}^{n_h} y_{ih}x_{ih} \right) \right]$$

Where:

n_h is the number of enrollees sampled in stratum h ;

N_h is the population frequency in stratum h ;

y_{ih} is the corrected risk score for the i th sampled enrollee in stratum h ;

x_{ih} is the original risk score for the i th sampled enrollee in stratum h ; and

$$\hat{R}_h = \frac{\sum_{i=1}^{n_h} y_{ih}}{\sum_{i=1}^{n_h} x_{ih}}$$

The square root of the estimated variance is the standard error (SE).

We proposed to use the issuer's corrected average risk score to compute an adjustment factor, based on the ratio between the corrected average risk score and the original average risk score that could be applied to adjust plan average risk for all risk adjustment covered plans within the issuer. We considered two options for applying the adjustment factor. Under the first option, we considered directly applying an adjustment factor to all of the issuer's risk adjustment covered plans. Under the second option, we considered

applying this adjustment only if the corrected average risk score and the recorded average risk score are statistically different. We are finalizing the second option, under which a critical parameter of the statistical test is the target confidence interval, which determines the stringency of the test. In the proposed rule, we considered performing the statistical test at the 90, 95, or 99 percent confidence interval. As we noted in the proposed rule, the OIG performs certain similar data validation tests using a 90 percent confidence

interval, while the Medicare Advantage risk adjustment data validation program uses a 99 percent confidence interval.

We are finalizing our proposal to apply an adjustment factor only if the corrected average risk score and recorded risk score are statistically different, using a 95 percent confidence interval. We note that we will use this approach with a 95 percent confidence interval in the initial years of the risk adjustment data validation program but will consider using other error estimation approaches and statistical

tests as risk adjustment data becomes available. Among the approaches that we may consider for future years would be an approach under which risk scores would be corrected only if a statistically significant difference in risk scores was demonstrated, but a more pronounced risk score adjustment would be applied.

Comment: Commenters generally supported applying an adjustment factor only if the corrected average risk score and recorded risk score are statistically different. However, a few commenters supported using a 99 percent confidence interval instead of the proposed 95 percent confidence interval. One commenter recommended using both a 90 percent and a 95 percent confidence interval but having CMS retain the discretion whether to apply an adjustment factor if statistical difference is discovered under the 90 percent confidence interval but not the 95 percent confidence interval. One commenter also recommended that the risk scores for enrollees without HCCs only be adjusted upward, not downward, since enrollees without HCCs are assigned the lowest error rate from among enrollees with HCCs.

Response: We believe that a 99 percent confidence interval could lead to under correction of bias in risk scores, and therefore, are finalizing a 95 percent confidence interval. We believe that this lower confidence interval will encourage issuers to correct practices that may lead to errors in the data validation process. We note that the risk scores of enrollees without HCCs may be adjusted upward or downward based on the review of demographic and medical documentation. For example, if an enrollee's age was incorrectly recorded, validation of that data could change the enrollee risk score, even if the enrollee had no HCCs.

Error Estimation Example

To illustrate the corrected average risk score and error estimation process described above, assume that a sample of 200 enrollees is selected for initial validation audit review for a particular issuer. From this sample, assume that a subsample of 20 enrollees is selected for second validation audit review. Assume the issuer's average recorded population risk score is 1.60 and the projected correct population risk score from the sample of 200 is 1.40, with a two-sided 95 percent confidence interval of 1.30 to 1.50.

The first step in the error estimation process will determine if the initial validation audit results should be corrected based on the second validation audit review or accepted without adjustment. We will perform a

pair-wise means test to compare the projected risk scores for the sample of 200 enrollees and the subsample of 20 enrollees.

For this example, assume that the statistical test fails (that is, there is a statistically significant difference between the projected risk scores in the sample of 200 and the subsample of 20).²⁴ We will then select an expanded subsample from the original sample of 200 enrollees. Assume that the larger subsample is a sample of 80 enrollees. Following selection of the larger second validation audit subsample, we will perform the pair-wise means test again. Assume the test fails again (that is, the pair-wise means test shows a statistically significant difference in the projected risk scores between the initial validation audit and the second validation audit for the sample of 100 enrollees—by assumption, 20 from the first subsample and 80 from the second subsample—selected in the second data validation audit). We will conclude that the risk scores in the sample of 200 enrollees need to be adjusted based on the results of the second validation audit.

In the second step of error estimation, HHS will adjust the risk scores in the sample of 200 using a one-for-one replacement for the risk scores of the 100 enrollees reviewed by the second validation auditor, and a uniform adjustment for the other enrollees in the initial validation audit sample. The one-for-one replacement will replace the risk scores calculated based on initial validation audit findings, with the risk scores calculated based on the second validation audit findings for the 100 enrollees. The remaining 100 enrollees that were not included in the second validation audit subsample will be adjusted based on the ratio of two projections: (1) The projected correct population risk score using the second validation audit findings in the subsample of 100 (assume this projected risk score is 1.50, with a two-sided 95 percent confidence interval of 1.30 to 1.70); divided by (2) the projected correct population risk score using the initial validation audit findings for the sample of 200 enrollees (equal to 1.40 based on the assumption noted above). The adjustment ratio is equal to $1.07 = 1.50/1.40$. Therefore, the risk scores of the remaining 100 enrollees not included in the second validation audit subsample will be increased by 7 percent.

²⁴ If the test passes, then no adjustments would be made to the sample of 200, and the projected results from this sample would be used to adjust average plan liability risk scores.

At that point, the adjusted average risk score of the initial validation sample would be calculated to derive a projected correct population average risk score for the issuer that would be compared to the issuer's recorded average risk score. The plan average risk scores for the issuer would then be adjusted, based on the ratio between the corrected average risk score and the recorded average risk score, as described above, if the issuer's recorded average risk score and the projected correct average risk score are significantly different.

(v) Appeals

We anticipate that the risk adjustment data validation appeals process will occur annually, beginning in the spring of the year in which the error rate will be applied to adjust risk scores and affect risk adjustment payments and charges. Because we are not applying error rates to adjust payments and charges for the initial 2 years of the risk adjustment program, the first year for which error rates will be applied to payments and charges will be 2016. These error rates will be used as the basis for adjustments to the payment transfers for 2017, which will take place in spring 2018. We anticipate the appeals process will begin in the spring of 2018, prior to the 2017 payment transfers. We will provide additional guidance on the appeals process and schedule in future rulemaking.

Comment: Commenters supported beginning the appeals process with the 2016 payment year. They also recommended leveraging existing appeals processes where applicable and providing at least 60 days to file an appeal. We received comments recommending that the individual reviewing the appeal be an independent entity with an appropriate level of coding, medical documentation, and audit experience. One commenter also recommended that the scope of the appeals be expanded to include initial validation audit results.

Response: We will provide additional guidance on the appeals process and schedule in future rulemaking.

(vi) Payment Transfer Adjustments

Risk adjustment payment transfer amounts will be based on adjusted plan average risk scores. The data validation audits will be used to develop a risk score error adjustment for each issuer, as described above. Each issuer's risk score adjustment will be applied to adjust the plan average risk score for each of the issuer's risk adjustment covered plans. This adjustment will be applied on a prospective basis

beginning with the risk adjustment data for benefit year 2016 (that is, the adjustments would take effect in 2018, during payment transfers for 2017). Because an issuer's adjusted plan average risk score is normalized as part of the risk adjustment payment calculation, the effect of an issuer's risk score error adjustment will depend upon its magnitude and direction compared to the average risk score error adjustment and direction for the entire market.

We are considering reporting the following summary findings to issuers for the initial 2 years of the program:

- State- or market-wide error rates.
- Issuer error rates.
- Initial validation audit or error rates.
- Projected financial impact of the proposed risk adjustments, as determined by the initial and second validation auditors.

The 2-year interval before risk adjustment data validation adjustments are applied to risk scores and affect payments and charges will provide initial validation auditors and issuers the opportunity to reform existing processes prior to the implementation of HHS payment transfer adjustments for the 2016 benefit year. We believe that the reports described above will help issuers and initial validation auditors better understand the likely effects of the risk adjustment data validation program in States where HHS operates risk adjustment. We are finalizing these provisions as proposed.

Comment: Commenters requested that HHS provide issuers with reports of their risk scores, as well as market risk scores pre- and post-audit. Commenters also requested that HHS provide issuers with State and market-wide error rates, issuer error rates, initial validation audit error rates, and the projected financial impact of the proposed risk adjustment, as determined by auditors. One commenter requested that HHS publicly report issuer error rates both nationally and for each State for each issuer. Another commenter was opposed to the public reporting of issuer error rates and requested that they be provided individually to issuers.

Response: We plan to publicly report aggregate summaries at the State, market, and initial validation auditor level. However, we will assess whether to publicly report initial validation auditor-level results. We plan to provide issuer-specific reports to the issuer and the initial validation auditor. We will provide further details on the reports in future guidance.

(vii) Oversight

The second final Program Integrity Rule outlined selected oversight provisions related to the premium stabilization programs, such as maintenance of records, sanctions for failing to establish a dedicated distributed data environment, and the application of a default risk adjustment charge to issuers in the individual and small group markets that fail to provide data necessary for risk adjustment. We proposed expanding on these provisions to include oversight related to risk adjustment data validation when HHS operates risk adjustment on behalf of a State, and are now finalizing those proposals.

Section 153.620 provides that an issuer that offers risk adjustment covered plans must comply with any data validation requests by the State or HHS on behalf of the State, and that an issuer that offers risk adjustment covered plans must also maintain documents and records, whether paper, electronic, or in other media, sufficient to enable the evaluation of the issuer's compliance with applicable risk adjustment standards, and must make that evidence available upon request to HHS, OIG, the Comptroller General, or their designee, or in a State where the State is operating risk adjustment, the State or its designee to any such entity.

Based on our authority under section 1321(c)(2) of the Affordable Care Act, we proposed in § 153.630(b)(9) that, when HHS operates risk adjustment on behalf of a State, an issuer of a risk adjustment covered plan that does not engage an initial validation auditor within the timeframe specified by HHS of the year following the benefit year, or that otherwise does not arrange for a risk adjustment initial validation audit that complies with applicable regulations, may be subject to CMPs. We stated that we intend to apply the proposed sanction so that the level of the enforcement action would be proportional to the level of the violation. While we reserve the right to impose penalties up to the maximum amounts proposed in § 156.805(c), as a general principle, we would work collaboratively with issuers to address problems in conducting the risk adjustment data validation process. In our application of the sanction, we would take into account the totality of the issuer's circumstances, including such factors as an issuer's previous record (if any), the frequency and level of the violation, and any aggravating or mitigating circumstances. We stated that our intent is to encourage issuers to address non-compliance and not to

severely affect their business, especially where the issuer demonstrates good faith in monitoring compliance with applicable standards, identifies any suspected occurrences of non-compliance, and attempts to remedy any non-compliance.

We proposed in § 153.630(b)(10) to assign a default risk adjustment charge to an issuer that does not hire an initial validation auditor or that otherwise does not submit initial validation audit results that comply with the regulations in subpart G and subpart H of part 153. We stated that we were considering whether this charge should be the same as the default charge in § 153.740(b) for failure to comply with data requirements, should be based on a default error rate, or should be calculated based on some other methodology. We are finalizing a default risk adjustment charge that will be calculated in the manner provided for in § 153.740(b), which is discussed elsewhere in this final rule.

Issuers may request technical assistance from HHS at any stage of the risk adjustment data validation process. HHS may also offer such assistance directly if we become aware of technical issues arising at any time during the risk adjustment data validation process. We plan to provide further assistance and clarification around the risk adjustment data validation process through a range of vehicles, including additional guidance, training materials, webinars, or user group calls.

Based on the comments received, we are finalizing a default risk adjustment charge at § 153.630(b)(10) for issuers that do not conduct the initial validation audit.

Comment: Commenters agreed with our proposal to impose CMPs if issuers do not engage an auditor within the specified timeframe, do not otherwise arrange for an initial validation audit that complies with applicable regulations, or are repeatedly out of compliance with risk adjustment data validation requirements, including not providing the initial and second validation audit auditors with information. One commenter supported assigning the issuer the highest possible default error rate that guarantees additional charges as a percent of premium or reduced payments as a percent of premium. Another commenter recommended that HHS enforce the initial validation audit requirement with a significant penalty for issuers that do not conduct the initial validation audit, while imposing lesser penalties if the initial validation audit results are not submitted in a timely manner.

Response: We agree that penalties should correspond to the severity of an issuer's non-compliance. We also agree with the commenter who suggested that HHS enforce the initial validation audit requirement with a significant penalty such as the default risk adjustment charge for issuers that do not conduct the initial validation audit, while imposing CMPs if the initial validation audit results are not submitted in a timely manner. As we noted previously and in the proposed rule, we intend to apply any proposed sanction so that the enforcement action would be proportional to the level of the violation.

(viii) Data Security

We recognize that the risk adjustment data validation process outlined here will require the transmission of sensitive data and documents between an issuer and the initial and second validation auditors. HHS takes seriously the importance of safeguarding protected health information and PII. As outlined in the white paper and the proposed rule, we believe that it will be necessary to specify standards for safeguarding this information through proper information storage and transmission methods.

We note that § 153.630(f)(2) currently requires an issuer to ensure that it and its initial validation auditor comply with the HIPAA information security standards described at §§ 164.308, 164.310, and 164.312 (HIPAA Security Rule) in connection with the initial validation audit, the second validation audit, and any appeals. In addition to these requirements, we continue to consider defining standards and expectations that would apply to issuers and initial and second validation auditors pertaining to data security, management, and transmission. These standards could require systems to safeguard and encrypt data "at rest" and "in transit," and to authenticate identities of users. They could also prohibit auditors from using or disclosing the information they receive for any purpose other than the audit and oversight. Similar standards have been implemented under the Medicare Advantage risk adjustment data validation process. We will address these issues and the treatment of initial and second validation auditors under HIPAA in future rulemaking or guidance.

Comment: Several commenters stated that compliance with the current provisions of the HIPAA Security Rule by issuers and their auditors will effectively safeguard the transmission of sensitive data and documents between

the issuer and the initial and second validation auditors. One commenter recommended that HHS adopt additional data security standards. One commenter requested that HHS base data security standards on applicable Medicare Advantage risk adjustment data validation standards, with specific penalties for breaches.

Response: Because of the sensitive nature of the risk adjustment data validation data, we recognize that it is essential that HHS have in place the proper standards and safeguards to ensure data security and privacy protections. We are continuing to evaluate the sufficiency of the current HIPAA Security Rule provisions, as well as the potential effectiveness of requiring additional data security, management, and transmission safeguards, including penalties for breaches. We intend to clarify our data security approach in future rulemaking or guidance.

(ix) Implementation Timeline

For the 2014 benefit year, we expect to implement risk adjustment data validation activities in early 2015. Implementation activities will begin with issuers submitting the identity of their initial validation auditor to HHS in accordance with § 153.630(b)(1). In the spring of 2015, we intend to utilize the data submitted by issuers for risk adjustment payments and charges and apply the sampling methodology described above to select the audit sample for each issuer for the initial validation audit. During the same timeframe, we will train issuers and initial validation auditors on the risk adjustment data validation process and the applicable standards for performing the initial validation audit, which will begin in the summer of 2015. Once the initial validation audit has concluded in the fall of 2015, HHS will begin the second validation audit process, which will continue into 2016. Risk adjustment data validation implementation activities for the 2014 benefit year data will conclude in 2016 after distribution of HHS findings to issuers, processing of appeals, and estimation and reporting of final risk scores. Since the 2014 benefit year is the first year of implementation of risk adjustment data validation, we expect to report on lessons learned from these activities, and to use this information to improve the risk adjustment data validation process.

We expect that risk adjustment data validation implementation activities will follow a similar schedule for each subsequent benefit year. The 2016 benefit year will be the first year when

payments and charges are adjusted. Those adjustments will occur after the conclusion of risk adjustment data validation activities for the 2016 benefit year, in the summer of 2018.

Comment: Commenters supported the reporting of lessons learned from the initial year risk adjustment data validation activities. One commenter was concerned that the initial 2-year time period would be insufficient to analyze error rates or determine the appropriate sampling approach. Several commenters suggested that issuers would need to receive audit results more promptly to be able to improve their processes for the 2017 plan year. One commenter urged HHS to begin the risk adjustment data validation process as soon as possible.

Response: We believe that the initial 2 years of risk adjustment will be sufficient to analyze error rates, determine a more effective sampling approach, and allow issuers to gain experience with the risk adjustment data validation process in time for payment adjustments to occur for the 2016 benefit year. Though final results for the 2014 benefit year will not become available until 2016, we believe issuers should be able to adjust their 2017 processes in time.

e. HHS Audits of Issuers of Risk Adjustment Covered Plans

We proposed in § 153.620(c) that HHS or its designee may audit an issuer of a risk adjustment covered plan, when HHS operates risk adjustment on behalf of a State, to assess the issuer's compliance with the requirements of subparts G and H of 45 CFR part 153. The issuer would also be required to ensure that its relevant contractors, subcontractors, or agents cooperate with the audit. We noted that we anticipate conducting targeted audits of issuers of risk adjustment covered plans informed by, among other criteria and sources, the data provided to HHS through the dedicated distributed data environment and any previous history of noncompliance with these standards. These audits would focus on aspects of the risk adjustment program that are not validated through the risk adjustment data validation program, such as whether a plan was a risk adjustment covered plan.

We also proposed that if an audit results in a finding of material weakness or significant deficiency (as these terms are defined in GAAS issued by the American Institute of Certified Public Accountants, and Government Auditing Standards issued by the Government

Accountability Office (GAO)²⁵ with respect to compliance with any requirement of subparts G or H of 45 CFR part 153, the issuer would be required to: (i) Within 30 calendar days of the issuance of the final audit report, provide a written corrective action plan to HHS for approval; (ii) implement that corrective action plan; and (iii) provide to HHS written documentation of the corrective actions once taken. We proposed that if HHS determines as the result of an audit that the issuer of the risk adjustment covered plan was required to pay additional risk adjustment charges or received risk adjustment payments to which it was not entitled, we may require the issuer to pay such amounts to the Federal government.

We are finalizing the audit provisions as proposed.

Comment: One commenter asked that if an audit identifies repeated noncompliance with the risk adjustment standards and the issuer fails to correct such issues, including failing to implement a corrective action plan, the issuer should be subject to a default risk adjustment charge or CMPs.

Response: Under § 153.620(c), an issuer of a risk adjustment covered plan must provide and implement a corrective action plan to rectify any material weakness or significant deficiency identified by HHS through an audit. Enforcement remedies are provided with respect to the risk adjustment program under § 153.740 when an issuer of a risk adjustment covered plan fails to comply the data requirements in §§ 153.700 through 153.730 or §§ 153.610 through 153.630. Enforcement remedies may be available through other Federal statutes, such as the False Claims Act, as well. While § 153.620(c) does not provide specific remedies for the failure to implement a corrective action plan, we note that HHS will consider the totality of circumstances in assessing penalties for non-compliance with risk adjustment standards under § 153.740, including those that occur in connection with a corrective action plan.

Comment: One commenter suggested that when an audit results in issuers owing risk adjustment, reinsurance, or risk corridors charges, those funds should be paid into the applicable

program and, where applicable, distributed pro rata to issuers of eligible plans in the program. The commenter further suggested that any reinsurance deficiencies identified and rectified after the program has ended should be directed to the risk adjustment program.

Response: As we stated in the proposed rule, if HHS determines as the result of an audit that an entity or issuer was required to pay risk adjustment, reinsurance, or risk corridors charges, HHS has the authority to require the entity or issuer to pay such amounts to the Federal government. We will address the distribution of funding deficiencies, including those identified after a temporary program has ended, in future rulemaking.

Comment: We received a number of comments regarding audit protocols and procedures applicable to the premium stabilization programs. In order to minimize the number and scope of data requests that issuers must respond to, commenters encouraged HHS to identify data elements, sample sizes, and other aspects of the audits in advance, and to streamline and coordinate data requests, given the overlap in data elements supporting the premium stabilization programs and the MLR program. Commenters suggested centralized audits so that auditors can consolidate data requests and follow-up requests for information. Commenters also encouraged HHS to work with States, issuers, contributing entities, and other stakeholders in advance of issuing data requests for audits. Additionally, commenters encouraged HHS to provide significant lead time for data collection and submission, and suggested that HHS limit its audits to samples of data when possible and expand those sample audits only upon a finding of material non-compliance. Commenters also suggested that HHS limit issuer audits to one per year.

Response: As stated in the proposed rule, to reduce the burden on issuers and HHS, to the extent practical, we intend to coordinate any audits of issuers and contributing entities with related audits of Exchange financial programs and premium stabilization programs, in order to limit the number of potential audits that an organization would experience. We intend to provide further details on the audit program, including timelines, procedures, and substantive requirements, in future rulemaking and guidance. We will consider the comments we received to this proposed rule and further feedback from stakeholders to ensure that our audit program is transparent and effective.

Comment: Some commenters asked that HHS perform audits from a centralized location, with no on-site audits.

Response: While we reserve the right to conduct on-site audits, as noted above, we intend to provide further details on the audit program in future rulemaking and guidance.

f. State-Submitted Alternate Risk Adjustment Methodology

For 2015, we are recertifying the alternate risk adjustment methodology submitted by Massachusetts and certified in the 2014 Payment Notice (78 FR 15439–15452). We are not certifying any other alternate risk adjustment methodologies for 2015.

3. Provisions and Parameters for the Transitional Reinsurance Program

The Affordable Care Act directs that a transitional reinsurance program be established in each State to help stabilize premiums for coverage in the individual market from 2014 through 2016. In the 2014 Payment Notice, we expanded on and modified the standards set forth in subparts C and E of the Premium Stabilization Rule, and established the reinsurance payment parameters and a uniform contribution rate for the 2014 benefit year. In this final rule, we finalize provisions from the proposed rule, including: additional standards regarding reinsurance contributions, the 2015 reinsurance payment parameters and uniform contribution rate, modifications to the 2014 reinsurance payments parameters, and certain oversight provisions for the reinsurance program.

a. Major Medical Coverage

Section 1341(b)(3)(B)(i) of the Affordable Care Act states that “the contribution amount for each issuer [must] proportionally reflect each issuer’s fully insured commercial book of business for all major medical products . . .” To provide additional clarification for contributing entities, we proposed to define “major medical coverage” in § 153.20 to mean health coverage for a broad range of services and treatments provided in various settings that provides minimum value in accordance with § 156.145. We noted in the proposed rule that this definition of major medical coverage only applies for the purpose of determining reinsurance contributions under section 1341 of the Affordable Care Act.

We are finalizing this provision as proposed, with one modification—we are modifying the definition of major medical coverage to include a specific reference to catastrophic plans and

²⁵ See Government Auditing Standards (2011 Revision), available at: <http://www.gao.gov/yellowbook>. For public companies, the Public Company Accounting Oversight Board (PCAOB) sets audit standards. See <http://pcaobus.org/Standards/Auditing/Pages/default.aspx>. For non-public companies, the AICPA sets audit standards. See <http://www.aicpa.org/Research/Standards/AuditAttest/Pages/SAS.aspx>.

individual and small group market plans subject to actuarial value requirements under § 156.140.

Comment: Several commenters supported our proposed definition of major medical coverage, stating that the reference to minimum value is a reasonable method to provide a consistent definition for major medical coverage. Other commenters asked that we exclude the reference to minimum value and continue to classify fully insured major medical coverage as that which provides hospitalization and medical services, or retain the definition of major medical coverage as it was defined in the preamble to the 2014 Payment Notice (78 FR 15456). One commenter stated that coverage before 2014 was not evaluated for minimum value and retroactive testing would be difficult to implement, administratively burdensome, difficult to audit, and that this definition could exclude a fairly large population from reinsurance contributions. Another commenter suggested that minimum value is confusing because it is not a concept that generally applies to individual health coverage and is only relevant for determining whether employer-sponsored coverage provides minimum value. One commenter noted that because the safe harbor method of calculating minimum value has not yet been finalized, minimum value cannot yet be determined.

Response: We believe that codification of this definition of major medical coverage will help issuers and group health plans more accurately determine their reinsurance contribution obligations. As noted in the proposed rule, we believe that minimum value is a reasonable way to clarify the definition of major medical coverage and reduce uncertainty as to whether reinsurance contributions are required of certain unique plan arrangements. In addition, we believe that the concept of minimum value will be familiar to issuers and group health plans, and believe that the minimum value calculator will enable the calculation of minimum value with minimal burden, regardless of when the coverage was first offered. In the event that the minimum value calculator is unsuitable for use in determining whether a particular plan provides minimum value (and, therefore, major medical coverage), the contributing entity may seek certification by an actuary consistent with § 156.145(a)(3) to establish whether the plan provides minimum value.

Comment: One commenter asked that we include in the definition of major medical coverage any coverage subject

to the actuarial value requirements because this would eliminate the need for plans subject to actuarial value requirements to also calculate minimum value.

Response: We agree with the commenter that this additional clarification would be helpful to eliminate this unneeded complexity, and are therefore finalizing a definition of major medical coverage to include explicit references to catastrophic plans and individual and small group market plans subject to the actuarial value requirements under § 156.140. As noted in the proposed rule (78 FR 72340), the minimum value standards established under 45 CFR 156.145 deem any coverage that meets any of the levels of coverage requirements described in 45 CFR 156.140 to satisfy minimum value requirements. The levels of coverage, in turn, are determined through calculation of AV between 60 to 90 percent. As such, plans that meet the AV requirements in accordance with 45 CFR 156.140 would not need to also calculate minimum value. We further note that catastrophic plans, as well as coverage offered in the individual and small group markets that are subject to the Affordable Care Act AV requirements, would be considered part of a contributing entity's "commercial book of business." Therefore, contributing entities must make reinsurance contributions on behalf of their enrollees with catastrophic coverage, as well as individual market coverage and small group coverage subject to the AV requirements under 45 CFR 156.140, absent another exception in § 153.400.

Comment: One commenter suggested that HHS clarify that short-term limited duration insurance, which is excluded from the definition of "individual health insurance coverage" under section 2791(b)(5) of the PHS Act,²⁶ is not major medical coverage and is therefore not required to make reinsurance contributions.

Response: In general, section 1341(b)(3)(B)(i) of the Affordable Care Act requires reinsurance contributions for "major medical coverage" that is considered to be part of a "commercial book of business," absent an applicable exemption. We are interpreting the term "major medical coverage" solely in the context of the obligation under the Affordable Care Act to make reinsurance

contributions. The question of whether coverage is subject to the rules that apply to "individual health insurance coverage" is separate from the question of whether it is "major medical coverage" for purposes of reinsurance contributions.

As we noted in the preamble to the 2014 Payment Notice (78 FR 15456), for purposes of whether a reinsurance contribution is required, we interpret the term "major medical coverage" in terms of the scope and extent of the coverage offered, not in terms of what other Federal requirements may apply to the coverage. Specifically, in the 2014 Payment Notice, we indicated that we interpreted "major medical coverage" to be coverage of a wide range of services not limited in scope (for example, vision or dental coverage) or extent (for example, coverage with very low annual dollar limits). Therefore, reinsurance contributions would be required with respect to a contributing entity's enrollees in a short-term limited duration plan to the extent the plan provides "major medical coverage," as we have interpreted that term. In this final rule, we are adopting as final the language in proposed § 153.20 that sets forth a specific standard for implementing our interpretation of "major medical coverage," as set forth in the 2014 Payment Notice. Specifically, under § 153.20, coverage will be considered "major medical coverage" for reinsurance contribution purposes if it covers a wide range of services, is not limited in scope, and provides a level of coverage that meets the minimum value test under § 156.145. While we are finalizing this standard in this final rule, because it implements our interpretation of "major medical coverage" as set forth in the 2014 Payment Notice, this standard will be applied in determining a contributing entity's reinsurance contribution liability for the 2014, 2015, and 2016 benefit years.

We recognize that the non-standard features of a short-term limited duration plan may make the minimum value calculator unsuitable for use with the plan in determining whether the plan provides minimum value (and, therefore, "major medical coverage"). In such an event, the contributing entity may seek certification by an actuary consistent with § 156.145(a)(3) to establish whether the plan provides minimum value.

b. Self-Administered, Self-Insured Plans

Following comments submitted with respect to the 2014 Payment Notice and the proposed Program Integrity Rule, we proposed to modify the definition of a

²⁶ Section 2791(b)(5) of the PHS Act provides: "The term 'individual health insurance coverage' means health insurance coverage offered to individuals in the individual market, but does not include short-term limited duration insurance." Available at: http://www.nadp.org/Libraries/HCR_Documents/phsa027.sflb.ashx.

“contributing entity” for the 2015 and 2016 benefit years to exclude self-insured group health plans that do not use a third party administrator (TPA) in connection with the core administrative functions of claims processing or adjudication (including the management of internal appeals) or plan enrollment. The preamble to the proposed rule discussed how section 1341(b) of the Affordable Care Act can reasonably be interpreted in more than one way with respect to whether a self-insured, self-administered plan is a contributing entity. The proposed modification recognized that some self-insured group health plans, which we believe would generally not be considered to be using the core services of a TPA, may use third parties for ancillary administrative support, and we noted that we would consider these plans to be self-administered for purposes of the reinsurance program. For purposes of the definition of “contributing entity,” we proposed to consider a TPA to be, with respect to a self-insured group health plan, an entity that is not under common ownership or control with the self-insured group health plan or its sponsor that provides administrative functions to the self-insured group health plan in connection with the core administrative services noted above. We sought comment on this definition, and whether certain types of service providers should be considered a TPA for these purposes.

In addition, we sought comment on whether the core administrative functions are the appropriate criteria for this revised definition, and what other administrative functions, such as medical management services, provider network development, or other support tasks, should be considered in determining whether a self-insured group health plan uses a TPA. We also sought comment on whether certain benefits or services, such as pharmaceutical benefits or behavioral health benefits, or a *de minimis* or small percentage of all benefits and services, may be performed by an unaffiliated service provider, which benefits or services should be excluded, and how such a *de minimis* amount or small percentage should be measured.

We are finalizing the proposed definition of “contributing entity” as proposed, with minor modifications to permit the use of unrelated third parties for provider network development and related services, and to provide for a *de minimis* exception.

Comment: Some commenters agreed with the proposed exemption, and stated that it had adequate statutory support and also accurately reflected

Congressional intent. Some commenters urged an expanded exemption. Some commenters disagreed with the proposed exemption as not required or supported by the statute, inconsistent with HHS’s prior position on the issue, or not supported by a clear policy rationale.

Response: Section 1341(b)(1)(A) of the Affordable Care Act can reasonably be interpreted in more than one way with respect to the applicability of reinsurance contributions to self-insured, self-administered plans. After receipt of comments submitted in response to the 2014 Payment Notice and the proposed Program Integrity Rule, we reconsidered this issue. Following this in-depth review, our view is that the better reading of section 1341 is that a self-insured, self-administered plan should not be a contributing entity, but in order to avoid disruption to contributing entities, we proposed to retain the prior definition of contributing entity for the 2014 benefit year. Section 1341(b)(1)(A) of the Affordable Care Act states that health insurance issuers and TPAs on behalf of group health plans are required to make reinsurance contributions, but does not refer to self-insured, self-administered plans. The provision’s reference to group health plans administered by TPAs, coupled with the omission of self-insured, self-administered plans, supports the proposed exemption. We also note that section 1341 of the Affordable Care Act supports the distinction between self-insured, self-administered plans and self-insured plans that use a TPA, since sections 1341(b)(1) and (b)(3)(B)(i) specifically refer to self-insured plans with TPAs and are silent as to self-insured, self-administered plans. Further support for this reading is found under section 1341(b)(3)(B) of the Affordable Care Act and § 153.400(a)(1)(ii), which provide that reinsurance contributions are to reflect a “commercial book of business.” While a group health plan administered by a TPA would normally be considered part of a “commercial book of business,” a self-insured, self-administered plan would not normally be considered part of an entity’s “commercial book of business.” For the reasons set forth above, HHS is finalizing the proposed exemption, with certain modifications discussed below.

Comment: Some commenters stated that adopting the proposed exemption would set a precedent permitting other contributing entities to seek exemptions from reinsurance contributions. Several commenters stated that the proposed exemption inappropriately treats self-insured plans with TPAs differently

from self-insured, self-administered plans, and will inequitably shift reinsurance costs from self-insured, self-administered plans to self-insured plans with TPAs and health insurance issuers. Several commenters stated that the proposed exemption inappropriately favors “union plans.”

Response: Self-insured, self-administered plans are a unique subset of potential contributing entities. The proposed exemption is narrowly drawn so that only a self-insured plan that does not use a TPA to perform its claims processing, claims adjudication, and enrollment functions would qualify for the exemption. As discussed in the preamble to the proposed rule, section 1341 of the Affordable Care Act supports the distinction between self-insured, self-administered plans and self-insured plans that use a TPA, since sections 1341(b)(1)(A) and (b)(3)(A) of the Affordable Care Act specifically refer to self-insured plans with TPAs and are silent as to self-insured, self-administered plans. In addition, section 1341(b)(3)(B) of the Affordable Care Act and § 153.400(a)(1)(ii) provide that reinsurance contributions are to reflect a “commercial book of business.” A self-insured, self-administered plan is fundamentally different from a health insurance issuer as well as a self-insured plan that uses a TPA, in that an insured plan and a self-insured plan with a TPA both involve an external commercial entity (the issuer or the TPA, which may itself be an issuer or an issuer affiliate). There will be no shifting of costs for 2014 because the exemption for self-insured, self-administered plans will only apply to the 2015 and 2016 benefit years. Based on comments received, our understanding is that relatively few plans will be eligible for the exemption. In addition, reinsurance payments will decrease substantially for the 2015 and 2016 benefit years, so all contributing entities will be responsible for substantially lower contributions for those years.

Finally, any self-insured plan that does not use a TPA for the core administrative functions of claims processing, claims adjudication (including the management of internal appeals), or enrollment may claim the exemption for the 2015 and 2016 benefit years, irrespective of whether the plan is jointly sponsored by a union and an employer or any other type of employer.

Comment: Several commenters urged HHS to expand the exemption significantly. For example, a number of commenters stated that all self-insured plans should be exempt from reinsurance contributions, or that self-

insured plans that use non-issuer TPAs should be exempt. Additionally, some of the commenters stated that it was inappropriate to have a different definition of contributing entity for the 2014 benefit year, and that the proposed exemption should apply for all three benefit years. According to these commenters, there is adequate time for contributing entities to make the necessary adjustments, and consequently, the change would not be disruptive in the 2014 benefit year.

Response: For the reasons discussed above and in the preamble to the 2014 Payment Notice (78 FR 15455), all self-insured plans are not exempt from reinsurance contributions. HHS also does not believe it has the authority to differentiate between TPAs that are issuers or issuer affiliates and non-issuer TPAs for purposes of the exemption. This is because sections 1341(b)(1)(A) and (b)(3)(A) of the Affordable Care Act only refers to issuers and TPAs, and does not distinguish between issuer TPAs and non-issuer TPAs. Exempting only non-issuer TPAs would treat similarly situated TPAs that perform comparable services for similar clients differently solely because one TPA is an issuer or issuer affiliate. In addition, we continue to believe that making the proposed exemption effective for the 2014 benefit year at this late stage would be disruptive to plans and issuers that have already set contribution rates and premiums, and could upset settled estimates with respect to expected reinsurance payments and contribution obligations. Therefore, we are retaining the proposal that this exemption only apply for the 2015 and 2016 benefit years.

Comment: Some commenters agreed with the proposed exemption, including the core functions test for determining when a self-insured plan uses a TPA. Some commenters objected to the proposed core functions approach on the grounds that it lacked clarity, was ambiguous, overly complex, or took the wrong factors into account. Some commenters stated that the proposed test was too broad in that it would be too easy for self-insured plans that use outside service providers to be deemed to be using a TPA, with the result that very few plans would be able to claim the proposed exemption. Another commenter indicated that the core functions test was unclear, and that too many plans would be able to claim the exemption. Some commenters suggested other tests to ascertain when a self-insured plan is self-administered or uses a TPA. For example, some commenters suggested a test which looks to whether

a self-insured plan is using a third party for a “full complement” of administrative functions or all services in connection with administering the plan. Another commenter suggested that the proper test was whether a plan retains legal responsibility to adjudicate claims and decide appeals. Some commenters urged limiting the exclusion to self-insured plans that do not utilize the services of third parties in any way to facilitate or assist in the proper administration of the plan.

Response: After a thorough review of the comments, we are generally retaining the proposed core functions analysis as a reasonable and objective indicator of which self-insured plans should be properly classified as self-administered for the limited purpose of determining whether such plans are contributing entities for reinsurance contribution purposes. In response to comments, we are clarifying that a self-insured plan must retain responsibility for claims payment, claims adjudication (including internal appeals), and enrollment in order to be regarded as self-administered during the 2015 and 2016 benefit years. Thus, subject to the exceptions described below, if a self-insured plan uses a third party for claims payment, claims adjudication, or enrollment, it would not be treated as self-administered for purposes of reinsurance contributions during the 2015 and 2016 benefit years. As suggested in comments, we are adopting certain modifications to our proposal regarding such issues as leasing of networks and *de minimis* use of third party services.

Comment: In the preamble to the proposed rule, HHS sought comment as to whether any other administrative functions should be considered in determining whether a self-insured plan uses a TPA for core administrative functions, including medical management, provider network development, and other support tasks.

Numerous commenters noted that self-insured plans very rarely develop and manage their own provider networks, and typically “lease” such networks from issuers. In these arrangements, the self-insured plan pays a fee to the issuer (or other entity) for the use of its provider network. The issuer (or other entity) bears the costs of developing and maintaining the networks, and also “reprices” the self-insured plan’s claims to take into account provider discounts the issuer has negotiated with members of its network. These commenters suggested that a self-insured plan that leases a network should not lose self-

administered status for reinsurance contributions purposes.

Response: HHS agrees with the commenters’ suggestion, and is clarifying in regulation text that if a self-insured plan “leases” a network from an unrelated third party and also obtains provider network development, claims repricing, and similar services, the plan will not lose self-administered status as a result.

Comment: In the preamble to the proposed rule, HHS sought comment as to whether a self-insured plan may outsource specific services, such as those relating to pharmaceutical benefits, without losing self-administered status, or whether an unaffiliated service provider may provide a *de minimis* or small percentage of all services for the plan. Commenters requested that a self-insured, self-administered plan be able to obtain prescription drug benefits provided by a pharmacy benefits manager (PBM), as well as services from specialized vendors for behavioral health, vision/dental benefits, or benefits with respect to which Medicare is the primary provider. The commenters noted the prevalence of these arrangements in the market, and that some of the outsourced benefits are exempt from reinsurance contributions. Commenters were divided as to whether a self-insured plan should be permitted to receive a *de minimis* percentage of all benefits and services from an unrelated third party without the plan losing self-administered status.

Response: In response to comments, we are clarifying the following in regulation text. First, a self-insured plan may outsource core administrative functions (claims processing, claims adjudication, and enrollment services) to an unrelated third party such as a PBM without losing self-administered status, provided that the underlying benefits are pharmacy benefits or excepted benefits as defined by section 2791(c) of the PHS Act. We clarify that medical benefits, other than pharmacy benefits or excepted benefits, cannot be outsourced by a self-insured, self-administered plan if the plan wants to retain its exemption from the definition of contributing entity. For example, if a self-insured plan enters into a separate contract for more than a *de minimis* amount of services related to mental health or substance abuse benefits, this contractual arrangement would disqualify the plan from the exemption. We also clarify that a self-insured plan may outsource a *de minimis* amount of core administrative services for benefits other than excepted benefits or pharmacy benefits to an unrelated party.

For this purpose, we clarify that a *de minimis* amount means up to 5 percent, as measured by the amount of enrollment or claims processing transactions for non-pharmacy and non-excepted benefits which are outsourced, or by the value of the outsourced enrollment or claims processing transactions for non-pharmacy and non-excepted benefits (measured by the cost of the outsourced services compared to the sum of those costs plus the fully loaded costs—that is, including an appropriate share of indirect costs, such as fixed and overhead expenses—reasonably allocated, borne by the self-insured plan for such services).

Comment: In certain multiemployer funds, the fund may use an administrator for certain purposes that is an affiliate of certain, but not all, sponsors. Several commenters requested clarification that this structure would not result in the fund losing otherwise applicable self-administered status.

Response: We are clarifying that a service provider that is affiliated with one or more sponsors other than the sponsor that is the contributing entity in the context of a multiemployer fund will not be a TPA, and would therefore not lose its self-administered status for purposes of reinsurance contributions in the 2015 and 2016 benefit years.

Comment: One commenter asked that HHS clarify whether a self-insured plan or its TPA is a contributing entity that must make reinsurance contributions.

One commenter stated that any entity providing services to plans subject to reinsurance should be required to submit contributions for their benefits.

Response: As noted in the preamble of the 2014 Payment Notice (78 FR 15455), pursuant to the definition of a contributing entity in § 153.20, “a self-insured group health plan that is a contributing entity is responsible for the reinsurance contributions, although it may use a TPA or administrative services-only contractor for transfer of the reinsurance contributions.”

Comment: One commenter stated that exempting self-insured, self-administered plans from making reinsurance contributions would increase the 2015 contribution rate by \$3 for all other contributing entities, and exempting these health plans has an unfair impact on those remaining entities subject to reinsurance contributions.

Response: Because we expect few entities to qualify for it, we estimate that the exclusion of self-insured, self-administered plans will have a small effect on the 2015 uniform contribution rate.

c. Uniform Reinsurance Contribution Rate

(i) Uniform Reinsurance Contribution Rate for the 2015 Benefit Year

Section 153.220(c) requires HHS to publish in the annual HHS notice of

benefit and payment parameters the uniform reinsurance contribution rate for the upcoming benefit year. Section 1341(b)(3)(B)(iii) of the Affordable Care Act specifies that \$10 billion for reinsurance contributions are to be collected from contributing entities in 2014, \$6 billion in 2015, and \$4 billion in 2016 (reinsurance payment pool). Additionally, sections 1341(b)(3)(B)(iv) and 1341(b)(4)(B) of the Affordable Care Act direct that \$2 billion in funds are to be collected for contributions to the U.S. Treasury in 2014, \$2 billion in 2015, and \$1 billion in 2016. Finally, section 1341(b)(3)(B)(ii) of the Affordable Care Act allows for the collection of additional amounts for administrative expenses. Taken together, these three components make up the total dollar amount to be collected from contributing entities for each of the 3 years of the reinsurance program under the uniform reinsurance contribution rate.

As discussed in the 2014 Payment Notice (78 FR 15459), each year, the uniform reinsurance contribution rate will be calculated by dividing the sum of the three amounts (the reinsurance payment pool, the U.S. Treasury contribution, and administrative costs) by the estimated number of enrollees in plans that must make reinsurance contributions:

Uniform Reinsurance Contribution Rate

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

We proposed collecting \$25.4 million for administrative expenses for the 2015 benefit year (or 0.4 percent of the \$6 billion to be dispersed). Therefore, the total amount to be collected would be approximately \$8.025 billion. Our estimate of the number of enrollees in plans that must make reinsurance contributions yields a 2015 annual per capita contribution rate of \$44, about \$3.67 per month. We are finalizing this contribution rate as proposed.

Comment: One commenter asked that HHS implement a two-tiered contribution rate, charging issuers more since they benefit from the program and self-insured group health plans less. Other commenters suggested that only issuers be required to make contributions allocated for the U.S. Treasury.

Response: The statute does not differentiate between the contribution amounts required from issuers and third party administrators on behalf of self-insured group health plans. As noted in the Premium Stabilization Rule (77 FR 17227), we are using a national, per capita contribution rate because it is a simpler approach that minimizes the administrative burden of collections.

(ii) Timing of Collection of Reinsurance Contributions

We proposed modifying our collection schedule for the reinsurance program, so that we collect the reinsurance contribution amounts for reinsurance payments and for administrative expenses earlier in the calendar year following the applicable benefit year, approximately in accordance with the schedule in

§ 153.405(c), but collect the reinsurance contribution amounts for payments to the U.S. Treasury in the last quarter of the calendar year following the applicable benefit year.

Under proposed § 153.405(c)(1), following submission of the annual enrollment count, HHS would notify a contributing entity of the reinsurance contribution amount allocated to reinsurance payments and administrative expenses to be paid for the applicable benefit year. If the enrollment count is timely submitted, HHS would notify the contributing entity by December of benefit year 2014, 2015, or 2016, as applicable. We note that, due to our desire to align the notification of reinsurance contributions due with our monthly payment and collections cycle, this schedule differs slightly from the schedule currently set

forth in § 153.405(c), which provides for notification by the later of 30 days of the submission of the annual enrollment count or by December 15. Under proposed § 153.405(c)(3), the contributing entity must remit this amount within 30 days after the date of the first notification.

The second installment covers the portion of the reinsurance contribution amount allocated to the payments for the U.S. Treasury to be paid for a benefit year. Under proposed § 153.405(c)(2), in the fourth quarter of the calendar year following the applicable benefit year, HHS would notify the contributing entity of the portion of the reinsurance contribution amount allocated for payments to the U.S. Treasury for the applicable benefit year. In accordance with proposed § 153.405(c)(3), a contributing entity would remit this amount within 30 days after the date of this second notification. We note that the contributing entity is required to submit an annual enrollment count only once for each benefit year under § 153.405(b), by not later than November 15th of the benefit year.

For the 2014 benefit year, of the \$63 annual per capita contribution rate, \$52.50 would be allocated towards reinsurance payments and administrative expenses, and \$10.50 towards payments to the U.S. Treasury. Therefore, if a contributing entity submits its enrollment count by November 15, 2014, a reinsurance contribution payment of \$52.50 per covered life would be invoiced in December 2014, and payable in January, 2015. Another reinsurance contribution payment of \$10.50 per covered life would be invoiced in the fourth quarter of 2015, and payable late in the fourth quarter of 2015. For the 2015 benefit year, the \$44 annual per capita contribution rate would be allocated \$33 towards reinsurance payments and administrative expenses, and \$11 towards payments to the U.S. Treasury. These amounts would similarly be payable in January 2016 and late in the fourth quarter of 2016, respectively.

In order to leave the MLR and risk corridors calculations unchanged, we clarified in the proposed rule that the two installment payments would be

included with 2014, 2015, and 2016 data, for purposes of the risk corridors and MLR reports due July 31, 2015, 2016, and 2017, respectively, despite the fact that the later installment would not have been paid at that time.

We are finalizing the bifurcated contribution collection schedule as discussed above.

Comment: Several commenters supported our proposal to collect reinsurance contributions via two collections. Many commenters supporting our proposal asked that contributing entities have the option to pay the entire contribution in one payment while other commenters asked that we return to one annual collection schedule, citing the increased administrative burden of making two collections. One commenter supporting the bifurcated collection schedule specifically supported our proposal that the full 2014 reinsurance contribution be included with 2014 MLR reporting, despite the fact that the second payment would not have occurred by the MLR reporting deadline.

Response: We recognize that the reinsurance collections provided for in the Affordable Care Act will result in substantial upfront payments from contributing entities for the reinsurance program. Therefore, in consideration of the comments received, we are finalizing our proposal to collect contributions via two payments. We will not permit contributing entities to choose between collection schedules for operational reasons.

Comment: One commenter expressed concern that the bifurcation of the collection of the 2014 contribution rate of \$63 per enrollee would not evenly divide into a per enrollee per month charge when split into payments of \$52.50 and \$10.50. The commenter suggested that we revise the 2014 contribution rate to require \$52.44 in the first payment (\$4.37 per enrollee per month) and \$10.56 in the second payment (\$0.88 per enrollee per month).

Response: We do not believe it is necessary that the contribution amounts divide evenly into a per enrollee per month charge and further note that certain of the permitted counting methods set forth in 45 CFR 153.405

will yield fractional enrollment counts, whether tallied at the annual or monthly level.

Comment: One commenter sought clarification on when HHS would invoice contributing entities if enrollment counts are submitted by November 15th of the applicable benefit year pursuant to § 153.405(b). The commenter asked that HHS invoice contributing entities by December 1st.

Response: As noted in the proposed rule, if a contributing entity submits its enrollment count for the 2014 benefit year by November 15, 2014, a reinsurance contribution payment of \$52.50 per covered life would be invoiced in December 2014, and payable in January, 2015. We anticipate that these invoices will align with our monthly payment and collections schedule. We will provide more specific timelines in future guidance.

Comment: One commenter asked that HHS defer the collection of contributions allocated to the U.S. Treasury until 2016.

Response: Sections 1341(b)(3)(B)(iv) and 1341(b)(4)(B) of the Affordable Care Act specify \$2 billion in funds are to be collected for contributions to the U.S. Treasury in 2014, \$2 billion in 2015, and \$1 billion in 2016. As noted in the 2014 Payment Notice (78 FR 15460), we do not believe HHS has authority under the statute to defer this collection.

(iii) Allocation of Uniform Reinsurance Contribution Rate

Section 153.220(c) provides that HHS is to set in the annual HHS notice of benefit and payment parameters for the applicable benefit year the proportion of contributions collected under the uniform reinsurance contribution rate to be allocated to reinsurance payments, payments to the U.S. Treasury, and administrative expenses. In the 2014 Payment Notice (78 FR 15460), we stated that reinsurance contributions collected for 2014 will be allocated pro rata to the reinsurance pool, administrative expenses, and the U.S. Treasury, up to \$12.02 billion. Similar to the pro rata approach set forth in the 2014 Payment Notice, in Table 2, we specify the proportions for 2015 (or amounts, as applicable):

TABLE 2—PROPORTION OF REINSURANCE CONTRIBUTIONS COLLECTED UNDER THE UNIFORM REINSURANCE CONTRIBUTION RATE FOR THE 2015 BENEFIT YEAR FOR REINSURANCE PAYMENTS, PAYMENTS TO THE U.S. TREASURY, AND ADMINISTRATIVE EXPENSES

	If total contribution collections under the uniform reinsurance contribution rate are less than or equal to \$8.025 billion	If total contribution collections under the uniform reinsurance contribution rate are more than \$8.025 billion
Proportion or amount for:		
Reinsurance payments	74.8 percent (\$6 billion/\$8.025 billion).	The difference between total collections and those contributions allocated to the U.S. Treasury and administrative expenses.
Payments to the U.S. Treasury	24.9 percent (\$2 billion/\$8.025 billion).	\$2 billion.
Administrative expenses	0.3 percent (\$25.4 million/\$8.025 billion).	\$25.4 million.

As shown in Table 2, if the total amount of contributions collected is less than or equal to \$8.025 billion, we will allocate approximately 74.8 percent of the reinsurance contributions collected to reinsurance payments, 24.9 percent of the reinsurance contributions collected to the U.S. Treasury, and 0.3 percent of the reinsurance contributions collected to administrative expenses.

To provide that all reinsurance contributions collected for a benefit year are paid out for claims for that benefit year, we proposed to amend § 153.230(d) to provide that if HHS determines that the amount of all reinsurance payments requested under the uniform payment parameters from all reinsurance-eligible plans in all States for a benefit year will not be equal to the amount of all reinsurance contributions collected for reinsurance payments under the uniform contribution rate in all States for an applicable benefit year, HHS will determine a uniform pro rata adjustment (up or down) to be applied to all such requests for reinsurance payments for all States. We proposed that each applicable reinsurance entity, or HHS on behalf of a State, reduce or increase the reinsurance payment amounts for the applicable benefit year by any adjustment required under that paragraph.

We sought comment on the proposal to use excess funds in a current benefit year, including whether any excess collections should be allocated to increasing coinsurance rates above 100 percent, or whether such funds should be used instead to change other reinsurance parameters, or used for future benefit years.

Because our proposed changes noted above would provide that all reinsurance contributions collected for a benefit year are paid out for claims for that benefit year, we proposed to delete and reserve § 153.235(b), which currently provides that any excess reinsurance contributions collected from contributing entities for any benefit year but unused for the applicable benefit year *must* be used for reinsurance payments in subsequent benefit years. We are finalizing our proposal to use excess contributions for reinsurance payments for the current benefit year by increasing the coinsurance rate up to 100 percent before rolling over any remaining funds to the next year. Therefore, we are not finalizing our proposal to delete and reserve § 153.235(b). We are finalizing our modification to § 153.230(d) to provide that if HHS determines that the amount of reinsurance payments requested under the uniform payment parameters will not be equal the amount of reinsurance contributions collected for reinsurance payments, HHS will determine a uniform adjustment (up or down) to be applied to all requests for reinsurance payments.

Comment: Some commenters supported our proposal to use excess funds in the current benefit year. Others asked that we roll over excess funds to potentially lower the contribution rate in future benefit years, or that excess funds be refunded to contributing entities. Some commenters who supported the use of excess funds in the current benefit year suggested that we only increase the coinsurance rate up to 100 percent and then roll over any additional funds to a subsequent benefit year, in order to avoid perverse

incentives to incur claims costs. One commenter supported increasing the coinsurance rate above 100 percent.

Response: We are finalizing our proposal to use excess reinsurance contributions for reinsurance payments in the current benefit year by increasing the coinsurance rate up to 100 percent before rolling over any remaining funds to the next year. We believe that a 100 percent ceiling on the coinsurance rate is appropriate, and will permit us to increase reinsurance payments in subsequent years if we collect more in contributions than are requested in payments.

(iv) Administrative Expenses

In the 2014 Payment Notice (78 FR 15460), we estimated that the Federal administrative expenses of operating the reinsurance program would be \$20.3 million, based on our estimated contract and operational costs. We proposed to use the same methodology to estimate the administrative expenses for the 2015 benefit year. These estimated costs would cover the costs related to contracts for developing the uniform reinsurance payment parameters and the uniform reinsurance contribution rate, collecting reinsurance contributions, making reinsurance payments, and conducting account management, data collection, program integrity and audit functions, operational and fraud analytics, training for entities involved in the reinsurance program, and general operational support. We proposed to exclude from these administrative expenses the costs associated with work performed by Federal personnel. To calculate our proposed reinsurance administrative expenses for the 2015 benefit year, we

divided HHS’s projected total costs for administering the reinsurance programs on behalf of States by the expected number of covered lives for which reinsurance contributions are to be made for the 2015 benefit year.

We estimated this amount to be approximately \$25.4 million for the 2015 benefit year. The 2015 estimate has increased from the 2014 estimate because we will be making reinsurance payments in 2015 for the 2014 benefit year, and as discussed below, will engage in program integrity and audit-related activity in 2015 to oversee the reinsurance program. We believe that this figure reflects the Federal government’s significant economies of scale, which helps to decrease the costs

associated with operating the reinsurance program. Based on our estimate of covered lives for which reinsurance contributions are to be made for the 2015 benefit year, we proposed a uniform reinsurance contribution rate of \$0.14 annually per capita for HHS administrative expenses. We provide details below on the methodology we used to develop the 2015 enrollment estimates.

For the 2014 benefit year, we allocated the administrative expenses equally between contribution and payment-related activities. Because we anticipate that our additional activities in the 2015 benefit year, including our program integrity and audit activities, will also be divided approximately

equally between contribution and payment-related activities, we again proposed to allocate the total administrative expenses equally between these two functions. Therefore, as shown in Table 3, we will apportion the annual per capita amount of \$0.14 of administrative expenses as follows: (a) \$0.07 of the total amount collected per capita for administrative expenses for the collection of contributions from health insurance issuers and group health plans; and (b) \$0.07 of the total amount collected per capita for administrative expenses for reinsurance payment activities, supporting the administration of payments to issuers of reinsurance-eligible plans.

TABLE 3—BREAKDOWN OF ADMINISTRATIVE EXPENSES

[Annual, per capita]

Activities	Estimated expenses
Collecting reinsurance contributions from health insurance issuers and group health plans	\$0.07
Calculation and disbursement of reinsurance payments	0.07
Total annual per capita expenses for HHS to perform all reinsurance functions	0.14

If HHS operates the reinsurance program on behalf of a State, HHS will retain the annual per capita fee to fund HHS’s performance of all reinsurance functions, which would be \$0.14. If a State establishes its own reinsurance program, HHS will transfer \$0.07 of the per capita administrative fee to the State for purposes of administrative expenses incurred in making reinsurance payments, and retain the remaining \$0.07 to offset the costs of collecting contributions. We note that the administrative expenses for reinsurance payments will be distributed to those States that operate their own reinsurance program in proportion to the State-by-State total requests for reinsurance payments made under the uniform reinsurance payment parameters. We received no comments on our proposed 2015 administrative expenses and are finalizing this provision as proposed.

d. Uniform Reinsurance Payment Parameters for 2015

Section 1341(b)(2)(B) of the Affordable Care Act directs the Secretary, in establishing standards for the transitional reinsurance program, to include a formula for determining the amount of reinsurance payments to be made to issuers for high-risk individuals that provides for the equitable allocation of funds. In the Premium Stabilization Rule (77 FR 17228), we provided that reinsurance payments to eligible issuers

will be made for a portion of an enrollee’s claims costs paid by the issuer (the coinsurance rate) that exceeds an attachment point (when reinsurance would begin), subject to a reinsurance cap (when the reinsurance program stops paying claims for a high-cost individual). The coinsurance rate, attachment point, and reinsurance cap together constitute the uniform reinsurance payment parameters.

Given the smaller pool of reinsurance contributions to be collected for the 2015 benefit year, as directed by the statute, we proposed that the 2015 uniform reinsurance payment parameters be established at an attachment point of \$70,000, a reinsurance cap of \$250,000, and a coinsurance rate of 50 percent. We estimate that these uniform reinsurance payment parameters will result in total requests for reinsurance payments of approximately \$6 billion for the 2015 benefit year.

As discussed in the 2014 Payment Notice (78 FR 15461), to assist with the development of the uniform reinsurance payment parameters and the premium adjustment percentage index, HHS developed the Affordable Care Act Health Insurance Model (ACAHiM). The ACAHiM estimates market enrollment, incorporating the effects of State and Federal policy choices, and accounting for the behavior of individuals and employers. The outputs of the ACAHiM, especially the estimated enrollment and

expenditure distributions, were used to analyze a number of policy choices relating to the proposed 2015 reinsurance contribution rate and 2015 uniform reinsurance payment parameters.

The ACAHiM generates a range of national and State-level outputs for 2015, including the level and composition of enrollment across markets given the eligible population in each State. The ACAHiM is described below in two sections: (1) The approach for estimating 2015 enrollment; and (2) the approach for estimating 2015 expenditures. The ACAHiM uses recent Current Population Survey (CPS) data adjusted for small populations at the State level, exclusion of undocumented immigrants, and population growth in 2015 to assign individuals to the various coverage markets.

Specifically, the ACAHiM assigns each individual to a single health insurance market as his or her baseline (pre-Affordable Care Act) insurance status. In addition to assuming that individuals currently enrolled in Medicare, TRICARE, or Medicaid will remain in such coverage, the ACAHiM takes into account the probability that a firm will offer employment-based coverage based on the CPS distribution of coverage offers for firms of a similar size and industry. Generally, to determine the predicted insurance enrollment status for an individual or family (the “health insurance unit” or

“HIU”), the ACAHIM calculates the probability that the firm will offer insurance, then models Medicaid eligibility, and finally models eligibility for advance payments of the premium tax credit and cost-sharing reductions under the Exchange. Whenever a transition to another coverage market is possible, the ACAHIM takes into account the costs and benefits of the decision for the HIU and assigns a higher probability of transition to those with the greatest benefit. The ACAHIM assumptions of the rate at which uninsured individuals will take-up individual market coverage are based on current take-up rates of insurance across States, varied by demographics and incomes and adjusted for post-Affordable Care Act provisions, such as advance payments of the premium tax credit and cost-sharing reductions.

Estimated expenditure distributions from the ACAHIM are used to set the uniform reinsurance payment parameters so that estimated contributions from all contributing entities equal estimated payments for all reinsurance-eligible plans. The ACAHIM uses the Health Intelligence Company, LLC (HIC) database from calendar year 2010, with the claims data trended to 2015 to estimate total medical expenditures per enrollee by age, gender, and area of residence. The expenditure distributions are further adjusted to take into account plan benefit design, or “metal” level (that is, “level of coverage,” as defined in § 156.20) and other characteristics of individual insurance coverage in an Exchange. To describe a State’s coverage market, the ACAHIM computes the pattern of enrollment using the model’s predicted number and composition of participants in a coverage market. These estimated expenditure distributions were the basis for the uniform reinsurance payment parameters. We are finalizing the 2015 reinsurance payment parameters as proposed.

Comment: Some commenters suggested that HHS keep the reinsurance payment parameters consistent between 2014 and 2015, and delay increasing the attachment point to \$70,000 and decreasing the coinsurance rate to 50 percent until 2016, or keep the 2014 and 2015 attachment points as close as possible. One commenter asked HHS to increase the contribution rate to account for increased costs during 2014 and 2015. Other commenters supported lowering the 2015 contribution rate and uniform reinsurance payment parameters.

Response: Section 1341(b)(3)(B)(iii) of the Affordable Care Act directs HHS to collect \$6 billion for reinsurance

payments in 2015. This is \$4 billion less than will be collected in 2014 for reinsurance payments. We believe that the lower coinsurance rate and higher attachment point we have proposed appropriately accounts for this smaller reinsurance payment pool. We also believe that maintaining the reinsurance cap for the 2015 benefit year will make it easier for issuers to estimate the effects of reinsurance, and reduce interference with the traditional commercial reinsurance market. As discussed above, to the extent that reinsurance contributions for 2015 exceed reinsurance payments requested, our policy of increasing the coinsurance rate up to 100 percent will help assure that the excess contributions are used to offset claims for high-cost individual market enrollees.

e. Adjustment Options

In the 2014 Payment Notice, we finalized the following uniform reinsurance payment parameters for the 2014 benefit year—a \$60,000 attachment point, a \$250,000 reinsurance cap, and an 80 percent coinsurance rate. However, updated information, including the actual premiums for reinsurance-eligible plans, as well as recent policy changes, suggest that our prior estimates of the uniform reinsurance payment parameters overestimated the total covered claims costs of individuals enrolled in reinsurance-eligible plans in 2014. To account for this, we proposed to decrease the 2014 attachment point to \$45,000. We are finalizing our proposal to decrease the 2014 attachment point to \$45,000.

Comment: Several commenters asked that HHS consider alternative relief for the transitional policy announced on November 14, 2013²⁷ that does not increase the burden on large employers and self-insured group health plans.

Response: The lowering of the 2014 attachment point will not result in additional contributions being collected from contributing entities. As noted in the proposed rule, we believe that our prior estimates of the 2014 uniform payment parameters overestimated the total covered claims costs of individuals enrolled in reinsurance-eligible plans in 2014, allowing these additional payments to be made from within the amount already being collected.

Comment: Several commenters supported lowering the 2014 attachment point to \$45,000. One commenter

suggested lowering the attachment point to \$20,000. Other commenters opposed lowering the attachment point, asking that HHS return to the finalized 2014 payment parameters, and urging that any excess funds should be rolled over to the subsequent benefit year and used to lower the contribution rate for all contributing entities. Some commenters who objected to the lowering of the attachment point stated that HHS should instead increase the reinsurance cap to \$500,000 to reimburse issuers for larger claims costs.

Response: As discussed above, the ACAHIM, which estimates market enrollment, incorporates the effects of State and Federal policy choices and accounts for the behavior of individuals and employers. These assumptions and projections, as well as the transitional policy announced in November 2013, resulted in an updated estimate of the 2014 individual and employer-sponsored insurance markets and expenditures, and permitted us to update our estimate of the 2014 uniform reinsurance payment parameters. We believe that lowering the attachment point to \$45,000 would allow the reinsurance program to make more payments for high-cost enrollees without increasing the contribution rate. We are not increasing the reinsurance cap to avoid interfering with traditional commercial reinsurance, which typically has attachment points in the \$250,000 range.

Comment: One commenter asked that the proposed modifications to the reinsurance program for the transitional policy be applied consistently in all States.

Response: These modifications will be applied consistently in all States.

f. Reinsurance-Eligible Plans

In this final rule, we clarify that in accordance with the policy established in the 2014 Payment Notice, student health plans are not eligible to receive reinsurance payments. Under § 147.145(b)(3), student health plans are not subject to the single risk pool requirement of section 1312(c) of the Affordable Care Act and § 156.80. Under § 153.234, a reinsurance-eligible plan’s covered claims costs for an enrollee incurred prior to the application of the following provisions do not count towards either the uniform reinsurance payment parameters or the State supplemental reinsurance payment parameters: § 147.102 (fair premiums); § 147.104 (guaranteed availability); § 147.106 (guaranteed renewability); § 156.80 (single risk pool); and subpart B of part 156 (essential health benefits). However, we note that a student health

²⁷ Letter to Insurance Commissioners, Center for Consumer Information and Insurance Oversight, November 14, 2013. Available at: <http://www.cms.gov/CCIIO/Resources/Letters/Downloads/commissioner-letter-11-14-2013.PDF>.

plan would be considered part of a contributing entity's "commercial book of business" and, to the extent that the plan provides major medical coverage, as defined in § 153.20, a contributing entity must make reinsurance contributions on behalf of their enrollees, absent another exception in § 153.400.

In response to this proposed rule, we received several comments asking that certain plans or coverage be eligible for reinsurance payments.

Comment: Several commenters requested that we permit State high-risk pools to be eligible for reinsurance payments for their high-risk enrollees. One commenter asked that the Federal government extend the Federal high-risk pool until all funds are depleted.

Response: As stated in the 2014 Payment Notice (78 FR 15455), under the definition of a reinsurance-eligible plan at § 153.20, State high-risk pools are not eligible to receive reinsurance payments for their enrollees because high risk pool coverage is not subject to the 2014 market reforms outlined under § 153.234 (that is, § 147.102 (fair premiums); § 147.104 (guaranteed availability); § 147.106 (guaranteed renewability); § 156.80 (single risk pool); and subpart B of part 156 (essential health benefits). Therefore, claims costs incurred by high risk pools would not be eligible for reinsurance payments. Funding for the Federal high risk pool, also known as the Pre-Existing Condition Insurance Plan program, is not addressed in this rule.

Comment: One commenter asked that HHS expand the reinsurance program to encompass transitional plans covered by the transitional policy outlined in the November 14, 2013 guidance,²⁸ while another commenter asked that HHS clarify that only plans that are subject to all of the 2014 market reforms established under the Affordable Care Act are eligible for reinsurance payments.

Response: As discussed above, under § 153.234, a reinsurance-eligible plan's covered claims costs for an enrollee incurred prior to the application of §§ 147.102, 147.104 (subject to 147.145), 147.106 (subject to 147.145), 156.80, and subpart B of part 156 do not count towards either the uniform reinsurance payment parameters or the State supplemental reinsurance payment parameters. Therefore, a transitional plan is not eligible for reinsurance payments. For the purpose of

reinsurance contributions, we note that contributing entities are required to make reinsurance contributions for their major medical coverage that is considered to be part of a "commercial book of business," subject to certain exceptions provided for in our regulations. As such, a contributing entity must make reinsurance contributions on behalf of its enrollees in transitional plans that provide major medical coverage, as defined in § 153.20, unless one of the exceptions provided under 45 CFR 153.400 applies to such coverage.

g. Deducting Cost-Sharing Reduction Amounts From Reinsurance Payments

Subpart H of 45 CFR part 153 governs the submission of medical and pharmacy claims to an issuer's dedicated distributed data environment. Under § 156.410, if an individual is determined eligible to enroll in an individual market Exchange QHP and elects to do so, the QHP issuer must assign the individual to a standard plan or cost-sharing plan variation based on the enrollment and eligibility information submitted by the Exchange. Issuers of individual market Exchange QHPs will receive cost-sharing reduction payments for enrollees that have effectuated coverage in cost-sharing plan variations. Therefore, in the 2014 Payment Notice (78 FR 15499), we stated that the enrollee-level data submitted by an issuer of a reinsurance-eligible plan must include claims data and data related to determining cost-sharing reductions provided through a cost-sharing plan variation to permit HHS to calculate an issuer's plan paid amounts on behalf of an enrollee. In the proposed rule, we explained the methodology HHS proposed to use to deduct the amount of cost-sharing reductions paid on behalf of an enrollee enrolled in a QHP in an individual market through an Exchange.

As specified in § 153.230, HHS will calculate reinsurance payments by applying the uniform reinsurance payment parameters for the applicable benefit year to the issuer's plan paid amounts on behalf of each enrollee in a reinsurance-eligible plan for the benefit year. However, this calculation may not always account for the cost-sharing reduction payments the QHP issuer receives for an enrollee, resulting in an issuer receiving payments twice for the same enrollee's total costs. In the proposed rule, we stated that we believe that the cost-sharing payment amounts provided by HHS to a QHP issuer for an enrollee in a plan variation should be deducted from the total plan paid amounts to avoid "double payment" to

the QHP issuer of the reinsurance-eligible plan because the QHP issuer is already being reimbursed for the value of the cost-sharing reductions provided.

Under the Secretary's authority under section 1341(b)(2)(B) of the Affordable Care Act to establish a payment formula for the reinsurance program that provides for the equitable allocation of available funds, we proposed a method through which HHS intends to account for cost-sharing reduction payments when calculating reinsurance payments for QHP issuers for reinsurance-eligible plans offered in an individual market. We proposed that for each enrollee enrolled in a QHP plan variation, we would subtract from the QHP issuer's total plan paid amounts for the enrollee in a reinsurance-eligible plan the difference between the annual limitation on cost sharing for the standard plan and the annual limitation on cost sharing for the plan variation. Because reinsurance payments are made for enrollees only when the issuer's total plan paid amounts exceed the attachment point (for example, \$45,000 in the 2014 benefit year), we believe that it is highly unlikely that an enrollee for which a QHP issuer is eligible for reinsurance payments will not have reached the annual limitation on cost sharing. Therefore, the difference between the two annual limitations on cost sharing is likely to be an accurate estimate of cost-sharing reduction payments provided by HHS to the QHP issuer. We proposed to apply this approach to calculating the amounts of cost-sharing reductions provided for an enrollee in a silver plan variation or a zero cost sharing plan variation.

For policies with multiple enrollees, such as family policies, we proposed to allocate the difference in annual limitation in cost sharing across all enrollees covered by the family policy in proportion to the enrollees' QHP issuer total plan paid amounts.

In contrast, we proposed not to reduce the QHP issuer's plan paid amounts for purposes of calculating reinsurance payments for an Indian in a limited cost sharing plan variation. We are finalizing these provisions as proposed.

Comment: Several commenters supported our proposed approach to account for cost-sharing reduction payments. One commenter asked, in the case of a policy with multiple enrollees, that the allocation be made in proportion to each family member's share of costs subject to cost sharing rather than to total costs.

Response: We appreciate the reasoning behind the comment, but believe that it will be operationally simpler to consider total plan paid

²⁸ Letter to Insurance Commissioners, Center for Consumer Information and Insurance Oversight, November 14, 2013. Available at: <http://www.cms.gov/CCIIO/Resources/Letters/Downloads/commissioner-letter-11-14-2013.PDF>.

amounts when accounting for cost-sharing reductions.

Comment: Several commenters recommended that HHS re-evaluate the methodology for family policies where each individual has a separate annual limitation on cost sharing, suggesting that HHS treat individuals with separate annual limitations on cost sharing as if they had each enrolled in an individual policy for the purposes of accounting for cost-sharing reduction payments in calculating reinsurance payments.

Response: For operational reasons, we believe it will be easier to allocate a family annual limitation on cost sharing across enrollees rather than make individual calculations.

Comment: One commenter sought clarification on how HHS's proposal to calculate the amount of cost-sharing reductions provided for an enrollee in a silver plan variation or a zero cost sharing plan variation would apply if an individual moves between plan variations during the benefit year.

Response: Because cost sharing accumulates over the benefit year across plan variations of the same standard plan, we will apply the adjustment for cost-sharing reductions based on the annual limitation on cost sharing applicable to the plan variation in which the enrollee was last enrolled during the benefit year.

Comment: One commenter asked for clarification regarding the following footnote set forth in the proposed rule (78 FR 72345, n. 16): "We note that because the annual limitation on cost sharing applies only to in-network services, it is possible that an enrollee could incur additional cost-sharing reductions on out-of-network services. However, except in the case of zero cost sharing plan variations, an issuer is not required to reduce cost sharing out-of-network, and we believe that an issuer will rarely choose to do so because the AV Calculator does not recognize any change in AV due to a reduction in out-of-network cost sharing. Although it is possible that an enrollee in a zero cost sharing plan variation could incur significant out-of-network cost-sharing reductions beyond the standard plan's annual limitation on cost sharing, we believe such a circumstance will be relatively rare because of the substantial out-of-pocket costs an enrollee would likely incur in the form of balance billing."

Response: We proposed the methodology described above to avoid reimbursing an issuer through reinsurance payments for claims costs for which it will be otherwise reimbursed through cost-sharing reduction payments. The footnote

explains that this methodology does not take into account cost-sharing reductions on out-of-network services because we believe that issuers have little incentive to provide cost-sharing reductions on out-of-network services for silver plan variations, and that it will be relatively rare that an enrollee in a zero cost sharing plan will incur substantial out-of-pocket costs beyond the standard plan's annual limitation on cost sharing. Thus, we stated that we believed that the effect of this limitation in our methodology would be small.

h. Audits

(i) HHS Audits of State-Operated Reinsurance Programs

We proposed in § 153.270(a) authority for HHS or its designee to conduct a financial and programmatic audit of a State-operated reinsurance program to assess compliance with the requirements of subparts B and C of 45 CFR part 153. We proposed that a State that establishes a reinsurance program be required to ensure that its applicable reinsurance entity and any relevant contractors, subcontractors, or agents cooperate with an audit of its reinsurance program by HHS or its designee. We stated that HHS anticipates conducting targeted audits of State-operated reinsurance programs based on the State summary report provided to HHS for each benefit year described in § 153.260(b), the results of the independent external audit conducted for each benefit year under § 153.260(c), and issuer input, among other factors.

We proposed in § 153.270(b) that if an audit by HHS results in a finding of material weakness or significant deficiency (as these terms are defined in GAAS issued by the American Institute of Certified Public Accountants, and Government Auditing Standards issued by the Government Accountability Office (GAO)²⁹) with respect to the State-operated reinsurance program's compliance with any requirement of subparts B or C of 45 CFR part 153, the State would be required to ensure that its applicable reinsurance entity provide a written corrective action plan to HHS for approval within 60 calendar days of the issuance of the final audit report. The State would ensure that the applicable reinsurance entity

implements the plan and provides to HHS written documentation of the corrective actions once taken.

(ii) HHS Audits of Contributing Entities

We proposed in § 153.405(i) that HHS or its designee have the authority to audit a contributing entity to assess its compliance with the requirements of subpart E of 45 CFR part 153. We stated that we anticipated conducting targeted audits of contributing entities based on, among other criteria and sources, data provided to HHS through the annual enrollment count submitted under § 153.405(b), and any previous history of noncompliance with these standards. We proposed that if HHS determines as the result of an audit that a contributing entity was required to pay additional reinsurance contributions, we might require the contributing entity to pay such amounts to the Federal government.

(iii) HHS Audits of Issuers of Reinsurance-Eligible Plans

We proposed in § 153.410(d) authority for HHS or its designee to audit an issuer of a reinsurance-eligible plan to assess its compliance with the requirements of subparts E and H of 45 CFR part 153. We also proposed that if an audit results in a finding of material weakness or significant deficiency (as these terms are defined in GAAS issued by the American Institute of Certified Public Accountants, and Government Auditing Standards issued by the Government Accountability Office (GAO)³⁰) with respect to compliance with any requirement of subpart E or H of 45 CFR part 153, the issuer be required to: (i) Within 30 calendar days of the issuance of the final audit report, provide a written corrective action plan to HHS for approval; (ii) implement that corrective action plan; and (iii) provide to HHS written documentation of the corrective actions once taken. We proposed that if HHS determines as the result of an audit that the issuer of a reinsurance-eligible plan has received reinsurance payments to which it was not entitled, we might require the issuer to pay such amounts back to the Federal government.

In the proposed rule, we noted that we anticipate conducting targeted audits of issuers of reinsurance-eligible plans based on, among other criteria and

²⁹ See Government Auditing Standards (2011 Revision), available at: <http://www.gao.gov/yellowbook>. For public companies, the Public Company Accounting Oversight Board (PCAOB) sets audit standards. See <http://pcaobus.org/Standards/Auditing/Pages/default.aspx>. For non-public companies, the AICPA sets audit standards. See <http://www.aicpa.org/Research/Standards/AuditAttest/Pages/SAS.aspx>.

³⁰ See Government Auditing Standards (2011 Revision), available at: <http://www.gao.gov/yellowbook>. For public companies, the Public Company Accounting Oversight Board (PCAOB) sets audit standards. See <http://pcaobus.org/Standards/Auditing/Pages/default.aspx>. For non-public companies, the AICPA sets audit standards. See <http://www.aicpa.org/Research/Standards/AuditAttest/Pages/SAS.aspx>.

sources, the data provided to HHS through the dedicated distributed data environment and any previous history of noncompliance with these standards. We stated that we anticipate that this audit will focus on claims records validating the requests for reinsurance payments submitted to the dedicated distributed data environments, as well as records indicating the plan was a reinsurance-eligible plan.

We addressed the general comments received on the proposed audit provisions in the preamble discussion of § 153.620(c) above, and address comments specific to the transitional reinsurance program audit provisions below. We are finalizing these provisions as proposed.

Comment: One commenter asked that audits of contributing entities be delayed until after the first year of the reinsurance program to enable issuers and self-insured group health plans to focus on compliance. Other commenters stressed the importance of prioritizing audits of contributing entities.

Response: We believe that audits of contributing entities may be necessary to ensure that the reinsurance program has sufficient funds to effectively stabilize premiums during the initial years of Exchange operation, particularly with respect to the 2014 benefit year, for which the largest amount of contributions will be collected. We are therefore not adopting the commenter's suggestion.

Comment: One commenter suggested audit processes that would reduce the burden on contributing entities. Specifically, the commenter asked that audit protocols include sufficient, advance written notice of the audit, and that requests for supporting documentation be limited to enrollment data maintained by or on behalf of the contributing entity and information related to whether the plan provides major medical coverage. The commenter also asked that contributing entities be able to satisfy requests for information in a reasonable manner and format, and that an audited contributing entity be granted appeal rights.

Response: We agree that any audit of a contributing entity should focus on records relating to enrollment in the applicable self-insured or insured plan, to confirm that the number of covered lives was correctly calculated and that the correct amount of reinsurance contributions was paid. Additionally, these audits may be used to identify entities that were required to but did not make reinsurance contributions. We will consider these comments when developing the protocols and procedures of our audits, such as

timeframes for notification, formats for submitting supporting documentation, and appeals of audit findings, as part of future rulemaking and guidance.

i. Same Covered Life

In the second final Program Integrity Rule (78 FR 65057), we stated that it is our intent not to require payment of reinsurance contributions more than once for the same covered life. We stated that we recognize that certain complex group health plan arrangements can lead to situations in which lives are covered by multiple arrangements, where it is unclear whether more than one health plan or issuer must make reinsurance contributions, and that we intended to provide clarity on the matter in future rulemaking. In the proposed rule, in § 153.400(a)(1), we clarified the general principle that reinsurance contributions are required for major medical coverage that is considered to be part of a commercial book of business, but are not required to be paid more than once with respect to the same covered life.

In addition, we proposed to add paragraph (vi) to § 153.400(a)(1), which provided that no reinsurance contributions would be required in the case of employer-provided group health coverage where (A) such coverage applies to individuals who are also enrolled in individual market health insurance coverage for which reinsurance contributions are required; or (B) such coverage is supplemental or secondary to group health coverage for which reinsurance contributions must be made for the same covered lives. This provision was proposed to address situations in which a person covered under a group health plan also obtains individual market coverage, and in which multiple group health plans cover the same lives. It also addressed a situation in which two spouses are each covered as dependents by the respective group health plans offered by their two independent employers. We are finalizing these provisions as proposed.

Comment: Several commenters supported our proposal that a contribution not be required with respect to the same life more than once, and our proposal at § 153.400(a)(1)(vi). Other commenters objected to our proposals, stating that information regarding whether coverage is supplementary or secondary is not available to the employer or issuers, and that therefore this proposal would be expensive to administer. One commenter asked if guidance would be forthcoming on how issuers are to

validate this exclusion if the coverage occurs among different issuers.

Response: As noted in the proposed rule, if it is not clear from the terms of the health plans which group health plan is supplemental, in keeping with § 153.400(a)(3), the group health plan that offers the greater portion of inpatient hospitalization benefits is deemed the primary health plan. If it is not clear from the terms of the health plans which group health plan is primary and which is secondary, we would defer to the arrangements on primary and secondary liability set forth by the respective plan sponsors, in accordance with applicable State coordination of benefit laws and regulations. In such a situation, we would hold a plan sponsor harmless from non-compliance actions for failure to pay reinsurance contributions to the extent the sponsor relied in good faith upon a written representation by the other sponsor that the other sponsor's coverage has primary liability for claims for particular covered lives (and is responsible for making reinsurance contributions with respect to those covered lives).

Comment: One commenter suggested an operational process of reporting under which plans that provide supplemental and secondary coverage to a participant must identify these participants to the primary major medical coverage and pay a portion of the reinsurance contribution for such participant.

Response: Under our proposal, if employer-provided group health coverage is secondary or supplemental coverage, the group health plan offering such supplemental or secondary coverage is not required to make partial or full contributions on behalf of participants who are also enrolled in a primary major medical plan. We do not wish to require an additional information disclosure in connection with this exemption.

Comment: One commenter suggested that we codify an exception permitting a contributing entity to automatically exclude coverage for any enrollee for which the coverage is secondary under coordination of benefit rules.

Response: Our rule would not extend this exception to coverage which is determined to be secondary under coordination of benefit rules if the entity that provides the primary coverage is not required to make reinsurance contributions. The intent of the rule and accompanying exceptions is to avoid double-counting of contributions, but the commenter's automatic exclusion (if adopted) could incorrectly result in no

reinsurance contributions being made with respect to a covered life.

Comment: One commenter asked that HHS clarify that with respect to supplemental or secondary coverage, any time a participant's spouse is covered as an employee by another group health plan, the participant's plan may exclude that spouse from the count of covered lives and could assume without written representation that the entity that covers the spouse as an employee would be responsible for paying the contribution without further verification.

Response: We decline to make that clarification because our rule would not extend the exception if the entity that provides the primary coverage is not required to make reinsurance contributions. The adoption of the commenter's automatic assumption could incorrectly result in no reinsurance contributions being made with respect to a covered life. As such, the entity covering the spouse as an employee would need to represent that it was responsible for making reinsurance contributions on behalf of the covered lives in order for the entity covering the spouse as a dependent to avail itself of the exemption.

Comment: Several commenters asked that the general principle that reinsurance contributions are not required to be paid more than once with respect to the same covered life be extended to the Patient-Centered Outcomes Research Institute fee for 2015 and beyond by the Treasury Department.

Response: The U.S. Department of the Treasury is responsible for administration of the Patient-Centered Outcomes Research Institute fee, and regulation of that fee is outside the scope of this rulemaking.

Comment: One commenter requested that HHS modify § 153.400 to provide that the secondary coverage exemption in § 153.400(a)(1)(vi) be determined based on the coverage a participant is enrolled in at the time of enrollment regardless of whether this coverage is terminated during the benefit year.

Response: A contributing entity must consider an enrollee's status throughout the benefit year such that if an enrollee in secondary coverage loses his or her primary medical coverage, the secondary coverage will have to account for that enrollee using one of the counting methods under § 153.405 when calculating its reinsurance contributions.

Comment: Several commenters asked that HHS clarify that certain types of coverage, even when provided in combination, are not subject to the

contribution requirement. Specifically, they asked that all dental and vision coverage be exempt from the contribution requirement because it is not major medical coverage. The commenters also asked that excepted benefits, prescription drug coverage, and other ancillary benefits such as hearing aid coverage may be offered by the same plan without that combination of coverage becoming subject to the reinsurance contribution requirement.

Response: Any plan not satisfying the definition of major medical coverage as set forth in § 153.20 is not required to make reinsurance contributions.

Comment: One commenter asked HHS to permit contributing entities to submit reinsurance contributions and comply with reporting requirements electronically. The commenter also asked HHS to allow contributing entities flexibility in correcting inadvertent errors when making reinsurance contributions.

Response: We will provide further details on how contributing entities should submit enrollment counts and reinsurance contributions in future guidance. We will work with contributing entities in establishing these operational processes.

j. Reinsurance Contributions and Enrollees Residing in the Territories

Section 1323(a)(1) of the Affordable Care Act provides that a U.S. territory may establish an Exchange, and any territory that elects to establish an Exchange will be "treated as a State" for purposes of the Exchange standards in sections 1311 through 1313 of the Affordable Care Act. In a letter dated December 10, 2012 to the governors of the U.S. territories, HHS stated that "if a territory establishes an approved Exchange, it may elect to establish a transitional reinsurance program . . . consistent with the provisions in section 1341 . . . of the Affordable Care Act." That letter further stated that if a territory does not establish a transitional reinsurance program, HHS would not do so on the territory's behalf, and that in order to operate a reinsurance program for the 2014 benefit year, the territory was required to notify HHS of its intention to do so by March 1, 2013. No territory has notified HHS of an intention to operate a reinsurance program.

We proposed in § 153.400(a)(1)(v) the following exception for when a contributing entity must make reinsurance contributions for its self-insured group health plans and health insurance coverage: To the extent that the coverage applies to enrollees with primary residence in a territory when

that territory does not operate a reinsurance program, the contributing entity would not be required to make reinsurance contributions for those enrollees. We proposed that a contributing entity be permitted to use any reasonable method to determine the primary residence of an enrollee, including using the last-known mailing address of the principal subscriber on the enrollee's policy. We are finalizing this provision as proposed.

Comment: Several commenters supported our proposal to exempt from the reinsurance contribution obligation enrollees who reside in a territory that does not operate a reinsurance program. One commenter asked that HHS amend the proposal to exempt enrollees in a major medical plan that is based or administered in a territory.

Response: We are finalizing this provision as proposed. It is possible that a major medical plan based or administered in a territory that does not operate a reinsurance program may have enrollees in the 50 States and the District of Columbia. As noted in the proposed rule, this provision aligns with the goals of the reinsurance program because reinsurance contributions would only be required with respect to those jurisdictions that benefit from the premium stabilization effects of the reinsurance program. Additionally, we note that a contributing entity is not required to allocate its covered lives by primary residence between the territories, on the one hand, and the 50 States and the District of Columbia, on the other hand, and must do so only if it wishes to exclude covered lives from reinsurance contributions under § 153.400(a)(1)(v).

k. Form 5500 Counting Method

In the 2014 Payment Notice (78 FR 15463), we established counting methods for calculating the annual enrollment for determining reinsurance contributions for self-insured group health plans, fully insured health plans, and plans that are partially insured and partially self-insured. One of the allowable methods for a self-insured group health plan is the Form 5500 counting method in § 153.405(e)(3). In the proposed rule, we amended § 153.405(e)(3), by changing the references from "benefit year" to "plan year" to clarify that a self-insured group health plan may use the enrollment set forth in the Form 5500 even if the group health plan is based on a plan year (as defined for the purposes of the Form 5500) other than the benefit year. Therefore, a self-insured group health plan that chooses to use the Form 5500 counting method and offers self-only

coverage would calculate the number of lives covered by adding the total participants covered at the beginning and end of the most current plan year, as reported on the Form 5500, then dividing by two. A self-insured group health plan that offers both self-only coverage and coverage other than self-only coverage would calculate the number of lives covered by adding the total participants covered at the beginning and the end of the most current plan year, as reported on the Form 5500. We are finalizing this amendment as proposed.

Comment: Several commenters supported our proposed amendment to the Form 5500 counting method. One commenter suggested modifying this amendment to make clear that a self-insured group health plan that offers both self-only coverage and coverage other than self-only coverage would calculate the number of lives covered by adding the numbers of total participants covered at the beginning and at the end of the most current plan year, as reported on the Form 5500 and then dividing by two to avoid double counting enrollees.

Response: We are finalizing this technical amendment as proposed. The Form 5500 counting method does not result in the double counting of enrollees. As discussed in the “2013 Instructions for Form 5500, Annual Return/Report of Employee Benefit Plan”³¹ a “participant” does not include covered dependents, accounting for the counting method used for coverage other than self-only.

4. Provisions for the Temporary Risk Corridors Program

a. Definitions

In the first final Program Integrity Rule, we provided that, in 45 CFR part 153, subpart F regarding risk corridors, any reference to a “qualified health plan” or “QHP” includes plans that are the “same” as a QHP or “substantially the same” as a QHP. We noted that plans that are substantially the same as a QHP will continue to be considered substantially the same even if they differ in terms of benefits, premiums, provider networks, or cost-sharing structure, provided that the differences are tied directly and exclusively to Federal or State requirements or prohibitions on the coverage of benefits that apply differently to plans depending on whether they are offered through an Exchange or outside of an Exchange. In the first final Program Integrity Rule, we recognized that OPM might issue

additional standards for multi-State plan (MSP) issuers in the future (for example, standards related to provider networks) that could create situations analogous to the ones we discuss above. In the proposed rule, we considered whether a plan that differs from a QHP (as defined at § 155.20) based on OPM standards would be considered to be “substantially the same” as a QHP for the purposes of participating in the risk corridors program, and stated that we were considering amending the definition of a QHP at § 153.500 in response. Because OPM has not issued MSP standards that create such analogous situations, in this final rule, we are not amending the definition of a plan that is substantially the same as a QHP in § 153.500, though we will consider doing so in the future.

Comment: One commenter recommended that any difference in QHPs offered off-Exchange that result from a requirement imposed by OPM, including differences in provider networks, should not disqualify a QHP from participation in the risk corridors program. The commenter also requested that HHS allow plans that include an optional rider to be included in the definition of “substantially the same.”

Response: The first final Program Integrity rule provided that a plan offered outside of an Exchange is substantially the same as an Exchange QHP, and thus will participate in the risk corridors program, if it differs from an Exchange QHP with respect to benefits, premiums, cost-sharing structure, and provider networks, provided that such differences are tied directly and exclusively to Federal or State benefit requirements that apply differently to plans depending on whether they are offered through or outside an Exchange. As discussed above, we will consider amending this standard if OPM promulgates standards that require analogous differences between QHPs offered through or outside Exchanges. We are not amending this definition to include optional riders to the extent these riders are not a result of differing Federal or State requirements with respect to Exchange and off-Exchange plans.

b. Compliance With Risk Corridors Standards

In the proposed rule, we outlined our proposed process for validating risk corridors data submissions and enforcing compliance with the risk corridors requirements in subpart F of 45 CFR part 153. Because the MLR and risk corridors programs will require similar data, we proposed to closely align the data submission, data

validation, audit provisions, and sanctions for the two programs.

For the 2014 benefit year, we proposed to collect risk corridors data through the same form used for MLR data collection, at the same time (July 31st of the year following the applicable benefit year). We noted that we would modify the collection instrument and adjust the operational aspects of data submission as necessary to ensure that the data collection process adheres to the requirements for both programs. We would leverage the data validation procedures that are used by the MLR program to uncover data inconsistencies, and would add additional validation steps that would allow us to identify QHP issuers and verify QHP-specific premium information. In addition, we stated that we were considering conducting an internal quality check of risk corridors data to ensure that the information submitted is consistent with information submitted for other programs (for example, premiums and claims data reported on the dedicated distributed data environment). We stated that, similar to the MLR process, we anticipate requiring issuers to resubmit corrected data after risk corridors data errors are identified.

To ensure the integrity of risk corridors data reporting, we proposed in § 153.540(a) to establish HHS authority to conduct post-payment audits of QHP issuers. Because similar data is used in the risk corridors and MLR calculations, we proposed to conduct the risk corridors audits using the existing MLR auditing process set forth at § 158.402 to reduce the time and expense (for both HHS and issuers) of conducting multiple audits on similar data.

The second final Program Integrity Rule provides that a QHP issuer on an FFE that fails to comply with the risk corridors provisions may be subject to decertification or CMPs, but does not extend this remedy to a QHP issuer on a State Exchange. In § 153.540(b), we proposed that HHS have the authority to assess CMPs on QHP issuers in State Exchanges in accordance with the same enforcement and sanction procedures that apply to QHP issuers on FFEs, under § 156.805. We noted that, consistent with our general approach relating to the application of sanctions, we would take various factors into account when determining the amount of a CMP, including an issuer’s record of prior compliance with risk corridors requirements, the gravity and the frequency of the violation, and the issuer’s demonstrated success in correcting violations that HHS has identified (for example, errors identified

³¹ Available at: <http://www.dol.gov/ebsa/pdf/2013-5500inst.pdf>.

in corrective action plans).³² We received no comments on our proposal. Because we are still developing our enforcement and audit programs for the risk corridors and MLR programs, we are not finalizing our proposed enforcement policy with regard to CMPs at this time. We note that noncompliance with risk corridors data submission requirements may be subject to enforcement actions under the False Claims Act, and that any failure to pay risk corridors charges may be subject to our debt collection rules.

In this final rule, we are finalizing our policy with respect to risk corridors data submission, data validation, and audits, as proposed.

Comment: Some commenters opposed our proposal to combine MLR and risk corridors data submission, data validation, and auditing processes. One commenter disagreed with the proposal to use the same form for reporting MLR and risk corridors data. The commenter stated that MLR and risk corridors calculations and reporting requirements are based upon different definitions and requirements, which would rule out the use of a single form. For example, the commenter noted, the programs use different definitions of group size, and require aggregation to different levels—QHP versus legal entity. The commenter also opposed the proposal to validate risk corridors data with data from the dedicated distributed data environment, because risk corridors data are based upon total claims, including capitation amounts, whereas the dedicated distributed data will include derived encounter values. Another commenter also advised against validating risk corridors data with data from the dedicated distributed data environment because of concerns that the dedicated distributed data environment would not be ready in time or would face short-term operational challenges that would prevent it from being a reliable source of claims data.

Response: We are finalizing our proposal to use data validation procedures that are employed by the MLR program to uncover data inconsistencies, and to add validation steps that would allow us to identify QHP issuers and verify QHP-specific premium information. We do not believe that differences in standards and requirements between the risk corridors and MLR programs preclude the use of a single form because similar data will be collected at the issuer and State level

for both programs. We also note that we will make some modifications to the form to capture any additional data, such as QHP-specific premium, that is specific to any one program. We believe that this approach is less burdensome for issuers and will prevent the submission of duplicative information.

We are also finalizing our proposal to conduct an internal quality check of risk corridors data to ensure that the information submitted is consistent with information submitted for other programs. However, in response to comment regarding the appropriateness of validating risk corridors information against data collected through the dedicated distributed environment, we are clarifying that we will only validate risk corridors data against other data sources if the data from the other data sources is sufficiently reliable and can be appropriately compared, including with respect to any data submitted through the dedicated distributed data environment for 2014.

Comment: One commenter was concerned that the proposed data collection program is geared toward fee-for-service payment systems and would not accommodate the unique challenges faced by organizations that operate, at least in part, through capitated or integrated health systems.

Response: We disagree that the data collection program established for the MLR program would not accommodate the experience of capitated or integrated health systems. The MLR data submission template that would be used for the submission of risk corridors data currently accommodates data submission from a variety of insurance and provider models.

Comment: We received several comments that supported our proposal to combine MLR and risk corridors audits as a way to reduce burden for issuers. One commenter additionally suggested that HHS use enrollment weighted selection criteria, identify outliers, and employ pooling methods similar to those used by the IRS for its auditing strategy. Another commenter encouraged HHS to coordinate risk corridors audits with those performed by State Departments of Insurance.

Response: In § 153.540, we are finalizing our proposal to conduct post-payment risk corridors audits using the existing MLR auditing process set forth at § 158.402. We agree that a combined data submission and audit process will reduce burden on issuers. We appreciate commenters' suggestions on the risk corridors audit process. We intend to work closely with State Departments of Insurance to share knowledge and coordinate our audit approach to the

extent practicable, in order to prevent duplicative audits in States that review information related to MLR reporting. We intend to issue detailed guidance on the auditing process in the future.

c. Participation in the Risk Corridors Program

Because the premium stabilization programs, including the risk corridors program, are intended to mitigate pricing uncertainty associated with the 2014 market reforms, particularly the rating rules at section 2701 of the PHS Act and § 147.102, we believe that the protections of these programs should be limited to plans that are subject to the premium rating rules. In the proposed rule, we proposed to amend the risk corridors rules to provide that a plan that is not subject to the market reform rules and premium rating rules would not participate in the risk corridors program. We proposed to add paragraph (f) to § 153.510 to provide that the risk corridors program would apply only to QHPs, as defined in § 153.500, including all plans offered through the individual market Exchange or SHOP, regardless of employer size, that are subject to the following provisions within title 45 of the CFR:

- § 147.102 (fair health insurance premiums).
- § 147.104 (guaranteed availability of coverage).
- § 147.106 (guaranteed renewability of coverage).
- § 147.150 (essential health benefits).
- § 156.80 (single risk pool) and subpart B of 45 CFR part 156 (essential health benefits package).

We also proposed that the employee counting method applicable under State law would determine whether a plan is considered to be offered in the small group market for purposes of the risk corridors program, even if the State definition does not take non-full-time employees into account, and thus could include some employers that would be large employers under the Federal definition. We noted that, for purposes of the risk corridors program, permitting the use of a State employee counting method that is inconsistent with the counting method set forth in Federal law differs from the approach taken under the MLR program and the proposed counting method for the risk adjustment program that is described elsewhere in this final rule. Under these programs, non-full-time employees must be counted. We also noted that the State's employee counting method would also be used to determine whether a plan that is not a QHP is part of the non-grandfathered individual or small group market within a State, and

³² We note that the good faith provision at 45 CFR 156.800(c) will not be applicable in this context because risk corridors activities, such as data submission and payment, begin in 2015.

would, therefore, be part of a QHP issuer's risk corridors data submission under § 153.530.

In this final rule, we are finalizing the risk corridors participation rules as proposed to exclude plans that are not subject to market rules and premium rating rules from participating in the risk corridors program. We are also finalizing our proposal that the employee counting methodology used for the purposes of determining which plans participate in the risk corridors program will be the State employee counting method.

Comment: We received three comments recommending that the experience of plans not compliant with the Affordable Care Act, including transitional plans, should be excluded from the risk corridors calculation, since those plans are not in the same risk pool.

Response: QHP issuers are required to submit risk corridors data for all of their non-grandfathered plans in a market within a State. We are clarifying that this data submission requirement excludes the experience of plans that are not subject to the Affordable Care Act market reform rules, and plans being offered pursuant to the transitional policy announced on November 14, 2013.³³ This is consistent with our single risk pool policy, which bases rate setting on the predicted EHB claims experience of all of an issuer's non-grandfathered plans within the individual or small group market (or merged markets in states that require merging the risk pools) that are subject to the Affordable Care Act's market reform rules, including the single risk pool requirement. As described in this section, only QHPs (as defined in § 153.500) are subject to risk corridors charges and eligible for risk corridors payments, and only if they are plans that are required to comply with specified Affordable Care Act market reform rules previously discussed.

Comment: Some commenters recommended that HHS expand the types of plans that would be subject to the risk corridors program. Some commenters suggested that we expand risk corridors to all plans compliant with the Affordable Care Act, not just plans that are the same or substantially the same as a QHP. One commenter suggested that the risk corridors program should apply to an off-Exchange plan that would otherwise qualify as an Exchange QHP.

³³ Letter to Insurance Commissioners, Center for Consumer Information and Insurance Oversight, November 14, 2013. Available at: <http://www.cms.gov/CCIIO/Resources/Letters/Downloads/commissioner-letter-11-14-2013.PDF>.

Response: Consistent with our current policy, only plans that are QHPs, the same as a QHP, or substantially the same as a QHP (as defined at § 153.500) will make or receive risk corridors payments. We believe that our existing policy preserves the intent of the risk corridors program, which is to share risk and stabilize premiums for QHPs, whether offered through or outside the Exchange. We believe that our expanded definition of a QHP for purposes of risk corridors serves to maintain the program's focus on QHPs while permitting these plans to be offered outside the Exchange, with only such minor variations as are required by law.

Comment: We received several comments that the definition of the small group market should be consistent between the premium stabilization programs, and that the State employee counting method should be used for all Affordable Care Act programs.

Response: As noted earlier in this final rule, we agree that consistency in counting methods across Affordable Care Act programs is important, and we plan to collaborate with other Federal agencies to develop a streamlined counting method in future rulemaking. For purposes of the risk corridors program, we interpret section 1342 of the Affordable Care Act to permit us to defer to State counting methodologies. However, as noted above, we interpret the employer size definitions in the Affordable Care Act to include non-full-time employees for purposes of determining small group status for purposes of risk adjustment. We therefore are finalizing our proposal that the employee counting methodology used for the purposes of determining which plans participate in the risk corridors program will be the State employee counting method.

d. Adjustment for the Transitional Policy

As previously noted, on November 14, 2013, the Federal government announced a transitional policy under which it will not consider certain health insurance coverage in the individual or small group markets that is renewed for a policy year starting after January 1, 2014, under certain conditions to be out of compliance with specified 2014 market rules, and requested that States adopt a similar non-enforcement policy.³⁴ CMS noted in a letter to the insurance commissioners of the 50 States and the District of Columbia that

³⁴ Letter to Insurance Commissioners, Center for Consumer Information and Insurance Oversight, November 14, 2013. Available at: <http://www.cms.gov/CCIIO/Resources/Letters/Downloads/commissioner-letter-11-14-2013.PDF>.

while the transitional policy would not have been anticipated by issuers in setting rates for 2014, the risk corridors program should help ameliorate unanticipated changes in premium revenue as a result of this policy. We also stated that we intended to explore ways to modify the risk corridors program to address any unanticipated effects of this policy.

In our proposed rule, we considered an adjustment to the risk corridors formula for the 2014 benefit year that would help to further mitigate any unexpected losses for issuers of plans subject to risk corridors attributable to the effects of the transitional policy, and noted that we were considering approaches that would limit the impact of the policy on the Federal budget. We considered implementing an adjustment to the risk corridors formula set forth in subpart F of part 153 for each of the individual and small group markets by increasing the profit margin floor (from 3 percent of after-tax profits) and the allowable administrative costs ceiling (from 20 percent of after-tax profits) in an amount sufficient to offset the effects of the transitional policy upon the claims costs of a model plan. We stated that this adjustment could increase a QHP issuer's risk corridors ratio and its risk corridors payment amount to help offset losses that might occur under the transitional policy as a result of increased claims costs not accounted for when setting 2014 premiums. We stated that we were considering applying this adjustment only to plans whose allowable costs (as defined at § 153.500) are at least 80 percent of their after-tax premiums, because issuers under this threshold would generally be required to pay out MLR rebates to consumers. We stated that because we believed that the Statewide effect on this risk pool would increase with an increase in the percentage enrollment in transitional plans in the State, we were considering having the State-specific percentage adjustment to the risk corridors formula also vary with the percentage enrollment in these transitional plans in the State. To estimate this State-specific effect of the transitional policy on average claims costs, we proposed to require all issuers participating in the individual and small group markets in a State to submit to HHS a member-month enrollment count for transitional plans and non-transitional plans in the individual and small group markets prior to the risk corridors July 31, 2015 data submission.

In the proposed rule, we stated we were also considering calculating the State-specific percentage adjustment by analyzing the effects of the transitional

policy upon a plan with the following specified characteristics: allowable costs (including claims) equal to 80 percent of premiums, Federal income taxes equal to 35 percent of pre-tax profits, other tax liability equal to 7.5 percent of premiums, and other administrative costs equal to 8 percent of premiums. We proposed to estimate the effect of the transitional policy upon the model plan's claims costs by assuming that allowable costs (including claims) among the transitional plans are 80 percent of the allowable costs that would have resulted from the broad risk pool, in the absence of the transitional policy. HHS would analyze that data, and publish the State-specific adjustments that issuers would use in the risk corridors calculations for the 2014 benefit year.

Finally, in the proposed rule, we stated that we were considering modifying the MLR formula to ensure that the proposed adjustment to the risk corridors program does not distort the implementation of MLR requirements, so that the rebates that would be owed absent the transitional policy and this adjustment would not substantially change.

We are finalizing the risk corridors adjustment policy as proposed. Consistent with our proposal, we are adding a definition of "adjustment percentage" to § 153.500, and are amending the definitions of risk corridors "profits" and "allowable administrative costs" in § 153.500 to account for the adjustment percentage. We are also adding a definition of "transitional State" to § 153.500. Finally, we are adding paragraph (e) to § 153.530 to require health insurance issuers in the individual and small group markets to submit enrollment data for the risk corridors adjustment. We are making a conforming change to § 153.530(d) to clarify that the July 31st submission deadline for risk corridors data does not apply to the enrollment data specified in § 153.530(e). We project that these changes, in combination with the changes to the reinsurance program finalized in this rule, will result in net payments that are budget neutral in 2014. We intend to implement this program in a budget neutral manner, and may make future adjustments, either upward or downward to this program (for example, as discussed below, we may modify the ceiling on allowable administrative costs) to the extent necessary to achieve this goal.

Comment: Several commenters recommended that HHS implement a risk corridors adjustment based on a national calculation instead of State-

level calculations, as we proposed. One commenter noted that the effect of the transitional policy on the State risk pool could vary by factors that we did not propose to account for, such as whether or not the State had a guaranteed issue law prior to 2014, and suggested that a national adjustment would help to mitigate the effect of these differences. Alternatively, the commenter suggested that HHS could provide an adjustment for different categories of States. A few commenters suggested that a national adjustment would reduce administrative burden on issuers and would be simpler to implement. However, several other commenters supported our approach of implementing a State-level adjustment, including the proposed approach of applying the adjustment based on enrollment in non-compliant plans within a State.

Response: We are finalizing our proposed approach to determine the risk corridors adjustment on a State-by-State basis. We believe that a State-based approach provides an appropriate means of accounting for differences in market composition, enrollment in transitional plans, and adoption of the transitional policy between States. Because a national approach would still require issuers to submit enrollment information to HHS in order to determine an accurate national risk corridors adjustment, we do not believe that a State-based approach would prove more burdensome for issuers.

Comment: One commenter recommended that the adjustment be extended through all three years of the temporary risk corridors program. However, another commenter believed that the adjustment should apply for the 2014 benefit year only, since issuers will be able to reflect the effect of the transitional policy in their pricing for subsequent benefit years.

Response: We agree with the comment that issuers will be able to reflect the effect of the transitional policy in their pricing for benefit years following 2014, and thus this specific risk corridors adjustment is needed for the 2014 benefit year only. Therefore, we are finalizing the risk corridors adjustment policy to apply the adjustment to eligible QHP issuers in transitional States for the 2014 benefit year only. However, as we discuss below, we are considering further changes to the risk corridors program.

Comment: Several commenters recommended that we apply the risk corridors transitional adjustment to all plans compliant with the Affordable Care Act, not just QHPs that are subject to the risk corridors program. Some commenters requested that any changes

to the risk corridors formula be applied uniformly to all issuers, including issuers of plans that are not compliant with Affordable Care Act requirements, rather than limited to issuers offering transitional policies. One commenter supported defining "transitional plans" to include "early renewal" plans that have been renewed in late 2013 and that will not be required to comply with the Affordable Care Act until the end of 2014.

Response: Because, as described above, the risk corridors program is intended to share risk and stabilize premiums for QHPs and substantially similar off-Exchange plans that differ only due to legal requirements, we decline to expand the participation criteria for the risk corridors transitional adjustment. Consistent with our existing regulations set forth in subpart F of part 153, any risk corridors payment or charge amount, including any adjusted payment or charge amount resulting from this transitional policy, will be calculated for a QHP issuer in proportion to the premium revenue that the issuer receives from its QHPs, as defined in § 153.500. Plans that do not comply with the Affordable Care Act market reforms will not participate in the risk corridors program, and data from these plans will not be included in a QHP issuer's risk corridors calculation, or the calculation of its risk corridors adjustment percentage.

We are also finalizing our proposal that a QHP issuer in a transitional State will receive the risk corridors adjustment only if its allowable costs are above 80 percent of after-tax premiums, and will receive that adjustment irrespective of whether the issuer offers transitional policies. Because the transitional policy may affect the overall risk pool in a transitional State, we believe that it is appropriate to provide the adjustment to a QHP issuer in that State even if the issuer does not offer a transitional policy.

Comment: Some commenters recommended that HHS completely remove the administrative costs ceiling for risk corridors. One of these commenters agreed with HHS's proposal that the allowable costs must be at least 80 percent of after-tax premiums, and another agreed with setting the profit floor according to the methodology outlined in the proposed rule. Another commenter recommended that the risk corridors formula be changed to reflect a standard ceiling of 22 percent for allowable administrative costs.

Response: As we discussed in the proposed rule, the adjustment to the risk

corridors calculation is meant to mitigate the effect of the transitional policy on QHP issuers in transitional States, and not in all States. However, we understand that issuers in all States are experiencing additional administrative costs as a result of transitional issues. We are carefully analyzing this proposal, and may propose implementing it in future rulemaking. If so, this change would apply in all States for the 2015 benefit year. We would also consider making corresponding changes to the risk corridors profit floor and to the MLR regulations.

Comment: We received comments on the interaction between the proposed risk corridors adjustment and MLR reporting. One commenter supported the proposal to modify the MLR formula so that the calculation of MLR rebates would not be affected by the transitional adjustment to the risk corridors program. One commenter believed that there was no need to modify the MLR formula because the formula would automatically account for any distortions, while another commenter recommended that HHS maintain the current structure of the MLR formula in order to prevent issuer confusion. We also received one comment suggesting that issuers should be able to account for administrative expenses that are related to implementing the risk corridors transitional adjustment as part of their MLR calculation for the following year.

Response: We are providing that issuers should exclude the effect of this transitional policy risk corridors adjustment from their MLR calculations. We are making conforming changes to the MLR reporting requirements in §§ 158.130(b)(5), 158.140(b)(4)(ii), and 158.240(c)(2). We note that this policy will not change the existing structure of the MLR or risk corridors formulas. Under this policy, issuers in the transitional States will use unadjusted risk corridors amounts (that is, a risk corridors transfer calculated as if the adjustment percentage, as defined in § 153.500, is equal to zero percent) in their MLR calculations.

Comment: One commenter recommended that HHS collect enrollment counts by the middle of the year so that issuers would be able to estimate their risk corridors transitional adjustment before the end of the year, in time for year-end financial reporting. Another commenter requested that issuers should be permitted to reduce the impact of the transitional policy through mid-year premium rate changes in the small group market that would

allow issuers to file rates as early as April 1, 2014.

Response: We are clarifying that we will collect transitional plan enrollment information and publish each State-specific adjustment in advance of when issuers would need to prepare their year-end financial reports. In response to comments, we are adding § 153.530(e) and making a conforming change to § 153.530(d) to specify that, although the July 31 deadline will continue to apply to the submission of risk corridors data that is necessary to calculate allowable costs and the target amount, the July 31 deadline will not apply to the collection of enrollment data for the risk corridors adjustment. As mentioned above, we intend to collect enrollment information before the July 31st deadline for submitting risk corridors data, so that issuers will know the risk corridors adjustment amount that applies to them before they are required to submit data on allowable costs and the target amount for the purposes of the risk corridors calculation. We currently anticipate conducting this collection at the beginning of 2015.

Comment: One commenter asked HHS to clarify that, for purposes of the target amount calculation, Federal income tax cannot be negative (that is, the Federal income tax amount would have a floor of zero).

Response: We clarify that, because the Federal income tax effects of losses in one plan can be offset by gains in another plan, the risk corridors formula will account for negative Federal income tax, and that we will not apply a floor to the Federal income tax amount used in the risk corridors formula.

5. Distributed Data Collection for the HHS-Operated Risk Adjustment and Reinsurance Programs

a. Discrepancy Resolution Process

(i) Confirmation of HHS Dedicated Distributed Data Environment Reports

We proposed an iterative discrepancy reporting process that would require an issuer of a risk adjustment covered plan or a reinsurance-eligible plan to notify HHS in a timely fashion of data and calculation discrepancies related to the data the issuer uploaded to its dedicated distributed data environment. This process would allow HHS and issuers sufficient time to resolve discrepancies, prior to HHS notifying issuers of final risk adjustment payments and charges and reinsurance payments. This process would also enable HHS to identify and address issues that affect multiple issuers throughout the benefit year.

Interim dedicated distributed data environment reports: In 2014, HHS

anticipates sending interim dedicated distributed data environment reports to issuers of risk adjustment covered plans and reinsurance-eligible plans that have loaded data onto their dedicated distributed data environments. We will also send interim reports to issuers of risk adjustment covered plans and reinsurance-eligible plans that do not load data to verify this result. Issuers of risk adjustment covered plans will receive interim reports that include preliminary risk adjustment information based on this data, and issuers of reinsurance-eligible plans will receive interim reports that include an estimate of the issuer's aggregated total claims eligible for reinsurance payments based on this data. We proposed in § 153.710(d) that within 30 calendar days of the date of an interim report, the issuer would be required either to confirm to HHS that the information in the interim report accurately reflects the data to which the issuer has provided access to HHS through its dedicated distributed data environment in accordance with § 153.700(a) for the timeframe specified in the report, or else to describe to HHS any discrepancy it identifies in the interim report. Following the identification of a discrepancy in an interim report, HHS would review the evidence submitted by the issuer, along with any other relevant data, and determine if the preliminary risk adjustment information or estimated payment amount at issue was properly calculated using the applicable data.

We note that for the issuer and HHS to effectively address and resolve discrepancies through the proposed interim reporting process, once an issuer's dedicated distributed data environment is established, the issuer will be required under § 153.700(a), on a quarterly basis, to make a complete and current enrollment file accessible to HHS through the dedicated distributed data environment, and make good faith efforts to make accurate and current claims files accessible to HHS through the dedicated distributed data environment. An issuer may later (up until April 30th of the year after the benefit year, as provided for in § 153.730) adjust these files with the most current information to account for changing enrollments or more current adjudications of claims in later periods.

Final dedicated distributed data environment report: We proposed that HHS would provide issuers with a final dedicated distributed data environment report following the applicable benefit year, after the April 30th data submission deadline. The final dedicated distributed data environment

report will include final risk scores and claims amounts eligible for reinsurance payments, each calculated from the issuer's data that was timely loaded onto the dedicated distributed data environment. As with the interim reports discussed above, we proposed in § 153.710(e) that the issuer be required, within 15 calendar days of the date of the final report, to either confirm to HHS that the information in the final dedicated distributed data environment report accurately reflects the data to which the issuer has provided access to HHS through its dedicated distributed data environment in accordance with § 153.700(a) for the benefit year specified in the report, or describe to HHS any discrepancy it identifies in the final report.

Notification of payments and charges: Last, as required under § 153.310(e) and § 153.240(b)(1)(ii), HHS will provide a notification to issuers specifying the risk adjustment and reinsurance payments due and risk adjustment charges owed for the applicable benefit year by June 30th of the year following the applicable benefit year. We anticipate providing this notification in the form of a report. We also anticipate providing a report on cost-sharing reduction reconciliation payments and charges for that benefit year in the same timeframe. Although we anticipate that the interim and final dedicated distributed data environment reports will permit HHS and issuers to resolve most data and payment discrepancies for risk adjustment and reinsurance before the June 30th report is issued, we recognize that some discrepancies might remain unresolved. Therefore, we proposed in § 153.710(f) that if a discrepancy that is first identified in an interim or final dedicated distributed data environment report in accordance with § 153.710(d)(2) or § 153.710(e)(2) remains unresolved after issuance of the June 30th report, an issuer of a risk adjustment covered plan or reinsurance-eligible plan is permitted to make a request for reconsideration using the process described in § 156.1220(a). To promote the goals of the premium stabilization programs and to ensure that risk adjustment and reinsurance payments are provided to an issuer of a risk adjustment covered plan or reinsurance-eligible plan in a timely fashion, we proposed to assess charges and make payments based on the amounts listed in the June 30th report, whether or not the issuer had submitted a request for reconsideration under § 156.1220(a), and to later correct any charges or payments determined to be

inaccurate under the administrative appeals process.

(ii) Reporting of Payments and Charges Under Reconsideration

We noted in the proposed rule that because risk adjustment payment and charge amounts and reinsurance payment amounts are factors in an issuer's risk corridors and MLR calculations, a delay in resolving final risk adjustment payments and charges and reinsurance payments could make it difficult for issuers to comply with reporting requirements under the risk corridors and MLR programs. Therefore, to clarify how issuers are to comply with these reporting requirements, we proposed in § 153.710(g)(1) that, notwithstanding any discrepancy report made under § 153.710(d)(2) or (e)(2), or any request for reconsideration under § 156.1220(a), unless the dispute has been resolved, an issuer be required to report, as applicable, for purposes of the risk corridors and MLR programs, the risk adjustment or reinsurance payment to be made to the Federal government, or the risk adjustment charge assessed by the Federal government, as reflected in the June 30th report.

If the amount of cost-sharing reductions a QHP issuer has provided is at issue because the issuer requested reconsideration of a cost-sharing reduction reconciliation payment or charge under § 156.1220(a), we proposed that for the purposes of the risk corridors and the MLR program, a QHP issuer would be required to report a cost-sharing reduction amount equal to the amount of the advance payments of cost-sharing reductions paid to the issuer by HHS for the benefit year as reflected in the HHS report on cost-sharing reduction reconciliation payments and charges. Additionally, we proposed that if a QHP issuer requests reconsideration of risk corridors payments or charges under § 156.1220(a), then for purposes of MLR reporting, the QHP issuer would be required to report the risk corridors payment to be made to the Federal government or charge assessed by the Federal government as reflected in the notification provided under § 153.510(d).

Finally, we proposed in § 153.710(g)(2) that an issuer be required to report any adjustment made following any discrepancy report made under paragraph (d)(2) or (e)(2), or any request for reconsideration under § 156.1220(a) with respect to any risk adjustment payment or charge, including an assessment of risk adjustment user fees, reinsurance payment, cost-sharing reconciliation

payment or charge, or risk corridors payment or charge, or following any audit, where the adjustment has not been accounted for in a prior risk corridors or MLR report, in the next following risk corridors and MLR report.

We are finalizing these provisions as proposed.

Comment: Several commenters supported the interim and final dedicated distributed data environment reports and discrepancy process, including the requirement to upload data on a quarterly basis. One commenter requested that HHS require, not merely allow, issuers to notify HHS in a timely fashion of data and calculation discrepancies.

Response: Under § 153.710(d) and § 153.710(e), an issuer will be required to notify HHS of any discrepancies within 30 calendar days of the date of an interim dedicated distributed data environment report and within 15 calendar days of the date of the final dedicated distributed data environment report.

Comment: One commenter stated that the quarterly reporting of data on an issuer's dedicated distributed data environment should not be required until HHS has provided issuers with the necessary documents, software, and support needed to ensure that the dedicated distributed data environment is running properly, with additional time provided for issuers to implement the software and test the system.

Response: We will not require issuers to make data available on the dedicated distributed data environment until we have provided them with the necessary documents, software, support, and time to establish the environment. We will issue future guidance regarding the initiation of quarterly data reporting. At that time, we will ask that issuers make a complete and current enrollment file accessible to HHS through the dedicated distributed data environment on a quarterly basis, while making good faith efforts to make accurate and current claims files accessible to HHS through that environment. As we stated in the proposed rule, an issuer may later (up until April 30th of the year after the benefit year, as provided for in § 153.730) adjust these files with the most current information to account for changing enrollments or more current adjudications of claims in later periods. However, we believe it is critical for issuers to provide quarterly uploads of enrollment and claims files to permit issuers and HHS to monitor data collection.

Comment: Many commenters asked for details on the timing of the interim reports. One commenter recommended

that HHS require quarterly reporting by the issuer to the dedicated distributed data environment one month after the end of each quarter. Commenters stressed the importance of receiving interim reports from HHS in late 2014 to early 2015 because these reports could be used for 2016 pricing and financial reporting obligations which occur prior to the June 30th notification deadline.

Response: We will issue future guidance regarding the timing of the interim reports.

Comment: Several commenters supported receiving interim reports identifying preliminary risk scores and estimates of the issuer's aggregated total claims eligible for reinsurance payments. Many commenters asked that HHS include additional information to enable calculation of risk adjustment payment transfers, and reinsurance payment amounts.

Specifically, commenters requested that the risk adjustment interim reports include: (1) The State average premium; (2) market average risk score; (3) preliminary Statewide risk score; (4) the geographic cost factors; (5) the two market-wide denominators (weighted adjusted risk score and weighted allowed rating factors) needed for the risk adjustment transfer formula; (6) enrollment counts by geographic region; (7) member-level (de-identified) data contributing to the risk score: risk adjusting categories, plan level or plan ID, age, sex, enrollment period, rating area and subsidy information, recommending that such information be displayed for each month included in the interim report; (8) AV; (9) induced demand factor; and (10) average rate factor. One commenter stated that since interim risk score calculations would not reflect true relative risk, HHS should publish statistical reports comparing the issuer with market average demographics, proportion of claims with HCCs, most prevalent HCCs, and other pertinent data.

Regarding the interim report for reinsurance, commenters asked that the interim reports include: (1) Member level claims amounts by month; (2) claim type; and (3) subsidy information necessary to validate the cost-sharing deduction.

Commenters also asked that HHS consult with issuers about the data submission requirements to accommodate diverse market practices due to provider submission patterns, State-specific regulations and different delivery system models.

Response: We will provide more details on the content of the interim

reports in future rulemaking or guidance, as appropriate.

Comment: Several commenters suggested that HHS provide information to issuers regarding data completeness or accuracy, data quality and ways to improve data submission in time for issuers to evaluate and correct such data issues prior to the final data submission deadline.

Response: As stated in the proposed rule, as part of the process for making data available to HHS on a dedicated distributed data environment, we anticipate providing an issuer a transactional process report that will identify data that has been attempted to be uploaded, but that has been rejected along with error codes. To fulfill its obligation to make these files available to HHS, an issuer will be required to either correct or accept the rejection of this data for the submission process to be considered complete. We also intend to provide summarized reports of file processing.

Comment: Some commenters supported the 15-calendar-day deadline to respond to the final dedicated distributed data environment report, while others asked that HHS provide 30 calendar days to respond to the final dedicated distributed data environment report.

Response: The shorter 15-calendar-day reporting timeframe for the final dedicated distributed data environment report is necessary so that HHS can notify issuers of their final risk adjustment payments and charges and final reinsurance payments by June 30th of the year following the applicable benefit year, as required under § 153.310(e) and § 153.240(b)(1)(ii).

Comment: One commenter asked that HHS develop penalties for non-compliance with the standards for the submission of data for the risk adjustment program.

Response: In § 153.740(a), we established HHS's authority to impose CMPs on issuers of risk adjustment covered plans who fail to provide HHS with access to the required data in such environment in accordance with § 153.700(a) or otherwise fail to comply with the requirements of §§ 153.700 through 153.730, or fail to adhere to the risk adjustment data submission and data storage requirements set forth in §§ 153.610 through 153.630.

Additionally, under § 153.740(b), HHS will assess a default risk adjustment charge if an issuer of a risk adjustment covered plan fails to establish a dedicated distributed data environment or fails to provide HHS with access to the required data in such environment in accordance with § 153.610(a),

§ 153.700, § 153.710, or § 153.730 such that HHS cannot apply the applicable Federally certified risk adjustment methodology to calculate the risk adjustment payment transfer amount.

b. Default Risk Adjustment Charge

As described in the second final Program Integrity Rule, if an issuer does not establish a dedicated distributed data environment or submits inadequate risk adjustment data, HHS would not have the required risk adjustment data from the issuer to calculate risk scores or payment transfers for the issuer. As a result, HHS would not be able to properly calculate risk adjustment payments and charges for the entire applicable market for the State. Under § 153.740(b), if an issuer of a risk adjustment covered plan fails to establish a dedicated distributed data environment or fails to provide HHS with access to risk adjustment data in such environment by April 30th of the year following the applicable benefit year in accordance with §§ 153.610(a), 153.700, 153.710, or 153.730 such that HHS cannot apply its Federally certified risk adjustment methodology to calculate the plan's risk adjustment payment transfer amount in a timely fashion, HHS will assess a default risk adjustment charge.

As described in the second final Program Integrity Rule, the total risk adjustment default charge for a risk adjustment covered plan would equal a per member per month (PMPM) amount multiplied by the plan's enrollment.

$$T_n = C_n * E_n$$

Where:

T_n = total default risk adjustment charge for a plan n ;

C_n = the PMPM amount for plan n ; and
 E_n = the total enrollment (total billable member months) for plan n .

In the second final Program Integrity Rule, we provided that E_n could be calculated using an enrollment count provided by the issuer, using enrollment data from the issuer's MLR and risk corridors filings for the applicable benefit year, or using other reliable data sources.

We considered several methods to calculate C_n , the PMPM amount for a plan. As discussed in the proposed Program Integrity Rule, one method would be to set a PMPM amount that is equal to the highest PMPM transfer charge that HHS calculates based on risk adjustment data submitted by risk adjustment covered plans in the applicable risk pool in the applicable market in the State. Such a method could yield a PMPM amount that would reflect a PMPM charge that reflects the

high end of the PMPM distribution in certain States. However, in a situation in which the risk adjustment covered plans that provide the necessary risk adjustment data have very similar risk scores, a PMPM amount calculated under this method may yield a relatively low default risk adjustment charge, and fail to provide adequate incentive for prompt establishment of a compliant dedicated distributed data environment.

A second option we considered was to assess a PMPM amount based on the standard deviation of the PMPM charge among all risk adjustment covered plans in the applicable risk pool in the applicable market in the State. The PMPM amount used to calculate the default risk adjustment charge would be an amount equal to the mean PMPM amount plus two such standard deviations. Such an approach could also yield a PMPM amount that is high but reflects the PMPM distribution in certain situations, but, again, low in others. The amount might also be quite unpredictable *ex ante*.

The third option we considered was to assess a charge equal to a fixed percentage of the Statewide average premium, which would be calculated as the enrollment-weighted mean of all risk adjustment covered plan average premiums in the applicable risk pool in the applicable market in the State. This option might be relatively straightforward to implement, but would yield a charge that is not linked to the distribution of PMPM amounts within the relevant risk pool in the market in the State.

We are finalizing an approach in which we will assess a PMPM default charge equal to the product of the Statewide average premium (expressed as a PMPM amount) for a risk pool and the 75th percentile plan risk transfer amount expressed as a percentage of the respective Statewide average PMPM premiums for the risk pool. The nationwide percentile would reflect only plans in States where HHS is operating the risk adjustment program and would be calculated based on the absolute value of plan risk transfer amounts. The PMPM amount determined using the method described here would be multiplied by the non-compliant plan's enrollment, as determined using the sources finalized in the second final Program Integrity Rule, to establish the plan's total default risk adjustment charge.

Comment: Several commenters stated they supported a default risk adjustment charge that would be understood by issuers and that would encourage compliance. Some commenters

supported using the greatest of the three proposed methodologies for calculating the default charge. Those commenters suggested that where there are a limited number of issuers in a market in a State, an alternate approach to the standard deviation-based methodology should be taken, such as one that relies on nationwide data. Another commenter suggested that the default charge be set at the charge that would be two standard deviations above the mean charge in a market for the first instance of noncompliance; and at a higher rate, such as the highest PMPM charge among risk adjustment plans in the risk pool, for a second instance of noncompliance in consecutive benefit years.

Response: We are finalizing an approach in which the default PMPM charge is set at a fixed percentage of the Statewide average premium, which would be calculated as the enrollment-weighted mean of all risk adjustment covered plan average premiums in the applicable risk pool in the applicable market in the State in which the non-reporting plan operates. To calculate the fixed percentage, HHS would calculate the absolute value of the risk transfer PMPM amount of each plan in a State risk pool as a percentage of the Statewide average premium for the State risk pool. These percentages would then be used to rank all transfers as a percentage of Statewide average premium in the same risk pool in all States where HHS operates the risk adjustment program. We would select the fixed percentage of Statewide average premium yielded at the 75th percentile of this distribution of transfers, then multiply this percentage by the Statewide average PMPM premium for the risk pool in which the non-reporting plan operates. We will monitor the default charges resulting from this methodology and may adjust the percentile at which we assess the appropriate fixed percentage to apply the default charge in future rulemaking.

c. Clarification of the Good Faith Safe Harbor

In the second final Program Integrity rule, we finalized § 153.740(a), which permits HHS to impose CMPs upon issuers of risk adjustment covered plans and reinsurance-eligible plans for failure to adhere to certain standards relating to their dedicated distributed data environments. In the preamble to that rule, we stated that if we are able to determine that an issuer of a risk adjustment covered plan or reinsurance-eligible plan is making good faith efforts to comply with the standards set forth in § 153.740(a), consistent with our

policy codified at § 156.800(c),³⁵ we would not seek to impose CMPs for noncompliance with those standards during 2014 (78 FR 65061). We further stated: "However, we note that nothing in this provision prohibits HHS from imposing CMPs in 2015 for noncompliance that occurred in 2014." We seek to clarify that this statement does not mean that HHS takes the position that it could impose CMPs for noncompliance with respect to 2014 standards, even if the issuer attempted in good faith to comply, simply by waiting until 2015.

We intended to convey that the good faith safe harbor does not apply to non-compliance with dedicated distributed data environment standards applicable during 2015, *even if the non-compliance in 2015 relates to data for the 2014 benefit year*. In 2014, issuers must establish dedicated distributed data environments and load data according to a quarterly schedule to be provided by HHS. The good faith safe harbor would apply, for example, to noncompliance with the 2014 schedule for establishing a dedicated distributed data environment and loading data. However, the data loading schedule applicable to 2014 risk adjustment and reinsurance data extends into 2015 (the final loading deadline is April 30, 2015, which will enable HHS to calculate risk adjustment payments and charges and reinsurance payments for the 2014 benefit year by June 30, 2015), and at this time, the good faith safe harbor does not extend to noncompliance with any 2015 obligations, even if those 2015 obligations apply with respect to 2014 data. As we stated in the preamble to the Program Integrity final rules (78 FR 54070 and 78 FR 65046), at the appropriate time, we may consider extending this good-faith compliance safe harbor.

We further note that our clarification of this preamble language does not preclude application of the good faith safe harbor under § 156.800(c) to noncompliance actions that occurred in 2013 with respect to 2014 standards.

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

1. Election To Operate an Exchange After 2014

We proposed to reduce the time that the State must have in effect an approved or conditionally approved Exchange Blueprint and readiness assessment from 12 months to 6.5 months prior to the Exchange's first

³⁵ 45 CFR 156.800(c) was finalized in the first final Program Integrity Final Rule.

effective date of coverage. HHS learned through the process of conditionally approving the first generation of State Exchanges that it is challenging to make an accurate assessment of a State's progress and its ability to complete an Exchange build 10 months prior to open enrollment and a year prior to the first date that insurance coverage for consumers would become effective. In addition, we believe that this amendment will give States more time prior to approval of the Exchange Blueprint to prepare for the transition from an FFE or State Partnership Exchange model to a State Exchange. We proposed to amend § 155.106(a)(2) by moving the deadline for the approval of the Exchange Blueprint for those States electing to establish and operate an Exchange after 2014 to June 15th of the previous plan year rather than January 1st of the previous plan year. We also proposed in the preamble to the proposed rule that the Exchange Blueprint application would be submitted on June 1st instead of on November 15th. This new timeframe will enable HHS to gauge the State's actual technical, business and operational progress as more indicative milestones should be reached by June 15th. We are finalizing the amendment to § 155.106(a)(2) as proposed.

Comment: Several commenters were concerned that moving the date to June 15th will compromise the operational efficiency of issuers planning to offer QHPs in these new Exchanges. Some commenters stated that the June 15th date will give issuers insufficient time to program their systems for State-specific processes and suggested that HHS require newly-electing Exchanges to use a standard file format if the Exchange intends to collect and remit premiums. Other commenters stated that the June 15th date provides insufficient time for plan testing of State systems to ensure a smooth transition from an FFE model to a State Exchange. Other commenters stated that the June 15th date will provide the necessary time and flexibility for States transitioning to a State Exchange.

Response: The June 15th date balances the needs of issuers to prepare products for the Exchanges with the needs of the States that wish to transition to a State Exchange. The QHP certification process of newly electing State Exchanges or transitioning Exchanges should not be delayed, as State DOIs, in the ordinary course of reviewing plans for compliance with State and Federal law, will be conducting their reviews of plans irrespective of the Exchange Blueprint deadline. DOI decisions will therefore

be available to inform certification decisions by a State Exchange, and there should be ample time for issuers to program their system as required by newly electing State Exchanges and as required by those FFE States transitioning to a State Exchange model. We encourage States and new State Exchanges to work with issuers on State-specific requirements and unique processes.

Comment: One commenter suggested that HHS monitor whether the 6.5 month deadline provides adequate time for HHS to assess readiness. In addition, the commenter suggested that 15 days between the Blueprint application due date of June 1st and the decision of approval or conditional approval might not allow for sufficient time for HHS to communicate with States. Finally, the commenter asked HHS to clarify when a State must have full approval as opposed to conditional approval, given the shorter timeframe. One commenter stated that the new deadline would not give HHS enough time to conduct critical IT testing for the Exchange and the health plans.

Response: HHS believes that the June 15th date provides adequate time to assess the readiness of the Exchange. As stated in the preamble, the January 1st date proved difficult for HHS to appropriately assess the readiness of State Exchanges. Fifteen days is sufficient time for communication between the States and HHS, as HHS envisions that States that are applying to become State Exchanges will be communicating with HHS well before June 1st and HHS will provide appropriate support and technical assistance. Finally, the proposed timeframe is sufficient for HHS to approve or conditionally approve the new State Exchanges.

2. Ability of States to Permit Agents and Brokers To Assist Qualified Individuals, Qualified Employers, or Qualified Employees Enrolling in QHPs

We proposed to add new § 155.220(i) to provide that paragraph (c)(3), which addresses enrollment in a QHP through the Exchange via an Internet Web site of an agent or broker, would apply to SHOPs for plan years beginning on or after January 1, 2015, in addition to the individual market Exchanges. Under the proposal, employers that have not traditionally worked with agents and brokers but have, in the past, utilized Internet Web sites of agents and brokers for purchasing insurance would have another option to learn about and participate in SHOP. We proposed to allow SHOPs, in States that allow this activity under State law, to permit

enrollment in a QHP through the SHOP by using an Internet Web site of an agent or broker under the standards outlined in § 155.220(c)(3) if a State SHOP or an FF-SHOP has the technical capability to make this possible. CMS does not currently anticipate that the FF-SHOPs will make this functionality available in 2015. We are finalizing this provision as proposed, but note that we have added a title to the provision.

Comment: A broad range of commenters supported permitting enrollment in a SHOP QHP through the Exchange via the Internet Web site of an agent or broker. While several commenters favored the expanded function for agents and brokers, some commenters also recommended that HHS require compliance with industry and consumer protections. Several commenters recommended that HHS explicitly include consumer protections and prohibit agents and brokers who offer Internet Web sites to help consumers enroll in coverage through the Exchange from using PII, including gender, age, income, or other characteristics, for immediate or future marketing purposes; that the Exchange make consumers aware of these agents' and brokers' financial incentives; and that the Exchange establish a formal system for monitoring agents and brokers who offer Internet Web sites to help consumers enroll in Exchange coverage, enforcing consumer protections against such agents and brokers, and terminating relationships with agents and brokers that violate those protections.

Response: Under § 155.220(c)(3), HHS has established safeguards to protect consumers who are using the Internet Web site of an agent or broker to complete a QHP selection for coverage offered, or to enroll in coverage in the individual market Exchanges. The same safeguards and requirements would also apply when consumers use an Internet Web site of an agent or broker to complete a QHP selection for coverage offered on a SHOP Exchange.

We note that SHOP agents and brokers must comply with section 1411(g) of the Affordable Care Act, which provides that PII may only be used for purposes of, and to the extent necessary in, ensuring the efficient operation of the Exchange. States that are approved to operate SHOP Exchanges must also establish privacy and security standards governing the use of PII by non-Exchange entities consistent with § 155.260, which also prohibits any use or disclosure of PII in violation of section 1411(g) of the

Affordable Care Act.³⁶ We further note that FF-SHOP agents and brokers must sign an agreement with the Exchange (FF-SHOP Agent Broker Agreement) that requires strict adherence to the Exchange's privacy and security standards established pursuant to 45 CFR 155.260. SHOP agents' and brokers' use and disclosure of PII is limited to the specific authorized functions outlined in the FF-SHOP Agent Broker Agreement and that Agreement also explicitly prohibits the use of PII for any purpose that is not identified as an authorized function. The use of PII for marketing purposes is not identified as an authorized function and is therefore prohibited.

Comment: One commenter recommended that HHS require that consumers who enroll in Exchange coverage through the Internet Web site of an agent or broker complete an eligibility application and the enrollment process through the SHOP to assure the SHOP remains the eligibility and enrollment system of record. One commenter further recommended that HHS require the SHOP to transmit enrollment information to a QHP or QDP issuer to ensure an issuer can effectuate enrollment of qualified employees. Another commenter recommended that the proposed rule be expanded to explicitly require that the Exchange retain responsibility for billing and premium aggregation services as required in regulation.

Response: In accordance with CMS regulations, the SHOP, not an agent or broker, will always complete eligibility determinations and the SHOP will remain the system of record for eligibility purposes. Additionally, in accordance with CMS regulations, the SHOP, not an agent or broker, will always be responsible for premium aggregation services as set forth in § 155.705(b)(4). Under § 155.705(b)(4), for plan years beginning on or after January 1, 2015, the SHOP must be responsible for all premium aggregation services and for routing payments from employers to issuers. Specifically, the SHOP must provide each qualified employer with a bill on a monthly basis

that identifies the employer contribution, the employee contribution, and the total amount that is due to issuers from the qualified employer; collect from each qualified employer the total amount due; make payments to QHP and QDP issuers in the SHOP for all enrollees; and maintain books, records, documents, and other evidence of accounting procedures and practices of the premium aggregation program for each benefit year for at least 10 years.

Comment: Several commenters recommended that agents and brokers who offer Exchange enrollment through an Internet Web site be required to list all QHP issuer offerings displayed on the relevant Exchange Web site and that the Exchange provide this information to the agent or broker. Some commenters specifically recommended that HHS specify that agents and brokers using non-Exchange Web sites must refrain from disclosing QHP prices and rates prior to the availability of such data on the SHOP Web site. Other commenters recommended that HHS contract with agents and brokers offering Exchange enrollment through an Internet Web site other than the Exchange Web site to prohibit the early release of data on QHP prices and data to ensure that QHP rates are not shared with competitors prior to the plan data being made public.

Response: As is required at § 155.220(c)(3)(iv) for agents and brokers assisting with enrollment in individual market Exchange coverage, the Internet Web site of the agent or broker used to complete the QHP selection must display all QHP data provided by the Exchange. Agents and brokers must also meet all standards for disclosure and display of QHP information contained in § 155.205(b)(1) and (c). As noted in the proposed Program Integrity Rule (78 FR 37046), we recognize that an Exchange may not be able to provide to agents and brokers certain data elements necessary to meet the § 155.205(b)(1) requirements, such as premium and rate information, depending upon confidentiality requirements, the agent or broker appointment with the QHP issuer, and State laws regarding agent and broker appointments. We therefore provided under § 155.220(c)(3)(i) that if less than all QHP data required under § 155.205(b)(1) is displayed on the agent's or broker's Internet Web site, the agent or broker must prominently display a standardized disclaimer provided by HHS stating that all information required under § 155.205(b)(1) for the QHP is available on the Exchange Web site and provide a Web link to the Exchange Web site. In

addition, for States in which HHS is operating an FFM, pursuant to § 155.220(c)(3)(vii), a second disclaimer is required that would include the following notifications: (1) The Internet Web site of the agent or broker is not an FFM Web site, (2) the Internet Web site of the agent or broker may not contain all QHP data available on the FFM Web site, and (3) the agent or broker is required to comply with all applicable Federal laws, including the standards specified in paragraph (c)(3) of § 155.220, and the standards established under 45 CFR 155.260 to protect the privacy and security of PII. The disclaimer must also contain a link to HealthCare.gov. The same requirements would apply to agents and brokers assisting with enrollment in SHOP coverage.

Comment: One commenter recommended that HHS require that the Internet Web site of an agent or broker that is used to complete a QHP selection through the Exchange display available QHPs in a manner that is as consistent with the Exchange Web site as possible.

Response: Under § 155.220(c)(3)(i), all QHP data on the Internet Web site of an agent or broker that is used to complete a QHP selection through the Exchange must be disclosed and displayed consistent with the requirements that apply to the Exchange Web site at 45 CFR 155.205(b)(1) and (c). Section 155.205(b)(1) generally requires that standardized comparative information be provided for each available QHP and 45 CFR 155.205(c) requires that information be displayed in a manner that is accessible to persons with limited English proficiency and persons with disabilities. In addition, as noted above, if an agent or broker Web site does not display all information required under § 155.205(b)(1) for a QHP, it must include the standardized disclaimer established under § 155.220(c)(3)(i). The same requirements would apply to agents and brokers assisting with enrollment in SHOP coverage. State laws and regulations may establish additional standards for this activity.

3. Privacy and Security of Personally Identifiable Information

In § 155.260(a), we proposed allowing the Secretary to determine that additional uses or disclosures of personally identifiable information (PII), which may not be directly connected to Exchange "minimum functions" as currently described in regulation, ensure the efficient operation of the Exchange, subject to privacy and security standards that Exchanges must establish. We proposed a process for

³⁶ 45 CFR 155.105(b)(1) provides that HHS will approve the operation of an Exchange established by the State if the State Exchange is able to carry out the required functions consistent with subparts C, D, E, F, G, H, and K of part 155. For States approved to operate only a SHOP Exchange, the Exchange must perform the minimum functions described in subpart H and all applicable provisions of other subparts referenced therein. 45 CFR 155.705(a) includes a reference to subparts C, E, K, and M of part 155. The privacy and security requirements for Exchanges are codified in subpart C. As such, all Exchanges, including all SHOPS, are subject to the privacy and security requirements at 45 CFR 155.260.

Exchanges to seek the Secretary's approval of other requested uses and disclosures of eligibility and enrollment PII that would ensure the efficient operation of the Exchange; comply with other applicable law and policy; and require the consent of the individual subject of the PII prior to the requested use or disclosure.

We also proposed in § 155.260(b) to clarify that the definition of a "non-Exchange entity" refers to any individual or entity that gains access to PII submitted to an Exchange, or collects, uses, or discloses PII gathered directly from applicants, qualified individuals, or enrollees while that individual or entity is performing functions agreed to with the Exchange. Examples of non-Exchange entities include, but are not limited to, Medicaid and CHIP agencies; Certified Application Counselors; in-person assisters; agents and brokers, including Web-brokers; QHP issuers; and other third parties that contract with the Exchange or other downstream entities that contract with non-Exchange entities.

We proposed to maintain the existing requirement for Exchanges to enter into a contract or agreement with non-Exchange entities, and we specified five required elements to be included in those contracts and agreements. We proposed three criteria that would provide a foundation and flexibility for Exchanges to set privacy and security standards as a condition of contract or agreement with non-Exchange entities while also aligning closely with the wide variety of non-Exchange entities, responsibilities, functions, operational environments, and technical infrastructures. These criteria would provide equivalent or more stringent protection than the standards which the Exchange has established and implemented for itself while aligning to the functions and operating environment of the non-Exchange entity.

The proposed requirement that standards be relevant to non-Exchange entities' duties and activities in relation to the Exchange introduced the concept of "relevant and applicable" and reflected our intent to address the various responsibilities assumed by non-Exchange entities and their associated technical infrastructures. We are finalizing the provisions as proposed.

Comment: Commenters generally expressed support for the proposed substantive and procedural requirements established in § 155.260(a)(1)(iii), including a consent requirement, for data uses and

disclosures not explicitly described in § 155.260(a)(1)(i) or (ii). Certain commenters noted that data required to determine eligibility and premium subsidies is extremely sensitive, necessitating strong privacy and security safeguards. Certain commenters emphasized the need to minimize sharing of PII to the minimum necessary to effectuate implementation of the Affordable Care Act and ensure the efficient operation of the Exchange.

Response: We concur with the commenters' suggestion that the sensitive nature of PII necessitates robust privacy and security safeguards, and we reiterate that the Secretary would review requestors' proposed privacy and security standards as part of the Secretary's proposed review process under § 155.260(a)(1)(iii)(B)(4). The proposed process establishes the requirement for requestors to describe how data will be protected with privacy and security standards that are compliant with § 155.260 and to show that a proposed use or disclosure will ensure the efficient operation of the Exchange consistent with section 1411(g)(2)(A) of the Affordable Care Act. If a requested use or disclosure does not satisfy these requirements, it would not be approved under the proposed process. We further recognize the imperative to maintain safeguards for eligibility and enrollment PII. Once the Secretary approves a proposed use or disclosure of eligibility and enrollment PII, the Exchange would be required to limit the use or disclosure of PII to the extent necessary to accomplish the proposed function, and the individual would need to provide consent before his or her eligibility and enrollment PII could be used or disclosed.

Comment: Some commenters supported our proposal at § 155.260(b)(3), which would require that non-Exchange entities meet privacy and security standards at least as protective as the standards the Exchange establishes and implements for itself. The commenters further recommended that the same standards apply to downstream entities to ensure PII continues to be protected once it reaches the downstream entity. One commenter further recommended that Exchanges form direct agreements with downstream entities rather than relying on non-Exchange entities to ensure their compliance with privacy and security standards. The commenter stressed that this is important because downstream entities may have different duties or operational and technical environments than the non-Exchange entities with which an Exchange has an agreement, and these differences may not be

properly accounted for in the Exchange's agreement with a non-Exchange entity.

Response: We proposed at § 155.260(b)(2) to maintain the existing requirement for Exchanges to enter into a contract or agreement with non-Exchange entities and we provided more details specifying the required elements of these contracts and agreements. We proposed in § 155.260(b)(2)(iv) that such a contract or agreement must require any downstream entities that meet the definition established in § 155.260(b)(1) to comply with the same privacy and security standards with which the non-Exchange entity agrees to comply under its contract or agreement with the Exchange. Further, we proposed in § 155.260(b)(3)(iii)(A) that the privacy and security standards to which non-Exchange entities are bound must consider the operational and technical environment in which the non-Exchange entity operates, and that these environments be assessed in light of the requirement in § 155.260(a)(5) to monitor, periodically assess and update security controls and related system risks to ensure continued effectiveness of those controls. Downstream entities are also subject to this criterion under proposed § 155.260(b)(2)(iv). Our adoption of these requirements in the final rule reflects our concurrence that it is important that the privacy and security standards continue to apply to PII as it moves to additional downstream entities.

Comment: Several commenters suggested that QHP issuers should not be considered non-Exchange entities under the definition proposed in § 155.260(b) because issuers' roles differ fundamentally from the roles and functions of other entities listed as non-Exchange entities in the proposed regulation. Certain commenters specified, as an example, that unlike other entities listed as non-Exchange entities, QHP issuers do not participate in the eligibility determination process because it is conducted entirely through the Exchange.

Response: Because the proposed definition of non-Exchange entities is broad and includes a variety of entities, we recognize that there can be considerable variation among non-Exchange entities. Different non-Exchange entity functions can result in variation in both the amount and type of access to PII and the technical characteristics of the non-Exchange entity's environment. We intended to address the lack of a regulatory mechanism to take these variations into account, and to alleviate potential

operational burdens for non-Exchange entities. We proposed that any individual or entity that gains access to PII submitted to an Exchange or accesses PII directly from individuals should be considered a non-Exchange entity. This approach defines a non-Exchange entity based on the entity's access to PII, not based on the roles or functions of the entity, and QHP issuers would qualify as non-Exchange entities based on this definition. We believe this approach appropriately addresses the fact that a QHP issuer's role may differ from that of other non-Exchange entities.

Comment: Several commenters suggested that QHP issuers should not be subject to the proposed regulatory requirements at § 155.260(b)(2) because they already are subject to the HIPAA Privacy, Security and Breach Notification Rules at 45 CFR Parts 160 and 164, as well as applicable State breach notification standards. Certain commenters requested that if issuers are classified as non-Exchange entities as proposed, we recognize the HIPAA Privacy, Security and Breach Notification Rules as sufficient for Exchange privacy and security standards under § 155.260(b). Certain commenters further explained that, because QHP issuers and their delegated and downstream entities already are subject to comprehensive privacy and security standards under HIPAA, requiring issuers to implement additional privacy and security standards would pose duplicative and potentially conflicting requirements and unnecessary administrative burdens. Certain commenters suggested that the proposed regulatory requirements for non-Exchange entities should not apply to QHP issuers because they already are subject to business associate agreement requirements that the proposed regulatory requirements would duplicate, imposing unnecessary administrative burdens on them.

Response: In its final form, § 155.260(b)(3)(i)–(iii) will allow an Exchange the flexibility to tailor privacy and security standards to particular types of non-Exchange entities so long as those standards remain strong in compliance with § 155.260. With respect to non-Exchange entities that currently are obligated to follow the HIPAA Privacy, Security and Breach Notification Rules, pursuant to written agreements required by § 155.260(b)(3), Exchanges will have the flexibility to deem non-Exchange entities in compliance with the specific privacy and security standards that the Exchange establishes for its non-Exchange entities by virtue of their

compliance with the HIPAA Privacy, Security and Breach Notification Rules or similar standards. This would be permissible so long as the Exchange determines that HIPAA Privacy, Security and Breach Notification Rules or similar standards are at least as protective as the standards the Exchange has established and implemented for itself in compliance with paragraph § 155.260(a)(3), so long as those standards' protections are extended to all PII created, collected, disclosed, accessed, maintained, stored, or used in connection with FFEs, and so long as the Exchange also requires non-Exchange entities to comply with the additional limitations on use and disclosure of PII in section 1411(g) of the Affordable Care Act. It would be incumbent upon the Exchange to evaluate whether such deeming arrangements would satisfy all of the criteria established for privacy and security standards under proposed § 155.260(b)(3). With respect to FFEs, pursuant to written agreements, they also will have the flexibility to deem QHP issuers, and agents and brokers who use QHP issuer information technology systems, to be in compliance with the specific privacy and security standards that the Exchange establishes for its non-Exchange entities by virtue of their compliance with the HIPAA Privacy, Security and Breach Notification Rules or similar standards, so long as the FFEs determine that those standards are at least as protective as the standards the FFEs have established and implemented for themselves in compliance with paragraph § 155.260(a)(3), so long as those standards' protections are extended to all PII created, collected, disclosed, accessed, maintained, stored, or used in connection with FFEs, and so long as the FFEs also require non-Exchange entities to comply with the additional limitations on use and disclosure of PII in section 1411(g) of the Affordable Care Act. We intend to issue guidance that will address in greater detail the applicability of the HIPAA Privacy, Security, and Breach Notification Rules and the additional limitations on use and disclosure of PII in section 1411(g) of the Affordable Care Act.

Comment: Certain commenters more specifically requested that QHP issuers be allowed to comply with the HIPAA Privacy, Security and Breach Notification Rules to satisfy the privacy and security requirements of § 155.260(b) because the enrollment and eligibility PII that QHP issuers receive from an Exchange does not merit a different level of protection than other

non-Exchange-based enrollment information that QHP issuers typically handle. Certain commenters explained that QHP issuers do not participate in the Exchange eligibility determination process, and only receive the results of such determinations in enrollment files that are substantially similar to the enrollment data that health plans and issuers receive or create for non-Exchange-based products that are subject to HIPAA Privacy and Security Rules and State breach notification standards. One commenter also noted that such enrollment files do not contain information from Federal agencies such as IRS and Department of Homeland Security.

Response: Under the final rule, Exchanges will have the flexibility to deem non-Exchange entities in compliance with the specific privacy and security standards that the Exchange establishes for its non-Exchange entities by virtue of their compliance with the HIPAA Privacy, Security and Breach Notification Rules or similar standards, so long as those standards are at least as protective as the standards the Exchange has established and implemented for itself in compliance with paragraph § 155.260(a)(3), and so long as they incorporate the additional limitations on use and disclosure of PII in section 1411(g) of the Affordable Care Act. It would be the responsibility of the Exchange to evaluate whether such deeming arrangements for privacy and security standards for non-Exchange entities would satisfy the criteria proposed in § 155.260(b)(3).

We proposed requirements in § 155.260(b)(3) that are intended to provide a foundation that Exchanges must use to define privacy and security standards for non-Exchange entities that afford a level of protection equal to that provided by the standards the Exchanges adopt for themselves. We proposed three criteria that would have to be met by the privacy and security standards to which an Exchange must bind non-Exchange entities, and we do require that these standards take into specific account the environment in which the non-Exchange entity operates. The first criterion in § 155.260(b)(3)(i) requires that any privacy and security standards must be as protective as the standards the Exchange sets for itself, consistent with all the principles and requirements listed under § 155.260(a). The second criterion requires that any privacy and security standards must also comply with requirements for workforce and contractor compliance, written policies and procedures, compliance with the

Code, and consequences of improper use and disclosure of information established by § 155.260(c), (d), (f) and (g). The third criterion requires that the privacy and security standards to which non-Exchange entities are bound take into consideration several factors, including the operating and technical environment in which the non-Exchange entity operates. These environments and the standards themselves should be assessed in light of the requirement established at § 155.260(a)(5) to monitor, periodically assess, and update security controls and related system risks to ensure the continued effectiveness of those controls. We would expect that an Exchange's contracts and agreements with non-Exchange entities would include privacy and security standards based on these criteria, as well as a proposed requirement at § 155.260(b)(3)(iii)(B) requiring those standards to be relevant and applicable to the non-Exchange entity's duties and activities in relation to the Exchange. We believe these rules allow sufficient flexibility for Exchanges to tailor privacy and security standards to the specific information non-Exchange entities will handle, including that information typically handled by QHP issuers.

Comment: Some commenters expressed concern that under the proposed regulatory language, an Exchange could require a QHP issuer to comply with CMS's "Minimum Acceptable Risk Standard for Exchanges (MARS-E) Suite of Documents: Guidance on Operational, Technical, Administrative, and Physical Safeguards."³⁷ One commenter further explained that because QHP issuers do not conduct eligibility analyses, only receiving eligibility results, requiring issuer compliance with the full suite of MARS-E requirements would have significant operational impacts and increase administrative costs without enhancing data security.

Response: Under the final rule, where an Exchange determines that a non-Exchange entity's compliance with MARS-E requirements are necessary to adequately protect PII and comply with § 155.260(b), it may indeed require such compliance under a written agreement with a non-Exchange entity. For example, FFE agreements with agents and brokers who will assist consumers with applications for determinations of eligibility to enroll in insurance

affordability programs, including QHPs, and/or to receive advance payments of premium tax credit and/or cost-sharing reductions using the FFE Web site, currently require compliance with MARS-E requirements. All agents and brokers providing such assistance through FFEs must comply with the FFE privacy and security standards for non-Exchange entities as a condition of their separate agreements with CMS. Agents and brokers who will use a QHP issuer's computers and work space controlled by a QHP issuer to perform these functions, must ensure those computers and work space are compliant with privacy and security provisions of their agreements with CMS. We believe that QHP issuers typically have procedures already in place to address general computer and work space security.

Comment: One commenter recommended that we clarify that limitations on use and disclosure under section 1411(g) of the Affordable Care Act apply only to PII concerning an "applicant." The commenter further explained that, once an individual is enrolled in a QHP, PII received during the application process should no longer be subject to section 1411(g), but instead should be subject to HIPAA privacy and security standards. The commenter also requested that if an applicant provides information to a QHP issuer, governed by section 1411(g) of the Affordable Care Act, and the applicant does not enroll in a QHP, the issuer should then be able to use and disclose the information consistent with HIPAA privacy and security standards after obtaining the applicant's consent.

Response: We clarify that as proposed in § 155.260(b)(1), any individual or entity that gains access to PII submitted to an Exchange or collects, uses or discloses PII gathered directly from applicants, qualified individuals, or enrollees while that individual or entity is performing the functions agreed to with the Exchange, is considered to be a non-Exchange entity. We proposed in § 155.260(b)(2) to maintain the existing requirement for Exchanges to enter into a contract or agreement with non-Exchange entities. We also state in § 155.260(b)(2)(ii) that in the required contract or agreement, the Exchange must impose a requirement for compliance with privacy and security standards, and specifically list or incorporate by reference the privacy and security standards and obligations with which the non-Exchange entity must comply, including obtaining consent consistent with the principle provided under § 155.260(a)(iv). Under the Final Rule, Exchanges will have the flexibility to deem non-Exchange entities in

compliance with the specific privacy and security standards that an Exchange establishes for its non-Exchange entities by virtue of their compliance with the HIPAA Privacy, Security and Breach Notification Rules or similar standards, so long as the Exchange determines that those standards are at least as protective as the standards the Exchange has established and implemented for itself in compliance with paragraph § 155.260(a)(3), so long as those standards' protections are extended to all PII created, collected, disclosed, accessed, maintained, stored, or used in connection with Exchange, and so long as the Exchange also requires non-Exchange entities to comply with the additional limitations on use and disclosure of PII in section 1411(g) of the Affordable Care Act.

Comment: One commenter expressed concern regarding the proposed requirement that non-Exchange entities inform the Exchange of any change in administrative, technical or operational environments defined as material in the contract. The commenter expressed concern that the definition of material changes that would trigger the reporting requirement could be overly broad in individual Exchange contracts. The commenter recommended that we clarify that the types of changes that would have to be reported be significant and have the possibility of altering the organization's overall security posture.

Response: At § 155.260(b)(2), we proposed to maintain the existing requirement for Exchanges to enter into a contract or agreement with non-Exchange entities, and we proposed five required elements of these contracts and agreements. One of those elements, in § 155.260(b)(2)(iv), would require the non-Exchange entity to inform the Exchange of any change in its administrative, technical or operational environment, as defined within the contract, which would require an alteration of the privacy and security standards within the contract or agreement to ensure those standards remain relevant and aligned with current operating environments. The intent of this requirement is to provide an opportunity for the Exchange and the non-Exchange entity to assess and revise the privacy and security standards to ensure their continued relevance.

4. Annual Open Enrollment Period for 2015

In § 155.410, as finalized in the Exchange Establishment Rule, we set forth provisions for initial and annual open enrollment periods. We proposed amending § 155.410(e) and (f), which pertain to the annual open enrollment

³⁷ The MARS-E suite of documents can be found at the following address: <http://www.cms.gov/ccio/resources/regulations-and-guidance/index.html#MinimumAcceptableRiskStandards>.

period and effective date for coverage after the annual open enrollment period. These amendments apply to non-grandfathered policies offered through and outside the Exchange.

In paragraph (e), we proposed adding a paragraph that would change the annual open enrollment period for the 2015 benefit year. We proposed that for all Exchanges, annual open enrollment would begin on November 15, 2014 and extend through January 15, 2015. This would give health insurance issuers an additional month in 2014 before they would need to begin accepting plan selections for the upcoming plan year and staggers the start of open enrollment for the Exchange from that for Medicare Advantage. It would give consumers the ability to have coverage starting January 1, 2015, or if they need more time, until January 15, 2015 to shop for, and select a QHP for the 2015 plan year. We also noted that if finalized, all Exchanges would be expected to delay their QHP certification dates by at least one month. This would give health insurance issuers additional time to monitor 2014 enrollments, prior to submitting their 2015 rates. We proposed to retain the October 15th to December 7th open enrollment period for subsequent benefit years.

In paragraph (f), we proposed adding a paragraph to address coverage effective dates for plan selections made during the annual open enrollment period for the 2015 benefit year. We proposed that coverage must be effective January 1, 2015, for plan selections received by the Exchange on or before December 15, 2014. We proposed that coverage must be effective February 1, 2015, for plan selections received by the Exchange from December 16, 2014³⁸ through January 15, 2015. In accordance with § 155.335(j), qualified individuals already enrolled in a QHP through the Exchange in 2014 who remain eligible for enrollment in a QHP would have their coverage continue into 2015, but they would have the ability to change QHPs until January 15, 2015. We also sought comment on whether there should be retrospective coverage to January 1, 2015, for any individual who signs up after December 15, 2014 in the open enrollment period to ensure continuity of coverage. We also proposed January 1st coverage effective dates for open enrollment for benefit years beginning on or after January 1, 2016.

³⁸ We note that the proposed rule contained a typographical error that referred to December 16, 2015, instead of the clearly intended December 16, 2014. This final rule finalizes the provision with the corrected date.

We are finalizing the regulation with an open enrollment end date of February 15, 2015 instead of January 15, 2015, for the benefit year beginning January 1, 2015, and we are adding coverage effective dates for enrollments during the period between January 16–February 15, 2015. We are not finalizing in this rule, the open enrollment period or effective dates for the benefit years beginning on or after January 1, 2016. Finally, for consistency within this section, we are changing the reference to “plans” in subparagraph (f)(1) to “QHPs.”

Comment: Many commenters supported the proposed open enrollment period dates and corresponding coverage effective dates. Some commenters proposed alternate open enrollment period date ranges for both the benefit year beginning on January 1, 2015, and for years beyond 2015. Other commenters opposed the proposed amendments to the rule. Issuers discouraged retroactive effective dates, in response to a solicitation for comments regarding retroactive effective dates.

Response: In response to comments recommending different ranges for the annual open enrollment period, we are finalizing this amendment so that open enrollment for the benefit year beginning January 1, 2015 begins November 15, 2014, and ends February 15, 2015. We are also adding a provision providing for the standard coverage effective date of March 1, 2015 for enrollments taking place between January 16 and 31, 2015. We believe that the additional time before open enrollment will enable the collection of additional rating experience that could have a positive benefit on reducing 2015 rates for consumers. We further believe that extending the open enrollment period to February 15, 2015 instead of January 15, 2015 is beneficial for consumers because it provides additional time to select a plan. We are not adding any requirements for retroactive coverage in connection with this annual open enrollment period. Because some commenters proposed alternate open enrollment period date ranges for benefit years beyond the one year beginning on January 1, 2015, we intend to propose open enrollment dates for the 2016 plan year in the 2016 draft Payment Notice. Finalizing open enrollment dates for the 2016 plan year in the 2016 Payment Notice will allow an additional year’s experiences to inform the finalization of realistic enrollment dates.

We note that non-grandfathered individual coverage sold on a date other than January 1st of the calendar year

would still be required to have the plan or policy year end on December 31, 2015 to comply with the requirement to be offered on a calendar policy year under 45 CFR 144.103 and 147.104(b)(2). We also note that this amendment to the open enrollment period applies to the individual health insurance market, both for plans offered through and outside the Exchanges, by virtue of the cross-reference at 45 CFR 147.104(b)(1)(ii), through which the dates of the individual market Exchange open enrollment period also apply to the individual market generally.

5. Functions of a SHOP

We proposed amending § 155.705(b)(1), which lists the rules regarding eligibility and enrollment to which SHOPS must adhere, to include mention of provisions regarding termination of coverage in the SHOPS and SHOP employer and employee eligibility appeals that were finalized in the first final Program Integrity Rule. We are finalizing this amendment with a minor change to replace the list of provisions in the current and proposed versions of the rule with a more general reference to subpart H. The change from the proposed rule text will help HHS keep the provision up to date.

We also proposed adding a new paragraph § 155.705(b)(3) to provide qualified employers with options to offer dental coverage after employee choice becomes available in the FF–SHOPS. We proposed that for plan years beginning on or after January 1, 2015, a FF–SHOP would have two methods by which to offer stand-alone dental plans (SADPs) to its employees and their dependents—either a single SADP or a choice of all SADPs available in an FF–SHOP after employee choice becomes available in the FF–SHOPS. We also noted in the preamble to the proposed 2015 Payment Notice that we were considering allowing qualified employers to offer all SADPs at a given dental AV level option, if the SADP AV level requirements were not eliminated in this rulemaking, and sought comments on this approach. Because we are now not finalizing the elimination of the SADP AV requirements, we are finalizing the policy to reflect this contemplated approach, giving employers the option of offering employees either a single qualified dental plan, or all dental plans at a single dental actuarial value level.

We proposed to re-designate § 155.705(b)(4)(ii) as (b)(4)(iii) and to add new paragraph (b)(4)(ii) to allow all SHOPS to establish one or more standard processes for premium calculation, payment, and collection

after the SHOP makes premium aggregation available. We also proposed provisions related to the processes FF-SHOPs would establish for premium calculation, payment, and collection under proposed § 155.705(b)(4)(ii). Consistent with § 155.720(b), which establishes that all SHOPs must establish a uniform enrollment timeline and process, including a specified list of activities such as establishment of effective dates of employee coverage, for all QHP issuers and qualified employers to follow, and consistent with § 155.720(d), which establishes that all SHOPs must follow the requirements set forth at § 155.705(b)(4), we proposed at § 155.705(b)(4)(ii)(A) that, after premium aggregation becomes available in the FF-SHOPs, employers in the FF-SHOPs would be required to make all premium payments—initial and subsequent—according to a timeline and process that HHS will establish through guidance. We anticipate that this payment timeline would require employers to make a full initial premium payment at least 2 days prior to the employer's desired coverage effectuation date, or perhaps longer, in order to provide a reasonable window of time for the relevant banks to process the payment transaction.

We solicited comments about whether this time frame would be reasonable for employers or issuers, about alternative time frames that might be more appropriate, and about the payment timeline and process for the FF-SHOPs generally, including the consideration that HHS should factor into the development of the payment timeline and process. In developing the premium payment timeline and process, HHS will consider its interest in operating and administering the FF-SHOPs efficiently, as well as issuers' interests in ensuring timely payment of premiums, and issuers' and employers' interests in establishing a fair and workable premium payment process. Section 155.735(c) and the Draft 2015 Letter to Issuers in the Federally-facilitated Marketplaces published on February 4, 2014 contain additional information about the payment timeline and process for payments subsequent to the initial premium payment. Finally, as discussed below in the preamble to § 156.285, we also proposed a conforming amendment to § 156.285(c)(7)(iii) to establish that an FF-SHOP issuer would be required to effectuate coverage unless it has received an enrollment cancellation from the FF-SHOP. We are finalizing these provisions as proposed.

At § 155.705(b)(4)(ii)(B), we proposed a methodology for prorating premiums in FF-SHOPs after premium aggregation

becomes available in those SHOPs in plan years beginning on or after January 1, 2015. We proposed that groups will be charged for the portion of the month for which the enrollee is enrolled. In the FF-SHOPs, premiums for coverage of less than 1 month will be prorated by multiplying the number of days of coverage in the partial month by the premium for 1 month divided by the number or days in the month. Issuers will charge and the FF-SHOP will collect for only the portion of coverage provided for the partial month. We also solicited comments about whether a standardized methodology regarding prorating premiums for partial month enrollment should be adopted across all individual market Exchanges. We are finalizing this provision as proposed, without adopting a standardized methodology across all individual market Exchanges.

We are finalizing in this rule amendments to § 155.705(b)(6) that were proposed in the "Program Integrity Rule" published in the June 19, 2013 *Federal Register* (78 FR 37032) on pages 37051–37052 and 37084. These amendments were proposed in conjunction with the issuer standards regarding the frequency of indexed rate updates that were codified at 45 CFR 156.80, and make explicit that this market-wide policy also applies to SHOPs. Because § 156.80 sets a market standard for mid-year rate updates of no sooner than quarterly, this provision is already in effect small-group-market-wide, including in all SHOPs. Specifically, we proposed to amend paragraph (b)(6)(i) to provide that SHOPs must require QHP issuers to make changes to rates at a uniform time that is no more frequently than quarterly. We also proposed at paragraph (b)(6)(ii) to provide issuers participating in the FF-SHOPs with the maximum amount of flexibility permitted under § 156.80 and the proposed amendment to § 155.705(b)(6)(i), standardize the effective dates for rate updates in the FF-SHOPs, and provide that FF-SHOP issuers must submit rates to HHS 60 days in advance of the effective date. Consistent with technical guidance provided to issuers through the Health Insurance Oversight System on April 8, 2013, issuers will be able to submit updated quarterly rates for the FF-SHOPs no sooner than for the third quarter of 2014, due to current system limitations.³⁹ Comments related to this provision were addressed when the

single risk pool provision was finalized on October 30, 2013 in the Program Integrity final rule. We are finalizing as proposed the amendment to § 155.705(b)(6)(i), but are finalizing the language proposed at § 155.705(b)(6)(ii) at § 155.705(b)(6)(i)(A) instead of at (b)(6)(ii), to make clear that we never intended for this proposal to supersede the language at current § 155.705(b)(6)(ii). We are also making a minor change in the language finalized at § 155.705(b)(6)(i)(A) to replace the word FF-SHOP with the term "Federally-facilitated SHOP."

We proposed at § 155.705(b)(11)(ii)(C) to provide FF-SHOPs, in plan years beginning on or after January 1, 2015, with the option of permitting a qualified employer to define a percentage contribution for full-time employees (as defined in § 155.20 and section 4980H(c)(4) of the Code) that differs from the percentage contribution the qualified employer defines for employees that are not full-time employees under that definition, to the extent permitted by applicable law. This proposal would also allow an FF-SHOP to permit an employer to define different percentage contributions toward premiums for dependent coverage for full-time and non-full-time employees. The FF-SHOPs would be allowed to define up to four different contribution levels: full-time employee-only, full-time employee dependent, non-full-time employee-only and non-full-time employee dependent. We are finalizing the substance of this provision as proposed, but we anticipate that the functionality to implement different contribution levels for full-time versus non-full-time employees and their dependents will not be available in the FF-SHOPs until sometime after January 1, 2015. We will provide adequate notice to issuers and employers before this functionality becomes available.

We also proposed a prohibition on composite premiums in the FF-SHOPs for plan years beginning on or after January 1, 2015, when a qualified employer elects to offer employee choice—that is, when the qualified employer offers its qualified employees all QHPs within the employer's selected level of coverage under § 155.705(b)(3)(iv)(A). To accomplish this objective, we proposed amendments to §§ 155.705(b)(11)(ii)(D) and 156.285(a)(4). While we are finalizing the proposed amendments to § 156.285(a)(4), as discussed below, we are *not* finalizing the proposed amendments to § 155.705(b)(11)(ii)(D), because those amendments would not carry out the intended policy, but would

³⁹ See Rates Changes for Small Group Market Plans and System Processing of Rates (April 8, 2013).

instead limit employers' ability to establish a fixed contribution to employee coverage, which was not an intended outcome of the proposals. We clarify that we have always interpreted § 155.705(b)(11)(ii)(D) to provide that, in an FF-SHOP, a State or employer may require that employer contributions be based on a calculated composite premium, which is, in effect, a composite premium calculated for the sole purpose of establishing a fixed dollar amount employer contribution to employee coverage, and is not a composite premium offered to the group plan by the issuer. When employer contributions are based on a calculated composite premium, this has the effect of equalizing employer contributions for a given plan such that the employer's contribution toward each enrollee's premium does not vary by the enrollee's age, but is instead a fixed dollar amount. In other words, the calculated composite premium described in § 155.705(b)(11)(ii)(D) is a separate concept from the composite premium addressed in § 147.102 and in our proposed amendments to § 156.285(a)(4). Accordingly, the fact that the FF-SHOPS will permit employers to use a calculated composite premium to determine employer contributions does not require issuers that are not otherwise required to offer composite premium rates to do so. Employers may also opt to set their contributions as a percentage of per-member premiums under a calculated composite premium approach or under a per-member premium approach. For these reasons, no modification to § 155.705(b)(11)(ii)(D) is necessary to carry out our intended policy on composite premiums in the FF-SHOPS. We are addressing comments on the proposed policy below, in the preamble section discussion related to final § 156.285(a)(4).

We also asked for comments on whether the calculation of user fees for the FF-SHOPS should be calculated based upon composite premiums or premiums calculated on per-member buildup. The methodology to calculate user fees for the FF-SHOPS will depend on how the group calculates a group's monthly premium. If a group uses a composite premium, the user fee will be based on this methodology. Similarly, if a group uses a per-member buildup approach, the user fee will reflect this methodology.

Comment: We received varying comments on our proposal to allow employers the ability to offer employees a choice of all SADPs available in an FF-SHOP. Several commenters supported our proposal of offering full

choice among all of the SADPs available in an FF-SHOP, and stated that the proposal would allow employees to choose a dental benefit that works best for their family and will lead to an increase in choice and competition in the small group market. Commenters supportive of the proposal also stated that allowing employers the flexibility to select whether to make available a single SADP or to make available all SADPs will encourage employer participation in the Exchanges. However, some commenters were opposed to allowing employee choice of SADPs, specifically requesting that this feature should be revisited in future plan years. Commenters opposed to the proposal stated that this additional choice will provide an additional layer of complexity for both the FF-SHOP Web site and administrative functionality. Some commenters said that it will also increase the risk of adverse selection, negatively affect competition, and increase prices for consumers.

Response: Allowing an employer flexibility to provide its employees and their dependents with a range of stand-alone dental coverage options advances our goal of increased choice and competition in FF-SHOPS. Allowing the option for qualified employers to offer all SADPs at a given dental AV level option (high and low) is similar to employee choice of QHPs in SHOPS, because under employee choice, an employer selects an actuarial value level (or "metal tier") of coverage and employees may select any QHP within that actuarial value level. Accordingly, as discussed in the preamble to the proposed rule, we considered whether to give employers the option of offering one SADP or all SADPs at one of the actuarial value levels set forth at § 156.150, but we did not ultimately propose regulation text reflecting that approach. Instead, we proposed providing employers with the option of offering all SADPs in an FF-SHOP, because another proposed amendment in this rulemaking would have done away with the actuarial value levels for SADPs set forth at § 156.150. Because that proposed amendment to § 156.150 will not be finalized, we can now amend our proposed regulation text to implement this alternative option. This modification would also address some commenters' concerns about too much risk when all SADPs are made available to employees in FF-SHOPS.

Comment: We received some comments stating that issuers should be allowed to price for the employer choice and employee choice for SADPs separately; that is, that issuers should be

permitted to charge a different premium to the employer based on whether the SADP is the only one offered or on whether the SADP is one among many plans being offered. Commenters stated that not allowing issuers to price separately for employer choice and employee choice will adversely affect competition and increase prices for consumers.

Response: 45 CFR 156.255(b) requires that, in order for a plan to be certified as a QHP, the plan's issuer "must charge the same premium rate without regard to whether the plan is offered through an Exchange . . ." This requirement applies to SADP QHPs under § 155.1065(a)(3). If a SADP QHP is priced differently based on whether it is being offered as the only SADP QHP or as one of several SADP QHPs under employee choice that would mean that the SADP QHP would have two different premium rates when offered through the Exchange. This necessarily means that one of these premium rates would be different from the premium rate of the same SADP QHP offered outside the Exchange, resulting in a different premium rate specifically with regard to whether the plan is offered through an Exchange. Therefore, the same SADP QHP cannot be offered at two different premium rates through the Exchange and continue to meet the certification requirement at § 156.255(b). Accordingly, we are not modifying the rule in response to this comment.

Comment: We received some suggestions that HHS require group minimum participation rates for SADPs.

Response: HHS interprets § 155.705(b)(10)(i) and (ii), the minimum participation requirement in the FF-SHOPS, to apply only to comprehensive medical QHPs offered through the FF-SHOPS. HHS did not intend for the FF-SHOP minimum participation requirements to apply to stand-alone dental coverage. Many of the adverse risk selection concerns that exist for medical plans do not apply to SADPs because SADPs, which are typically excepted benefits, are not subject to many of the market reforms applicable to other QHPs, and can therefore address adverse selection with more flexibility, through different premium rating and benefit design methodologies.

Comment: Some commenters supported our proposal to provide options for dental coverage in the FF-SHOPS. However, they believe that an additional option should be taken into consideration which includes allowing employers to offer all SADPs but at a given AV level.

Response: Because we are not removing the AV standards for SADPs as was initially proposed in this rulemaking, we are modifying our proposal to allow employers the option to offer either a single QDP, or all dental plans at a single dental actuarial value level of coverage.

Comment: Several commenters support allowing a SHOP to establish standard processes for premium calculation, premium payment, and premium collection. Further, several commenters believe it should be a requirement of all SHOP Exchanges both FF-SHOPs and State-based SHOPs. Some commenters also stated that the SHOP should involve issuers in the development of the process and that HHS should release a proposed version that is open for comment before it is finalized. Commenters further stated that HHS should build on existing industry models. One commenter also suggested ensuring that timelines are feasible such that employers and employees are not told that coverage will be effectuated on a given date, only to find that processes broke down and coverage was not effectuated due to insufficient processing time.

Response: HHS will provide a premium payment process that is efficient and workable and may, in the future, establish through rulemaking a standard process for all SHOP Exchanges. We will continue to work with issuers and other stakeholders to further refine the timeline and process for premium payments.

Comment: We received several comments on standardizing the prorating methodology in FF-SHOPs. Many commenters recognize the need to standardize pro-ration of premiums in an employee choice environment when the FF-SHOP is responsible for billing and payment remittance to multiple issuers for a single group and several commenters supported our proposed methodology of pro-rating premiums. One commenter specifically stated that this policy should only be used for initial enrollment due to birth or adoption and termination and not applied on an ongoing basis. However, some commenters opposed our proposal and suggested we adopt current industry practice of using a mid-month “wash” approach where we would charge for the entire month when the coverage effective date is before the 15th of the month and do not charge for an employee or dependent plan taking effect after the 15th of the month.

Response: FF-SHOPs will be responsible for collecting all premiums from participating qualified employers starting in 2015. It is impractical for the

FF-SHOPs to accommodate the existing variation in pro-rated premium methodologies that exist across States and issuers. We believe our approach is fair for all issuers as they will receive the amount owed them based on the number of days an enrollee is covered. We are finalizing the proposed provision with no changes such that groups would be charged for the portion of the month for which the subscriber is enrolled.

Comment: One commenter supported the approach to adopt a standardized methodology regarding prorating premiums for partial month enrollment across all individual market Exchanges and several commenters expressed concern or sought clarification about such an approach. One commenter believed that setting a standardized methodology was unnecessary because individual market Exchanges do not perform premium aggregation. Another commenter opposed the approach, noting that the commenter believed that it would create gaps in coverage, disruption in other standard enrollment and billing processes designed to operate on a monthly basis, and not align with the U.S. Department of the Treasury regulation concerning the treatment of partial month enrollment for the purpose of minimum essential coverage.

Response: In future rulemaking, we intend to propose that an individual market Exchange may establish one or more standard processes for premium calculation, and that the FFE will establish one consistent with the methodology finalized at § 155.705(b)(4)(ii)(B) of this final rule for the FF-SHOPs. By taking this approach, we would eliminate issues where consumers who transition to Medicaid are charged premiums for days on which they are enrolled in Medicaid, which is effective no earlier than the date of application. It would also be consistent with proposed 26 CFR 1.36B-3(d)(2)⁴⁰ which specifies that when coverage is terminated before the last day of the month, and the issuer reduces or refunds a portion of the monthly premium, the premium tax credit is adjusted using the same methodology described in this final rule for the FF-SHOPs.

Comment: We received several comments on our proposal to give the FF-SHOPs the authority to permit qualified employers to contribute differently to the premiums of full-time

and part-time employees. Some commenters supported our proposal though suggested we let employers determine how many hours constitute a full-time employee. Some commenters opposed our proposal because it would be too complicated to implement. They suggested that the FF-SHOP ask an employer to calculate the percentage or dollar amount of contributions instead of defining a standard contribution level. Other commenters suggested we delay implementing this SHOP feature until after the online portal and premium aggregation services are fully functional. One commenter specifically recommends HHS work with issuers and the premium aggregator to ensure that the FF-SHOP is fully capable of supporting this function.

Response: To ensure we have fully tested this contribution methodology, while we are finalizing the proposed provision giving the FF-SHOPs the option to permit qualified employers to contribute differently in the premiums of full-time and part-time employees, we will not be offering employers this option until sometime after January 1, 2015. We will provide issuers and employers adequate notice before this option becomes available. We further note that it would not be consistent with the definition of a “full-time employee” at 45 CFR 155.20 for the FF-SHOPs to permit employers to determine how many hours constitute a full-time employee.

Comment: Some commenters expressed their preference that FF-SHOP user fees should be based on per-member buildup—even when employers offering a single plan are charged composite premiums pursuant to § 147.102.

Response: The FFE user fee is calculated by multiplying the user fee rate by the premium charged by the issuer for each policy under the plan where enrollment is through a FFE. For issuers participating in an FF-SHOP, the user fee rate is multiplied by the premium calculated under the methodology used to calculate a group’s monthly premium. For example, if a group is using a composite premium, the user fee will be based on the composite premium. If a group uses a per-member buildup approach, the user fee will reflect this methodology.

6. Eligibility Determination Process for SHOP

We proposed to amend paragraph § 155.715(c)(4) to replace a reference to sections 1411(b)(2) and (c) of the Affordable Care Act with a reference to Subpart D of 45 CFR part 155, and to add a reference to eligibility

⁴⁰ Minimum Value of Eligible Employer-Sponsored Plans and Other Rules Regarding the Health Insurance Premium Tax Credit Proposed Rule published in the May 3, 2013 *Federal Register* (78 FR 25915).

verifications as well as to eligibility determinations. The proposed changes would make explicit our interpretation of our current regulations, under which a SHOP is prohibited from performing any individual market eligibility determinations or verifications as described in Subpart D, which, for example, includes making eligibility determinations for advance payments of the premium tax credit and cost sharing reductions in the individual market Exchange. We are finalizing this provision as proposed.

We also proposed amending § 155.715(d) to address when SHOP eligibility adjustment periods would be triggered. We proposed providing eligibility adjustment periods for both employers and employees only when there is an inconsistency between information provided by an applicant and information collected through optional verification methods under § 155.715(c)(2). The proposal would eliminate the potential for unnecessary delay created under the current regulation, while providing SHOP applicants with an opportunity to address inconsistencies between a submitted application and trusted third-party data sources that a SHOP might utilize to verify eligibility under the optional verification process established in § 155.715(c)(2). The applicability of SHOP eligibility adjustment periods would be limited to circumstances where such a discrepancy occurs, and the applicant would be provided an opportunity to submit documentation proving the information submitted on the application is correct without having to initiate a formal eligibility appeal. We also proposed to amend paragraphs (d)(1) and (d)(2) to provide for eligibility adjustment periods when information submitted on an application is inconsistent with information collected through an optional verification process under § 155.715(c)(2).

We are finalizing the provisions as proposed.

Comment: One commenter asked for clarity on how the inconsistency process would work to ensure that eligibility and payment systems are in sync. Issuers and aggregators will need to know immediately when an inconsistency results in a group no longer being eligible for coverage so that they will not continue to provide coverage and so they don't continue to collect premiums.

Response: Enrollment for a group might not begin until any discrepancies being reviewed through the eligibility adjustment process for the employer are resolved, but if it does, there is no

reason why the issuer must terminate enrollment for the group if the employer is not determined eligible. Under guaranteed availability, the issuer generally must make the plan available both inside and outside the SHOP. If the employer is determined ineligible, an issuer may generally continue to offer coverage to a group, and the SHOP will work with the issuer to resolve any concerns related to premium payments that the employer had made to the SHOP.

7. Application Standards for SHOP

We proposed to amend § 155.730 to make explicit our interpretation of our current regulations, under which SHOPS are prohibited from collecting any information on SHOP applications other than what is required to make SHOP eligibility determinations or effectuate enrollment through the SHOP. We proposed to re-designate paragraph § 155.730(g) as paragraph (g)(1) and add new paragraph (g)(2) to provide that a SHOP is not permitted to collect information on the single employer or single employee application that is not necessary to determine SHOP eligibility or effectuate enrollment through the SHOP. We did not receive any comments on this proposal and we are finalizing the provisions as proposed.

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

1. Provisions Related to Cost Sharing

In the proposed rule, we proposed several provisions and parameters for the 2015 benefit year related to cost sharing, including a number of provisions relating to indexing of premium growth. For the reasons described in the proposed rule and considering the comments received, we are generally finalizing these provisions as proposed, with a few modifications. However, we note that with respect to our methodology for indexing premium growth, we will continue to analyze additional methodologies in upcoming years, especially as additional data become available, and may modify these provisions if appropriate.

a. Premium Adjustment Percentage

Section 1302(c)(4) of the Affordable Care Act directs the Secretary to determine an annual premium adjustment percentage, which is used to set the rate of increase for four parameters detailed in the Affordable Care Act: the maximum annual limitation on cost sharing (defined at § 156.130(a)), the maximum annual

limitation on deductibles for plans in the small group market (defined at § 156.130(b)), and the assessable payment amounts under section 4980H(a) and (b) of the Code (finalized at 26 CFR 54.4980H in the “Shared Responsibility for Employers Regarding Health Coverage,” published in the February 12, 2014 **Federal Register** (79 FR 8544)). Section 156.130(e) of 45 CFR provides that the premium adjustment percentage is the percentage (if any) by which the average per capita premium for health insurance coverage for the preceding calendar year exceeds such average per capita premium for health insurance for 2013, and that this percentage will be published annually in the HHS notice of benefit and payment parameters.

We proposed to establish a methodology for estimating average per capita premium for purposes of calculating the premium adjustment percentage. In selecting this methodology, we considered the following four criteria:

(1) *Comprehensiveness*—the premium adjustment percentage should be calculated based on the average per capita premium for health insurance coverage for the entire market, including the individual and group markets, and both fully insured and self-insured group health plans;

(2) *Availability*—the data underlying the calculation should be available by the summer of the year that is prior to the calendar year so that the premium adjustment percentage can be published in the annual HHS notice of benefit and payment parameters in time for issuers to develop their plan designs;

(3) *Transparency*—the methodology for estimating the average premium should be easily understandable and predictable; and

(4) *Accuracy*—the methodology should have a record of accurately estimating average premiums.

Based on these criteria, we proposed that the premium adjustment percentage be calculated based on the projections of average per enrollee private health insurance premiums from the National Health Expenditure Accounts (NHEA), which is estimated by the CMS Office of the Actuary. To calculate the premium adjustment percentage for the 2015 calendar year, we proposed to use the most recent NHEA projections of average per enrollee private health insurance premiums for 2013 and 2014 (\$5,128 and \$5,435, respectively).⁴¹

⁴¹ See <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/>

Under that methodology, the premium adjustment percentage for 2015 would be (5,435–5,128)/5,128, or 6.0 percent.

We also considered several other sources of premium data, and sought comment on additional sources of data we should consider, and our choice of methodology. Several commenters suggested that, at least in the initial years, NHEA projections of per enrollee private health insurance premiums may not be the most appropriate source of data for calculating premium growth because it is influenced by changes in benefit design and market composition. One commenter, who supported the use of NHEA data generally, suggested that premium growth from 2013 to 2014 would be unreliable because those data will reflect issuer uncertainty about the costs of covering a previously uninsured population, and that true premium growth, reflecting any rebates required to be paid after the end of the year, could be lower. Another commenter, who supported using different NHEA data, suggested using an index tied to projected medical costs.

In response to these comments, we will calculate the premium adjustment percentage using different NHEA data—the NHEA projections of per enrollee employer-sponsored insurance (ESI) premiums. This data overlaps very significantly with the private health insurance data—according to the CMS Office of the Actuary, approximately 88 percent of enrollees in 2014 will be covered by employer-sponsored insurance. However, because it will exclude premiums from the individual market, which is likely to be most affected by the significant changes in benefit design and market composition in the early years of implementation of market reforms and is most likely to be subject to risk premium pricing (which, as the commenter noted, may be paid back to consumers after the end of the year in the form of rebates), we believe it will provide a more appropriate measure of average per capita premiums for health insurance coverage for the initial years. And because the data are also from the well-known NHEA, we believe it continues to meet our selection criteria.

Using the ESI data and our proposed methodology, the premium adjustment percentage for 2015 is the percentage (if any) by which the most recent NHEA projection of per enrollee ESI premiums for 2014 (\$5,664) exceeds the most recent NHEA projection of per enrollee

ESI premiums for 2013 (\$5,435), or 4.213431463 percent.⁴² We note that as updated 2013 NHEA data become available, we may update the 2013 estimate for purposes of calculating the premium adjustment percentage for years after 2015.

We further note that after the initial years of implementation of market reforms, once the premium trend is more stable, we may propose to change our methodology. For example we may consider changing our methodology to reflect the broader NHEA per enrollee private health insurance premium data. Additionally, as new data on health insurance premiums become available through the Exchanges and other sources, we intend to review the methodology for calculating the premium adjustment percentage. We also intend to establish consistent methodologies for indexing Affordable Care Act parameters.

In summary, we are finalizing the premium adjustment percentage methodology as proposed, using NHEA projections of per enrollee ESI premiums in place of private health insurance premiums. This premium adjustment percentage will be used to increase the maximum annual limitation on cost sharing, the maximum annual limitation on deductibles for plans in the small group market, and the assessable payment amounts under section 4980H(a) and (b) of the Code. In the preamble to the proposed rule, when calculating the proposed annual limitation on cost sharing for 2015, we rounded to the multiple of \$50 that is higher than the number calculated by the formula. However, we have since learned that the convention for similar language in related tax policies is to round to the multiple of \$50 that is lower than the number calculated by the formula. We strive to align policies wherever possible. As such, in future rulemaking that will be effective prior to the start of the application period for qualified health plans for the 2015 benefit year, we are considering aligning the rounding rules, and rounding to the lower multiple of \$50.

Maximum Annual Limitation on Cost Sharing for Calendar Year 2015. Under § 156.130(a)(2), for the 2015 calendar year, cost sharing for self-only coverage may not exceed the dollar limit for

calendar year 2014 increased by an amount equal to the product of that amount and the premium adjustment percentage for 2015. For other than self-only coverage, the limit is twice the dollar limit for self-only coverage. Using the premium adjustment percentage of 4.213431463 percent for 2015 we established above, and the 2014 maximum annual limitation on cost sharing of \$6,350 for self-only coverage, which was published by the IRS on May 2, 2013,⁴³ the 2015 maximum annual limitation on cost sharing would be \$6,600 for self-only coverage and \$13,200 for other than self-only coverage, if we were to interpret § 156.130(d) and the statute to round the self-only limitation *down* to the next lower multiple of 50.

Maximum Annual Limitation on Deductibles for Plans in the Small Group Market for Calendar Year 2015.

Under § 156.130(b)(2), for the 2015 calendar year, the annual deductible for a health plan in the small group market may not exceed, for self-only coverage, the maximum annual limitation on deductibles for calendar year 2014 increased by an amount equal to the product of that amount and the premium adjustment percentage for 2015, and for other than self-only coverage, the limit is twice the dollar limit for self-only coverage. Using the premium adjustment percentage for 2015 of 4.213431463 percent we established above and the 2014 maximum annual limitation on deductibles of \$2,000 for self-only coverage, as specified in § 156.130(b)(1)(i), the 2015 maximum annual limitation on deductibles would be \$2,050 for self-only coverage and \$4,100 for other than self-only coverage, if we were to interpret § 156.130(d) and the statute to round the self-only limitation *down* to the next lower multiple of 50. We note that pursuant to 45 CFR 156.130(b)(3), a health plan's deductible may exceed the 2015 maximum annual limitation on deductibles described above in instances where the plan may not reasonably reach the AV of a given level of coverage without exceeding the annual deductible limit.

Comment: We received three comments in support of our proposal to use data from the National Health Expenditure Accounts. However, we also received several comments expressing concern with the increase in the cost-sharing limits resulting from the proposed premium adjustment percentage methodology, and the

ProjectionsMethodology2012.pdf and Table 17 in <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Proj2012.pdf> for additional information.

⁴² See <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ProjectionsMethodology2012.pdf> and Table 17 in <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Proj2012.pdf> for additional information.

⁴³ See <http://www.irs.gov/pub/irs-drop/rp-13-25.pdf>.

potential impact on affordability and consumer access to care. Commenters noted that because the maximum annual limitation on cost sharing is set based on the premium growth rate for the previous years, consumers could see increased premiums in one year and then increased out-of-pocket costs in the following year (as well as any additional premium increases)—in effect, experiencing impacts twice. Another commenter noted that the proposal would result in the divergence of the maximum annual limitation on cost sharing from the cost-sharing limit set by the IRS for high deductible health plans, which is adjusted based on the Consumer Price Index.⁴⁴ Some commenters stated that the premium adjustment percentage should not be applied until at least 2016, after the Federal government has evaluated consumer experience under the 2014 parameters. Other commenters argued that the premium adjustment percentage should not be affected by the changes in benefit design and market composition that occur between 2013 and 2014. Instead, the commenters argue that the premium adjustment percentage should be based only on the change in the cost of medical services, or on the Consumer Price Index.

Response: In response to comments, as discussed above, we are finalizing our proposed methodology for calculating the premium adjustment percentage, using NHEA projections of per enrollee ESI premiums in place of private health insurance premiums. We believe that NHEA per enrollee ESI premium data will appropriately capture the underlying drivers of premium growth, and reflect the average per capita premium for the majority of health insurance coverage in the United States. In addition, ESI data tends to be more stable and is less influenced by one-time changes in benefit design and market composition.

We do not believe it would be appropriate to use the Consumer Price Index as the basis for estimating premium growth. The Consumer Price Index captures only price changes for a fixed basket of a much broader set of goods, and thus does not reflect the drivers of health insurance premiums. Specifically, the Consumer Price Index would exclude non-price factors that influence medical costs, and thus premiums, such as changes in the utilization or intensity of medical care. Because of this, the Consumer Price Index (both for all items and for medical care) has historically increased at a slower rate than premiums. We are

concerned that consistently constraining the premium adjustment percentage and the cost-sharing limits to a lower rate of growth that is not reflective of the drivers of health insurance premiums may prevent issuers from adequately adjusting plan designs to offset costs, which could result in higher premiums. We clarify that the maximum annual limitation on cost sharing established at § 156.130(a)(2) does not supersede the cost-sharing limit for high deductible health plans established by the IRS under § 223(c)(2)(A)(ii) of the Code.

Comment: One commenter recommended that the premium adjustment percentage be rounded to the nearest tenth of a percentage point, rather than the proposed “nearest decimal point.”

Response: To better align with other tax- and benefit-related indexation provisions, we specify that the premium adjustment percentage will be rounded to ten significant digits. The percentage for calendar year 2015 is 4.213431463 percent.

Comment: We received two comments reporting wide variation in the application across States of the maximum annual limitation on deductibles for plans in the small group market. Commenters acknowledged the need for flexibility in order to meet actuarial value standards, but requested that HHS monitor the application of this policy.

Response: We recognize the need to balance between the required deductible limit and the ability of issuers to offer a variety of cost sharing approaches within the plan designs available to employers. We intend to work with States to assess the need for additional guidance in this area, as the States are the primary enforcers of this limit.

b. Reduced Maximum Annual Limitation on Cost Sharing

Sections 1402(a) through (c) of the Affordable Care Act direct issuers to reduce cost sharing for EHBs for eligible individuals enrolled in a silver level QHP. In the 2014 Payment Notice, we established standards related to the provision of these cost-sharing reductions. Specifically, in 45 CFR part 156 subpart E, we specified that QHP issuers must provide cost-sharing reductions by developing plan variations, which are separate cost-sharing structures for each eligibility category that change how the cost sharing required under the QHP is to be shared between the enrollee and the Federal government. At § 156.420(a), we detailed the structure of these plan variations and specified that QHP issuers must ensure that each silver plan

variation has an annual limitation on cost sharing no greater than the applicable reduced maximum annual limitation on cost sharing specified in the annual HHS notice of benefit and payment parameters. Although the amount of the reduction in the maximum annual limitation on cost sharing is specified in section 1402(c)(1)(A) of the Affordable Care Act, section 1402(c)(1)(B)(ii) of the statute states that the Secretary may adjust the cost-sharing limits to ensure that the resulting limits do not cause the AVs of the health plans to exceed the levels specified in 1402(c)(1)(B)(i) (that is, 73 percent, 87 percent or 94 percent, depending on the income of the enrollee(s)). Accordingly, in the 2014 Payment Notice, we established a process for determining the appropriate reductions in the maximum annual limitation on cost sharing. First, we identified the maximum annual limitation on cost sharing applicable to all plans that will offer the EHB package. Second, we analyzed the effect on AV of the reductions in the maximum annual limitation on cost sharing described in the statute. Last, we adjusted the reductions in the maximum annual limitation on cost sharing, if necessary, to ensure that the AV of a silver plan variation will not exceed the AV specified in the statute. Below, we describe our analysis for the 2015 benefit year and our results, which we finalize as proposed.

Reduced Maximum Annual Limitation on Cost Sharing for Benefit Year 2015. We developed three model silver level QHPs and analyzed the impact on their AVs of the reductions described in the Affordable Care Act to a maximum annual limitation on cost sharing for self-only coverage (\$6,600). The model plan designs are based on data collected for QHP certification for 2014 to ensure that they represent a range of plan designs that we expect issuers to offer at the silver level of coverage through an Exchange. For 2015, the model silver level QHPs include a PPO with a typical cost-sharing structure (\$6,600 annual limitation on cost sharing, \$1,700 deductible, and 20 percent in-network coinsurance rate), a PPO with a lower annual limitation on cost sharing (\$4,500 annual limitation on cost sharing, \$2,000 deductible, and 20 percent in-network coinsurance rate), and an HMO (\$6,600 annual limitation on cost sharing, \$2,100 deductible, 20 percent in-network coinsurance rate, and the following services with copays that are not subject to the deductible or coinsurance: \$500 inpatient stay per

⁴⁴ See section 223(g) of the Code.

day, \$350 emergency department visit, \$25 primary care office visit, and \$50 specialist office visit). All three model QHPs meet the AV requirements for silver health plans.

We then entered these model plans into the AV Calculator developed by HHS, and observed how the reductions in the maximum annual limitation on cost sharing specified in the Affordable Care Act affected the AVs of the plans. We found that the reduction in the maximum annual limitation on cost sharing specified in the Affordable Care Act for enrollees with household incomes between 100 and 150 percent of the FPL (2/3 reduction in the maximum annual limitation on cost sharing), and 150 and 200 percent of the

FPL (2/3 reduction), does not cause the AV of any of the model QHPs to exceed the statutorily specified AV level (94 and 87 percent, respectively). In contrast, the reduction in the maximum annual limitation on cost sharing specified in the Affordable Care Act for enrollees with a household income between 200 and 250 percent of FPL (1/2 reduction), does cause the AVs of two of the model QHPs to exceed the specified AV level of 73 percent. As a result, we are finalizing our proposal that the maximum annual limitation on cost sharing for enrollees in the 2015 benefit year with a household income between 200 and 250 percent of FPL be reduced by approximately 1/5, rather than 1/2, as shown in Table 4.⁴⁵ We are

further finalizing as proposed a requirement that the maximum annual limitation on cost sharing for enrollees with household incomes between 100 and 200 percent of the FPL be reduced by approximately 2/3, in alignment with the statute. As discussed in the proposed rule, these reductions in the maximum annual limitation on cost sharing align with the 2014 reductions and should adequately account for unique plan designs that may not be captured by our three model QHPs. Applying the same parameters as those specified for 2014 will reduce the administrative burden for issuers related to designing new plans, and provide greater continuity for enrollees.

TABLE 4—REDUCTIONS IN MAXIMUM ANNUAL LIMITATION ON COST SHARING FOR 2015

Eligibility category	Reduced maximum annual limitation on cost sharing for self-only coverage for 2015	Reduced maximum annual limitation on cost sharing for other than self-only coverage for 2015
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(i) (that is, 100–150 percent of FPL)	\$2,250	\$4,500
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(ii) (that is, 150–200 percent of FPL)	2,250	4,500
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(iii) (that is, 200–250 percent of FPL)	5,200	10,400

Comment: We received two comments supporting the proposed reductions in the maximum annual limitation on cost sharing for 2015, with the caveat that HHS should monitor provider payments to ensure that cost-sharing reductions do not come at the expense of provider reimbursement. Another commenter stated that HHS should reduce the maximum annual limitation on cost sharing for enrollees with a household income between 200 and 250 percent of the FPL to be more in line with the reduction specified in section 1402(c)(1)(A)(ii) of the Affordable Care Act.

Response: As discussed in the proposed rule, selecting a reduction for the maximum annual limitation on cost sharing that is less than the reduction specified in the statute will not reduce the benefit afforded to enrollees in aggregate because QHP issuers are required to further reduce their annual limitation on cost sharing, or reduce other types of cost sharing, to meet the specified AV for the plan variation. Therefore, we are finalizing the reductions to the maximum annual limitation on cost sharing for 2015 as proposed. We do not address policy

related to provider payments in this rule.

Comment: We also received a comment stating that, in addition to reducing the maximum annual limitation on cost sharing, HHS should require issuers to exempt prescription drugs from any deductibles required under a silver plan variation.

Response: As discussed in the 2014 Payment Notice, we believe the current cost-sharing reduction standards strike the appropriate balance between protecting consumers and preserving QHP issuer flexibility. As a result, we do not intend to propose any additional cost-sharing reduction plan design requirements at this time.

c. Design of Cost-Sharing Reduction Plan Variations

Following our implementation of Exchange operations for 2014, we learned that a number of issuers designed QHPs with cost-sharing parameters that apply to both EHB and benefits that are not EHB. For example, one issuer sought to establish a common deductible across all benefits. For the zero cost sharing plan variation of this QHP, this would result in a substantial

deductible being applied entirely to benefits that are not EHB. As a result, we proposed to remove the standards in § 156.420(c) and (d) that require that a QHP and each of its plan variations have the same out-of-pocket spending for benefits other than EHB. Instead, we proposed that the standard in § 156.420(e)—that cost sharing for EHB from a provider (including a provider outside the plan’s network) required of an enrollee in a silver plan variation may not exceed the corresponding cost sharing required in the standard silver plan or any other silver plan variation of that plan with a lower AV—would also apply to out-of-pocket spending required of enrollees in silver plan variations for a benefit that is not an EHB. Similarly, we proposed in § 156.420(d) that the out-of-pocket spending required of enrollees in the zero cost sharing plan variation of a QHP for a benefit that is not an EHB from a provider (including a provider outside the plan’s network) may not exceed the corresponding out-of-pocket spending required in the limited cost sharing plan variation of the QHP, which in turn may not exceed the corresponding out-of-pocket spending

⁴⁵ We note that although the revised interpretation of the rounding standard for the maximum annual limitation on cost sharing is not yet finalized, we would not expect a different

interpretation of the rounding standard to result in a significant change in our analysis of the reductions in the maximum annual limitation on cost sharing. As a result, we are finalizing these

reductions in the maximum annual limitation on cost sharing for 2015 in this rule.

required in the QHP with no cost-sharing reductions.

We are finalizing the provisions as proposed, with one modification. To ensure continuity across the plan variations, we clarify in § 156.420(d) that the out-of-pocket spending required of enrollees in the zero cost sharing plan variation of a QHP for a benefit that is not an EHB from a provider (including a provider outside the plan's network) may not exceed the corresponding out-of-pocket spending required in the limited cost sharing plan variation of the QHP and the corresponding out-of-pocket spending required in the silver plan variation of the QHP for individuals eligible for cost-sharing reductions under § 155.305(g)(2)(i), in the case of a silver QHP. This modification responds to commenters' concerns that issuers may use this flexibility to selectively attract certain enrollees, and is consistent with our general policy that an enrollee in a cost-sharing reduction plan variation be provided with plan features, including out-of-pocket spending, provider network, and benefits, that are at least as good as those offered under the standard plan or any other plan variation designed to be less generous.

We also clarify that in the case of an issuer participating in an Exchange that only requires issuers to submit one zero cost sharing plan variation with the lowest premium for a set of standard plans, as described in the 2014 Payment Notice at 78 FR 15494, the issuer must ensure that the out-of-pocket spending requirement for each non-EHB benefit of the submitted zero cost sharing plan variation is less than or equal to the lowest out-of-pocket spending requirement for the same benefit of a silver plan variation for individuals eligible for cost-sharing reductions under § 155.305(g)(2)(i), if the silver plan is included in the set of standard plans.

Under these provisions, each cost-sharing reduction plan variation will continue to provide the most cost savings for which an enrollee is eligible; however, QHP issuers will be able to—though are not required to—reduce out-of-pocket spending for benefits that are not EHB for enrollees in plan variations in order to offer simpler cost-sharing designs that are consistent across EHB and benefits that are not EHB. We note, however, that in accordance with section 1402(d)(4) of the Affordable Care Act, any reductions in out-of-pocket spending for benefits that are not EHB will not be reimbursed by the Federal government because payments for cost-sharing reductions only apply to EHB.

Comment: One commenter strongly supported the proposal, stating that it will allow issuers the flexibility to develop plans that best meet the needs of the low-income population. Conversely, another commenter stated that issuers may use this flexibility to design plans that attract healthier beneficiaries and may offset any costs through premium increases. Several logistical concerns were also raised by commenters about how HHS would ensure that Federal reimbursement is not provided for these reductions, and how issuers would report and implement these reductions.

Response: As described in § 156.430(c), issuers may only submit information on reductions in cost sharing for EHB, and HHS will not provide reimbursement for reductions in out-of-pocket spending for benefits other than EHB. In addition, our changes to § 156.420(d) and (e) provide additional flexibility only with respect to different plan variations, and those provisions do not permit issuers to selectively lower cost sharing in a manner that disadvantages low-income consumers. As a result, we do not believe issuers will have any additional opportunity to attract healthy enrollees. Therefore, we are finalizing this provision as proposed, with the minor modification discussed above. We will provide additional guidance in the future for issuers on how to report out-of-pocket spending for benefits that are not EHB for purposes of QHP certification.

d. Advance Payments of Cost-Sharing Reductions

Section 1402(c)(3) of the Affordable Care Act directs a QHP issuer to notify the Secretary of cost-sharing reductions made under the statute, and directs the Secretary to make periodic and timely payments to the QHP issuer equal to the value of those reductions. Section 1412(c)(3) of the Affordable Care Act permits advance payments of cost-sharing reduction amounts to QHP issuers based upon amounts specified by the Secretary. Under these authorities, we established a payment approach in the 2014 Payment Notice under which monthly advance payments made to issuers to cover projected cost-sharing reduction amounts are reconciled after the end of the benefit year to the actual cost-sharing reduction amounts.

To implement this approach, we specified in § 156.430(a) that a QHP issuer must provide to the Exchange an estimate of the dollar value of the cost-sharing reductions to be provided over the benefit year, calculated in

accordance with the methodology specified by HHS in the annual HHS notice of benefit and payment parameters. We further specified in the 2014 Payment Notice that QHP issuers did not need to submit an estimate of the dollar value of the cost-sharing reductions for the 2014 benefit year, except in the case of a limited cost sharing plan variation.⁴⁶ Instead, the Exchange sent the data that issuers submitted under §§ 156.420 and 156.470, including the AV of the standard plan and plan variation, and the EHB portion of expected allowed claims costs, to HHS for the calculation of the cost-sharing reduction advance payment rates. HHS then approved the rates and sent them back to the Exchange so that the cost-sharing reduction advance payment amounts could be reported as part of the 834 enrollment transactions, pursuant to § 156.340(a). HHS then provided advance payments to QHP issuers.

Based on our experience implementing this process for the 2014 benefit year, we proposed certain modifications to §§ 155.1030, 156.430, and 156.470. We believe these modifications will simplify the process and improve the accuracy of the calculations. Specifically, we proposed to remove the requirement detailed in § 156.430(a) that issuers develop estimates of the dollar value of the cost-sharing reductions to be provided, and instead proposed to modify § 155.1030(b)(3) to provide that an Exchange be required to use the methodology specified in the annual HHS notice of benefit and payment parameters to calculate advance payment amounts for cost-sharing reductions. We also proposed to modify § 155.1030(b)(4) so that the Exchange would no longer be required to submit issuers' advance payment estimates to HHS for approval prior to the start of the benefit year. The Exchange would simply calculate the advance payment amounts and transmit the amounts to HHS via the 834 enrollment transaction, pursuant to § 156.340(a). We then proposed in § 156.430(b)(1) that HHS provide periodic advance payments to QHP issuers based on the amounts transmitted by the Exchange. Lastly, we proposed conforming modifications to §§ 155.1030(b)(1) and 156.470(a), to remove the obligation for QHP issuers to submit, and Exchanges to review, the EHB allocation of the expected allowed

⁴⁶ If an issuer sought advance payments for the cost-sharing reductions provided under the limited cost sharing plan variation of a health plan it offers, we specified in § 156.430(a)(2) that the issuer was required to submit an estimate of the dollar value of the cost-sharing reductions to be provided.

claims costs for the plans, because this data would not be used in the proposed 2015 methodology for calculating cost-sharing reduction advance payments.

Methodology for Calculating Advance Payment Amounts for Cost-Sharing Reductions for 2015. For the 2015 benefit year, we proposed that the Exchanges use a methodology for calculating the advance payment amounts that would not require QHP issuers to submit an estimate of the value of cost-sharing reductions to be provided or the EHB portion of expected allowed claims costs, as previously required under § 156.470(a), and that

would not require Exchanges to transfer data on advance payment amounts to HHS prior to the start of the benefit year. Specifically, we proposed that Exchanges calculate the monthly advance payment amount for a specific policy as the product of (x) the total monthly premium for the specific policy, and (y) a cost-sharing reduction plan variation multiplier. The cost-sharing reduction plan variation multiplier would convert the monthly premium into the appropriate monthly advance payment amount, based on the following formula:

$$\text{Cost-Sharing Reduction Plan Variation Multiplier} = \text{Factor to Remove Administrative Costs} * \text{Factor to Convert to Allowed Claims Cost} * \text{Induced Utilization Factor} * (\text{Plan Variation AV} - \text{Standard Plan AV})$$

Where,
 Factor to Remove Administrative Costs = 0.8 for all plan variations, based on the individual market MLR of 80 percent;
 Factor to Convert to Allowed Claims Costs = the quotient of 1 and the AV for the standard plan, not accounting for any *de minimis* variation;
 Induced Utilization Factor = one of the following factors, depending on the plan variation:

TABLE 5—INDUCED UTILIZATION FACTORS FOR PLAN VARIATIONS

Cost-sharing reduction plan variation	Induced utilization factor
73 percent AV silver plan variation	1.00
87 percent AV silver plan variation	1.12
94 percent AV silver plan variation	1.12
Limited cost sharing plan variation of bronze QHP	1.15
Limited cost sharing plan variation of silver QHP	1.12
Limited cost sharing plan variation of gold QHP	1.07
Limited cost sharing plan variation of platinum QHP	1.00
Zero cost sharing plan variation of bronze QHP	1.15
Zero cost sharing plan variation of silver QHP	1.12
Zero cost sharing plan variation of gold QHP	1.07
Zero cost sharing plan variation of platinum QHP	1.00

Standard Plan AV = the AV specified for each level of coverage at § 156.140(b), not accounting for *de minimis* variation (that is, 60, 70, 80, or 90 percent for a

bronze, silver, gold, or platinum QHP, accordingly); and
 Plan Variation AV = one of the following actuarial values, depending on the plan

variation, not accounting for *de minimis* variation:

TABLE 6—ACTUARIAL VALUES FOR PLAN VARIATIONS

Cost-sharing reduction plan variation	Plan variation AV (percent)
73 percent AV silver plan variation	73
87 percent AV silver plan variation	87
94 percent AV silver plan variation	94
Limited cost sharing plan variation of bronze QHP	87
Limited cost sharing plan variation of silver QHP	87
Limited cost sharing plan variation of gold QHP	94
Limited cost sharing plan variation of platinum QHP	94
Zero cost sharing plan variation of bronze QHP	100
Zero cost sharing plan variation of silver QHP	100
Zero cost sharing plan variation of gold QHP	100
Zero cost sharing plan variation of platinum QHP	100

The proposed induced utilization factors would be consistent with the corresponding factors established in the 2014 Payment Notice. For the limited cost sharing plan variations, we derived the induced utilization factors based on the actuarial values proposed above, and the same assumptions used to develop the induced utilization factors for the other plan variations. We proposed to update the induced utilization factors for all plan variations

in future rulemaking as more data becomes available, and stated that at that time we would consider applying them to the risk adjustment methodology that HHS will use when operating risk adjustment on behalf of a State.

The proposed methodology also utilizes the actuarial values of the standard plans and plan variations, not accounting for *de minimis* variation. Although this may slightly reduce the

accuracy of the calculations, we believe it would have little overall impact, and would reduce the administrative burden on Exchanges because Exchanges would not need to develop specific multipliers for each QHP and associated plan variations. However, this approach required us to estimate an actuarial value for each type of limited cost sharing plan variation. We estimated that on average, the AV of the limited cost sharing plan variations of bronze

and silver QHPs would be 87 percent, and the AV of the limited cost sharing plan variations of gold and platinum QHPs would be 94 percent. We developed these estimates based on the data submitted by QHP issuers seeking advance payments for limited cost sharing plan variations that will be offered in benefit year 2014.

We believe the proposed methodology will improve the accuracy of the advance payments because it is based on the total premium for each policy, which in accordance with the rating rules described in §§ 147.102 and 156.80, is based on expected allowed claims costs, adjusted for the plan design and provider network, the number of individuals covered by the policy, rating area, age, and tobacco use. We are finalizing the modifications to §§ 155.1030, 156.430, and 156.470 as proposed, as well as the methodology for calculating advance payment amounts for cost-sharing reductions for 2015.

Comment: We received one comment in support of the proposed changes to the process for calculating advance payments, stating that the changes would reduce the overall administrative burden and streamline reporting requirements for issuers. We also received some comments stating that it is too early to make changes to the process, which commenters stated would require issuers to alter their systems and develop new processes for validating the advance payment amounts. One commenter noted that under the proposed process, each Exchange will be responsible for calculating the advance payment amounts as opposed to one Federal agency, which could create the potential for more errors. The commenter was also concerned with the proposal to base the advance payment amounts on the premium for the policy, as premium data could be inaccurate and subject to a complex reconciliation process. The commenters also stated that the issuer should be allowed to validate the advance payment amounts before they are finalized.

Response: We continue to believe that the modifications to the advance payment calculation process will reduce the administrative burden for all parties because issuers will be required to submit less data, and Exchanges will no longer be required to submit data to HHS prior to the start of the benefit year for the calculation and approval of the advance payment amounts. That approval process will no longer be necessary because the advance payments will be simply calculated based on the product of the cost-sharing

reduction plan variation multiplier specified by HHS and the premium for the policy. This modification to the calculation should also reduce the administrative burden for issuers reviewing the advance payment amounts as part of the discrepancy reporting process because the advance payments will be based on premiums, which we presume issuers would review in connection with the advance payments of the premium tax credit. We also anticipate that FFE issuers will be able to review premium information prior to the start of the benefit year through the plan preview process. In addition, HHS plans to validate that the advance payment amounts reported via the 834 enrollment transaction are calculated in accordance with the methodology specified by HHS. Thus, we believe that this methodology and validation process should ensure the protection of Federal funds, while simultaneously limiting the administrative burden on QHP issuers and Exchanges.

Comment: One commenter expressed concern that the proposed methodology for calculating advance payments would result in lower advance payments amounts that would not cover issuers' costs. Another commenter stated that issuers should be able to request a change to the advance payment amounts mid-year if the amounts do not align with actual cost-sharing reduction amounts provided.

Response: Although we acknowledge that there are some limitations to this methodology (for example, the multiplier does not make a plan-specific adjustment for the cost of non-EHB, or account precisely for costs for large families with children not accounted for in the premium), we believe that a very small number of QHPs would be affected by these limitations, and any inaccuracies in the advance payments would be corrected through the cost-sharing reduction reconciliation process. In addition, as described at § 156.430(b)(2), HHS may adjust the advance payment amount for a particular QHP during the benefit year if the QHP issuer provides evidence that the advance payments are likely to be substantially different than the cost-sharing reduction amounts that the QHP provides.

2. Provisions on FFE User Fees

a. FFE User Fee for the 2015 Benefit Year

Section 1311(d)(5)(A) of the Affordable Care Act contemplates an Exchange charging assessments or user fees to participating health insurance

issuers to generate funding to support its operations. If a State does not elect to operate an Exchange or does not have an approved Exchange, section 1321(c)(1) of the Affordable Care Act directs HHS to operate an Exchange within the State. In addition, 31 U.S.C. 9701 permits a Federal agency to establish a charge for a service provided by the agency. Accordingly, at § 156.50(c), we specified that a participating issuer offering a plan through an FFE must remit a user fee to HHS each month that is equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year and the monthly premium charged by the issuer for each policy under the plan where enrollment is through an FFE.

OMB Circular No. A-25 Revised (Circular No. A-25R) establishes Federal policy regarding user fees, and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public. As in benefit year 2014, issuers seeking to participate in an FFE in benefit year 2015 will receive two special benefits not available to the general public: (1) the certification of their plans as QHPs; and (2) the ability to sell health insurance coverage through an FFE to individuals determined eligible for enrollment in a QHP. Activities performed by the Federal government that do not provide issuers participating in an FFE with a special benefit will not be covered by this user fee.

Circular No. A-25R further states that user charges should generally be set at a level so that they are sufficient to recover the full cost to the Federal government of providing the service when the government is acting in its capacity as sovereign (as is the case when HHS operates an FFE). We proposed to set the 2015 user fee rate for all participating issuers at 3.5 percent. This rate is the same as the 2014 user fee rate.⁴⁷

We are finalizing the 2015 user fee rate as proposed. Because we wish to continue to encourage issuers to offer plans through an FFE, we sought and have received an exception from OMB to the policy in Circular No. A-25R that the 2015 user fee be set to recover full

⁴⁷ OMB granted HHS an exception to the policy in Circular No. A-25R, allowing HHS to set the user fee rate for 2014 at 3.5 percent, rather than a higher rate which would have allowed HHS to recover full costs. This rate was chosen because we wished to encourage issuers to offer plans on FFEs and to align with the administrative cost structure of State Exchanges.

costs. We expect to cover full costs in future years.

Comment: We received several comments stating that both the 2014 and 2015 user fee rate should be lower because of the technical problems associated with FFE operations. Although the FFE performs important functions, issuers have had to take a larger role in supporting the processing of enrollment files and payments. One commenter specifically stated that the FF-SHOP user fee for 2014 should be waived due to the operational delays. Another commenter suggested that the 2014 user fee should be waived to offset issuers' costs resulting from an unbalanced risk pool. For the same reason, the commenter also suggested the annual fee imposed on health insurance providers, described in section 9010 of the Affordable Care Act, should be waived. Some other commenters noted that the 2015 user fee should be lower as a result of gains in operational efficiency and the expected increase in the number of State Exchanges.

Response: As discussed above, Circular A-25R specifies that a user charge should be assessed against recipients of special benefits derived from Federal activities beyond those received by the general public. Despite the 2014 technical issues, participating issuers will continue to receive special benefits through Federal activities. For example, issuers participating in an FF-SHOP will continue to receive the special benefits of the certification of their plans as QHPs and the ability to sell health insurance coverage to employers determined eligible to participate in the SHOP. In addition, we do not expect the cost to the Federal government of providing these special benefits to change appreciably. As a result, we are not changing the 2014 user fee rate. We are also finalizing the 2015 user fee rate at 3.5 percent, as proposed, based on the expected number of Federally-facilitated Exchanges in 2015 and our projected costs.

Changes to the risk pool will be addressed through the premium stabilization programs. Standards regarding the annual fee imposed on health insurance providers were finalized by the IRS on November 29, 2013 (78 FR 71476), and we direct commenters with questions regarding that fee to the IRS. Finally, we agree that over time we expect operational efficiencies and increases in the number of State Exchanges and will continue to take these factors into account when determining the annual FFE user fee rate.

Comment: We received two comments on the underlying structure of the FFE user fee. One commenter recommended that HHS establish broad-based financing for the FFE, such as an assessment on all health care industry entities. If the existing fee structure is kept, the commenter stated that it should only be paid by consumers and small employers that purchase coverage through an FFE. The commenter also stated that the user fee should not be set as a percent of premium, as the cost to run an Exchange is not related to the cost of coverage. In contrast, another commenter stated that the user fee should continue to be calculated as a percent of premium, which ensures the user fee is adjusted based on the size of the issuer's book of business.

Response: The FFE user fee will continue to be assessed as a percent of the monthly premium charged by issuers participating in an FFE. In accordance with Circular A-25R, issuers are charged the user fee in exchange for receiving special benefits beyond those that accrue to the general public. Setting the user fee as a percent of premium ensures that the user fee generally aligns with the business generated by the issuer as a result of participation in an FFE.

Comment: One commenter also recommended that HHS publish cost estimates for the FFE, disclose how funds will be spent, and develop performance metrics for the FFE. The commenter stated that any increase in an issuer's aggregate liability for FFE user fees should be capped at changes in the Consumer Price Index, and that total user fee collections across all issuers should be capped at the level of expended costs. The commenter urged that if user fee collections exceed FFE costs, issuers should receive a rebate or credit against future fees.

Response: HHS will continue to publish cost estimates through the Federal budget process, and performance results from time to time, as has been our practice thus far. We will also continue to set the user fee based on the expected costs to the Federal government of providing the special benefits to issuers; however, for 2015 as noted above, we sought and have received an exception to this policy from OMB because we wish to continue to encourage issuers to offer plans through an FFE. We expect to cover full costs in future years. Because we set the user fee to no more than cover Federal costs (and in the case of 2014 and 2015, at less than our predicted costs), we do not expect user fee collections to exceed the Federal cost of operating the FFE.

b. Adjustment of FFE User Fee

Section 2713(a)(4) of the PHS Act, as added by the Affordable Care Act and incorporated into the ERISA and the Code, directs non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage to provide benefits for certain women's preventive health services without cost sharing.⁴⁸ The Preventive Services Rule (78 FR 39870, July 2, 2013) established accommodations with respect to the contraceptive coverage requirement for health coverage established or maintained or arranged by eligible organizations.⁴⁹

Each organization seeking to be treated as an eligible organization under the Preventive Services Rule is required to self-certify that it meets the definition of an eligible organization. In the case of an eligible organization with a self-insured plan, a copy of the self-certification must be provided to all TPAs with which it or its plan has contracted. Upon receipt of the copy of the self-certification, the TPA may decide not to enter into, or remain in, a contractual relationship with the eligible organization to provide administrative services for the plan. A TPA that receives a copy of the self-certification and that agrees to enter into or remain in a contractual relationship with the eligible organization to provide administrative services for the plan must provide or arrange for separate payments for certain contraceptive services for participants and beneficiaries in the plan without cost sharing, premium, fee, or other charge to plan participants or beneficiaries, or to the eligible organization or its plan. The TPA can provide such payments on its own, or it can arrange for an issuer or other entity to provide these payments. In either case, the payments are not health insurance policies and the TPA can make arrangements with an issuer offering coverage through an FFE to obtain reimbursement for its costs

⁴⁸ The women's preventive health services referenced by PHS Act section 2713(a)(4) are provided for in comprehensive guidelines supported by the Health Resources and Services Administration (HRSA). On August 1, 2011, HRSA adopted and released guidelines for women's preventive health services based on recommendations of the independent Institute of Medicine.

⁴⁹ Under the Preventive Services Rule, an eligible organization is an organization that: (1) Opposes providing coverage for some or all of the contraceptive services required to be covered under section 2713 of the PHS Act and the companion provisions of ERISA and the Code on account of religious objections; (2) is organized and operates as a nonprofit entity; (3) holds itself out as a religious organization; and (4) self-certifies that it satisfies the first three criteria.

(including an allowance for administrative costs and margin) through an adjustment to the FFE user fee paid by the issuer.

At § 156.50(d), we established standards related to the administration of the user fee adjustment. Specifically, in § 156.50(d)(3)(ii), we stated that the user fee adjustment will include an allowance for administrative costs and margin that is no less than 10 percent of the total dollar amount of the payments for contraceptive services, and that HHS would specify the allowance for a particular calendar year in the annual HHS notice of benefit and payment parameters.

For user fee adjustments sought in 2015 for the cost of payments for contraceptive services provided in 2014, we proposed an allowance for administrative costs and margin equal to 15 percent of the total dollar amount of the payments for contraceptive services defined in § 156.50(d)(3)(i).⁵⁰ We proposed this allowance based on our analysis described in the proposed rule of the administrative costs that we expect each entity involved in the arrangement to incur. We are finalizing the allowance for administrative costs and margin at 15 percent, as proposed.

Comment: We received several comments expressing concern that the proposed allowance would not adequately cover administrative costs. One commenter emphasized that the allowance should take into account startup costs, including systems development, contract negotiations, customer service outreach, and provider support. Another commenter stated that there will be wide variation in administrative costs depending on whether the TPA operates in a State with an FFE, or if the beneficiaries live in multiple States. The commenter also noted that TPAs may incur care coordination costs related to contraceptive services, which should be covered by the allowance. As a result, the commenter recommended that HHS permit TPAs to accept either the 15 percent allowance or request a different amount based on expected costs. Another commenter noted that amounts paid for contraceptive services may be low compared to fixed administrative costs, particularly if the payment is for a low cost generic drug. The commenter suggested that HHS provide a greater allowance for administrative costs and margin when the volume of

contraceptive services falls below a set threshold.

Response: As discussed in the proposed rule, the proposed allowance was set to cover the administrative costs and margin for all of the entities involved in the relationship. We recognize that administrative costs may vary between TPAs depending upon their arrangement with an issuer participating in an FFE and the total costs of contraceptive services for which they provide payment. However, we believe that the proposed allowance should adequately cover expected administrative costs for the majority of TPAs and the issuers through which they receive the FFE user fee adjustment. We do not intend to allow TPAs to submit requests for greater allowances for administrative costs and margin, or for different categories of costs, such as startup or overhead costs, because it would be difficult to verify these costs and sufficiently safeguard Federal funds.

Comment: One commenter requested clarification that the FFE user fee adjustment is intended to cover the full cost of the payments for certain contraceptive services, plus an additional 15 percent, for administrative costs and margin.

Response: As described in § 156.50(d)(3), the user fee adjustment will be equal in value to the sum of the dollar amount of the payments for contraceptive services, plus a 15 percent allowance for administrative costs and margin.

Comment: We received several general comments on the accommodation for eligible organizations with a self-insured plan. Commenters noted that there is no requirement for issuers participating in an FFE to enter into arrangements with TPAs of eligible organizations with self-insured plans. As a result, commenters requested that HHS identify an alternative method to reimburse TPAs.

Response: In this final rule, we are specifically establishing the allowance for administrative costs and margin. As discussed in the Preventive Services Rule, we continue to believe the allowance for administrative costs and margin should provide an incentive for issuers to enter into arrangements with TPAs of eligible organizations with self-insured plans.

Comment: One commenter requested that HHS modify the standards related to MLR to align with the accommodations finalized in the Preventive Services Rule.

Response: We do not believe it is necessary to modify the regulations, but instead provided guidance on this topic

in the preamble to the Preventive Services Rule (see 78 FR 39886).⁵¹ Specifically, we noted that under 45 CFR part 158, participating issuers may deduct from premiums as licensing and regulatory fees any amounts paid out to a third party administrator or incurred by or for the issuer in contraceptive claims costs under the accommodations for self-insured group health plans of eligible organizations, plus the allowance for administrative cost and margin allowed under 45 CFR 156.50(d)(3)(ii), along with their net FFE user fee paid to HHS. We further here clarify that an issuer of group health insurance coverage that makes payments for contraceptive services for participants and beneficiaries of its insured health plans under the accommodations for eligible organizations rules may treat those payments as an adjustment to claims costs for purposes of MLR and risk corridors program calculations. As discussed in the Preventive Services Rule, this adjustment would compensate for any increase in incurred claims associated with making payments for contraceptive services.

3. AV Calculation for Determining Level of Coverage

Section 2707(a) of the PHS Act and Section 1302 of the Affordable Care Act direct non-grandfathered health insurance issuers in the individual and small group markets, including QHPs, to ensure that plans meet a level of coverage specified in section 1302(d)(1) of the Affordable Care Act and codified at § 156.140(b). On February 25, 2013, HHS published the EHB Rule implementing section 1302(d) of the Affordable Care Act, which sets forth the requirement that, to determine the level of coverage for a given metal tier level, the calculation of AV be based upon the provision of EHB to a standard population. Section 156.135(a) establishes that AV is to be calculated using the AV Calculator developed and made available by HHS.

HHS recognizes that certain routine changes will on occasion need to be made to facilitate the AV Calculator's ongoing operation by ensuring that it

⁵¹ That guidance stated that “. . . for purposes of the medical loss ratio and the risk corridors program, participating issuers should report the sum of: (1) The net FFE user fee paid to HHS; (2) any amounts paid out to a third party administrator or incurred by or for the participating issuer in contraceptive claims costs under the accommodation for self-insured group health plans of eligible organizations provided in these final regulations; and (3) the allowance for administrative costs and margin provided under 45 CFR 156.50(d)(3)(ii), as licensing and regulatory fees referenced in 45 CFR 158.161(a).”

⁵⁰ We note that the submission of the dollar amount of the payments for contraceptive services is subject to the oversight standards detailed at 45 CFR 156.50(d)(7), as well as the False Claims Act, 31 U.S.C. 3729–3733.

can accommodate changes in the marketplace or product design over time and due to the changing cost of providing health care services in the market. In accordance, we proposed to update certain aspects of the AV Calculator on a regular basis, but no more frequently than annually.

In proposed § 156.140(g), HHS proposed to update the AV Calculator as follows. First, we proposed to update for the annual limit on cost sharing and related functions based on a projected estimate to enable the AV Calculator to comply with § 156.130(a)(2). Second, we proposed to update the continuance tables to reflect more current enrollment data when HHS has determined that the enrolled population has materially changed, defined as more than 5 percent different. Third, we proposed to update the algorithms when HHS has determined the need to adapt the AV Calculator for use by additional plan designs or to allow the AV Calculator to accommodate potential new types of plan designs, where such adaptations can be based on actuarially sound principles and will not have a substantial effect on the AV calculations performed by the then current AV Calculator. To identify new industry practices and technical advances, we proposed a process to consult annually with the American Academy of Actuaries and to take into consideration feedback received through CMS Actuarial Value email address at: actuarialvalue@cms.hhs.gov. Fourth, we also proposed to update the continuance tables to reflect more current claims data no more than every 3 and no less than every 5 years and to annually trend the claims data when the trending factor is more than 5 percent different, calculated on a cumulative basis. To trend the AV Calculator, we proposed to use premium data and/or standard population data in years when the underlying claims data are not being updated in the AV Calculator, and in years where the claims data are being updated, we proposed to trend the Calculator based on the updated claims data. Lastly, we proposed to update the AV Calculator user interface when a change would be useful to a broad group of users of the AV Calculator, would not affect the function of the AV Calculator, and would be technically feasible.

Along with the parameters for updating the AV Calculator, we also proposed to amend § 156.135(a) to clarify that issuers would be required to use the AV Calculator published by HHS for a given benefit year or, in cases where a State has obtained HHS approval to use State specific data in the AV Calculator, issuers would be

required to use that AV Calculator HHS has published for the given benefit year, adjusted to use the State's data (State AV Calculator).

Lastly, we solicited comments on the proposed 2015 AV Calculator and AV Calculator methodology that would replace the 2014 versions of the Calculator and methodology, respectively. For the 2015 AV Calculator, HHS proposed to make minor changes to the design and inputs into the AV Calculator and did not propose updating the claims data, including the trending factor, or the enrollment data, since data were not yet available.

We are finalizing the regulatory provisions as proposed but we are not finalizing the 2015 AV Calculator and 2015 AV Calculator methodology. Rather, under the regulatory parameters for updating the AV Calculator, we are finalizing the 2014 AV Calculator to account for the estimated annual limit on cost sharing of \$6,850 and will update the 2014 AV Calculator methodology accordingly. These materials will also include non-substantive amendments to correct and clarify language, as well as some clarifying frequently asked questions, that do not reflect changes in the functioning of the AV Calculator. Through this final rule, the amended 2014 documents are being finalized as the 2015 AV Calculator and AV Calculator methodology.

Comment: Several commenters recommended that since the proposed version of the 2015 AV Calculator and the parameters to update the AV Calculator in the future can impact the AV of plan designs, CMS should increase the *de minimis* range to prevent issuers from having to make benefit changes in order to be able to continue offering the same plans, including plans for 2015 plans being offered in 2014. Other commenters submitted technical comments on the 2015 AV Calculator updates, as well as recommended that we not update the AV Calculator for 2015 unless other circumstances were met.

Response: We do not intend to change the *de minimis* range. The *de minimis* range is intended to allow plans to float within a reasonable range and is not intended to freeze plan designs preventing innovation in the market.

Because the AV Calculator is a dynamic tool, it is impossible to make changes to the Calculator's algorithms without potentially impacting the AV output. However, we limited the changes in the proposed 2015 AV Calculator to promote stability of the AV Calculator and to help better ensure that

issuers did not have to make benefit changes in 2015 in order to remain within the *de minimis* range. For instance, we did not update the enrollment or claims data because actual data were not available and we did not want to update the AV Calculator based on another projection. In fact, the vast majority of the updates to the proposed 2015 AV Calculator were the direct result of comments that we had received from issuers on improvements in the algorithms and adding additional functionality to the AV Calculator based actuarially sound principles to allow more issuers to use the AV Calculator without adjustment.

Given the limited changes that were being made in the proposed 2015 AV Calculator and that we were not updating the AV Calculator based on the enrollment and claims data for 2015, we are finalizing the 2014 AV Calculator as the 2015 AV Calculator with an updated estimated annual limit on cost sharing to help ensure that issuers do not have to make benefit changes between year 1 and year 2.

Since we are not finalizing the proposed 2015 AV Calculator at this time, with the exception of the updated estimated annual limit on cost sharing, we do not address the technical comments on the proposed 2015 AV Calculator and methodology, but we will take them under consideration if we propose updates to the AV Calculator in the future.

Comment: Commenters wanted the final version of the 2015 AV Calculator to be available early in 2014 and recommended that we ensure that issuers have enough time to work with the final version of the AV Calculator, proposing various annual deadlines.

Response: We recognize that issuers need time to work with the final version of the Calculator to develop their plan designs for a given benefit year. By finalizing the amended 2014 AV Calculator as the 2015 AV Calculator, our intention is to reduce the burden on issuers for 2015 in having to make adjustments to plan designs and do any recalculations with changes to the AV Calculator.

In future years, our intention with finalizing the provisions under § 156.135(g) is to allow us the option to release the final AV Calculator earlier in the year. However, certain updates to the AV Calculator will be dependent on the timeline of availability of the necessary data elements. Thus, while we will work to make the AV Calculator available as early as possible, we intend to release it no later than the end of the first quarter of the preceding the benefit year.

Comment: Some commenters expressed concern about the frequency and potential fluctuations as a result of the updates based on enrollment data, especially given the potential for dramatic changes in the enrolled population in the initial years. Commenters recommended that the enrollment and claims data updates be made as soon as possible or at the same time. Others asked for clarification on the types of statistics being used for the updates and the exact year that we intend to start updating based on enrollment data.

Response: Our policy is to consider updating the AV Calculator, starting with the 2016 AV Calculator, annually based on enrollment data when the combined measurement of the effects of shifts in gender or age statistics are materially different, which we define as more than 5 percent. We are finalizing this threshold for updating based on enrollment data of more than 5 percent to help ensure that updates based on enrollment data are limited. We also recognize the importance of balancing changes in the AV Calculator between ensuring that the AV Calculator is more accurately reflecting the current market and ensuring that any change to the AV Calculator minimizes the disruptions to current plan designs.

Comment: A commenter recommended that we consider updating based on utilization by income. Others expressed concern about the cost sharing limits in the AV Calculator. Comments included a request for additional information on the trending factor update particularly regarding the use of premium data, as well as a recommendation to set a higher threshold for applying the trend factor.

Response: AV is the calculation of a plan's cost sharing generosity that is applied to a standard population and does not take into account utilization by income level. Information on the development of the standard population is included in the AV Calculator methodology document. Income level is factored into other parts of the market, such as the enrollee's eligibility for cost sharing reductions. The cost sharing limits in the AV Calculator are reflective of the requirements under section 1302(c) of the Affordable Care Act, as implemented in regulations codified at § 156.130(a)(2).

When updating the trending factor in the AV Calculator, we will use two sources of data, one to reflect the individual market and one to reflect the small group market, to develop a single trend factor that could be applied to the AV Calculator that could be based on

the premium rate data and/or the standard population data compared from year to year. For premium rate data, these updates will be reflective of a combination of utilization and unit price increases. We intend to use the premium data to trend the Calculator because it is a reliable source of data that is easily accessible and a good indicator of the market cost changes from year to year. This premium rate data will be modified for proper actuarial adjustments to develop the trend factor, including adjustments for the transitional reinsurance program. These adjustments will be detailed in the AV Calculator methodology. As we discussed in the proposed rule, we will consider trending the AV Calculator every year and in cases, where the trend factor is cumulatively more than 5 percent different from the previous time the AV Calculator was updated, we would implement the trend factor.

Comment: Commenters requested additional guidance on a variety of topics related to the AV Calculator as well as analysis of AV policy. Other commenters expressed concern that updates to the algorithms could impact plans' AV. Some commenters requested the opportunity to provide input on future updates to the AV Calculator and requested information about how these updates would apply to the minimum value calculator and any State AV Calculator.

Response: The standard that we will apply in making algorithm adaptations will be to have the minimum impact possible on the outcomes produced by the AV Calculator generally while still allowing it to be adaptable to the new types of plan designs and allowing more types of plan designs to use the AV Calculator. However, as noted above, because the AV Calculator is a dynamic tool, it is impossible to make changes to the Calculator's algorithms without potentially impacting the AV output.

Guidance on the operation and functions of the AV Calculator is included in both the AV Calculator Methodology and the AV Calculator User Guide. As we update the AV Calculator in future plan years, we will revise these documents to provide our analysis and clarification where possible. In addition to taking into consideration stakeholder feedback that is submitted to the CMS Actuarial Value email address at actuarialvalue@cms.hhs.gov during the year, we will consult with the American Academy of Actuaries as well as the National Association of Insurance Commissioners and will intend to release a draft version of the AV Calculator through guidance for comment. This guidance will

include an updated AV Calculator Methodology to explain the changes that were made to the AV Calculator. We also intend to provide future guidance on the parameters for updating a State AV Calculator. The Department of Treasury and the Internal Revenue Service are aware of our updates to the AV Calculator and may consider updates to the minimum value calculator.

Comment: We received two comments on potential data sources for family plans. Other commenters requested additional clarity on incorporating family plans as well as recommending that issuers should not be required to include family coverage in their AV calculation.

Response: We are interested in learning more about the potential for States' all payer claims databases systems to account for family plan cost sharing, but since many of these systems are still in development, we will monitor these systems to consider this option in the future. In the meantime, we will continue to maintain the policy for accounting for family plans that we provided in the "2014 Letter to Issuers on Federally-facilitated and State Partnership Exchanges."⁵²

We believe that determining AV based on the cost sharing applicable to an individual is appropriate for most family plans and that for most plans, the amount of the change in AV due to a more exact calculation of family cost sharing is likely to be within the *de minimis* range. However, if the issuers finds that this approach will not yield an appropriate AV for a specific family plan, then the issuer should use an alternative AV calculation method under § 156.135(b) providing the appropriate documentation. We will continue to consider potential AV calculation modifications in this area.

4. National Annual Limit on Cost Sharing for Stand-Alone Dental Plans in an Exchange

We proposed to impose a specific annual limit on cost sharing for the pediatric dental EHB when offered through a stand-alone dental plan (SADP) of \$300 for one covered child and \$400 for two or more covered children. The annual limit on cost sharing was proposed to apply for SADPs certified by all Exchanges. Further, due to the limited variation in cost sharing with a decreased annual limit on cost sharing, we proposed

⁵² Letter to Issuers on Federally-facilitated and State Partnership Exchanges, April 5, 2013, available at: http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2014_letter_to_issuers_04052013.pdf.

removing the AV requirement applicable to SADPs offered through the Exchanges that had been established previously through rulemaking.

We are finalizing the annual limit on cost sharing with an increase compared to the proposed levels, to apply to SADPs certified by all Exchanges nationally. In response to comments that the actuarial value would still be a valuable standard for SADPs, we are not finalizing our proposal to delete the actuarial value requirement at § 156.150(b).

Comment: Several commenters voiced concerns about a lowered annual limit on cost sharing, primarily related to the anticipated increase in premiums and concerns that a reduced annual limit on cost sharing would result in plan designs that impose deductibles on more of the preventive pediatric dental services. Commenters stated that these higher up-front costs would be a deterrent to consumers purchasing SADPs for their children if the pediatric dental EHB was not included in the QHP. Some commenters suggested that CMS wait to change the limit until more information is available on the first year of experience and to avoid disruption for consumers in the plan designs for year two, and a number suggested that the family to single limit ratio remain 2:1. Other commenters supported the approach for its impact on reducing the total out-of-pocket costs for a consumer enrolled separately in QHPs and SADPs.

Response: We understand that trade-offs exist between the different cost levers in a plan design, such as premiums, deductibles, and annual limits on cost sharing. Accordingly, we requested comment on the proposed annual limits on cost sharing, and specifically whether a higher or lower limit would be appropriate for the pediatric dental EHB. In light of the comments received, we are finalizing the SADP annual limits on cost sharing with increases of \$50 on the single child limit and \$300 on the limit for two or more children. The national annual limits on cost sharing for the pediatric dental EHB when offered as part of a stand-alone dental plan are \$350 for one covered child and \$700 for two or more covered children. We believe that this will provide more benefit design flexibility to dental issuers, which will reduce the potential impact on premiums and other cost-sharing, while also furthering our originally stated goal in the proposed rule of reducing the total annual limit on cost sharing for consumers who are enrolled in both QHPs and SADPs. The greater increase in the limit for two or more children enrollees is to retain the 2:1 ratio of

family, as suggested by commenters, to be consistent with the ratio for medical plans.

Comment: Regarding the removal of the AV standards, most commenters suggested that CMS return to the previous AV standards so that consumers would continue to have a means of comparison between the relative levels of coverage and out of concern that, without such standards, SADPs could transfer more cost sharing to up-front deductibles that would result in an AV below 70 percent.

Response: We believe that the commenters raised valid points regarding the value to a consumer of an AV level and, accordingly, we will not finalize the deletion of the actuarial value standards for SADPs previously established in the EHB Rule. The standard for SADPs is that they must meet *either* the 70 percent or 85 percent AV level. We understand that with the reduction in the annual limit on cost sharing, the lower of the two limits—70 percent—may be more difficult to meet, but in such cases the SADP could instead target the 85 percent level.

Comment: A small number of commenters supported the approach to having the annual limit on cost sharing for the pediatric dental EHB in SADPs as a national limit, as opposed to allowing State flexibility.

Response: We agree with the commenter and are finalizing the rule to apply nationally.

5. Additional Standards Specific to SHOP

We proposed adding paragraph (a)(4)(i) to § 156.285 to provide that a qualified employer in the SHOP that becomes a large employer would continue to be rated as a small employer, regardless of whether the QHP being sold through the SHOP is sold in the small group market or the large group market. To assure consistency of pricing within the SHOP, we proposed to require a QHP offered through the SHOP to comply with the rating rules described in § 147.102. Nothing in this proposal prevents such an employer from choosing to buy a guaranteed issue new policy (without small group rating rules) in the large group market outside of the SHOP. We are making a minor change from the proposed rule to add “being sold through the SHOP” to § 156.285(a)(4)(i).

We proposed in amendments to § 156.285(a)(4)(ii) to not allow for composite premiums in the FF–SHOPS when an employer chooses a level of coverage and makes all QHPs within that level available to its employees. In the proposed rule preamble, we also

indicated that we were considering extending the proposed limitation on composite premiums to SADPs in the FF–SHOPS, and invited comment on whether such a prohibition should be adopted. We acknowledge that this proposal would create a limited exception to § 147.102(c)(3) and that it would preempt State laws requiring or permitting composite premiums in the small group market, but we believe this proposal to be limited in scope and tailored to provide for administrative efficiency and uniformity, system compatibility among the FF–SHOPS, and increased competition and choice in the small group market. We are finalizing the provisions with a change reflecting that, in response to comments solicited and received on whether the proposal to limit composite premiums in an employee choice environment should be extended to SADPs, we have decided to extend that limitation to SADPs when an employer opts to offer employees the choice of all SADPs at a dental actuarial value level.

Because the proposed amendments to § 155.705(b)(4) summarized above are being finalized as proposed, all SHOPS will be permitted to establish standard methods for premium payment under § 155.705(b)(4), as part of carrying out the premium aggregation function, and HHS will establish through guidance a process and timeline for employers to follow when remitting premium payments to the FF–SHOPS once premium aggregation becomes available in the FF–SHOPS. We anticipate that after premium aggregation becomes available in the FF–SHOPS, an FF–SHOP would transmit premium payments—both initial and subsequent—to issuers on a regular schedule and anticipate that this would be no more frequently than once a week.

We proposed adding § 156.285(c)(7)(ii) to establish that a QHP issuer offering a QHP through an FF–SHOP would be required to enroll a qualified employee unless it receives a cancellation notice for that employer from the FF–SHOP. This operational scenario would arise only in the case of an employer’s initial premium payment. For regular monthly payments from a participating SHOP employer, the requirements of the payment timeline and process established in accordance with new § 155.705(b)(4)(ii)(A) (as finalized in this rule) and the termination provisions of § 155.735 would apply. We are finalizing this provision as proposed.

Comment: Several commenters supported our proposal to limit composite premiums in FF–SHOPS to employers who choose to offer their

employees a single QHP. In addition to supporting our proposal, many of these commenters stressed that composite premiums should always be optional for issuers participating in FF-SHOPs (unless required by State law or regulation). A few commenters, however, support composite premiums for employee choice and believe it will add to the value-proposition of FF-SHOPs.

Response: As we discussed in the preamble to the proposed rule, our proposal to make composite premiums in the FF-SHOPs unavailable to qualified employers offering employee choice was motivated by our concern that the amendments to § 147.102 finalized in this rule would adversely affect issuers in an employee choice environment, creating an incentive for issuers to avoid participating in the FF-SHOPs and undermining the Affordable Care Act's goals of increased choice and competition in the small group market. That is because, under the composite premium provisions of § 147.102(c)(3), if an issuer offers composite premiums, the average enrollee premium amount established at the time of the initial group enrollment would not change until renewal, even if the composition of the group changes in the interim. For example, if several older employees joined the group or several employees terminated their coverage, the composite premium would remain the same until renewal. Because any risk related to a change in the group's composition is divided among issuers in an employee choice environment, they would be taking on proportionately more risk than in a single plan environment where the issuer would be assuming the risk—good and bad—for the entire group. In light of these concerns, we continue to think the prohibition on composite premiums in an employee choice environment is warranted, and are finalizing this policy as proposed through the amendment to § 156.285(a)(4), so as to not allow for composite premiums in an employee choice environment.

Comment: We received some comments agreeing with our proposal to extend to SADPs in the FF-SHOPs the proposed limitation on composite premiums in an FF-SHOP when an employer selects a level of coverage and makes all QHPs within that level available to its employees.

Response: In response to these comments, we are modifying the final rule to provide that the limitation on composite premiums in an employee choice environment applies to both medical QHPs and SADPs, in circumstances where the employer

offers employees a choice of all plans at a given AV level or dental AV level. As is the case with composite premiums for medical QHPs, we believe composite premiums for SADPs could potentially adversely affect issuers when the employer offers employees all SADPs at a given dental AV level, and could create an incentive for SAMP issuers to avoid participating in the FF-SHOPs and undermine the Affordable Care Act's goals of increased choice and competition in the small group market. Therefore, we have finalized this provision with additional language establishing that the limitation on composite premiums also applies for SADPs when employees are given a choice of SADPs at a given dental AV level.

Comment: We received varying comments on our proposal to require issuers in FF-SHOPs to effectuate coverage unless they receive a cancellation notice for non-payment of premium. Some commenters supported our proposal to require issuers to effectuate coverage if the FF-SHOP does not send a cancellation transaction prior to the coverage effective date. Some commenters opposed our proposal, stating that issuers should not be required to effectuate coverage before receiving the initial premium payment from the FF-SHOP. One commenter stated that issuers typically have payments in hand prior to coverage effectuation, giving issuers time to ensure that member enrollment packets can be sent out prior to the enrollment cut-off date. One commenter took a similar position, though suggested that issuers be allowed to pend claims until the initial payment is received by the FF-SHOP. Another commenter stated that the proposed policy could lead to provider reluctance to participate in Exchange plans. Finally, one comment suggested that a potential solution to this timing issue would be for the FF-SHOP to transmit daily payments to issuers.

Response: This rule does not require issuers to effectuate coverage if the FF-SHOP does not receive a premium payment by the deadline established for the FF-SHOP. If payment is not received by the FF-SHOP prior to that deadline, CMS will issue a cancellation notice, or, in the case of payments subsequent to the initial premium payment, a termination notice to issuers for non-payment of premium. In addition, we anticipate sending issuers weekly premium payments, so the length of time between receipt of payment and premium remittance is not expected to be more than approximately one week. Therefore, we are not

modifying our proposal in response to these comments.

6. Meaningful Difference Standard for QHPs in the FFEs

Section 1311(e)(1)(B) of the Affordable Care Act, codified at § 155.1000(c)(2), sets forth the standard that the Exchange may certify a health plan as a QHP if it determines that making the plan available through the Exchange is in the interests of qualified individuals and qualified employers in the State or States in which such Exchange operates. Therefore, as a means of ensuring that all QHPs offered through an FFE are in the interest of qualified individuals and qualified employers, we proposed that, to be certified as a QHP in an FFE, a plan must be considered “meaningfully different” from all other plans offered by the same issuer through the same Exchange, and we proposed a standard for what is meant by the term “meaningfully different.”

In § 156.298(a), we proposed that the FFEs and FF-SHOPs would impose a meaningful difference requirement when approving a QHP application for certification of multiple QHPs within a service area and level of coverage in the Exchange from a single issuer. Due to the special characteristics of the SAMP market, HHS proposed not to require meaningful difference as a condition for certification among SADPs at this time. We proposed, in § 156.298(b), that a plan within a service area and metal tier (bronze, silver, gold, or platinum, and catastrophic coverage) would be considered meaningfully different from other plans if a reasonable consumer (the typical consumer buying health insurance coverage) would be able to identify at least two material differences among seven⁵³ key characteristics between the plan and other plans to be offered by the same issuer. The key characteristics were proposed in paragraphs (b)(1)–(b)(7), and include (1) cost sharing; (2) provider networks; (3) covered benefits (including prescription drugs); (4) plan type (for example, HMO or PPO); (5) premiums; (6) health savings account eligibility; and (7) self-only, non-self-only, or child-only coverage offerings. We proposed that, at a minimum, a reasonable consumer would have to be able to identify two or more of the characteristics proposed at § 156.298(b) as different in order for the plan to pass the meaningful difference test. Therefore, within a service area and level of coverage in an Exchange, if two

⁵³ We acknowledge that the proposed 2015 Payment Notice listed seven elements, but referred erroneously to eight elements.

plans submitted by a single issuer seeking QHP certification vary among their cost sharing and covered benefits features but have the same premiums, the plans would be deemed as having met the meaningful difference test.

Furthermore, to ensure that consumers have an adequate number of plan options across all metal levels of coverage, we proposed at § 156.298(c), that if HHS determines that the plan offerings at a particular metal level (including catastrophic plans) within a county are limited, plans submitted for certification at that level within that county would not be subject to the meaningful difference requirement.

To provide flexibility for issuers that merge with or acquire another issuer that is a separate legal entity, HHS proposed in § 156.298(d), a 2-year meaningful difference transition period starting from the date on which a QHP issuer (acquiring entity) obtains or merges with another issuer. We proposed in paragraph (d) that during the first 2 plan years after a merger or acquisition, the acquiring entity can offer plans that were recently obtained or merged from another issuer that do not meet the meaningful difference standard.

We are finalizing the provisions with the following modifications. To address concerns with the proposed meaningful difference standard, we have modified § 156.298(b) to have the standard set at one material difference rather than two, and have removed premiums as one of the characteristics among which plans must be different. We are not finalizing the text proposed at § 156.298(b)(5) and are therefore renumbering the provisions proposed at § 156.298(b)(1)–(7) as § 156.298(b)(1)–(6). To be consistent with previous HHS language used for other guidance and regulation, we have modified § 156.298(b)(6) (previously § 156.298(b)(7)) to read “child-only plan offerings” rather than “child-only offerings.”

Comment: Several commenters were supportive of the standard in general, but they also recommended modifying the standard from two differences to one to be consistent with the guidance CMS released for the 2014 coverage year. Furthermore, issuers believed strongly that one material difference (that is, plan type of HMO vs. PPO) would have a large enough impact for consumers to be able to differentiate plans from one another.

Response: Based on the comments received, we agree that one material difference (that is, plan type of HMO vs. PPO) would have a large enough impact for consumers to be able to differentiate plans from one another, which satisfies

our policy goal of ensuring the ability to readily differentiate and compare plan choices, leading to informed decisions. Accordingly, we are finalizing the standard at § 156.298(b) with a modification from two material differences to one.

Comment: Several commenters opposed the inclusion of premiums as a material difference among the key characteristics at the proposed § 156.298(b)(5), to use when determining if the meaningful difference standard is met. Specifically, commenters noted that premiums alone are not indicators of difference in plan design, but rather a function of plan design difference that are already accounted for in the other characteristics included in the proposed list.

Response: We agree based on the strong feedback from commenters that premiums alone are not indicators of difference in plan design. Therefore, we have revised § 156.298(b) so that premium is no longer included as a material difference option. We have renumbered the remaining characteristics accordingly.

Comment: Commenters expressed concern over the vague descriptions of the characteristics associated with the proposed standard and requested more robust quantitative standards for issuers to follow for the 2015 benefit year. For instance, several commenters requested further guidance on the cost-sharing characteristic.

Response: While we understand the reasoning for having more robust quantitative standards, we are not adding more robust quantitative standards to the characteristics because we believe that the characteristics are generally sufficiently detailed for issuers to be able to design QHPs that would be meaningfully different under this standard.

Comment: Some commenters expressed concern with the limited plan availability exception proposed at § 156.298(c). Commenters stated that they believed this exception may lead to cherry-picking of particular counties by issuers and anti-competitive practices to saturate the market.

Response: This policy helps to ensure that consumers have adequate plan choice in every county within the marketplace. We are finalizing this provision of the proposed policy as written.

Comment: Several commenters agreed with the approach of limiting an issuer's participation in the FFEs should there be significantly different rate increases for its QHPs and non-QHPs, based on the Exchange's authority under sections

1311(e)(1) and (e)(2) of the Affordable Care Act. Moreover, commenters thought that it is important for HHS to take sufficient action to ensure that a given plan in the FFE is in the interest of qualified individuals and qualified employees. Conversely, other commenters opposed the proposed policy as they noted that numerous components of the Affordable Care Act that mitigate adverse selection between QHP and non-QHPs already exist, so there is no need for HHS to impose a new protection for the FFEs.

Response: We appreciate all the feedback and comments regarding the proposed approach. We are not finalizing any new policy related to limiting participation in the FFEs on this basis and will take this feedback into consideration for future rulemaking.

7. Quality Standards: Establishment of Patient Safety Standards for QHP Issuers

In § 156.1110, we proposed that during phase one, a QHP issuer that contracts with hospitals that have more than 50 beds, must verify that they are Medicare-certified or have been issued a Medicaid-only CMS certification number (CCN), and are subject to Medicare Hospital Conditions of Participation (CoPs) requirements found in 42 CFR part 482 (specifically, standards regarding a quality assessment and performance improvement program and a discharge planning process). We proposed to direct QHP issuers to maintain documentation, including but not limited to the CCN for each hospital, to demonstrate compliance. We further proposed that a QHP issuer must make this documentation available to the Exchange, upon request by the Exchange, and in a time and manner specified by the Exchange. Lastly, we proposed that a QHP issuer must ensure that each of its QHPs meet these initial patient safety standards for plan or policy years beginning on or after January 1, 2015. Additional patient safety standards for QHP issuers would be implemented over time, under the Secretary's authority under section 1311(h)(2) of the Affordable Care Act. We noted that we anticipate establishing phase two implementation which would begin January 1, 2017 or when we issue further regulations based on a reassessment of the Exchange market, whichever is later, to include standards around hospitals and Patient Safety Organizations (PSO), health care providers, and health care quality improvement mechanisms. We noted that implementing all of the requirements described in section

1311(h) by January 1, 2015, could result in a shortage of qualified hospitals and providers available for contracting with QHPs.

We are finalizing this approach as proposed with one modification. We are modifying the documentation standard in § 156.1110(b) to remove “including, but not limited to, the CCN,” to indicate that only the CCN is required to be collected.

Comment: Many commenters agreed with the proposed provisions that we outlined in the proposed rule and supported the use of Medicare Hospital CoPs requirements in the initial phase of implementation of patient safety standards. Many commenters also expressed support for the phase-in approach to implementing the patient safety reporting standards for QHP issuers. They stated that the proposed approach was reasonable to ensure adequate numbers of hospitals in QHP networks and to safeguard patient access to health care services. Commenters agreed with HHS’s rationale that currently, there is insufficient capacity of Patient Safety Organizations (PSOs) and expressed concern that any more stringent standards than what was proposed would have negative effects on patient access and breadth of networks.

Response: We are finalizing the regulation as proposed with one minor change to the documentation standard, as discussed above. By finalizing as proposed, we believe that this approach to implementation of section 1311(h) would ensure that QHP issuers have sufficient hospitals and health care providers to contract with, while providing consumers with access to health care that meets adequate safety and quality standards.

Comment: Several commenters did not support the delay of the QHP issuer requirement of ensuring contracted hospitals have agreements with PSOs and disagreed with the proposed length of the phase-in period. These commenters disagreed regarding constraints for hospitals to enter into agreements with PSOs and for issuers to track such information. One commenter stated that Medicare Hospital CoPs requirements are not a proper substitute for hospital PSO relationships. Other commenters requested that CMS ensure that the phase-in lasts no more than one year as patient safety reporting is important to inform consumer choice and for health system improvement.

Response: We believe that the proposed phase-in for standards will ensure that QHP issuers and their contracted hospitals demonstrate the implementation of patient safety

activities while allowing time to develop more robust standards. We believe that establishing standards requiring hospital agreements with PSOs would be overly burdensome and an inefficient use of resources for the majority of hospitals and QHP issuers at this time. We believe it is important for hospitals to take adequate time to assess their unique patient safety data collection and analysis needs and to establish agreements with the appropriate PSOs. Further, we believe the proposed approach allows QHP issuers the opportunity to monitor patient safety of their network hospitals for meaningful compliance with patient safety standards. As the Exchange market evolves and as enrollment increases, we believe that patient safety reporting standards for QHP issuers should be enhanced. We do not intend phase one standards to be a substitute for hospital and PSO agreements. We believe that the first phase of implementation and aligning with Medicare Hospital CoPs requirements is appropriate at this time because the approach allows for effective alignment of hospital quality standards, clear standards for issuers and hospitals, and sufficient patient access to health care, in time to meet the statutory deadline of January 1, 2015.

Comment: A few commenters expressed concerns that the proposed rule fails to acknowledge successes of PSOs and participating providers and potentially has a negative impact on the progress in patient safety. Some commenters stated that those hospitals participating in PSO programs should be differentiated or rewarded using a preferred quality provider designation.

Response: We acknowledge that there are many successful, existing patient safety initiatives among health care providers across the country, including work by PSOs. In addition, we continue to encourage robust QHP provider networks that promote access to quality health care services. We believe the standards in the proposed rule support existing patient safety initiatives by providing a balanced approach to minimize potential duplication of hospital quality standards and ensure that individuals have the necessary access to health care. We recognize that many hospitals already have established agreements with PSOs but we do not believe it is necessary to require such agreements of hospitals at this time. We do not intend to restrict hospitals and QHP issuers from including such information in their marketing materials if they choose to.

Comment: One commenter supported the proposed approach as integrated

delivery systems are not able to follow the requirements of the Patient Safety Quality Improvement Act (PSQIA) which create barriers to the free flow of information between providers and the integrated health plan issuer of a QHP. One commenter was concerned with regard to the integrated system’s ability to participate in PSOs and encouraged the development of a reasonable alternative.

Response: We understand the commenter’s concern of the unique challenges of an integrated health care delivery system to participate in the Federal PSO program established under the PSQIA. As we state in the preamble to this final rule, we intend to issue future rulemaking regarding the establishment of reasonable exceptions pursuant to the Secretary’s authority in section 1311(h)(2) of the Affordable Care Act and will welcome additional comments at that time.

Comment: A few commenters were concerned that the proposed standards require QHP issuers to contract only with Medicare-certified hospitals and would therefore have a negative effect on patient access and breadth of networks. Specifically, commenters requested clarification that the standards only applied to Medicare-certified hospitals and would not restrict contracting with non-Medicare hospitals. They also asked for clarity that the standards did not apply to hospitals that may be temporarily without CCNs.

Response: We are clarifying that the standards do not require QHP issuers to only contract with Medicare-certified hospitals. As we stated in the proposed rule, the standards are designed to not significantly limit hospital participation in QHP networks and as proposed, would prevent a potential shortage of qualified hospitals and providers available for contracting with QHPs. The proposed standards in § 156.1110 establishes that a QHP issuer that contracts with a hospital with greater than 50 beds must verify that the hospital is Medicare-certified or has been issued a Medicaid-only CCN. However, QHP issuers are not prevented from contracting with other types of hospitals and providers.

Comment: One commenter cautioned CMS against implementing duplicative standards on hospitals and noted the hospital value-based purchasing programs and other quality reporting requirements included in the Affordable Care Act as potential areas for alignment. A few commenters made suggestions as to alignment of hospital standards across Medicare, Medicaid, and commercial markets.

Response: We believe the proposed standards to align with Medicare Hospital CoPs requirements for Quality Assurance and Performance Improvement programs and discharge planning in the initial years of implementation minimizes duplication and we intend to continue efforts to align with existing and effective Federal, State, and private health care quality reporting initiatives as well as other quality reporting requirements in the Affordable Care Act to minimize duplication. Comments regarding programs other than Exchanges and QHP issuers (such as hospital value-based purchasing programs) are outside the scope of this final rule.

Comment: One commenter urged CMS to establish standards, or at the least a framework, for 1311(g), related to quality improvement strategy reporting by QHP issuers, before implementing the second phase of section 1311(h) of the Affordable Care Act. The commenter stated that it is inappropriate to request issuers to comment on the future phase without providing standards for 1311(g) of the Affordable Care Act.

Response: We understand the commenter's concern of establishing standards regarding QHP quality improvement strategies in accordance with section 1311(g) of the Affordable Care Act prior to the future phase of implementation of patient safety standards. We intend to issue rulemaking in the future and will welcome comments to inform implementation of 1311(g) at that time. We agree with the commenter regarding the importance of harmonization of quality and patient safety reporting standards for QHP issuers.

Comment: One commenter suggested that phase one implementation of the standards should require hospitals to undergo an external evaluation by expert surveyors similar to the Medicare requirement for accredited hospitals.

Response: We believe that the proposed standards are adequate for phase one implementation of patient safety reporting for QHP issuers without placing undue burden on issuers or hospitals. We do not intend to duplicate standards for hospital survey and certification processes already in place and we also do not intend to interfere with hospital accreditation processes.

Comment: Many commenters supported the proposal to apply the patient safety reporting requirements to hospitals with more than 50 beds.

Response: We are finalizing the statutory distinction of number of hospital beds to be greater than 50 beds as proposed.

Comment: One commenter requested CMS to clarify what it considers to be a section 1861(e) hospital, including the types of hospitals. The commenter requested confirmation of their understanding that CMS intends for this provision to apply only to hospitals that are subject to the CoPs standards for Quality Assurance and Performance Improvement programs and discharge planning, which is broader than general acute care hospitals. Some commenters expressed concern that the proposed standards do not apply to hospitals with fewer beds, children's hospitals, critical access hospitals, inpatient psychiatric facilities or other hospitals that do not participate in Medicare or Medicaid.

Response: Section 1861(e) of the Social Security Act refers to the definition of the term, hospital. We clarify that the hospitals that are included in these proposed standards are those that are subject to the Medicare Hospital CoPs and that are Medicare-certified or are Medicaid-only hospitals that have CCNs. QHP issuers may continue to contract with other types of hospitals or providers that are not included in this reference; however, the issuer would not have to maintain the associated hospital CCNs based on these standards. For example, although we do not specifically identify psychiatric hospitals that are defined by 1861(f) of the Social Security Act, the proposed standards do not prevent QHP issuers from contracting with such hospitals. QHP issuers would not be required to collect and maintain CCNs for such hospitals in accordance with § 156.1110 but again, would be able to continue to contract with such hospitals. We encourage all hospitals and health care providers to engage in patient safety improvement activities with the goal of reducing harm and achieving better patient health outcomes. In the second phase of implementation, we will assess the feasibility of applying future patient safety reporting standards to other types of hospitals and will solicit comment at that time.

Comment: Several commenters did not support the proposed methodology for collecting and documenting a hospital's CCN as it could be burdensome to QHP issuers. Several other commenters offered suggestions for different methods that HHS could use, including having HHS collect the information from a hospital's accrediting entity or using publicly available data, such as Medicare's Provider of Services file. Another commenter asked that we specify what other documentation may be required in addition to a hospital's CCN.

Response: We acknowledge that there may be other sources for collecting a hospital's CCN; however, we believe that the QHP issuer should have the responsibility of tracking their contracted hospitals adherence to the standards we have proposed. In the final rule, we are modifying the documentation standard to direct QHP issuers to maintain only the CCNs for each hospital that these standards apply to. We maintain the collection and reporting of CCNs but we have removed reference to any other documentation.

Comment: One commenter seeks clarification that QHP issuers meet the documentation requirements for Medicare-certified or Medicaid-only CCN hospitals simply by providing Exchanges proof of those hospitals' certification or CCN, as provided to the QHP by the contracted hospital.

Response: We clarify that the QHP issuer would meet the documentation standard by providing the Exchange, upon request by the Exchange, the applicable hospitals' CCNs as provided by the contracted hospitals. We also clarify that it is the responsibility of the QHP issuer to ensure that accurate CCN information is maintained.

Comment: Several commenters disagreed with the proposed length of the phase-in period and requested that HHS ensure that the phase-in lasts no more than one year as patient safety reporting is important to inform consumer choice and for health system improvement. Another commenter requested that the phase-in period be shortened to one year.

Response: We maintain that the first phase of implementation would be for 2 years beginning January 1, 2015 or until we issue further regulations based on a reassessment of the Exchange market, whichever is later. We believe that this provides ample time for Exchange markets to develop, QHP provider networks to grow, PSOs to continue expanding, continued research regarding more robust patient safety standards for QHP issuers and examples of comparable activities to be included as reasonable exceptions.

Comment: Several commenters provided detailed suggestions for implementing the future phase of patient safety reporting standards including reasonable exceptions to the requirements and a number of comments regarding the core aspects of a hospital patient safety program, discharge planning program, health care quality improvement activities, and how QHPs can effectively track patient safety activities. Some commenters requested additional details regarding phase two

to be provided now so that stakeholders may have time to prepare.

Response: We intend to promulgate future rulemaking outlining a proposed approach and will seek additional public comment at that time.

8. Financial Programs

a. Netting of Payments and Charges

In the 2014 Payment Notice, HHS established a monthly payment and collections cycle for the advance payments of the premium tax credit, cost-sharing reductions, and FFE user fees, and an annual payment and collections cycle for the premium stabilization programs and reconciliation of cost-sharing reductions. For 2014, to streamline our payments and collections process, we provided in § 156.1215(a) that each month HHS will determine amounts owed to or by a QHP issuer by netting amounts owed by the QHP issuer to the Federal government against payments due to the QHP issuer for advance payments of the premium tax credit, advance payments of cost-sharing reductions, and payment of FFE user fees. In addition to this netting across these programs, as further described below, the monthly calculation of amounts due will reflect current information related to enrollment for past months, including information related to excess payments previously made. Finally, amounts owed to or by a QHP issuer will be netted across all entities operating under the same taxpayer identification number (TIN). This process will permit HHS to calculate amounts owed each month, and pay or collect those amounts from issuers more efficiently. When netting occurs, HHS will demand amounts due only when there is a net balance due to the Federal government.

Additionally, a number of annual payment flows will begin in 2015 for the risk adjustment program, the reinsurance program, the risk corridors program, and cost-sharing reduction reconciliation. To streamline payment and charge flows from all of these programs—advance payments of the premium tax credit, advance payments and reconciliation of cost-sharing reductions, FFE user fees, and the premium stabilization programs—we proposed in § 156.1215(b) that HHS may net amounts owed to the Federal government against payments due to an issuer (or an affiliated issuer under the same TIN) under these programs in 2015 and later years. We believe that this process will enable HHS to operate a monthly payment cycle that will be efficient for both issuers and HHS.

In § 156.1215(c), we proposed that any amount owed to the Federal government by an issuer and its affiliates for advance payments of the premium tax credit, advance payments of and reconciliation of cost-sharing reductions, FFE user fees, risk adjustment, reinsurance, and risk corridors after netting be the basis for calculating a debt owed to the Federal government. We proposed that payments and collections under all of these programs occur under an integrated monthly payment and collection cycle.

After considering the comments received, we are finalizing these provisions as proposed.

Comment: We received several comments supporting the proposed netting provisions in § 156.1215. However, one commenter asked HHS to net in a rolling fashion every month, and wait until the end of the calendar year to invoice issuers for any remaining balance.

Response: We believe that issuers should pay amounts owed on a monthly basis. Under our debt collection rules, these amounts owed could begin to accrue interest and penalties in subsequent months.

Comment: In response to our request for comment on payment timeframes, some commenters asked HHS to amend § 156.1210 in order to give issuers 15 business days, rather than 15 calendar days, to file discrepancy reports.

Response: The 15-calendar-day deadline established in § 156.1210 is necessary to permit HHS to resolve discrepancies by the next month's payment and collection process. Under § 156.1210(b), HHS will work with issuers that report discrepancies after 15 calendar days as long as the late reporting is not due to misconduct on the part of the issuer.

b. Confirmation of HHS Payment and Collections Reports

Under § 156.1210(a), an issuer must respond to the payment and collections report issued by HHS within 15 calendar days of receipt of the report by either confirming the report or notifying HHS if there is a discrepancy between the data provided in the payment and collections report and the data that the issuer has. Under § 156.1210(b), if an issuer reports a discrepancy in a payment and collections report later than 15 calendar days after receipt of the report, HHS will work with the issuer to resolve the discrepancy as long as the late reporting was not due to misconduct on the part of the issuer. Any resolution to such an identified discrepancy is reflected in a later

payment and collections report and the invoice generated under that later report does not affect the debt established by the invoice generated in connection with the earlier report.

We proposed that if an issuer notifies HHS of a discrepancy under § 156.1210(a) or (b), it would trigger an administrative discrepancy resolution process. Specifically, under § 156.1220(a), following the end of the benefit year, if the issuer remains dissatisfied with the results of that process, the issuer may make a request for reconsideration. To decrease the administrative burden on issuers, HHS, and the Exchanges, and in recognition of the number and timing of the data flows involved, we proposed not to retroactively adjust previous months' payment and collections reports and amounts previously due. The amount invoiced for a particular month, reflecting netted amounts as described above, constitutes an amount owed to the Federal government. As more accurate data become available to HHS, the Exchange, and the issuer, we proposed that this later information not reduce or increase the previous determination of an amount owed. Rather, the information is captured in subsequent months and reflected in subsequent payment cycles, and reflected in later invoices. Thus, an issuer would be required to pay the full amount of any invoice issued in connection with a payment and collection report for a month even if the issuer notes a discrepancy that may later be resolved as a credit in a later invoice. Therefore, we proposed to add paragraph (c) to § 156.1210 to provide that discrepancies in payment and collections reports identified to HHS under that section be addressed in subsequent payment and collections reports, and would not be used to change debts determined pursuant to invoices generated under previous payment and collections reports.

After considering comments on this approach, we are finalizing these provisions as proposed.

Comment: One commenter supported our proposal not to retroactively adjust HIX 820 payment and collections reports and amounts previously due. Another commenter asked HHS to amend proposed § 156.1215 to specify that HHS will delineate payments and charges by program and by issuer, so that issuers can track HHS netting, keep accurate track of payments by programs, and avoid penalties and fines for late payments.

Response: The HHS monthly payment and collections report will detail charges, payments, and netting by

program for each payee group. Each payee group consists of one or more issuers with the same TIN and is established and organized by a parent health insurer. In addition to this monthly statement, HHS anticipates providing issuers with more detailed reports relating to certain programs.

Comment: One commenter asked when HHS will make payments to issuers for reinsurance, risk adjustment, and cost-sharing reduction reconciliation.

Response: We will issue guidance on the timing of these payments in the future.

c. Administrative Appeals

In the proposed rule, we proposed an administrative appeals process designed to address unresolved discrepancies in advance payments of the premium tax credit, advance payments of cost-sharing reductions, FFE user fee payments, payments and charges for the premium stabilization programs, cost-sharing reduction reconciliation payments and charges, and assessments of default risk adjustment charges.

In § 156.1220(a), we proposed that an issuer be permitted to file a request for reconsideration of a processing error by HHS,⁵⁴ HHS's incorrect application of the relevant methodology, or HHS's mathematical error only with respect to: (1) Advance payments of the premium tax credit, advance payment of cost-sharing reductions and FFE user fee charges; (2) risk adjustment payments or charges for a benefit year, including an assessment of risk adjustment user fees; (3) reinsurance payments for a benefit year; (4) a risk adjustment default charge for a benefit year; (5) a reconciliation payment or charge for cost-sharing reductions for a benefit year; or (6) risk corridors payments or charges for a benefit year. For a dispute regarding advance payments of the premium tax credit, advance payments of cost-sharing reductions, or FFE user fee amounts for a benefit year, we proposed that a request for reconsideration be required to be filed within 30 calendar days after the issuer receives a final reconsideration notification specifying the aggregate amount of advance payments of the premium tax credit, advance payments of cost-sharing reductions, and FFE user fees for the

applicable benefit year. We sought comment on this proposal, including on the minimum materiality threshold that should be required for an issuer to seek reconsideration.

For a dispute regarding a risk adjustment payment or charge, including an assessment of risk adjustment user fees, a reinsurance payment, a default risk adjustment charge, a cost-sharing reduction reconciliation payment or charge, or a risk corridors payment or charge, we proposed that a request for reconsideration be filed within 30 calendar days of receipt of the applicable notification of payments and charges from HHS.

In proposed § 156.1220(a)(3)(i) (§ 156.1220(a)(4)(i) in this final rule), we proposed that the request for reconsideration specify the findings or issues that the issuer challenges, and the reasons for the challenge. In proposed § 156.1220(a)(3)(ii) (§ 156.1220(a)(4)(ii) in this final rule), we proposed that a reconsideration with respect to a processing error by HHS, HHS's incorrect application of the relevant methodology, or HHS's mathematical error be permitted to be requested only if, to the extent the issue could have been previously identified by the issuer to HHS under § 153.710(d)(2) or (e)(2), it was so identified and remains unresolved. Similarly, in proposed § 156.1220(a)(3)(iii) (§ 156.1220(a)(4)(iii) in this final rule), we proposed that a reconsideration with respect to advance payments of the premium tax credit, advance payments of cost-sharing reductions, and FFE user fees be permitted to be requested only if, to the extent the issue could have been previously identified by the issuer to HHS under § 156.1210, it was so identified and remains unresolved. We proposed that an issuer be permitted to request reconsideration if it previously identified an issue under § 156.1210 after the 15-calendar-day deadline, but that the issuer's late discovery of the issue was not due to misconduct on the part of the issuer.

In § 156.1220(a)(3)(iv) (§ 156.1220(a)(4)(iv) in this final rule), we proposed that the issuer be permitted to include in the request for reconsideration additional documentary evidence that HHS should consider. Such documents could not include data that was to have been filed by the applicable data submission deadline, but could include evidence of the timely submission of such documents.

In § 156.1220(a)(4) (§ 156.1220(a)(5) in this final rule), we proposed that in conducting the reconsideration, HHS would review the payment

determination, the evidence and findings upon which it was based, and any additional documentary evidence submitted by the issuer. HHS would also have the discretion to review any other evidence it believes is relevant in deciding the reconsideration (and would provide the issuer a reasonable opportunity to review and rebut the evidence), and would then inform the issuer of the final decision in writing. We proposed that an issuer would be required to prove its case by a preponderance of the evidence with respect to issues of fact.

In § 156.1220(a)(5) (§ 156.1220(a)(6) in this final rule), we proposed that a reconsideration decision would be final and binding for decisions regarding the advance payments of the premium tax credit, advance payments of cost-sharing reductions, and FFE user fees. A reconsideration with respect to other matters would be subject to the outcome of a request for informal hearing filed in accordance with proposed § 156.1220(b). We proposed in § 156.1220(b) that an issuer that elects to challenge the reconsideration decision for the final risk adjustment payment or charge, including an assessment of risk adjustment user fees; reinsurance payment; default risk adjustment charge; cost-sharing reduction reconciliation payment or charge; or risk corridors payment or charge for a benefit year provided under paragraph (a) of § 156.1220 would be entitled to an informal hearing before a CMS hearing officer. In § 156.1220(b)(1), we proposed that a request for an informal hearing be made in writing and filed with HHS within 15 calendar days of the date the issuer receives the reconsideration decision. In § 156.1220(b)(2), we proposed that the request for an informal hearing be required to include a copy of the reconsideration decision and specify the findings or issues in the decision that the issuer is challenging and its reasons for the challenge. We also proposed that HHS be permitted to submit for review by the CMS hearing officer a statement of the reasons supporting the reconsideration decision.

In § 156.1220(b)(3)(i), we proposed that the issuer would receive a written notice of the time and place of the informal hearing at least 15 calendar days before the scheduled date. In § 156.1220(b)(3)(ii), we proposed that the CMS hearing officer would neither receive testimony nor accept any new evidence that was not presented with the reconsideration request or in any statement provided by HHS. The scope of the CMS hearing officer's review would be limited to the statements provided by the issuer and HHS and the

⁵⁴ A processing error could result from HHS accessing the data submitted by the issuer on the dedicated distributed data environment in an incomplete or incorrect manner. We note that under proposed § 156.1220(a)(4)(i)-(ii), an issuer may not submit new data for consideration in an appeal if the data was not submitted prior to the applicable data submission deadline, but may submit documentary evidence to support a contention that data was timely submitted.

record that was before HHS in making the reconsideration determination. We would require that the issuer prove its case by clear and convincing evidence with respect to issues of fact and would permit the issuer to be represented by counsel in the informal hearing.

In § 156.1220(b)(4), we proposed that, following the informal hearing, the CMS hearing officer send the decision and the reasons for the decision to the issuer. We proposed that this decision be final and binding, but subject to any Administrator's review initiated in accordance with proposed § 156.1220(c).

We proposed in § 156.1220(c)(1) that if the CMS hearing officer upholds the reconsideration decision, the issuer be permitted to request a review by the Administrator of CMS within 15 calendar days of receipt of the CMS hearing officer's decision.⁵⁵ The request for a review by the Administrator of CMS would be required to specify the findings or issues in the decision that the issuer is challenging, and the reasons for the challenge. We proposed that HHS be permitted to submit for review by the Administrator of CMS a statement supporting the decision of the CMS hearing officer.

In § 156.1220(c)(2), we proposed that the Administrator of CMS or a delegate review the hearing officer's decision, any written documents submitted by HHS or the issuer, as well as any other information included in the record of the CMS hearing officer's decision, and determine whether to uphold, reverse, or modify the CMS hearing officer's decision. We proposed that the issuer be required to prove its case by clear and convincing evidence with respect to issues of fact. We proposed that the Administrator's determination be considered final and binding.

In response to comments, we are finalizing these provisions with the following modifications: We are extending the deadline to file a request for reconsideration to 60 calendar days instead of 30 calendar days, and the deadline for filing an informal hearing to 30 calendar days instead of 15 calendar days. We are also providing that these deadlines will run from the date of issuance of the notification and reconsideration decision, rather than the date an issuer receives the notification or reconsideration decision. Finally, we are providing that an issuer has 15 calendar days to request review by the

Administrator from the date of the CMS hearing officer decision, rather than from the date of receipt of the decision.

We are also providing for a minimum materiality threshold that an issuer must meet in order to request reconsideration for (1) advance payments of the premium tax credit, advance payments of cost-sharing reductions, or Federally-facilitated Exchange user fees (2) risk adjustment payment or charges (3) reinsurance payments (4) risk adjustment default charges (5) reconciliation payments or charges for cost-sharing reductions and (6) risk corridors payments or charges. That threshold is equal to the lesser of 1 percent of the applicable payment or charge listed in the prior enumerated categories payable to or due from the issuer for a benefit year, or \$10,000. For example, an issuer that received \$75,000 in advance payments of cost-sharing reductions would need to seek reconsideration of at least \$7,500 in those advance payments to meet the minimum materiality threshold, and an issuer that received \$800,000 in reinsurance payments would need to seek reconsideration of at least \$10,000 in reinsurance payments.

Comment: Several commenters supported the proposed administrative appeals process. Some commenters asked that HHS allow issuers to appeal reconsideration decisions regarding advance payments of the premium tax credit, cost-sharing reductions, and FFE user fees.

Response: Issuers can dispute advance payments of the premium tax credit, advance payments of cost-sharing reductions, and FFE user fees amount on a monthly basis through the discrepancy report process set forth in § 153.1210, prior to receiving the final reconsideration notice in the summer of the year following the applicable benefit year. Furthermore, the methodology for calculating these payments provides few factors on which a request for reconsideration may be made. Given these considerations, we believe that providing one level of administrative appeal for advance payments of the premium tax credit, advance payments of cost-sharing reductions, and FFE user fees will provide issuers ample opportunity to resolve any discrepancies.

Comment: Several commenters sought extensions in the proposed timeframe for filing an appeal. Commenters asked that issuers have 60 calendar days to file a request for reconsideration, rather than 30 calendar days. The commenters also asked that issuers have 30 calendar days, rather than 15 calendar days to file a request for an informal hearing.

Response: We appreciate the need for additional time to analyze final notifications, and are amending § 156.1220(a)(2) to allow issuers 60 calendar days to file a request for reconsideration and § 156.1220(b)(1) to allow issuers 30 calendar days to request an informal hearing before a CMS hearing officer. In order to reduce the scope for disputes on when notifications are received, we are also amending our proposed policies to clarify that these timeframes will begin at the date of issuance of the notification and reconsideration decision rather than the date an issuer receives the notification or reconsideration decision.

Comment: Several commenters supported a minimum materiality threshold that should be required to seek reconsideration. One commenter suggested a minimum threshold of 1 percent of total payments made to or charges assessed on the issuer for a benefit year, while other commenters supported a materiality threshold equal to the lesser of 1 percent of total payments made to or charges assessed on the issuer for a benefit year, or \$10,000.

Response: We are amending our proposed rule to set a minimum materiality threshold for an issuer to request reconsideration under § 156.1220(a)(1) for (1) advance payments of the premium tax credit, advance payments of cost-sharing reductions, or FFE user fees; (2) risk adjustment payment or charges; (3) reinsurance payments; (4) risk adjustment default charges; (5) reconciliation payments or charges for cost-sharing reductions; and (6) risk corridors payments or charges only if the amount in dispute is equal to or exceeds 1 percent of the applicable payment or charge payable to or due from the issuer for the benefit year, or \$10,000, whichever is less. We are adopting a per-category calculation rather than an overall calculation because we do not believe the threshold should be artificially low if the issuer happens to have balancing payments and charges across the various programs.

Comment: Commenters asked that HHS provide detailed guidance on how to reflect amounts subject to reconsiderations and appeals in MLR filings.

Response: We are finalizing § 153.710(g), which provides details on how amounts subject to administrative appeals process should be reported for the purposes of MLR and risk corridors. Issuers must report, for the purposes of risk corridors and MLR, the risk adjustment or reinsurance payment to

⁵⁵ Consistent with the Medicare Advantage risk adjustment data validation audit dispute and appeal processes set forth in 42 CFR 422.311, we intend to propose in future rulemaking that CMS may also request review by the Administrator of a CMS hearing officer's decision.

be made by the Federal government, or the risk adjustment charge assessed by the Federal government, as reflected in the June 30th report, regardless of the amount in dispute. A QHP issuer would be required to report a cost-sharing reduction amount equal to the amount of the advance payments of cost-sharing reductions paid to the issuer by HHS for the benefit year, as reflected in the HHS report on cost-sharing reduction reconciliation payments and charges. Additionally, if a QHP issuer requests reconsideration of risk corridors payments or charges, then for purposes of MLR reporting, the QHP issuer would be required to report the risk corridors payment to be made to the Federal government or charge assessed by the Federal government as reflected in the notification provided under § 153.510(d). As stated in § 153.710(g)(2), an issuer must report any adjustment made following any discrepancy report made under paragraphs (d)(2) or (e)(2), or any request for reconsideration under § 156.1220(a) with respect to any risk adjustment payment or charge, including an assessment of risk adjustment user fees, reinsurance payment, cost-sharing reconciliation payment or charge, or risk corridors payment or charge, or following any audit, where the adjustment has not been accounted for in a prior risk corridors or MLR report, in the next following risk corridors and MLR report.

IV. Provisions of the Final Regulations

For the most part, this final rule incorporates the provisions of the proposed rule. Those provisions of this final rule that differ from the proposed rule are as follows:

1. Part 144—Requirements Relating to Health Insurance Coverage

We are finalizing the amendment to the definition of “policy year” for student health insurance coverage with a minor revision to remove the word “individual” from the reference to “individual health insurance coverage.”

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

We are restructuring § 147.102(c)(3) as paragraphs (c)(3)(i) through (iii).

We are amending new § 147.102(c)(3)(ii) to provide that an issuer offering composite premiums is subject to the standards of new paragraph (c)(3)(iii), and to specify that the requirement that the total group premium must equal that the sum of per-member premiums is determined at

the time of applicable enrollment at the beginning of the plan year.

We are amending new § 147.102(c)(3)(iii) to provide that the standards in this paragraph apply in connection with a group health plan in the small group market.

We are amending new § 147.102(c)(3)(iii)(A) to clarify that composite premiums are calculated based on applicable enrollment of “participants and beneficiaries” at the beginning of the plan year, and deleting references to participants and beneficiaries elsewhere in this paragraph.

We are adding new § 147.102(c)(3)(iii)(B) to establish a two-tiered composite premium structure for small group market issuers that offer composite premiums. States may establish an alternate tiered-composite methodology with approval from HHS.

We are adding new § 147.102(c)(3)(iii)(C) to provide that an issuer cannot include any rating variation for tobacco use in a composite premium but instead must apply any applicable tobacco rating factor on a per-member basis, pursuant to applicable State law.

We are adding new § 147.102(c)(3)(iii)(D) to provide that issuers offering composite premiums with respect to a particular product offered in the small group market in a State must do so uniformly for all group health plans enrolling in that product, giving those group health plans the option to pay premiums based on a composite premium methodology, to the extent permitted by applicable State law and subject to § 156.285(c) of this final rule (prohibiting composite premiums in connection with employee choice in the FF-SHOPs).

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

a. Provisions and Parameters for the Permanent Risk Adjustment Program

We are amending § 153.630(b)(1) to provide that the issuer must attest that it has no conflicts of interest with the initial validation auditor to its knowledge, following reasonable investigation, and must attest that it has obtained an equivalent representation from the initial validation auditor.

We are amending § 153.630(b)(7)(i) to provide that an enrollee’s risk score must be validated by enrollment and demographic data review in a manner to be determined by HHS.

We are amending § 153.630(b)(7)(iv) to provide that, for the initial years of

risk adjustment data validation (the 2014 and 2015 benefit years), the senior reviewer may possess 3 or more years of experience.

We are amending § 153.630(b)(8) to provide that, for the initial years of risk adjustment data validation (the 2014 and 2015 benefit years), the initial validation auditor may meet an inter-rater reliability standard of 85 percent for validating review outcomes in accordance with the standards established by HHS.

b. Provisions and Parameters for the Transitional Reinsurance Program

We are amending the definition of “contributing entity” in § 153.20 to mean, for the 2015 and 2016 benefit years, a health insurance issuer and a self-insured group health plan (including a group health plan that is partially self-insured and partially insured, where the health insurance coverage does not constitute major medical coverage) that uses a TPA in connection with claims processing or adjudication (including the management of internal appeals) or plan enrollment for services other than for pharmacy benefits or excepted benefits within the meaning of section 2791(c) of the PHS Act. Notwithstanding the foregoing, a self-insured group health plan that uses an unrelated third party to obtain provider network and related claim repricing services, or uses an unrelated third party for up to 5 percent of claims processing or adjudication or plan enrollment for services other than for pharmacy or excepted benefits, will not be deemed to use a TPA, based on either the number of transactions processed by the third party, or the volume of the claims processing and adjudication and plan enrollment services provided by the third party.

We are amending the definition of “major medical coverage” in § 153.20 to include any catastrophic plan, or individual or small group market coverage subject to actuarial value requirements under § 156.140.

We are not finalizing our proposal to delete and reserve § 153.235(b).

c. Provisions for the Temporary Risk Corridors Program

We are adding a definition of “adjustment percentage” to § 153.500, and are amending the definitions of “profits” and “allowable administrative costs” in § 153.500 to account for the adjusted amount.

We are adding a definition of “transitional State” to § 153.500.

We are making a conforming change to § 153.530(d) to clarify that the July 31 submission deadline for risk corridors

data does not apply to the enrollment data specified in § 153.530(e).

We are adding paragraph (e) to § 153.530 to require health insurance issuers in the individual and small group markets to submit enrollment data for the risk corridors adjustment.

We are not finalizing our proposal in § 153.540 to establish our authority to assess CMPs for failure of an issuer to comply with applicable risk corridors rules.

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

a. Annual Open Enrollment Period for 2015

For consistency within this section, we are modifying § 155.410(f)(1) to refer to “QHPs” instead of “plans,” we are amending § 155.410(f)(1)(ii) to correct a typographical error referring to December 16, 2015 instead of 2014, we are amending § 155.410(e)(1) to change the close of the open enrollment period for 2015 to February 15, 2015, and we are amending § 155.410(f)(1)(iii) to provide for the applicable coverage effective dates for enrollments between January 16 and 31, 2015. We are not finalizing § 155.410(e)(2) or § 155.410(f)(2), as proposed.

b. Functions of a Small Business Health Options Program

We are modifying § 155.705(b)(3)(v)(B), which now allows an employer to choose to make available all stand-alone dental plans offered through an FF–SHOP at a level of coverage as described in § 156.150(b)(2).

We are finalizing amendments to § 155.705(b)(6) that were originally proposed in the Program Integrity proposed rule. We are finalizing language proposed at § 155.705(b)(6)(ii) at § 155.705(b)(6)(i)(A) instead of at (b)(6)(ii), to make clear that we never intended for this proposal to supersede the language at current § 155.705(b)(6)(ii), and are making a minor change to replace the word FF–SHOP with the term “Federally-facilitated SHOP.”

We added a heading to § 155.220(i).

We are not finalizing the proposed amendment to § 155.705(b)(11)(ii)(D).

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

a. Provisions Related to Cost Sharing

We clarify in § 156.420(d) that the out-of-pocket spending required of enrollees in the zero cost sharing plan variation of a QHP for a benefit that is

not an essential health benefit from a provider (including a provider outside the plan’s network) may not exceed the corresponding out-of-pocket spending required in the limited cost sharing plan variation of the QHP and the corresponding out-of-pocket spending required in the silver plan variation of the QHP for individuals eligible for cost-sharing reductions under § 155.305(g)(2)(i), in the case of a silver QHP.

b. National Annual Limit on Cost Sharing for Stand-Alone Dental Plans in an Exchange

We are finalizing the annual limit on cost sharing with an increase compared to the proposed levels, to apply to SADPs certified by all Exchanges nationally.

We are not finalizing our proposal to delete the actuarial value requirement at § 156.150(b).

c. Additional Standards Specific to SHOP

We have modified § 156.285(a)(4)(i) to add the words “being sold through the SHOP” to provide clarity to the regulation text finalized at § 156.285(a)(4)(i).

We have modified § 156.285(a)(4)(ii) to provide that the policy expressed in that provision also applies to SADPs in the Federally-facilitated SHOP, if the employer elects to offer coverage to its employees under § 155.705(b)(3)(v)(B) as finalized in this rule.

d. Meaningful Difference Standard for Qualified Health Plans in the FFEs

We have modified § 156.298(b) to have the standard set at one material difference rather than two and have removed premiums as one of the characteristics among which plans must be different.

We are not finalizing the text proposed at § 156.298(b)(5) and are therefore renumbering the provisions proposed at § 156.298(b)(1) through (b)(7) as § 156.298(b)(1) through (b)(6) in this final rule.

e. Quality Standards: Establishment of Patient Safety Standards for QHPs Issuers

We are modifying the documentation standard in § 156.1110(b) to remove the reference to information other than the CCN to indicate that only the CCN is required to be collected.

f. Financial Programs

We are extending the deadline for an issuer to request reconsideration from 30 to 60 calendar days in § 156.1220(a)(3).

We are extending the deadline for an issuer to request an informal hearing before a CMS hearing officer from 15 calendar days to 30 calendar days in § 156.1220(b)(1).

We are modifying in § 156.1220(a)(3), § 156.1220(b)(1) and § 156.1220(c)(1) the date from which certain appeals-related deadlines will run so that the deadlines will run from the date of issuance of the notification, reconsideration decision, or CMS hearing officer decision, rather than the date an issuer receives the notification or decision.

We are establishing a minimum materiality threshold that an issuer must meet in order to request reconsideration for (1) advance payments of the premium tax credit, advance payments of cost-sharing reductions, or Federally-facilitated Exchange user fees (2) risk adjustment payment or charges (3) reinsurance payments (4) risk adjustment default charges (5) reconciliation payments or charges for cost-sharing reductions and (6) risk corridors payments or charges in § 156.1220(a)(2). That threshold is equal to the lesser of 1 percent of the applicable payment or charge listed in the prior enumerated categories payable to or due from the issuer for a benefit year, or \$10,000.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. This final rule contains information collection requirements (ICRs) that are subject to review by OMB. A description of these provisions is given in the following paragraphs with an estimate of the annual burden, summarized in Table 7. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

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

We generally used data from the Bureau of Labor Statistics to derive average labor costs (including capital

costs, overhead, and fringe benefits) for estimating the burden associated with the ICRs.

A. ICRs Related to HHS Audits of State-Operated Reinsurance Programs (§ 153.270)

Under § 153.270, HHS or its designee may conduct a financial and programmatic audit of a State-operated reinsurance program to assess compliance with reinsurance program requirements. Under this provision, if an audit results in a finding of material weakness or significant deficiency, a State must ensure that the applicable reinsurance entity provides a written corrective action plan to HHS for approval within 60 calendar days of the issuance of the final audit report. The burden associated with meeting this third party disclosure requirement includes the burden for a State that establishes a reinsurance program to ensure that its applicable reinsurance entity and any relevant contractors, subcontractors, or agents cooperate with and take appropriate actions in connection with any audit, and the burden associated with preparing and submitting a corrective action plan to HHS for approval. Because only one State will operate reinsurance in the 2014 benefit year, this collection is exempt from the PRA under 44 U.S.C. 3502(3)(A)(i), and we will not seek approval from OMB for this information collection requirement. We discuss the impact associated with HHS audits of State-operated reinsurance programs in the Regulatory Impact Analysis section of this final rule.

B. ICRs Regarding Issuer and Entity Administrative Burden Related to Audits for the Premium Stabilization Programs (§ 153.405(i); § 153.540(a); § 153.410(d); § 153.620(c))

This final rule provides HHS or its designee with the authority to audit QHP issuers, contributing entities, and issuers of risk adjustment covered plans or reinsurance-eligible plans to assess compliance with the requirements of subparts E, F, G and H of part 153, as applicable. As mentioned earlier in this rule, where possible, we intend to align the risk corridors audit process with the audits conducted for the MLR program. Therefore, we believe that the issuer burden associated with the risk corridors audit is already accounted for as part of the Supporting Statement for the MLR program approved under OMB control number 0938–1164.

These provisions will require a third-party disclosure requirement of issuers of risk adjustment covered plans and issuers of reinsurance-eligible plans to

prepare and compile the financial and programmatic information necessary to comply with the audit. In the proposed rule, we estimated that it would take a total of approximately 60 hours of preparation time for each onsite review and an additional 30 hours of onsite time for each issuer, at an hourly labor cost of \$53.75 and a total cost of approximately \$4,838 for each issuer. Because we have not finalized our audit protocols, it is difficult to accurately estimate an audit rate. However, we believe that it is reasonable to assume that approximately 120 issuers, representing roughly 5 percent of issuers of risk adjustment covered plans or reinsurance-eligible plans, would be audited. Therefore, we estimated an aggregate burden of 10,800 hours and \$580,500 for issuers as a result of this requirement.

For contributing entities, we estimated that the disclosure burden would be substantially less because the audit would be simpler. We estimated the burden to be approximately one-quarter of that of an issuer of a risk adjustment covered plan or a reinsurance-eligible plan, or approximately 22.5 hours (at an hourly rate of \$53.75) at a cost of approximately \$1,209 for each contributing entity. We estimated that approximately 1 percent of contributing entities would be audited, representing 226 contributing entities. Therefore, we estimated an aggregate burden of 5,085 hours, or \$273,319, as a result of this requirement.

Comment: One commenter stated that HHS's burden estimates were unreasonable. In particular, the commenter believed that the initial meeting by issuers of risk adjustment covered plans and reinsurance-eligible plans with auditors would involve more personnel and labor hours.

Response: In response to this comment, we are revising our estimate for the onsite review portion of the audit to reflect the labor costs associated with additional personnel who would generally be expected to be involved in meetings and reviews. The new burden estimate includes 2 hours to schedule the onsite activities with the compliance reviewer (at an hourly labor cost of \$53.75), 32 hours for an introductory meeting involving 8 managers, 12 hours for three managers to tour with reviewers onsite, 15 hours of interview time with three managers, 8 hours to walk through processes with the reviewer, and 16 hours for concluding meetings, resulting in a total of 85 hours of onsite time for each issuer. Therefore, we estimate it will take 60 hours of preparation time and an additional 85 hours of onsite time for each issuer. We

now estimate it will require a total of 145 hours at a cost of approximately \$7,794 for each issuer to make information available to HHS for an onsite review. For approximately 120 issuers, representing roughly 5 percent of issuers of risk adjustment covered plans or reinsurance-eligible plans that might be audited in a year, we now estimate an aggregate burden of 17,400 hours and \$935,280 for issuers as a result of this requirement.

For contributing entities, we now estimate the burden to be approximately 37 hours at a cost of approximately \$1,989 for each contributing entity, or about one quarter of that of an issuer of a risk adjustment covered plan or a reinsurance-eligible plan. We estimate that approximately 1 percent of contributing entities will be audited, representing 226 contributing entities. Therefore, we now estimate an aggregate burden of 8,362 hours, or \$449,514 for contributing entities as a result of this requirement.

We will revise the information collection currently approved under OMB Control Number 0938–1155 with an October 31, 2015 expiration date to account for this additional burden.

C. ICRs Regarding Potential Adjustments for Transitional Plans (§ 153.500–§ 153.540)

We will make adjustments to the premium stabilization programs to help mitigate any unexpected losses for QHP issuers with plans that are affected by the transitional policy described in the preamble of this rule. To effectuate potential adjustments, we must estimate the State-specific effect on average claims costs. We thus will require all issuers participating in the individual and small group markets in a State to submit to HHS a member-month enrollment count for transitional plans and non-transitional plans in the individual and small group markets. This submission will occur in 2015 prior to the risk corridors July 31, 2015 data submission deadline. HHS will analyze that enrollment data, and publish the State-specific adjustments that issuers would use in the risk corridors calculations for the 2014 benefit year. To reduce the burden on issuers, we are considering coordinating this data collection with other data collections for the premium stabilization programs.

We estimate that there will be approximately 2,400 issuers in the individual and small group markets in the 2014 benefit year, and that it will take an insurance analyst approximately 30 minutes (at an hourly labor cost of \$38.49) to estimate enrollment in

transitional plans and non-transitional plans and submit this information to HHS. Therefore, we estimate a cost of approximately \$19.25 for each issuer, and an aggregate cost of \$46,200 for all individual and small group market issuers (though this cost may be lower depending upon the data collection method we adopt). Because we anticipate collecting this information in early 2015, and because we expect to issue additional clarifying guidance on this policy, we will seek OMB approval and solicit public comment on this data collection requirement at a future date.

D. ICRs Regarding Risk Corridors Data Validation (§ 153.530 and § 153.540)

For the 2014 benefit year, we will collect risk corridors data using the same form as is used for MLR data collection, at the same time (July 31st of the year following the applicable benefit year). We intend to modify the MLR collection form for benefit year 2015, approved under OMB control number 0938–1164, to add reporting elements (for example, QHP-specific premium amounts) that are required under the risk corridors data submission requirements at § 153.530. We intend to include these data elements in an amendment to the information collection approved under OMB control number 0938–1164 for MLR data submission that we will publish for public comment and advance for OMB approval in the future.

Because the MLR and risk corridors programs will require similar data, we estimate that submitting the data elements required for the risk corridors program will impose limited additional burden on issuers. We estimate that it will take each QHP issuer approximately 1.5 hours, representing 1 hour for an insurance analyst (at an hourly labor cost of \$38.49) and 30 minutes for a senior manager (at an hourly labor cost of \$77), to input and review data that is specific to the risk corridors program in the MLR and risk corridors reporting form for benefit year 2015. In the proposed ICR, we estimated that 1,200 QHP issuers would submit risk corridors data for the 2014 benefit year in the 2015 risk corridors and MLR reporting cycle. We are revising that estimate to reflect our most recent estimate of the number of QHP issuers that have registered in our Health Insurance Oversight System (HIOS) for the 2014 benefit year, and now estimate that approximately 475 QHP issuers will submit data. Therefore, we now estimate an aggregate burden of 712.5 hours (at a total cost of approximately \$36,573) for QHP issuers as a result of this requirement. We will revise the

information collection currently approved under OMB Control Number 0938–1155 with an October 31, 2015 expiration date to account for this additional burden.

E. ICRs Regarding Data Validation Requirements When HHS Operates Risk Adjustment (§ 153.630)

Pursuant to § 153.630(b)(1) of this final rule, an issuer of a risk adjustment covered plan must engage one or more independent auditors to perform an initial validation audit of a sample of its risk adjustment data selected by HHS. This provision also requires the issuer to provide HHS with the identity of the initial validation auditor, and attest to the absence of conflicts of interest between the initial validation auditor (or the members of its audit team, owners, directors, officers, or employees) and the issuer (or its owners, directors, officers, or employees), in a timeframe and manner to be specified by HHS. We previously estimated the cost to issuers to conduct an initial validation audit in the 2014 Payment Notice and the associated information collection request approved under OMB Control Number 0938–1155 with an October 1, 2015 expiration date. Therefore, the burden associated with this reporting requirement is the time and effort necessary to report the auditor's identity to HHS. We estimate it will take an insurance operations analyst (at an hourly labor cost of \$38.49) and a senior manager (at an hourly labor cost of \$77) each approximately 15 minutes to prepare and send an electronic report to HHS. Therefore, for 2,400 risk adjustment covered issuers in the individual and small group markets, the aggregate burden associated with this requirement is 1,200 hours, at an approximate cost of \$69,300.

In § 153.630(b)(8), we require the initial validation auditor to measure and report to the issuer and HHS, in a manner and timeframe specified by HHS, the inter-rater reliability rates among its reviewers. Also in this provision, we require that the initial validation auditor achieve a minimum consistency measure of 95 percent for demographic, enrollment, and health status review outcomes (85 percent for 2014 and 2015). We believe establishing standards for inter-rater reliability among reviewers is standard practice in the industry and will not result in extra cost for the initial validation auditor. Therefore, the burden associated with this reporting requirement is the time and effort for the initial validation auditor to report the inter-rater reliability rate to the issuer and to HHS.

We estimate it will take an insurance operations analyst (at an hourly labor cost of \$38.49) and a senior manager (at an hourly labor cost of \$77) each approximately 15 minutes to report the inter-rater reliability rate to the issuer and to HHS. Therefore, assuming that 2,400 issuers of risk adjustment covered plans each engage one independent auditor to perform the initial validation audit, the aggregate burden associated with this requirement is 1,200 hours, at an approximate cost of \$69,300. We will revise the information collection currently approved under OMB Control Number 0938–1155 with an October 31, 2015 expiration date to account for this additional burden.

F. ICRs Regarding Quarterly Data Submissions (§ 153.700(a))

Section 153.700 provides that issuers of a risk adjustment covered plan or a reinsurance-eligible plan must establish a dedicated distributed data environment and provide data access to HHS, in a manner and timeframe specified by HHS, for any HHS-operated risk adjustment and reinsurance program. In this final rule, we clarify this timeframe, requiring that an issuer must make good faith efforts to make complete, current enrollment and claims files accessible through its dedicated distributed data environments no less frequently than quarterly, once the issuer's dedicated distributed data environment is established.

Based on HHS's most recent estimate of fully insured issuers in the individual and small group markets, we estimate that 2,400 issuers will be subject to the requirement to establish a dedicated data environment to either receive reinsurance payments or make risk adjustment transfers. Although in this rule we clarify that issuers must make this data available to HHS on a quarterly basis, the information collection and the aggregate burden associated with this requirement is already accounted for under the Premium Stabilization Rule Supporting Statement that is approved under OMB control number 0938–1155 with an October 31, 2015 expiration date. We will revise that supporting statement to specify that issuers must comply with this information collection requirement on a quarterly basis.

G. ICRs Related to Confirmation of Dedicated Distributed Data Environment Reports (§ 153.700(d) and (e))

Under § 153.710(d) of this final rule, we require that within 30 calendar days of the date of an interim dedicated distributed data environment report from HHS, an issuer of a reinsurance-

eligible or risk adjustment covered plan must either confirm to HHS that the information in the interim reports for the risk adjustment and reinsurance programs accurately reflects the data to which the issuer has provided access to HHS through its dedicated distributed data environment in accordance with § 153.700(a) for the timeframe specified in the report, or describe to HHS any inaccuracy it identifies in the interim report. Similar to the interim report process, in § 153.710(e), we require that the issuer either confirm to HHS that the information in the final dedicated distributed data environment report accurately reflects the data to which the issuer has provided access to HHS through its dedicated distributed data environment in accordance with § 153.700(a) for the benefit year specified in the report, or describe to HHS any inaccuracy it identifies in the final dedicated distributed data environment report within 15 calendar days of the date of the report.

We estimate that 2,400 issuers of risk adjustment covered plans and reinsurance-eligible plans will be subject to this requirement, and that issuers will compare enrollee condition codes with risk scores and analyze claims costs to confirm information in the interim and final dedicated distributed data environment reports. On average, we estimate that it will take an insurance operations analyst (at an hourly labor cost of \$38.49) approximately 2 hours to respond to an interim report and 6 hours to respond to the final dedicated distributed data environment report. Therefore, we estimate an aggregate burden of 19,200 hours and \$739,008 for 2,400 issuers as a result of this requirement. We will revise the information collection currently approved under OMB Control Number 0938–1155 with an October 31, 2015 expiration date to account for this additional burden.

H. ICRs Regarding Privacy and Security of Personally Identifiable Information (§ 155.260(a))

In § 155.260(a), we state that an Exchange, at its option, may submit to the Secretary a request for approval of a proposed use or disclosure of eligibility and enrollment PII. The Exchange submitting such a request would describe the nature of the proposed use or disclosure and how it would ensure the efficient operation of the Exchange consistent with section 1411(g)(2)(A) of the Affordable Care Act, and describe the efficiency. The requesting Exchange also would describe how the information to be used or disclosed would be protected in

compliance with the privacy and security standards established by the Exchange and describe those protections. While this reporting requirement is subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.3(h)(1). This reporting is not intended as a substitute for a collection of information of, or to monitor, compliance with regulatory standards. Therefore, we are not seeking approval from OMB for these information collection requirements.

I. ICRs Regarding Advance Payments of Cost-Sharing Reductions (§§ 155.1030, 156.430, 156.470)

Based on our experience implementing the process for calculating advance payments of cost-sharing reductions for the 2014 benefit year, we are modifying §§ 155.1030, 156.430, and 156.470. However, because our previous methodology used data collected through vehicles that are used for other purposes, we expect these changes to only marginally reduce the reporting burden for issuers and Exchanges. Therefore, we will not be revising the burden estimates in the corresponding PRA packages at this time.

J. ICRs Regarding Quality Standards: Establishment of Patient Safety Standards for QHP Issuers (§ 156.1110)

In § 156.1110, we describe the information collection, recordkeeping, and disclosure requirements that a QHP issuer must meet to demonstrate compliance with the patient safety standards finalized in this rule. The burden estimate associated with these standards includes the time and effort required for QHPs to maintain and submit hospital CMS Certification Numbers to the Exchange, upon request, that demonstrates that each of its contracted hospitals with greater than 50 beds meets the patient safety standards required in § 156.1110(a). In the near future, HHS intends to publish a rule proposing more specific quality standards for Exchanges and QHPs and will solicit public comment. At that time and per requirements outlined in the PRA, we intend to estimate the burden on QHPs to comply with the patient safety provisions of § 156.1110.

K. ICRs Regarding Administrative Appeals (§ 156.1220)

In § 156.1220, we establish an administrative appeals process to address unresolved discrepancies for advance payment of the premium tax credit, advance payment and reconciliation of cost-sharing reductions, FFE user fees, and the

premium stabilization programs, as well as any assessment of a default risk adjustment charge under § 153.740(b).

In § 156.1220(a) as finalized in this rule, an issuer may file a request for reconsideration to contest a processing error by HHS, HHS's incorrect application of the relevant methodology, or HHS's mathematical error for the amount of: (1) Advance payment of the premium tax credit, advance payment of cost-sharing reductions or an FFE user fee charge for a particular month; (2) risk adjustment payments or charges for a benefit year, including an assessment of risk adjustment user fees; (3) reinsurance payments for a benefit year; (4) a risk adjustment default charge for a benefit year; (5) a reconciliation payment or charge for cost-sharing reductions for a benefit year; or (6) risk corridors payments or charges for a benefit year. While the hours involved in a request for reconsideration may vary, for purposes of this burden estimate we estimate that it will take an insurance operations analyst 1 hour (at an hourly labor cost of \$38.49) to make the comparison and submit a request for reconsideration to HHS. We estimate that 24 issuers, representing approximately 1 percent of all issuers that may be eligible for reinsurance payments, risk adjustment payments or charges (including any assessment of risk adjustment user fees or a default risk adjustment charge), advance payment and reconciliation of cost-sharing reductions, advance payment of the premium tax credit, and FFE user fees, will submit a request for reconsideration, resulting in a total aggregate burden of approximately \$924. We will revise the information collection currently approved OMB Control Number 0938–1155 with an October 31, 2015 expiration date to account for this additional burden.

In § 156.1220(b) of this final rule, an issuer that is dissatisfied with the reconsideration decision regarding: (1) Risk adjustment payments and charges, including an assessment of risk adjustment user fees; (2) reinsurance payments; (3) default risk adjustment charge; (4) reconciled cost-sharing reduction amounts; or (5) risk corridors payments or charges, provided under paragraph (a) of § 156.1220, is entitled to an informal hearing before a CMS hearing officer, if a request is made in writing within 30 calendar days of the date of the reconsideration decision. Further review is available from the Administrator of CMS. However, we believe these processes will occur extremely infrequently. Since collections from fewer than 10 entities are exempt from the PRA under 44

U.S.C. 3502(3)(A)(i), we will not seek PRA approval for this information collection requirement.

TABLE 7—ANNUAL REPORTING, RECORDKEEPING AND DISCLOSURE BURDEN

Regulation section(s)	Number of respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting (\$)	Total labor cost of reporting (\$)	Total capital/maintenance costs (\$)	Total cost (\$)
§ 153.405	226	226	37.00	8,362	53.75	449,514	0	449,514
§ 153.410; § 153.620	120	120	145.00	17,400	53.75	935,280	0	935,280
§ 153.500 – § 153.540	2,400	2,400	0.50	1,200	38.49	46,200	0	46,200
§ 153.540	475	475	1.50	712.5	51.33	36,573	0	36,573
§ 153.630(b)(1)	2,400	2,400	0.50	1,200	57.75	69,300	0	69,300
§ 153.630(b)(8)	2,400	2,400	0.50	1,200	57.75	69,300	0	69,300
(§ 153.700(d) and (e))	2,400	2,400	8.00	19,200	38.49	739,008	0	739,008
§ 156.1220	24	24	1.00	24	38.49	924	0	924
Total	^a3,245	2,346,099	0	2,346,099

^a ICRs associated with § 153.500, § 153.630(b)(1), § 153.630(b)(8) and § 153.700(d) and (e) apply to the same respondents, so the total number of unique respondents is 3,970.

We have submitted an information collection request to OMB for review and approval of the ICRs contained in this final rule. The requirements are not effective until approved by OMB and assigned a valid OMB control number.

To obtain copies of the supporting statement and any related forms for the paperwork collections referenced above, access CMS's Web site at <http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html> or email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office at 410-786-1326.

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

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or
2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, CMS-9972-F. Fax: (202) 395-5806; or Email: OIRA_submission@omb.eop.gov.

VI. Regulatory Impact Analysis

A. Statement of Need

This final rule provides standards related to the premium stabilization programs (risk adjustment, reinsurance, and risk corridors) that will protect issuers from the potential effects of adverse selection and protect consumers from increases in premiums due to issuer uncertainty. The Premium Stabilization Rule and the 2014 Payment Notice provided detail on the implementation of these programs, including the specific parameters applicable to these programs. This final

rule provides additional standards with respect to composite premiums, privacy and security of personally identifiable information, the open enrollment period for 2015, the AV Calculator, the annual limitation on cost sharing for stand-alone dental plans, the meaningful difference standard for QHPs offered through an FFE, patient safety standards for issuers of QHPs, the Small Business Health Options Program, cost-sharing parameters, cost-sharing reductions, and FFE user fees.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects (\$100 million or more in any one year).

OMB has determined that this rule is “economically significant” within the meaning of section 3(f)(1) of Executive Order 12866, because it is likely to have an annual effect of \$100 million in any one year. Accordingly, we have prepared an RIA that presents the costs and benefits of this final rule.

Although it is difficult to discuss the wide-ranging effects of these provisions in isolation, the overarching goal of the premium stabilization programs and Exchange-related provisions and policies of the Affordable Care Act is to make affordable health insurance available to individuals who do not have access to affordable employer-sponsored coverage. The provisions within this final rule are integral to the goal of expanding access to affordable coverage. For example, the premium stabilization programs decrease the risk of financial loss that health insurance issuers might otherwise expect in 2015 and the advance payments of the premium tax credit and cost-sharing reduction programs assist low- and moderate-income consumers and Indians in purchasing health insurance. The combined impacts of these provisions affect the private sector, issuers, and consumers, through increased access to health care services, including preventive services, decreased uncompensated care, lower premiums, establishment of patient safety standards, and increased plan transparency. Through the reduction in financial uncertainty for issuers and increased affordability for consumers, these provisions are expected to increase access to health coverage.

In this RIA, we discuss the requirements in this final rule related to cost sharing and FFE user fees, as well as new oversight provisions for the premium stabilization programs. We also discuss the impact of the

transitional policy discussed earlier on the risk corridors and reinsurance programs, and the impact on reinsurance contributions of the change in the definition of contributing entities.

Comment: Several commenters stated that the proposed regulatory impact statement lacked an adequate economic analysis. In particular, the commenters criticized listing only \$2 million in annual costs and \$14 million in transfer payments for a rule determined by OMB to involve costs of \$100 million or more annually. One commenter said HHS should have included its internal analysis of the effect of regulation on enrollment and premium in this impact statement, and the omission of this analysis appeared to be a willful attempt to withhold information from the public. The commenter asked HHS to spell out how the rule affects premium costs, employer costs, and taxpayer subsidies.

Response: We previously estimated the annualized impact on issuers, contributing entities, and States of transfers and other programs in the Premium Stabilization Rule and in the 2014 Payment Notice. Therefore, to avoid double-counting, Table 8 contains only incremental changes incurred as a result of provisions in this rule. The results of HHS's internal analyses were used to set reinsurance rates discussed in the 2014 Payment Notice, and again in this rule, where we estimate that, in 2015, reinsurance payments from the Federal government to individual market issuers will result in premium decreases in the individual market of between 5 and 6 percent relative to expected premiums without reinsurance. As detailed below, for this analysis, we continue to believe that the best available estimates of the impact of the Affordable Care Act on the Federal budget, enrollment in health insurance programs, and revenue collection are by the Congressional Budget Office. The CBO's most recent updates are available

at <http://www.cbo.gov/sites/default/files/cbofiles/attachments/43900-2014-02-ACATables.pdf>.

In our proposed rule, we noted that we were preparing an RIA because, while we were uncertain of the exact magnitude of the effect of the proposed adjustments to the risk corridors and reinsurance programs as a result of the transitional policy, we believed that the impact of the proposed adjustments and the impact of the other provisions in the proposed rule would reach the level of economic significance defined by OMB. In this final rule, we are finalizing our adjustment to the risk corridors program as proposed, and are lowering the reinsurance attachment point. Although it is difficult to estimate the exact impact of these policies, we describe our preliminary analysis of their monetary effect on health insurance issuers and the Federal government below.

Comment: A commenter criticized the regulatory analysis for failing to analyze and directly address the impact of the proposed rule's provision to exclude certain self-administered, self-insured group health plans from payment of reinsurance contributions, and requested that HHS disclose the number of participants and types of plans excluded and the per participant charge. Another commenter estimated the change would affect 14 million covered lives and increase the per capita contribution from remaining entities by \$3.

Response: It is difficult to estimate the number of self-insured, self-administered group health plans that might be excluded from reinsurance contributions as a result of the provision in this rule. While we solicited information on the number of such organizations, we did not receive comments with quantitative detail. Therefore, we have not changed our proposed estimate.

C. Impact Estimates of the Payment Notice Provisions and Accounting Table

In accordance with OMB Circular A-4, Table 8 depicts an accounting statement summarizing HHS's assessment of the benefits, costs, and transfers associated with this regulatory action.

This final rule implements standards for programs that will have numerous effects, including providing consumers with affordable health insurance coverage, reducing the impact of adverse selection, and stabilizing premiums in the individual and small group health insurance markets and in an Exchange. We are unable to quantify certain benefits of this final rule—such as increased patient safety and improved health and longevity due to increased insurance enrollment, and certain costs—such as the cost of providing additional medical services to newly-enrolled individuals. The effects in Table 8 reflect qualitative impacts and estimated direct monetary costs and transfers resulting from the provisions of this final rule for contributing entities, States, Exchanges, and health insurance issuers. The annualized monetized costs described in Table 8 reflect direct administrative costs (including costs associated with labor, capital, overhead, and fringe benefits) to States and health insurance issuers as a result of the provisions in this rule, and include administrative costs estimated in the Collection of Information section. We note that the estimated transfers in Table 8 do not reflect any user fees paid by insurance issuers for FFEs because we cannot estimate those fee totals. We also note that, while the 2015 reinsurance contribution rate is lower than the 2014 reinsurance contribution rate, total reinsurance administrative expenses will increase from 2014 to 2015.

TABLE 8—ACCOUNTING TABLE

Benefits:

Qualitative:

- * Increased enrollment in the individual market leading to improved access to health care for the previously uninsured, especially individuals with medical conditions, which will result in improved health and protection from the risk of catastrophic medical expenditures.
- * A common marketing standard covering the entire insurance market, reducing adverse selection and increasing competition.
- * Robust oversight of programs that use Federal funds to ensure proper use of taxpayer dollars.
- * Access to higher quality health care through the establishment of patient safety standards.
- * Increasing coverage options for small employers and part-time employees while mitigating the effect of adverse selection.

Costs:

	Estimate	Year dollar	Discount rate	Period covered
Annualized Monetized (\$/year)	2.35 million	2014	7 percent	2014–2017
	2.35 million	2014	3 percent	2014–2017

Quantitative:

- * Costs incurred by issuers and contributing entities to comply with provisions in this rule.
- * Costs incurred by States for complying with audits of State-operated reinsurance programs.

Transfers:

	Estimate	Year dollar	Discount rate	Period covered
Annualized Monetized (\$/year)	– 17.25 million	2014	7 percent	2014–2017
	– 16.76 million	2014	3 percent	2014–2017

- * Transfers reflect incremental cost increases from 2014–2015 for reinsurance administrative expenses and the risk adjustment user fee, which are transfers from contributing entities and health insurance issuers to the Federal government.
- * Unquantified: Lower premium rates in the individual market due to the improved risk profile of the insured, competition, and pooling.

This RIA expands upon the impact analyses of previous rules and utilizes the CBO analysis of the Affordable Care Act’s impact on Federal spending, revenue collection, and insurance enrollment. The CBO’s estimates remain the most comprehensive for provisions pertaining to the Affordable Care Act, and include Federal budget impact estimates for provisions that HHS has not independently estimated. The CBO’s February 2014 baseline projections estimated that 25 million enrollees will enroll in Exchange coverage by 2018, including approximately 20 million Exchange enrollees who will be receiving premium tax credits or cost-sharing reductions.⁵⁶ CBO forecasts that 92 percent of non-elderly Americans will receive coverage by 2017. Participation rates among potential enrollees are expected to be lower in the first few years of Exchange availability

as employers and individuals adjust to the features of the Exchanges. Table 9 summarizes the effects of the risk adjustment and reinsurance programs on the Federal budget for fiscal years 2014 through 2017, with the additional, societal effects of this final rule discussed in this RIA. We do not expect the provisions of this final rule to significantly alter CBO’s estimates of the budget impact of the risk adjustment and reinsurance programs. CBO updated scoring for the Premium Stabilization programs and found all three programs will reduce the deficit by \$8 billion over the budget window. For risk corridors, CBO now estimates the Federal government will pay \$8 billion to issuers from FYs 2015–2017, but that collections for this program will total \$16 billion, for a net yield of \$8 billion to the Federal government. We note that transfers associated with the risk

adjustment and reinsurance programs were previously estimated in the Premium Stabilization Rule; therefore, to avoid double-counting, we do not include them in the accounting statement for this final rule (Table 8).

In addition to utilizing CBO projections, HHS conducted an internal analysis of the effects of its regulations on enrollment and premiums. Based on these internal analyses, we anticipate that the quantitative effects of the provisions in this rule are consistent with our previous estimates in the 2014 Payment Notice for the impacts associated with the cost-sharing reduction program, the advance payments of the premium tax credit program, the premium stabilization programs, and FFE user fee requirements for health insurance issuers.

⁵⁶ “Updated Estimates for the Insurance Coverage Provisions of the Affordable Care Act,” Congressional Budget Office, February 2014.

TABLE 9—ESTIMATED FEDERAL GOVERNMENT OUTLAYS AND RECEIPTS FOR THE RISK ADJUSTMENT AND REINSURANCE PROGRAMS FROM FY 2013–2017

[In billions of dollars]

Year	2014	2015	2016	2017	2013–2017
Risk Adjustment, Reinsurance, and Risk Corridors Program Payments	0	20	19	23	62
Risk Adjustment, Reinsurance, and Risk Corridors Program Collections	0	21	21	27	69

Source: Congressional Budget Office. 2014. *Appendix B: Updated Estimates of the Insurance Coverage Provisions of the Affordable Care Act*. February 4, 2014.

Risk Adjustment

The risk adjustment program is a permanent program created by the Affordable Care Act that transfers funds from lower risk, non-grandfathered plans to higher risk, non-grandfathered plans in the individual and small group markets, inside and outside the Exchanges. In subparts D and G of the Premium Stabilization Rule (45 CFR part 153) and in the 2014 Payment Notice, we established standards for the administration of the risk adjustment program.

A State approved or conditionally approved by the Secretary to operate an Exchange may establish a risk adjustment program, or have HHS do so on its behalf. As described in the 2014 Payment Notice, if HHS operates risk adjustment on behalf of a State, it will fund its risk adjustment program operations by assessing a risk adjustment user fee on issuers of risk adjustment covered plans. For the 2015 benefit year, we estimate that the total cost for HHS to operate the risk adjustment program on behalf of States for 2015 will be approximately \$27.3 million, and that the risk adjustment user fee will be \$0.96 per enrollee per year for HHS to operate the risk adjustment program on behalf of States for 2015.

In § 153.620(c) of this final rule, we establish that HHS or its designee may audit an issuer of a risk adjustment covered plan, when HHS operates risk adjustment on behalf of a State, to assess the issuer's compliance with the requirements of subparts G and H of 45 CFR part 153. As discussed above, HHS intends to fund risk adjustment operations (not including Federal personnel costs), including risk adjustment program integrity and audit functions, by collecting a per capita user fee from issuers of risk adjustment covered plans. Therefore, we believe that the costs to the Federal government associated with the risk adjustment audit activities in this final rule will be covered through the risk adjustment user fee, and that there will be no

impact for the Federal government as a result of the audit provisions. The audit provision would result in additional costs for issuers of risk adjustment covered plans related to gathering information and preparing for an audit. We discuss the administrative costs associated with this requirement for issuers in the Collection of Information section of this final rule.

Although this final rule will result in some additional administrative burden for issuers of risk adjustment covered plans as a result of the requirements for risk adjustment data validation and submission of discrepancy reports in response to interim and final dedicated distributed data environment reports, we note that much of the impact associated with establishing a dedicated distributed data environment and a risk adjustment data validation process has previously been estimated in the Premium Stabilization Rule and the 2014 Payment Notice. We do not believe that provisions contained within this rule substantially alter the previous estimates. We describe these administrative costs in the Collection of Information Requirements section of this rule.

Reinsurance

The Affordable Care Act directs that a transitional reinsurance program be established in each State to help stabilize premiums for coverage in the individual market from 2014 through 2016. In the 2014 Payment Notice, we expanded upon the standards set forth in subparts C and E of the Premium Stabilization Rule (45 CFR part 153) and established the 2014 uniform reinsurance payment parameters and national contribution rate. In this final rule, we set forth the 2015 uniform reinsurance payment parameters and contribution rate, and certain oversight provisions related to the operation of the reinsurance program.

Section 153.220(c) provides that HHS will publish the uniform per capita reinsurance contribution rate for the upcoming benefit year in the annual HHS notice of benefit and payment

parameters. Section 1341(b)(3)(B)(iii) of the Affordable Care Act specifies that \$10 billion for reinsurance contributions is to be collected from contributing entities in 2014 (the reinsurance payment pool), \$6 billion in 2015, and \$4 billion in 2016. Additionally, sections 1341(b)(3)(B)(iv) and 1341(b)(4) of the Affordable Care Act direct that \$2 billion in funds is to be collected for contribution to the U.S. Treasury in 2014, \$2 billion in 2015, and \$1 billion in 2016. Finally, section 1341(b)(3)(B)(ii) of the Affordable Care Act allows for the collection of additional amounts for administrative expenses. Taken together, these three components make up the total dollar amount to be collected from contributing entities in each of the three years of the reinsurance program under the uniform per capita contribution rate.

For the 2015 benefit year, if HHS operates the reinsurance program on behalf of a State, HHS would retain \$0.14 as an annual per capita fee to fund HHS's performance of all reinsurance functions. If a State establishes its own reinsurance program, HHS would transfer \$0.07 of the per capita administrative fee to the State for purposes of administrative expenses incurred in making reinsurance payments, and retain the remaining \$0.07 to offset the costs of contribution collection.

To safeguard the use of Federal funds in the transitional reinsurance program, we provided in § 153.270(a) of this final rule that HHS or its designee may conduct a financial and programmatic audit of a State-operated reinsurance program to assess compliance with the requirements of subparts B and C of 45 CFR part 153. As discussed above, HHS intends to fund reinsurance operations (not including Federal personnel costs), including program integrity and audit functions, by collecting as part of the uniform contribution rate, administrative expenses associated with operating the reinsurance program from all reinsurance contributing entities. Therefore, we believe that the costs to the Federal government associated with

the reinsurance audit activities in this final rule would be covered through the reinsurance contribution rate, and that there would be no net budget impact for the Federal government as a result of the audit provision. Because this audit requirement would direct a State that establishes a reinsurance program to ensure that its applicable reinsurance entity and any relevant contractors, subcontractors, or agents cooperate with an audit, and would direct the State to provide to HHS for approval a written corrective action plan; implement the plan; and provide to HHS written documentation of the corrective actions once taken, if the audit resulted in a finding of material weakness or significant deficiency, the requirement does impose a cost on States operating reinsurance. However, we believe that State-operated reinsurance programs would already electronically maintain the information necessary for an audit as part of their normal business practices and as a result of the maintenance of records requirement set forth in § 153.240(c), no additional time or effort will be necessary to develop and maintain audit information. We estimate that it will take a compliance analyst (at an hourly labor cost of \$53.75) 40 hours to gather the necessary information required for an audit, 5 hours to prepare a corrective action plan based on the audit findings and 64 hours to implement and document, if necessary, the corrective actions taken. We also estimate a senior manager (at an hourly labor cost of \$77) will take 5 hours to oversee the transmission of audit information to HHS and to review the corrective action plan prior to submission to HHS, and 16 hours to oversee implementation of any corrective actions taken. Therefore, we estimate a total administrative cost of approximately \$7,476 for each State-operated reinsurance program as a result of this audit requirement. For the one State that will operate reinsurance for the 2014 benefit year, we estimate a burden of approximately \$7,476 as a result of this requirement. Although we have estimated the cost of a potential audit in this RIA, we note that we may not audit State-operated reinsurance programs.

In § 153.405(i) and § 153.410(d), we establish that HHS may audit contributing entities and issuers of reinsurance-eligible plans to assess compliance with reinsurance program requirements. We discuss the costs to contributing entities and issuers of reinsurance-eligible plans as a result of this requirement in the Collection of Information section of this proposed

rule. We intend to combine issuer audits for the premium stabilization programs whenever practicable to reduce the financial burden of these audits on issuers. Consequently, we anticipate that, because issuers of reinsurance-eligible plans may also be subject to risk adjustment requirements, we would conduct these audits in a manner that avoids overlapping review of information that is required for both programs.

In this final rule, we are finalizing with modifications the definition of a contributing entity for the purpose of reinsurance contributions. Specifically, we exempt self-insured, self-administered plans that do not use a TPA to perform claims processing, claims adjudication, and enrollment functions from the requirement to make reinsurance contributions for the 2015 and 2016 benefit years. As stated earlier in this regulatory impact analysis, it is difficult to estimate the number of self-insured, self-administered group health plans that might be affected by this modification. We did not receive quantitative estimates in comments, although as previously stated, we expect that few entities will qualify for this exemption. Therefore, we have not changed our proposed 2015 reinsurance contribution rate.

Risk Corridors

The Affordable Care Act created a temporary risk corridors program for the years 2014, 2015, and 2016 that applies to QHPs, as defined in § 153.500. The risk corridors program is a mechanism for sharing risk for allowable costs between the Federal government and QHP issuers. The Affordable Care Act established the risk corridors program as a Federal program; consequently, HHS will operate the risk corridors program under Federal rules with no State variation. The risk corridors program will help protect against inaccurate rate setting in the early years of the Exchanges by limiting the extent of issuer losses and gains. HHS intends to implement this program in a budget neutral manner.

As mentioned elsewhere in this rule, for the 2014 benefit year, we are making an adjustment to the risk corridors formula that would help mitigate potential QHP issuers' unexpected losses that are attributable to the effects of the transitional policy. We also estimate that this adjustment would result in direct administrative costs for individual and small group market issuers that are discussed in the Collection of Information section of this final rule. Because of the difficulty associated with predicting State

enforcement of the 2014 market rules and estimating the enrollment in transitional plans and in QHPs, it is difficult to estimate the precise magnitude of this impact on aggregate risk corridors payments and charges at this time.

Our initial modeling suggests that this adjustment for the transitional policy could increase the total risk corridors payment amount made by the Federal government and decrease risk corridors receipts, resulting in an increase in payments. However, we estimate that even with this change, the risk corridors program is likely to be budget neutral or, will result in net revenue to the Federal government. The magnitude of this effect seems likely to be substantially smaller than the magnitude of the effect of the transitional policy itself (because risk corridors applies only to the extent of an issuer's QHP business), and the magnitude of the effect of the reduction of the reinsurance attachment point and potential increased coinsurance payout. Because reinsurance receipts are a parameter in the risk corridors calculation, the increase in reinsurance payments that would result from lowering the attachment point and potentially increasing the coinsurance rate would exert downward pressure on an issuer's risk corridors ratio. Consequently, while the transitional risk corridors adjustment will result in higher risk corridors payments than would occur if no transitional adjustment were in place, we believe that the risk corridors program as a whole will be budget neutral or, will result in net revenue to the Federal government in FY 2015 for the 2014 benefit year. We note that even with an estimated increase in outlays, CBO still projects the Premium Stabilization programs to reduce the deficit by approximately \$8 billion over the budget window. HHS intends to implement this program in a budget neutral manner.

To ensure the integrity of risk corridors data reporting, we establish HHS authority in § 153.540(a) of this final rule to conduct post-payment audits of QHP issuers. We are contemplating several ways to reduce issuer burden, such as conducting the risk corridors audits using the existing MLR audit process or conducting risk corridors audits under an overall issuer audit program. Therefore, as described in the Collection of Information section of this rule, we believe that the cost for issuers that would result from this audit requirement is already accounted for as part of the MLR audit process.

Provisions Related to Cost Sharing

The Affordable Care Act provides for the reduction or elimination of cost sharing for certain eligible individuals enrolled in QHPs offered through the Exchanges. This assistance will help many low- and moderate-income individuals and families obtain health insurance—for many people, cost sharing is a barrier to obtaining needed health care.⁵⁷

To support the administration of the cost-sharing reduction program, we are finalizing reductions in the maximum annual limitation on cost sharing for silver plan variations for 2015 and minor modifications to the standards relating to the design of cost-sharing reduction plan variations. We are also finalizing certain modifications to the methodology for calculating advance payments for cost-sharing reductions. However, we do not believe these changes will result in a significant economic impact. Therefore, we do not believe the provisions related to cost-sharing reductions in this rule as finalized will have an impact on the program established by and described in the 2014 Payment Notice.

In this final rule, we also establish the methodology for calculating the premium adjustment percentage, and finalize the premium adjustment percentage for the 2015 benefit year. Section 156.130(e) provides that the premium adjustment percentage is the percentage (if any) by which the average per capita premium for health insurance coverage for the preceding calendar year exceeds such average per capita premium for health insurance for 2013, and that this percentage will be published annually in the HHS notice of benefit and payment parameters. The annual premium adjustment percentage that is issued sets the rate of increase for four parameters detailed in the Affordable Care Act: the annual limitation on cost sharing (defined at § 156.130(a)); the annual limitation on deductibles for plans in the small group (defined at § 156.130(b)); and the section 4980H(a) and section 4980H(b) assessable payment amounts (proposed at 26 CFR 54.4980H in the “Shared Responsibility for Employers Regarding Health Coverage,” published in the **Federal Register** January 2, 2013 (78 FR 218)). We believe that the 2015

premium adjustment percentage is well within the parameters used in the modeling of the Affordable Care Act, and do not expect that it will alter CBO’s February 2014 baseline estimates of the budget impact.

Annual Open Enrollment Period

We revised § 155.410(e) and (f) to amend the dates for the annual open enrollment period and related coverage effective dates. These amendments would benefit issuers at no additional cost, as Exchanges will delay their QHP certification dates by at least one month, giving issuers additional time. Because open enrollment dates will be moved forward, Exchanges will still have the same amount of time for the QHP certification process, and we do not anticipate that this comes at an additional cost to Exchanges. Consumers would have the benefit of a more beneficial open enrollment period, without any additional demand placed on them.

Calculation of Plan Actuarial Value

Issuers may incur minor administrative costs associated with altering cost-sharing parameters of their plan designs to ensure compliance with AV requirements when utilizing the AV Calculator from year-to-year. These requirements were established in the EHB Rule and are in accordance with the provisions in this final rule. Since issuers have extensive experience in offering products with various levels of cost sharing and since these modifications are expected to be relatively minor for most issuers, HHS expects that the process for computing AV with the AV Calculator will not demand many additional resources.

User Fees

To support the operation of FFEs, we require in § 156.50(c) that a participating issuer offering a plan through an FFE must remit a user fee to HHS each month equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year and the monthly premium charged by the issuer for each policy under the plan where enrollment is through an FFE. For the 2015 benefit year, we are establishing a monthly user fee rate equal to 3.5 percent of the monthly premium. We do not have an aggregate estimate of the collections from the user fee at this time because we do not yet have a count of the number of States in which HHS will run an FFE or FF-SHOP in 2015.

SHOP

The SHOPs facilitate the enrollment of eligible employees of small employers into small group health insurance plans. A qualitative analysis of the costs and benefits of establishing a SHOP was included in the RIA published in conjunction with the Exchange Establishment Rule.⁵⁸ This RIA addresses the additional costs and benefits of the modifications in this final rule to the SHOP sections of the Exchange Establishment Rule.

In this rule, we revise § 155.705(b)(1), which lists the rules regarding eligibility and enrollment to which the SHOPs must adhere, to include additional provisions regarding termination of coverage in SHOPs and SHOP employer and employee eligibility appeals that were finalized in the first final Program Integrity Rule. In § 155.705(b)(3), we establish that an employer in the FF-SHOPs has the option to offer its employees either a single SADP or a choice of all SADPs available at a single SADP actuarial value level for plan years beginning on or after January 1, 2015.

We are also amending § 155.705(b)(4) to allow SHOPs performing premium aggregation to establish a standard method for premium calculation, payment, and collection. We are establishing that in the FF-SHOPs, after premium aggregation becomes available in plan years beginning on or after January 1, 2015, employers will be required to remit premiums to the FF-SHOP in accordance with a payment timeline and process established by HHS through guidance, and that premiums for coverage of less than 1 month will be prorated by multiplying the number of days of coverage in the partial month by the premium for 1 month divided by the number of days in the month. We believe this approach to prorating to be the fairest for both consumers and issuers because an enrollee will pay for the portion of coverage provided for a partial month.

In this rule, we are finalizing amendments to § 155.705(b)(6) that were originally proposed in the Program Integrity proposed rule published in the June 19, 2013 **Federal Register** (78 FR 37032) to establish that SHOPs must require all issuers to make any changes to rates at a uniform time that is no more frequently than quarterly, as is the case small-group-market-wide. The finalized amendments would also provide that issuers participating in the FF-SHOPs with the maximum amount of flexibility permitted under the

⁵⁷ Brook, Robert H., John E. Ware, William H. Rogers, Emmett B. Keeler, Allyson Ross Davies, Cathy D. Sherbourne, George A. Goldberg, Kathleen N. Lohr, Patricia Camp and Joseph P. Newhouse. *The Effect of Coinsurance on the Health of Adults: Results from the RAND Health Insurance Experiment*. Santa Monica, CA: RAND Corporation, 1984. Available at: <http://www.rand.org/pubs/reports/R3055>.

⁵⁸ Available at: <http://ccio.cms.gov/resources/files/Files2/03162012/hie3r-ria-032012.pdf>.

market-wide rules and the amendment to § 155.705(b)(6)(i), standardize the effective dates for rate updates in the FF–SHOPs, and provide that FF–SHOP issuers must submit rates to HHS 60 days in advance of the effective date. Consistent with technical guidance provided to issuers through the Health Insurance Oversight System on April 8, 2013, issuers will be able to submit updated quarterly rates for the FF–SHOPs no sooner than for the third quarter of 2014, due to current system limitations. This provision is being finalized at § 156.705(b)(6)(i) and (i)(A), leaving current § 155.705(b)(6)(ii) in place, as we did not intend to replace it.

We also are amending § 155.705(b)(11) to provide additional flexibility with respect to an employer's ability to define a percentage contribution toward premiums under the employer selected reference plan in the FF–SHOPs. Although we proposed and rejected a similar approach in the 2014 Payment Notice because we concluded it was inconsistent with the uniformity provisions established in Internal Revenue Service Notice 2010–82, which require employers to contribute a uniform percentage to employee premiums in order to claim a small business tax credit, we believe small employers are best able to determine whether offering different contribution levels are in the best interest of the business and its employees. We believe that this additional flexibility will bring the FF–SHOPs more in line with current small group market practices and provide an additional incentive for small employers to participate in the FF–SHOPs. Additionally, we believe that providing a mechanism that allows different contribution levels based on full-time or non-full-time status may encourage some employers to offer coverage to non-full-time employees. While we are finalizing this provision as proposed, we note that this option is not expected to become available in the FF–SHOPs until sometime after January 1, 2015.

In this rule, we amend § 155.715 to provide SHOP eligibility adjustment periods for both employers and employees only when there is an inconsistency between information provided by an applicant and information collected through optional verification methods under § 155.715(c)(2), rather than when an employer submits information on the SHOP single employer application that is inconsistent with the eligibility standards described in § 155.710 or when the SHOP receives information on the employee's application that is

inconsistent with the information provided by the employer, as current paragraph § 155.715(d) provides. We also amend paragraph (c)(4) to replace a reference to sections 1411(b)(2) and (c) of the Affordable Care Act with a reference to Subpart D of 45 CFR part 155, and to add a reference to eligibility verifications as well as to eligibility determinations. The changes as finalized in this rule will prohibit a SHOP from performing any individual market Exchange eligibility determinations or verifications as described in Subpart D, which, for example, includes making eligibility determinations for advance payments of the premium tax credit and cost sharing reductions in the individual market Exchange.

In § 155.730 we provide that SHOPs are not permitted to collect information from applicants, employers, or employees that is not necessary to determine SHOP eligibility or effectuate enrollment through a SHOP. Limiting the information required of an applicant helps to protect consumer privacy and promote efficiency and streamlining of the SHOP application process.

In § 155.220, we establish that for plan years beginning on or after January 1, 2015 SHOPs, in States that permit this activity under State law, may permit enrollment in a SHOP QHP through the Internet Web site of an agent or broker under the standards set forth in § 155.220(c)(3). Permitting an employer to complete QHP selection through the Internet Web site of an agent or broker is an additional potential enrollment channel that would provide small employers with another avenue to the SHOPs. While we are finalizing this provision as proposed, we do not expect that FF–SHOPs will offer this option in 2015. For clarity, we are making the technical change to add a title to § 155.220(i) to say, “*Use of agents' and brokers' Internet Web sites for SHOP.*”

In § 156.285 of this rule as finalized, we establish that when premium aggregation becomes available in FF–SHOPs for plan years beginning on or after January 1, 2015, if an issuer does not receive an enrollment cancellation transaction from the FF–SHOP, it should effectuate coverage even if the issuer would not receive an employer's initial premium payment from the FF–SHOP prior to the coverage effective date. We also establish that a qualified employer in the SHOP that becomes a large employer, regardless of whether the QHP being sold through the SHOP is sold in the small group market or the large group market, will continue to be rated as a small employer and that

issuers cannot offer composite premiums in the FF–SHOPs when employee choice becomes available and an employer offers employees a level of coverage rather than a single plan. Furthermore, we establish that when employee choice is offered in the FF–SHOPs, composite premiums will not be allowed when the employer elects to offer its employees all plans in an actuarial value (or metal tier) selected by the employer, and we extend this limitation to SADP issuers when employers offer employees a choice of all SADPs at a dental AV level.

We do not expect the policies as finalized in this rule and related to the SHOP to create any new significant costs for small businesses, employees, or the FF–SHOPs.

Patient Safety

The patient safety requirements established in this final rule will be implemented in phases, to ensure that QHP issuers contract with hospitals that meet adequate safety and quality standards. The final rule requires QHP issuers to collect and maintain CCNs for each of its contracted hospitals that are certified for more than 50 beds. It also requires that this documentation, if requested by the Exchange, be submitted in a form and manner specified by the Exchange. QHP issuers already have established procedures and relationships to contract with hospitals including obtaining hospital identification information. Therefore, HHS believes that there will not be a significant additional cost for a QHP issuer to collect and maintain CCNs. QHP issuers will incur costs to submit this information, if requested, to the Exchange. We discuss the burden associated with submitting this information in the Collection of Information section of this final rule.

D. Regulatory Alternatives Considered

We considered a number of alternatives to our approach to program integrity for the premium stabilization programs. For example, although we finalized in previous rulemaking our framework for the risk adjustment data validation program to be used when we operate risk adjustment on behalf of a State, the preamble to this rule as proposed discussed and sought comment on a number of alternative approaches to the detailed methodology made final in this rule. For example, we suggested a number of options for confidence intervals and whether to use tests of statistical significance in determining plan average risk score adjustments. We also suggested an expedited second validation audit

approach to permit more time for inter-auditor discussions and appeals. We suggested a number of ways to calculate a default risk adjustment charge for an issuer that fails to provide initial validation audits.

In the preamble discussion of our proposed modifications to the risk adjustment methodology, we considered not providing for an induced demand adjustment for Medicaid expansion plan variations, but we believe that not doing so would underestimate the riskiness of those plans, potentially leading to higher premiums for those plans.

In § 153.270, we establish in this rule that HHS may audit State-operated reinsurance programs to ensure appropriate use of Federal funds. We also considered not proposing that HHS have such authority. However, we believe that because HHS will collect reinsurance contributions and because a State's issuers' reinsurance requests affect the availability of reinsurance funds for issuers in other States, we think it is critical for HHS to have the authority to perform these audits, so that issuers and States are confident that they will receive the correct allocation of the reinsurance payments. We also considered proposing that HHS have the authority to audit a State-operated risk adjustment program. However, we decided not to do so because those programs do not take in Federal funds and those programs have little impact on the health insurance markets in other States.

In the preamble discussion of the 2015 reinsurance payment parameters, we also considered, when setting forth the proposed 2015 reinsurance payment parameters, a set of different uniform reinsurance payment parameters, but believe those alternative uniform reinsurance payment parameters would have unduly raised the complexity of estimating the effects of reinsurance for issuers.

As detailed in the preamble discussion regarding our proposed approach to estimating cost-sharing reduction amounts in connection with reinsurance calculations, we considered a number of alternative approaches to this estimation. Finally, we considered a number of different approaches to the discrepancy and administrative appeals process proposed in § 153.710 and § 156.1220. Some of these approaches would have provided for lengthier and more formal administrative appeals processes, including for advance payments of the premium tax credit, advance payment for cost-sharing reductions, and FFE user fees in 2014. We did not adopt that approach for these 2014 programs, and instead rely

on operational discrepancy reports and one-level of administrative appeals—a request for reconsideration—because we believe that this approach will be simpler and less expensive, and will permit operations specialists, issuers and HHS to resolve most problems more quickly. We considered relying solely on a simpler operational discrepancy report process for the premium stabilization programs and cost-sharing reductions reconciliation in 2015, but decided that due to the complexity of the calculations involved in these programs and the potential magnitude of the payment flows, issuers would prefer that these calculations be subject to more formal administrative processes.

Multiple alternatives were considered to the proposed SHOP approaches, and these are discussed in detail above.

We considered requiring QHP issuers to only contract with hospitals that have agreements with one of the 79 listed PSOs; however, as we stated in preamble, this could result in a shortage of qualified hospitals and providers available for contracting with QHPs. We also considered establishing exceptions for hospitals and QHP issuers to these requirements. However, we believe that the phase in approach for implementing these requirements effectively balances the priorities for making quality health care accessible and safe in the Exchanges.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of the final rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The RFA generally defines a “small entity” as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of “small entity.” HHS uses a change in revenues of more than 3 to 5 percent as its measure of significant economic impact on a substantial number of small entities.

In this final rule, we provide provisions for the risk adjustment, reinsurance, and risk corridors programs, which are intended to stabilize premiums as insurance market reforms are implemented and Exchanges facilitate increased enrollment. Because we believe that insurance companies

offering comprehensive health insurance policies generally exceed the size thresholds for “small entities” established by the SBA, we do not believe that an initial regulatory flexibility analysis is required for such firms.

For purposes of the RFA, we expect the following types of entities to be affected by this proposed rule:

- Health insurance issuers.
- Group health plans.
- Reinsurance entities.

We believe that health insurance issuers and group health plans would be classified under the North American Industry Classification System (NAICS) code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of \$35.5 million or less would be considered small entities for these NAICS codes. Issuers could possibly be classified in 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard would be \$30 million or less.

In this final rule, we establish requirements for employers that choose to participate in a SHOP Exchange. Coverage through the SHOPS is limited by statute to small employers, which the statute defines as employers who employed on average at least one but not more than 100 employees in a given plan year. For plan years beginning before January 1, 2016, the statute also provides that states may elect to define a small employer as having at least one but not more than 50 employees, on average, in a given plan year. For this reason, we expect that many employers who would be affected by the rule would meet the SBA standard for small entities. We do not believe that the provisions in this final rule impose requirements on employers offering health insurance through the SHOP that are more restrictive than the current requirements on small employers offering employer-sponsored insurance. Additionally, as discussed in the RIA, we believe the policy will provide greater choice for both employees and employers. We believe the processes that we have established constitute the minimum requirements necessary to implement the SHOP program and accomplish our policy goals, and that no appropriate regulatory alternatives could be developed to further lessen the compliance burden.

We believe that a substantial number of sponsors of self-insured group health plans could qualify as “small entities.” This rule provides HHS with the authority to audit these entities. However, we do not believe that the burden of these audits is likely to reflect

more than 3 to 5 percent of such an entity's revenues.

F. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a State, local, or Tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. In 2014, that threshold is approximately \$141 million. Although we have not been able to quantify the user fees that will be associated with this final rule, the combined administrative cost and user fee impact on State, local, or Tribal governments and the private sector may be above the threshold. Earlier portions of this RIA constitute our UMRA analysis.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications. Because States have flexibility in designing their Exchange and Exchange-related programs, State decisions will ultimately influence both administrative expenses and overall premiums. States are not required to establish an Exchange or risk adjustment or reinsurance program. For States electing to operate an Exchange, risk adjustment, or reinsurance, much of the initial cost of creating these programs will be funded by Exchange Planning and Establishment Grants. After establishment, Exchanges will be financially self-sustaining, with revenue sources at the discretion of the State. Current State Exchanges charge user fees to issuers.

In HHS's view, while this final rule does not impose substantial direct requirement costs on State and local governments, this regulation has Federalism implications due to direct effects on the distribution of power and responsibilities among the State and Federal governments relating to determining standards relating to health insurance that is offered in the individual and small group markets. Each State electing to establish an Exchange must adopt the Federal standards contained in the Affordable Care Act and in this final rule, or have in effect a State law or regulation that implements these Federal standards.

However, HHS anticipates that the Federalism implications (if any) are substantially mitigated because under the statute, States have choices regarding the structure and governance of their Exchanges and risk adjustment and reinsurance programs. Additionally, the Affordable Care Act does not require States to establish these programs; if a State elects not to establish any of these programs or is not approved to do so, HHS must establish and operate the programs in that State.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have Federalism implications or limit the policy making discretion of the States, HHS has engaged in efforts to consult with and work cooperatively with affected States, including participating in conference calls with and attending conferences of the National Association of Insurance Commissioners, and consulting with State insurance officials on an individual basis.

Throughout the process of developing this final rule, HHS has attempted to balance the States' interests in regulating health insurance issuers, and Congress' intent to provide access to Affordable Insurance Exchanges for consumers in every State. By doing so, it is HHS's view that we have complied with the requirements of Executive Order 13132.

H. Congressional Review Act

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

List of Subjects

45 CFR Part 144

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 147

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

45 CFR Part 153

Administrative practice and procedure, Adverse selection, Health care, Health insurance, Health records,

Organization and functions (Government agencies), Premium stabilization, Reporting and recordkeeping requirements, Reinsurance, Risk adjustment, Risk corridors, Risk mitigation, State and local governments.

45 CFR Part 155

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

45 CFR Part 156

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

45 CFR Part 158

Administrative practice and procedure, Claims, Health care, Health insurance, Health plans, Penalties, Reporting and recordkeeping requirements, Premium revenues, Medical loss ratio, Rebating.

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR parts 144, 147, 153, 155, 156, and 158 as set forth below:

PART 144—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

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

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

■ 2. Section 144.103 is amended by revising the first sentence in paragraph

(1) of the definition of “Policy year” to read as follows:

§ 144.103 Definitions.

* * * * *

Policy year * * *

(1) A grandfathered health plan offered in the individual health insurance market and student health insurance coverage, the 12-month period that is designated as the policy year in the policy documents of the health insurance coverage. * * *

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

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

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

■ 4. Section 147.102 is amended by revising paragraph (c)(3) to read as follows:

§ 147.102 Fair health insurance premiums.

* * * * *

(c) * * *

(3) Application to small group market—(i) In the case of the small group market, the total premium charged to a group health plan is determined by summing the premiums of covered participants and beneficiaries in accordance with paragraph (c)(1) or (2) of this section, as applicable.

(ii) Subject to paragraph (c)(3)(iii) of this section, nothing in this section prevents a state from requiring issuers to offer to a group health plan, or an issuer from voluntarily offering to a group health plan, premiums that are based on average enrollee premium amounts, provided that the total group premium established at the time of applicable enrollment at the beginning of the plan year is the same total amount derived in accordance with paragraph (c)(1) or (2) of this section, as applicable.

(iii) Effective for plan years beginning on or after January 1, 2015, an issuer that, in connection with a group health plan in the small group market, offers premiums that are based on average enrollee premium amounts under paragraph (c)(3)(ii) of this section must—

(A) Ensure an average enrollee premium amount calculated based on applicable enrollment of participants and beneficiaries at the beginning of the plan year does not vary during the plan year.

(B) Unless a state establishes and CMS approves an alternate rating

methodology, calculate an average enrollee premium amount for covered individuals age 21 and older, and calculate an average enrollee premium amount for covered individuals under age 21. The premium for a given family composition is determined by summing the average enrollee premium amount applicable to each family member covered under the plan, taking into account no more than three covered children under age 21.

(C) Pursuant to applicable state law, ensure that the average enrollee premium amount calculated for any individual covered under the plan does not include any rating variation for tobacco use permitted under paragraph (a)(1)(iv) of this section. The rating variation for tobacco use permitted under paragraph (a)(1)(iv) of this section is determined based on the premium rate that would be applied on a per-member basis with respect to an individual who uses tobacco and then included in the premium charged for that individual.

(D) To the extent permitted by applicable state law and, in the case of coverage offered through a Federally-facilitated SHOP, as permitted by § 156.285(a)(4) of this subchapter, apply this paragraph (c)(3)(iii) uniformly among group health plans enrolling in that product, giving those group health plans the option to pay premiums based on average enrollee premium amounts.

* * * * *

■ 5. Section 147.145 is amended by revising paragraph (b)(1)(ii) to read as follows:

§ 147.145 Student health insurance coverage.

* * * * *

(b) * * *

(1) * * *

(ii) For purposes of section 2702 of the Public Health Service Act, a health insurance issuer that offers student health insurance coverage is not required to accept individuals who are not students or dependents of students in such coverage, and, notwithstanding the requirements of § 147.104(b), is not required to establish open enrollment periods or coverage effective dates that are based on a calendar policy year or to offer policies on a calendar year basis.

* * * * *

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

■ 6. The authority citation for part 153 continues to read as follows:

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

■ 7. Section 153.20 is amended by revising the definition of “contributing entity” and adding in alphabetical order a definition of “major medical coverage” to read as follows:

§ 153.20 Definitions.

* * * * *

Contributing entity means—

(1) A health insurance issuer; or

(2) For the 2014 benefit year, a self-insured group health plan (including a group health plan that is partially self-insured and partially insured, where the health insurance coverage does not constitute major medical coverage), whether or not it uses a third party administrator; and for the 2015 and 2016 benefit years, a self-insured group health plan (including a group health plan that is partially self-insured and partially insured, where the health insurance coverage does not constitute major medical coverage) that uses a third party administrator in connection with claims processing or adjudication (including the management of internal appeals) or plan enrollment for services other than for pharmacy benefits or excepted benefits within the meaning of section 2791(c) of the PHS Act. Notwithstanding the foregoing, a self-insured group health plan that uses an unrelated third party to obtain provider network and related claim repricing services, or uses an unrelated third party for up to 5 percent of claims processing or adjudication or plan enrollment, will not be deemed to use a third party administrator, based on either the number of transactions processed by the third party, or the volume of the claims processing and adjudication and plan enrollment services provided by the third party. A self-insured group health plan that is a contributing entity is responsible for the reinsurance contributions, although it may elect to use a third party administrator or administrative services-only contractor for transfer of the reinsurance contributions.

* * * * *

Major medical coverage means, for purposes only of the requirements related to reinsurance contributions under section 1341 of the Affordable Care Act, a catastrophic plan, an individual or a small group market plan subject to the actuarial value requirements under § 156.140 of this subchapter, or health coverage for a broad range of services and treatments provided in various settings that

provides minimum value as defined in § 156.145 of this subchapter.

* * * * *

■ 8. Section 153.230 is amended by revising paragraph (d) to read as follows:

§ 153.230 Calculation of reinsurance payments made under the national contribution rate.

* * * * *

(d) *Uniform adjustment to national reinsurance payments.* If HHS determines that all reinsurance payments requested under the national payment parameters from all reinsurance-eligible plans in all States for a benefit year will not be equal to the amount of all reinsurance contributions collected for reinsurance payments under the national contribution rate in all States for an applicable benefit year, HHS will determine a uniform pro rata adjustment to be applied to all such requests for reinsurance payments for all States. Each applicable reinsurance entity, or HHS on behalf of a State, must reduce or increase the reinsurance payment amounts for the applicable benefit year by any adjustment required under this paragraph (d).

■ 9. Section 153.270 is added to subpart C to read as follows:

§ 153.270 HHS audits of State-operated reinsurance programs.

(a) *Audits.* HHS or its designee may conduct a financial and programmatic audit of a State-operated reinsurance program to assess compliance with the requirements of this subpart or subpart B of this part. A State that establishes a reinsurance program must ensure that its applicable reinsurance entity and any relevant contractors, subcontractors, or agents cooperate with any audit under this section.

(b) *Action on audit findings.* If an audit results in a finding of material weakness or significant deficiency with respect to compliance with any requirement of this subpart or subpart B, the State must ensure that the applicable reinsurance entity:

(1) Within 60 calendar days of the issuance of the final audit report, provides a written corrective action plan to HHS for approval;

(2) Implements that plan; and

(3) Provides to HHS written documentation of the corrective actions once taken.

■ 10. Section 153.400 is amended by revising paragraph (a)(1) introductory text and adding paragraphs (a)(1)(v) and (vi) to read as follows:

§ 153.400 Reinsurance contribution funds.

(a) * * *

(1) In general, reinsurance contributions are required for major medical coverage that is considered to be part of a commercial book of business, but are not required to be paid more than once with respect to the same covered life. In order to effectuate that principle, a contributing entity must make reinsurance contributions for lives covered by its self-insured group health plans and health insurance coverage except to the extent that:

* * * * *

(v) Such plan or coverage applies to individuals with primary residence in a territory that does not operate a reinsurance program.

(vi) In the case of employer-provided group health coverage:

(A) Such coverage applies to individuals with individual market health insurance coverage for which reinsurance contributions are required; or

(B) Such coverage is supplemental or secondary to group health coverage for which reinsurance contributions must be made for the same covered lives.

* * * * *

■ 11. Section 153.405 is amended by revising paragraphs (c) and (e)(3) and adding paragraph (i) to read as follows:

§ 153.405 Calculation of reinsurance contributions.

* * * * *

(c) *Notification and payment.* (1) Following submission of the annual enrollment count described in paragraph (b) of this section, HHS will notify the contributing entity of the reinsurance contribution amount allocated to reinsurance payments and administrative expenses to be paid for the applicable benefit year.

(2) In the fourth quarter of the calendar year following the applicable benefit year, HHS will notify the contributing entity of the portion of the reinsurance contribution amount allocated for payments to the U.S. Treasury for the applicable benefit year.

(3) A contributing entity must remit reinsurance contributions to HHS within 30 days after the date of a notification.

* * * * *

(e) * * *

(3) Using the number of lives covered for the most current plan year calculated based upon the “Annual Return/Report of Employee Benefit Plan” filed with the Department of Labor (Form 5500) for the last applicable time period. For purposes of this paragraph (e)(3), the number of lives covered for the plan year for a plan offering only self-only coverage equals the sum of the total

participants covered at the beginning and end of the plan year, as reported on the Form 5500, divided by 2, and the number of lives covered for the plan year for a plan offering self-only coverage and coverage other than self-only coverage equals the sum of the total participants covered at the beginning and the end of the plan year, as reported on the Form 5500.

* * * * *

(i) *Audits.* HHS or its designee may audit a contributing entity to assess its compliance with the requirements of this subpart.

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

§ 153.410 Requests for reinsurance payment.

* * * * *

(d) *Audits.* HHS or its designee may audit an issuer of a reinsurance-eligible plan to assess its compliance with the requirements of this subpart and subpart H of this part. The issuer must ensure that its relevant contractors, subcontractors, or agents cooperate with any audit under this section. If an audit results in a finding of material weakness or significant deficiency with respect to compliance with any requirement of this subpart or subpart H, the issuer must complete all of the following:

(1) Within 30 calendar days of the issuance of the final audit report, provide a written corrective action plan to HHS for approval.

(2) Implement that plan.

(3) Provide to HHS written documentation of the corrective actions once taken.

■ 13. Section 153.500 is amended by revising the definitions of “allowable administrative costs” and “profits” and adding in alphabetical order definitions for “adjustment percentage” and “transitional State” to read as follows:

§ 153.500 Definitions.

* * * * *

Adjustment percentage means, with respect to a QHP:

(1) For benefit year 2014, for a QHP offered by a health insurance issuer with allowable costs of at least 80 percent of after-tax premium in a transitional State, the percentage specified by HHS for such QHPs in the transitional State; and otherwise

(2) Zero percent.

* * * * *

Allowable administrative costs mean, with respect to a QHP, the sum of administrative costs of the QHP, other than taxes and regulatory fees, plus profits earned by the QHP, which sum is limited to the sum of 20 percent and

the adjustment percentage of after-tax premiums earned with respect to the QHP (including any premium tax credit under any governmental program), plus taxes and regulatory fees.

* * * * *

Profits mean, with respect to a QHP, the greater of:

(1) The sum of three percent and the adjustment percentage of after-tax premiums earned; and

(2) Premiums earned of the QHP minus the sum of allowable costs and administrative costs of the QHP.

* * * * *

Transitional State means a State that does not enforce compliance with §§ 147.102, 147.104, 147.106, 147.150, 156.80, or subpart B of part 156 of this subchapter for individual market and small group health plans that renew for a policy year starting between January 1, 2014, and October 1, 2014, in accordance with the transitional policy outlined in the CMS letter dated November 14, 2013.

■ 14. Section 153.510 is amended by adding paragraph (f) to read as follows:

§ 153.510 Risk corridors establishment and payment methodology.

* * * * *

(f) *Eligibility under health insurance market rules.* The provisions of this subpart apply only for plans offered by a QHP issuer in the SHOP or the individual or small group market, as determined according to the employee counting method applicable under State law, that are subject to the following provisions: §§ 147.102, 147.104, 147.106, 147.150, 156.80, and subpart B of part 156 of this subchapter.

■ 15. Section 153.530 is amended by revising paragraph (d) and adding paragraph (e) to read as follows:

§ 153.530 Risk corridors data requirements.

* * * * *

(d) *Timeframes.* For each benefit year, a QHP issuer must submit all information required under paragraphs (a) through (c) of this section by July 31 of the year following the benefit year.

(e) *Requirement to submit enrollment data for risk corridors adjustment.* A health insurance issuer in the individual or small group market of a transitional State must submit, in a manner and timeframe specified by HHS, the following:

(1) A count of its total enrollment in the individual market and small group market; and

(2) A count of its total enrollment in individual market and small group market policies that meet the criteria for

transitional policies outlined in the CMS letter dated November 14, 2013.

■ 16. Section 153.540 is added to subpart F to read as follows:

§ 153.540 Compliance with risk corridors standards.

HHS or its designee may audit a QHP issuer to assess its compliance with the requirements of this subpart. HHS will conduct an audit in accordance with the procedures set forth in § 158.402(a) through (e) of this subchapter.

■ 17. Section 153.620 is amended by adding paragraph (c) to read as follows:

§ 153.620 Compliance with risk adjustment standards.

* * * * *

(c) *Audits.* HHS or its designee may audit an issuer of a risk adjustment covered plan to assess its compliance with the requirements of this subpart and subpart H of this part. The issuer must ensure that its relevant contractors, subcontractors, or agents cooperate with any audit under this section. If an audit results in a finding of material weakness or significant deficiency with respect to compliance with any requirement of this subpart or subpart H of this part, the issuer must complete all of the following:

(1) Within 30 calendar days of the issuance of the final audit report, provide a written corrective action plan to HHS for approval.

(2) Implement that plan.

(3) Provide to HHS written documentation of the corrective actions once taken.

■ 18. Section 153.630 is amended by revising paragraph (b)(1) and adding paragraphs (b)(5) through (10) to read as follows:

§ 153.630 Data validation requirements when HHS operates risk adjustment.

* * * * *

(b) * * *

(1) An issuer of a risk adjustment covered plan must engage one or more independent auditors to perform an initial validation audit of a sample of its risk adjustment data selected by HHS. The issuer must provide HHS with the identity of the initial validation auditor, and must attest to the absence of conflicts of interest between the initial validation auditor (or the members of its audit team, owners, directors, officers, or employees) and the issuer (or its owners, directors, officers, or employees), to its knowledge, following reasonable investigation, and must attest that it has obtained an equivalent representation from the initial

validation auditor, in a timeframe and manner to be specified by HHS.

* * * * *

(5) An initial validation audit must be conducted by medical coders certified as such and in good standing by a nationally recognized accrediting agency.

(6) An issuer must provide the initial validation auditor and the second validation auditor with all relevant source enrollment documentation, all claims and encounter data, and medical record documentation from providers of services to each enrollee in the applicable sample without unreasonable delay and in a manner that reasonably assures confidentiality and security in transmission.

(7) The risk score of each enrollee in the sample must be validated by—

(i) Validating the enrollee’s enrollment data and demographic data in a manner to be determined by HHS.

(ii) Validating enrollee health status through review of all relevant medical record documentation. Medical record documentation must originate from the provider of the services and align with dates of service for the medical diagnoses, and reflect permitted providers and services. For purposes of this section, “medical record documentation” means clinical documentation of hospital inpatient or outpatient treatment or professional medical treatment from which enrollee health status is documented and related to accepted risk adjustment services that occurred during a specified period of time. Medical record documentation must be generated under a face-to-face or telehealth visit documented and authenticated by a permitted provider of services;

(iii) Validating medical records according to industry standards for coding and reporting; and

(iv) Having a senior reviewer confirm any enrollee risk adjustment error discovered during the initial validation audit. For purposes of this section, a “senior reviewer” is a reviewer certified as a medical coder by a nationally recognized accrediting agency who possesses at least 5 years of experience in medical coding. However, for validation of risk adjustment data for the 2014 and 2015 benefit years, a senior reviewer may possess 3 or more years of experience.

(8) The initial validation auditor must measure and report to the issuer and HHS, in a manner and timeframe specified by HHS, its inter-rater reliability rates among its reviewers. The initial validation auditor must achieve a consistency measure of at

least 95 percent for his or her review outcomes. However, for validation of risk adjustment data for the 2014 and 2015 benefit years, the initial validation auditor may meet an inter-rater reliability standard of 85 percent for review outcomes.

(9) Enforcement actions. If an issuer of a risk adjustment covered plan fails to engage an initial validation auditor or to submit the results of an initial validation audit to HHS, HHS may impose civil money penalties in accordance with the procedures set forth in § 156.805 of this subchapter.

(10) Default data validation charge. If an issuer of a risk adjustment covered plan fails to engage an initial validation auditor or to submit the results of an initial validation audit to HHS, HHS will impose a default risk adjustment charge.

* * * * *

■ 19. Section 153.710 is amended by adding paragraphs (d), (e), (f), and (g) to read as follows:

§ 153.710 Data requirements.

* * * * *

(d) *Interim dedicated distributed data environment reports.* Within 30 calendar days of the date of an interim dedicated distributed data environment report from HHS, the issuer must, in a format specified by HHS, either:

(1) Confirm to HHS that the information in the interim report accurately reflects the data to which the issuer has provided access to HHS through its dedicated distributed data environment in accordance with § 153.700(a) for the timeframe specified in the report; or

(2) Describe to HHS any discrepancy it identifies in the interim dedicated distributed data environment report.

(e) *Final dedicated distributed data environment report.* Within 15 calendar days of the date of the final dedicated distributed data environment report from HHS, the issuer must, in a format specified by HHS, either:

(1) Confirm to HHS that the information in the final report accurately reflects the data to which the issuer has provided access to HHS through its dedicated distributed data environment in accordance with § 153.700(a) for the benefit year specified in the report; or

(2) Describe to HHS any discrepancy it identifies in the final dedicated distributed data environment report.

(f) *Unresolved discrepancies.* If a discrepancy first identified in an interim or final dedicated distributed data environment report in accordance with paragraphs (d)(2) or (e)(2) of this

section remains unresolved after the issuance of the notification of risk adjustment payments and charges or reinsurance payments under § 153.310(e) or § 153.240(b)(1)(ii), respectively, an issuer of a risk adjustment covered plan or reinsurance-eligible plan may make a request for reconsideration regarding such discrepancy under the process set forth in § 156.1220(a) of this subchapter.

(g) *Risk corridors and MLR reporting.*

(1) Notwithstanding any discrepancy report made under paragraph (d)(2) or (e)(2) of this section, or any request for reconsideration under § 156.1220(a) of this subchapter with respect to any risk adjustment payment or charge, including an assessment of risk adjustment user fees; reinsurance payment; cost-sharing reconciliation payment or charge; or risk corridors payment or charge, unless the dispute has been resolved, an issuer must report, for purposes of the risk corridors and MLR programs:

(i) The risk adjustment payment to be made or charge assessed, including an assessment of risk adjustment user fees, by HHS in the notification provided under § 153.310(e);

(ii) The reinsurance payment to be made by HHS in the notification provided under § 153.240(b)(1)(ii);

(iii) A cost-sharing reduction amount equal to the amount of the advance payments of cost-sharing reductions paid to the issuer by HHS for the benefit year; and

(iv) For medical loss ratio report only, the risk corridors payment to be made or charge assessed by HHS as reflected in the notification provided under § 153.510(d).

(2) An issuer must report any adjustment made following any discrepancy report made under paragraph (d)(2) or (e)(2) of this section, or any request for reconsideration under § 156.1220(a) of this subchapter with respect to any risk adjustment payment or charge, including an assessment of risk adjustment user fees; reinsurance payment; cost-sharing reconciliation payment or charge; or risk corridors payment or charge; or following any audit, where such adjustment has not been accounted for in a prior risk corridors or medical loss ratio report, in the next following risk corridors or medical loss ratio report.

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

■ 20. Authority citation for part 155 continues to read as follows:

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

■ 21. Section 155.106 is amended by revising paragraph (a)(2) to read as follows:

§ 155.106 Election to operate an Exchange after 2014.

(a) * * *

(2) Have in effect an approved, or conditionally approved, Exchange Blueprint and operational readiness assessment at least 6.5 months prior to the Exchange’s first effective date of coverage; and

* * * * *

■ 22. Section 155.220 is amended by adding paragraph (i) to read as follows:

§ 155.220 Ability of States to permit agents and brokers to assist qualified individuals, qualified employers, or qualified employees enrolling in QHPs.

* * * * *

(i) *Use of agents’ and brokers’ Internet Web sites for SHOP.* For plan years beginning on or after January 1, 2015, in States that permit this activity under State law, a SHOP may permit agents and brokers to use an Internet Web site to assist qualified employers and facilitate enrollment of qualified employees in a QHP through the Exchange, under paragraph (c)(3) of this section.

■ 23. Section 155.260 is amended by revising paragraphs (a)(1) and (2) and (b) to read as follows:

§ 155.260 Privacy and security of personally identifiable information.

(a) * * *

(1) Where the Exchange creates or collects personally identifiable information for the purposes of determining eligibility for enrollment in a qualified health plan; determining eligibility for other insurance affordability programs, as defined in § 155.20; or determining eligibility for exemptions from the individual responsibility provisions in section 5000A of the Code, the Exchange may only use or disclose such personally identifiable information to the extent such information is necessary:

(i) For the Exchange to carry out the functions described in § 155.200;

(ii) For the Exchange to carry out other functions not described in paragraph (a)(1)(i) of this section, which the Secretary determines to be in compliance with section 1411(g)(2)(A) of the Affordable Care Act and for

which an individual provides consent for his or her information to be used or disclosed; or

(iii) For the Exchange to carry out other functions not described in paragraphs (a)(1)(i) and (ii) of this section, for which an individual provides consent for his or her information to be used or disclosed, and which the Secretary determines are in compliance with section 1411(g)(2)(A) of the Affordable Care Act under the following substantive and procedural requirements:

(A) *Substantive requirements.* The Secretary may approve other uses and disclosures of personally identifiable information created or collected as described in paragraph (a)(1) of this section that are not described in paragraphs (a)(1)(i) or (ii) of this section, provided that HHS determines that the information will be used only for the purposes of and to the extent necessary in ensuring the efficient operation of the Exchange consistent with section 1411(g)(2)(A) of the Affordable Care Act, and that the uses and disclosures are also permissible under relevant law and policy.

(B) *Procedural requirements for approval of a use or disclosure of personally identifiable information.* To seek approval for a use or disclosure of personally identifiable information created or collected as described in paragraph (a)(1) of this section that is not described in paragraphs (a)(1)(i) or (ii) of this section, the Exchange must submit the following information to HHS:

(1) Identity of the Exchange and appropriate contact persons;

(2) Detailed description of the proposed use or disclosure, which must include, but not necessarily be limited to, a listing or description of the specific information to be used or disclosed and an identification of the persons or entities that may access or receive the information;

(3) Description of how the use or disclosure will ensure the efficient operation of the Exchange consistent with section 1411(g)(2)(A) of the Affordable Care Act; and

(4) Description of how the information to be used or disclosed will be protected in compliance with privacy and security standards that meet the requirements of this section or other relevant law, as applicable.

(2) The Exchange may not create, collect, use, or disclose personally identifiable information unless the creation, collection, use, or disclosure is consistent with this section.

* * * * *

(b) *Application to non-Exchange entities.* (1) *Non-Exchange entities.* A non-Exchange entity is any individual or entity that:

(i) Gains access to personally identifiable information submitted to an Exchange; or

(ii) Collects, uses, or discloses personally identifiable information gathered directly from applicants, qualified individuals, or enrollees while that individual or entity is performing functions agreed to with the Exchange.

(2) Prior to any person or entity becoming a non-Exchange entity, Exchanges must execute with the person or entity a contract or agreement that includes:

(i) A description of the functions to be performed by the non-Exchange entity;

(ii) A provision(s) binding the non-Exchange entity to comply with the privacy and security standards and obligations adopted in accordance with paragraph (b)(3) of this section, and specifically listing or incorporating those privacy and security standards and obligations;

(iii) A provision requiring the non-Exchange entity to monitor, periodically assess, and update its security controls and related system risks to ensure the continued effectiveness of those controls in accordance with paragraph (a)(5) of this section;

(iv) A provision requiring the non-Exchange entity to inform the Exchange of any change in its administrative, technical, or operational environments defined as material within the contract; and

(v) A provision that requires the non-Exchange entity to bind any downstream entities to the same privacy and security standards and obligations to which the non-Exchange entity has agreed in its contract or agreement with the Exchange.

(3) When collection, use or disclosure is not otherwise required by law, the privacy and security standards to which an Exchange binds non-Exchange entities must:

(i) Be consistent with the principles and requirements listed in paragraphs (a)(1) through (6) of this section, including being at least as protective as the standards the Exchange has established and implemented for itself in compliance with paragraph (a)(3) of this section;

(ii) Comply with the requirements of paragraphs (c), (d), (f), and (g) of this section; and

(iii) Take into specific consideration: (A) The environment in which the non-Exchange entity is operating;

(B) Whether the standards are relevant and applicable to the non-Exchange

entity's duties and activities in connection with the Exchange; and

(C) Any existing legal requirements to which the non-Exchange entity is bound in relation to its administrative, technical, and operational controls and practices, including but not limited to, its existing data handling and information technology processes and protocols.

* * * * *

■ 24. Section 155.410 is amended by revising paragraphs (e) and (f) to read as follows:

§ 155.410 Initial and annual open enrollment periods.

* * * * *

(e) *Annual open enrollment period.*

For the benefit year beginning on January 1, 2015, the annual open enrollment period begins on November 15, 2014, and extends through February 15, 2015.

(f) *Effective date for coverage after the annual open enrollment period.* For the benefit year beginning on January 1, 2015, the Exchange must ensure coverage is effective -

(1) January 1, 2015, for QHP selections received by the Exchange on or before December 15, 2014.

(2) February 1, 2015, for QHP selections received by the Exchange from December 16, 2014 through January 15, 2015.

(3) March 1, 2015, for QHP selections received by the Exchange from January 16, 2015 through February 15, 2015.

* * * * *

■ 25. Section 155.705 is amended by:

■ a. Revising paragraph (b)(1);

■ b. Adding paragraph (b)(3)(v);

■ c. Redesignating paragraph (b)(4)(ii) as (b)(4)(iii);

■ d. Adding new paragraph (b)(4)(ii);

■ e. Revising paragraph (b)(6)(i); and

■ f. Revising paragraph (b)(11)(ii)(C).

The additions and revisions read as follows:

§ 155.705 Functions of a SHOP.

* * * * *

(b) * * *

(1) Enrollment and eligibility functions. The SHOP must adhere to the requirements outlined in Subpart H.

* * * * *

(3) * * *

(v) For plan years beginning on or after January 1, 2015, a Federally-facilitated SHOP will provide a qualified employer a choice of two methods to make stand-alone dental plans available to qualified employees and their dependents:

(A) The employer may choose to make available a single stand-alone dental plan.

(B) The employer may choose to make available all stand-alone dental plans offered through a Federally-facilitated SHOP at a level of coverage as described in § 156.150(b)(2) of this subchapter.

(4) * * *

(ii) The SHOP may establish one or more standard processes for premium calculation, premium payment, and premium collection.

(A) Qualified employers in a Federally-facilitated SHOP must make premium payments according to a timeline and process established by HHS;

(B) For a Federally-facilitated SHOP, the premium for coverage lasting less than 1 month must equal the product of:

(1) The premium for 1 month of coverage divided by the number of days in the month; and

(2) The number of days for which coverage is being provided in the month described in paragraph (b)(4)(ii)(B)(1) of this section.

* * * * *

(6) * * *

(i) Require all QHP issuers to make any change to rates at a uniform time that is no more frequently than quarterly.

(A) In a Federally-facilitated SHOP, rates may be updated quarterly with effective dates of January 1, April 1, July 1, or October 1 of each calendar year, beginning with rates effective no sooner than July 1, 2014. The updated rates must be submitted to HHS at least 60 days in advance of the effective date of the rates.

(B) [Reserved]

* * * * *

(11) * * *

(ii) * * *

(C) The employer will define a percentage contribution toward premiums for employee-only coverage under the reference plan and, if dependent coverage is offered, a percentage contribution toward premiums for dependent coverage under the reference plan. To the extent permitted by other applicable law, for plan years beginning on or after January 1, 2015, a Federally-facilitated SHOP may permit an employer to define a different percentage contribution for full-time employees from the percentage contribution it defines for non-full-time employees, and it may permit an employer to define a different percentage contribution for dependent coverage for full-time employees from the percentage contribution it defines for dependent coverage for non-full-time employees.

* * * * *

■ 26. Section 155.715 is amended by revising paragraphs (c)(4), (d)(1)

introductory text, and (d)(2) introductory text to read as follows:

§ 155.715 Eligibility determination process for SHOP.

* * * * *

(c) * * *

(4) May not perform individual market Exchange eligibility determinations or verifications described in subpart D of this part.

(d) * * *

(1) When the information submitted on the SHOP single employer application is inconsistent with information collected from third-party data sources through the verification process described in § 155.715(c)(2), the SHOP must—

* * * * *

(2) When the information submitted on the SHOP single employee application is inconsistent with information collected from third-party data sources through the verification process described in § 155.715(c)(2), the SHOP must—

* * * * *

■ 27. Section 155.730 is amended by revising paragraph (g) to read as follows:

§ 155.730 Application standards for SHOP.

(g) *Additional safeguards.* (1) The SHOP may not provide to the employer any information collected on the employee application with respect to spouses or dependents other than the name, address, and birth date of the spouse or dependent.

(2) The SHOP is not permitted to collect information on the single employer or single employee application unless that information is necessary to determine SHOP eligibility or effectuate enrollment through the SHOP.

■ 28. Section 155.1030 is amended by revising paragraphs (b)(1), (3), and (4) to read as follows:

§ 155.1030 QHP certification standards related to advance payments of the premium tax credit and cost-sharing reductions.

* * * * *

(b) * * *

(1) The Exchange must collect and review annually the rate allocation and the actuarial memorandum that an issuer submits to the Exchange under § 156.470 of this subchapter, to ensure that the allocation meets the standards set forth in § 156.470(c) and (d) of this subchapter.

* * * * *

(3) The Exchange must use the methodology specified in the annual HHS notice of benefit and payment parameters to calculate advance

payment amounts for cost-sharing reductions, and must transmit the advance payment amounts to HHS, in accordance with § 156.340(a) of this subchapter.

(4) HHS may use the information provided to HHS by the Exchange under this section for oversight of advance payments of cost-sharing reductions and premium tax credits.

* * * * *

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

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

Authority: Title I of the Affordable Care Act, sections 1301–1304, 1311–1312, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, and 1412, Pub. L. 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

■ 30. Section 156.135 is amended by revising paragraph (a) and adding paragraph (g) to read as follows:

§ 156.135 AV calculation for determining level of coverage.

(a) *Calculation of AV.* Subject to paragraphs (b) and (d) of this section, to calculate the AV of a health plan, the issuer must use the AV Calculator developed and made available by HHS for the given benefit year.

* * * * *

(g) *Updates to the AV Calculator.* HHS will update the AV Calculator as follows, HHS will:

(1) Update the annual limit on cost sharing and related functions based on a projected estimate to enable the AV Calculator to comply with § 156.130(a)(2);

(2) Update the continuance tables to reflect more current enrollment data when HHS has determined that the enrolled population has materially changed;

(3) Update the algorithms when HHS has determined the need to adapt the AV Calculator for use by additional plan designs or to allow the AV Calculator to accommodate potential new types of plan designs, where such adaptations can be based on actuarially sound principles and will not have a substantial effect on the AV calculations performed by the then current AV Calculator;

(4) Update the continuance tables to reflect more current claims data no more than every 3 and no less than every 5 years and to annually trend the claims data when the trending factor is more

than 5 percent different, calculated on a cumulative basis; and

(5) Update the AV Calculator user interface when a change would be useful to a broad group of users of the AV Calculator, would not affect the function of the AV Calculator, and would be technically feasible.

■ 31. Section 156.150 is amended by revising paragraph (a) to read as follows:

§ 156.150 Application to stand-alone dental plans inside the Exchange.

(a) *Annual limitation on cost-sharing.* For a stand-alone dental plan covering the pediatric dental EHB under § 155.1065 of this subchapter in any Exchange, cost sharing may not exceed \$350 for one covered child and \$700 for two or more covered children.

* * * * *

■ 32. Section 156.285 is amended by adding paragraph (a)(4) and revising paragraph (c)(7) to read as follows:

§ 156.285 Additional standards specific to SHOP.

(a) * * *

(4)(i) Adhere to the premium rating standards described in § 147.102 of this subchapter regardless of whether the QHP being sold through the SHOP is sold in the small group market or the large group market; and

(ii) Effective in plan years beginning on or after January 1, 2015, a QHP issuer in a Federally-facilitated SHOP may not offer to an employer premiums that are based on average enrollee premium amounts under § 147.102(c)(3) of this subchapter, if the employer elects to offer coverage to its employees under § 155.705(b)(3)(iv)(A) of this subchapter. This paragraph (a)(4)(ii) also applies to stand-alone dental plans in a Federally-facilitated SHOP, if the employer elects to offer coverage to its employees under § 155.705(b)(3)(v)(B) of this subchapter.

* * * * *

(c) * * *

(7) A QHP issuer must enroll a qualified employee only if the SHOP—

(i) Notifies the QHP issuer that the employee is a qualified employee;

(ii) Transmits information to the QHP issuer as provided in § 155.400(a) of this subchapter; and

(iii) Effective for QHPs offered through a Federally-facilitated SHOP in plan years beginning on or after January 1, 2015, does not send a cancellation notice to the QHP issuer prior to the effective date of coverage.

* * * * *

■ 33. Section 156.298 is added to subpart C to read as follows:

§ 156.298 Meaningful difference standard for Qualified Health Plans in the Federally-facilitated Exchanges.

(a) *General.* Subject to paragraph (b)(2) of this section, starting in the 2015 coverage year, in order to be certified as a QHP offered through a Federally-facilitated Exchange, a plan must be meaningfully different from all other QHPs offered by the same issuer of that plan within a service area and level of coverage in the Exchange, as defined in paragraph (b) of this section.

(b) *Meaningful difference standard.* A plan is considered meaningfully different from another plan in the same service area and metal tier (including catastrophic plans) if a reasonable consumer would be able to identify one or more material differences among the following characteristics between the plan and other plan offerings:

- (1) Cost sharing;
- (2) Provider networks;
- (3) Covered benefits;
- (4) Plan type;
- (5) Health Savings Account eligibility;

or

(6) Self-only, non-self-only, or child-only plan offerings.

(c) *Exception for limited plan availability.* If HHS determines that the plan offerings at a particular metal level (including catastrophic plans) within a county are limited, plans submitted for certification in that particular metal level (including catastrophic plans) within that county will not be subject to the meaningful difference requirement set forth in paragraph (b) of this section.

(d) *Two-year transition period for issuers with new acquisitions.* During the first 2 years after a merger or acquisition in which an acquiring issuer obtains or merges with another issuer, the FFEs may certify plans as QHPs that were previously offered by the acquired or merged issuer without those plans meeting the meaningful difference standard set forth in paragraph (b) of this section.

■ 34. Section 156.420 is amended by revising paragraphs (c), (d), and (e) to read as follows:

§ 156.420 Plan variations.

* * * * *

(c) *Benefit and network equivalence in silver plan variations.* A standard silver plan and each silver plan variation thereof must cover the same benefits and providers. Each silver plan variation is subject to all requirements applicable to the standard silver plan (except for the requirement that the plan have an AV as set forth in § 156.140(b)(2)).

(d) *Benefit and network equivalence in zero and limited cost sharing plan*

variations. A QHP and each zero cost sharing plan variation or limited cost sharing plan variation thereof must cover the same benefits and providers. The out-of-pocket spending required of enrollees in the zero cost sharing plan variation of a QHP for a benefit that is not an essential health benefit from a provider (including a provider outside the plan's network) may not exceed the corresponding out-of-pocket spending required in the limited cost sharing plan variation of the QHP and the corresponding out-of-pocket spending required in the silver plan variation of the QHP for individuals eligible for cost-sharing reductions under § 155.305(g)(2)(i) of this subchapter, in the case of a silver QHP. The out-of-pocket spending required of enrollees in the limited cost sharing plan variation of the QHP for a benefit that is not an essential health benefit from a provider (including a provider outside the plan's network) may not exceed the corresponding out-of-pocket spending required in the QHP with no cost-sharing reductions. A limited cost sharing plan variation must have the same cost sharing for essential health benefits not described in paragraph (b)(2) of this section as the QHP with no cost-sharing reductions. Each zero cost sharing plan variation or limited cost sharing plan variation is subject to all requirements applicable to the QHP (except for the requirement that the plan have an AV as set forth in § 156.140(b)).

(e) *Decreasing cost sharing and out-of-pocket spending in higher AV silver plan variations.* The cost sharing or out-of-pocket spending required of enrollees under any silver plan variation of a standard silver plan for a benefit from a provider (including a provider outside the plan's network) may not exceed the corresponding cost sharing or out-of-pocket spending required in the standard silver plan or any other silver plan variation thereof with a lower AV.

* * * * *

■ 35. Section 156.430 is amended by removing and reserving paragraph (a) and by revising paragraph (b)(1) to read as follows:

§ 156.430 Payment for cost-sharing reductions.

(b) * * *

(1) A QHP issuer will receive periodic advance payments based on the advance payment amounts calculated in accordance with § 155.1030(b)(3) of this subchapter.

* * * * *

■ 36. Section 156.470 is amended by revising paragraph (a) to read as follows:

§ 156.470 Allocation of rates for advance payments of the premium tax credit.

(a) *Allocation to additional health benefits for QHPs.* An issuer must provide to the Exchange annually for approval, in the manner and timeframe established by HHS, for each health plan at any level of coverage offered, or intended to be offered, in the individual market on an Exchange, an allocation of the rate for the plan to:

(1) EHB, other than services described in § 156.280(d)(1); and

(2) Any other services or benefits offered by the health plan not described in paragraph (a)(1) of this section.

* * * * *

■ 37. Section 156.1110 is added to Subpart L to read as follows:

§ 156.1110 Establishment of patient safety standards for QHP issuers.

(a) *Patient safety standards.* A QHP issuer that contracts with a hospital with greater than 50 beds must verify that the hospital, as defined in section 1861(e) of the Social Security Act, is Medicare-certified or has been issued a Medicaid-only CMS Certification Number (CCN) and is subject to the Medicare Hospital Conditions of Participation requirements for—

(1) A quality assessment and performance improvement program as specified in 42 CFR 482.21; and

(2) Discharge planning as specified in 42 CFR 482.43.

(b) *Documentation.* A QHP issuer must collect the CCN, from each of its contracted hospitals with greater than 50 beds, to demonstrate that those hospitals meet patient safety standards required in paragraph (a) of this section.

(c) *Reporting.* (1) A QHP issuer must make available to the Exchange the documentation referenced in paragraph (b) of this section, upon request by the Exchange, in a time and manner specified by the Exchange.

(2) Issuers of multi-State plans, as defined in § 155.1000(a) of this subchapter, must provide the documentation described in paragraph (b) of this section to the U.S. Office of Personnel Management, in the time and manner specified by the U.S. Office of Personnel Management.

(d) *Effective date.* A QHP issuer must ensure that each QHP meets patient safety standards in accordance with paragraph (a) of this section effective for plan years beginning on or after January 1, 2015.

■ 38. Section 156.1210 is amended by adding paragraph (c) to read as follows:

§ 156.1210 Confirmation of HHS payment and collections reports.

* * * * *

(c) *Discrepancies to be addressed in future reports.* Discrepancies in payment and collections reports identified to HHS under this section will be addressed in subsequent payment and collections reports, and will not be used to change debts determined pursuant to invoices generated under previous payment and collections reports.

■ 39. Section 156.1215 is added to Subpart M to read as follows:

§ 156.1215 Payment and collections processes.

(a) *Netting of payments and charges for 2014.* In 2014, as part of its monthly payment and collections process, HHS will net payments owed to QHP issuers and their affiliates under the same taxpayer identification number against amounts due to the Federal government from the QHP issuers and their affiliates under the same taxpayer identification number for advance payments of the premium tax credit, advance payments of cost-sharing reductions, and payment of Federally-facilitated Exchange user fees.

(b) *Netting of payments and charges for later years.* In 2015 and later years, as part of its payment and collections process, HHS may net payments owed to issuers and their affiliates operating under the same tax identification number against amounts due to the Federal government from the issuers and their affiliates under the same taxpayer identification number for advance payments of the premium tax credit, advance payments of and reconciliation of cost-sharing reductions, payment of Federally-facilitated Exchange user fees, and risk adjustment, reinsurance, and risk corridors payments and charges.

(c) *Determination of debt.* Any amount owed to the Federal government by an issuer and its affiliates for advance payments of the premium tax credit, advance payments of and reconciliation of cost-sharing reductions, Federally-facilitated Exchange user fees, risk adjustment, reinsurance, and risk corridors, after HHS nets amounts owed by the Federal government under these programs, is a determination of a debt.

■ 40. Section 156.1220 is added to subpart M to read as follows:

§ 156.1220 Administrative appeals.

(a) *Requests for reconsideration.* (1) *Matters for reconsideration.* An issuer may file a request for reconsideration under this section to contest a processing error by HHS, HHS's incorrect application of the relevant

methodology, or HHS's mathematical error only with respect to the following:

(i) The amount of advance payment of the premium tax credit, advance payment of cost-sharing reductions or Federally-facilitated Exchange user fees charge for a benefit year;

(ii) The amount of a risk adjustment payment or charge for a benefit year, including an assessment of risk adjustment user fees;

(iii) The amount of a reinsurance payment for a benefit year;

(iv) The amount of a risk adjustment default charge for a benefit year;

(v) The amount of a reconciliation payment or charge for cost-sharing reductions for a benefit year; or

(vi) The amount of a risk corridors payment or charge for a benefit year.

(2) *Materiality threshold.*

Notwithstanding paragraph (a)(1) of this section, an issuer may file a request for reconsideration under this section only if the amount in dispute under paragraph (a)(1)(i) through (vi) of this section, as applicable, is equal to or exceeds 1 percent of the applicable payment or charge listed in that subparagraph payable to or due from the issuer for the benefit year, or \$10,000, whichever is less.

(3) *Time for filing a request for reconsideration.* The request for reconsideration must be filed in accordance with the following timeframes:

(i) For advance payments of the premium tax credit, advance payments of cost-sharing reductions, or Federally-facilitated Exchange user fee charges, within 60 calendar days after the date of the final reconsideration notification specifying the aggregate amount of advance payments of the premium tax credit, advance payments of cost-sharing reductions, and Federally-facilitated Exchange user fees for the applicable benefit year;

(ii) For a risk adjustment payment or charge, including an assessment of risk adjustment user fees, within 60 calendar days of the date of the notification provided by HHS under § 153.310(e) of this subchapter;

(iii) For a reinsurance payment, within 60 calendar days of the date of the notification provided by HHS under § 153.240(b)(1)(ii) of this subchapter;

(iv) For a default risk adjustment charge, within 60 calendar days of the date of the notification of the default risk adjustment charge;

(v) For reconciliation of cost-sharing reductions, within 60 calendar days of the date of the notification provided by HHS of the cost-sharing reduction reconciliation payment or charge; and

(vi) For a risk corridors payment or charge, within 60 calendar days of the date of the notification provided by HHS under § 153.510(d) of this subchapter.

(4) *Content of request.* (i) The request for reconsideration must specify the findings or issues specified in paragraph (a)(1) of this section that the issuer challenges, and the reasons for the challenge.

(ii) Notwithstanding paragraph (a)(1) of this section, a reconsideration with respect to a processing error by HHS, HHS's incorrect application of the relevant methodology, or HHS's mathematical error may be requested only if, to the extent the issue could have been previously identified by the issuer to HHS under § 153.710(d)(2) or (e)(2) of this subchapter, it was so identified and remains unresolved.

(iii) Notwithstanding paragraph (a)(1) of this section, a reconsideration with respect to advance payments of the premium tax credit, advance payments of cost-sharing reductions, and Federally-facilitated Exchange user fees may be requested only if, to extent the issue could have been previously identified by the issuer to HHS under § 156.1210, it was so identified and remains unresolved. An issuer may request reconsideration if it previously identified an issue under § 156.1210 after the 15-calendar-day deadline, but late discovery of the issue was not due to misconduct on the part of the issuer.

(iv) The issuer may include in the request for reconsideration additional documentary evidence that HHS should consider. Such documents may not include data that was to have been filed by the applicable data submission deadline, but may include evidence of timely submission.

(5) *Scope of review for reconsideration.* In conducting the reconsideration, HHS will review the appropriate payment and charge determinations, the evidence and findings upon which the determination was based, and any additional documentary evidence submitted by the issuer. HHS may also review any other evidence it believes to be relevant in deciding the reconsideration, which will be provided to the issuer with a reasonable opportunity to review and rebut the evidence. The issuer must prove its case by a preponderance of the evidence with respect to issues of fact.

(6) *Reconsideration decision.* HHS will inform the issuer of the reconsideration decision in writing. A reconsideration decision is final and binding for decisions regarding the advance payments of the premium tax credit, advance payment of cost-sharing

reductions, or Federally-facilitated Exchange user fees. A reconsideration decision with respect to other matters is subject to the outcome of a request for informal hearing filed in accordance with paragraph (b) of this section.

(b) *Informal hearing.* An issuer may request an informal hearing before a CMS hearing officer to appeal HHS's reconsideration decision.

(1) *Manner and timing for request.* A request for an informal hearing must be made in writing and filed with HHS within 30 calendar days of the date of the reconsideration decision under paragraph (a)(5) of this section.

(2) *Content of request.* The request for informal hearing must include a copy of the reconsideration decision and must specify the findings or issues in the decision that the issuer challenges, and its reasons for the challenge. HHS may submit for review by the CMS hearing officer a statement of its reasons for the reconsideration decision.

(3) *Informal hearing procedures.* (i) The issuer will receive a written notice of the time and place of the informal hearing at least 15 calendar days before the scheduled date.

(ii) The CMS hearing officer will neither receive testimony nor accept any new evidence that was not presented with the reconsideration request and HHS statement under paragraph (b) of this section. The CMS hearing officer will review only the documentary evidence provided by the issuer and HHS, and the record that was before HHS when HHS made its reconsideration determination. The issuer may be represented by counsel in the informal hearing, and must prove its case by clear and convincing evidence with respect to issues of fact.

(4) *Decision of the CMS hearing officer.* The CMS hearing officer will send the informal hearing decision and the reasons for the decision to the issuer. The decision of the CMS hearing officer is final and binding, but is subject to the results of any Administrator's review initiated in accordance with paragraph (c) of this section.

(c) *Review by the Administrator.* (1) If the CMS hearing officer upholds the reconsideration decision, the issuer may request review by the Administrator of CMS within 15 calendar days of the date of the CMS hearing officer's decision. The request for review must specify the findings or issues that the issuer challenges. HHS may submit for review by the Administrator a statement supporting the decision of the CMS hearing officer.

(2) The Administrator will review the CMS hearing officer's decision, the

statements of the issuer and HHS, and any other information included in the record of the CMS hearing officer's decision, and will determine whether to uphold, reverse, or modify the CMS hearing officer's decision. The issuer must provide its case by clear and convincing evidence with respect to issues of fact. The Administrator will send the decision and the reasons for the decisions to the issuer.

(3) The Administrator's determination is final and binding.

PART 158—ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS

■ 41. The authority citation for part 158 continues to read as follows:

Authority: Section 2718 of the Public Health Service Act (42 U.S.C. 300gg–18), as amended.

■ 42. Section 158.130 is amended by revising paragraph (b)(5) to read as follows:

§ 158.130 Premium revenue.

* * * * *

(b) * * *

(5) Account for the net payments or receipts related to the risk adjustment, risk corridors (using an adjustment percentage, as described in § 153.500 of this subchapter, equal to zero percent), and reinsurance programs under sections 1341, 1342, and 1343 of the Patient Protection and Affordable Care Act, 42 U.S.C. 18061, 18062, 18063.

* * * * *

■ 43. Section 158.140 is amended by revising paragraph (b)(4)(ii) to read as follows:

§ 158.140 Reimbursement for clinical services provided to enrollees.

* * * * *

(b) * * *

(4) * * *

(ii) Receipts related to the transitional reinsurance program and net payments or receipts related to the risk adjustment and risk corridors programs (calculated using an adjustment percentage, as described in § 153.500 of this subchapter, equal to zero percent) under sections 1341, 1342, and 1343 of the Patient Protection and Affordable Care Act, 42 U.S.C. 18061, 18062, 18063.

* * * * *

■ 44. Section 158.240 is amended by revising paragraph (c)(2) to read as follows:

§ 158.240 Rebating premium if the applicable medical loss ratio standard is not met.

* * * * *

(c) * * *

(2) For example, an issuer must rebate a pro rata portion of premium revenue if it does not meet an 80 percent MLR for the individual market in a State that has not set a higher MLR. If an issuer has a 75 percent MLR for the coverage it offers in the individual market in a State that has not set a higher MLR, the issuer must rebate 5 percent of the premium paid by or on behalf of the enrollee for the MLR reporting year after subtracting a pro rata portion of taxes and fees and accounting for payments or receipts related to the reinsurance, risk adjustment and risk corridors programs (calculated using an adjustment percentage, as described in § 153.500 of this subchapter, equal to zero percent). If the issuer's total earned premium for the MLR reporting year in the individual market in the State is \$200,000, the issuer received transitional reinsurance payments of \$2,500, and made net payments related to risk adjustment and risk corridors of

\$20,000 (calculated using an adjustment percentage, as described in § 153.500 of this subchapter, equal to zero percent), the issuer's gross earned premium in the individual market in the State would be \$200,000 plus \$2,500 minus \$20,000, for a total of \$182,500. If the issuer's Federal and State taxes and licensing and regulatory fees, including reinsurance contributions, that may be excluded from premium revenue as described in §§ 158.161(a), 158.162(a)(1) and 158.162(b)(1), allocated to the individual market in the State are \$15,000, and the net payments related to risk adjustment and risk corridors, reduced by reinsurance receipts, that must be accounted for in premium revenue as described in §§ 158.130(b)(5), 158.221, and 158.240, are \$17,500 (\$20,000 reduced by \$2,500), then the issuer would subtract \$15,000 and add \$17,500 to gross premium revenue of \$182,500, for a base of \$185,000 in premium. The issuer

would owe rebates of 5 percent of \$185,000, or \$9,250 in the individual market in the State. In this example, if an enrollee of the issuer in the individual market in the State paid \$2,000 in premiums for the MLR reporting year, or 1/100 of the issuer's total premium in that State market, then the enrollee would be entitled to 1/100 of the total rebates owed by the issuer, or \$92.50.

* * * * *

Dated: February 26, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Approved: February 27, 2014.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2014-05052 Filed 3-5-14; 4:15 pm]

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