

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 144, 147, 153, 155, and 156

[CMS-9954-P]

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: Proposed rule.

SUMMARY: This proposed 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 proposes additional standards with respect to composite rating, 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: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 26, 2013.

ADDRESSES: In commenting, please refer to file code CMS-9954-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-9954-P, P.O. Box 8016, Baltimore, MD 21244-8016.

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

3. *By express or overnight mail.* You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and

Human Services, Attention: CMS-9954-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

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

FOR FURTHER INFORMATION CONTACT: For general information: Sharon Arnold, (301) 492-4286; Laurie McWright, (301) 492-4311; or Jeff Wu, (301) 492-4305.

For matters related to student health insurance coverage and composite rating: Jacob Ackerman, (301) 492-4179.

For matters related to the risk adjustment program generally, the small group counting requirements, the risk adjustment methodology, and the methodology for determining the reinsurance contribution rate and payment parameters: Kelly Horney, (410) 786-0558.

For matters related to reinsurance generally, oversight of the premium stabilization programs, distributed data collection, and administrative appeals: Adrienne Glasgow, (410) 786-0686.

For matters related to reinsurance contributions: Adam Shaw, (410) 786-1019.

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

For matters related to cost-sharing reductions, the premium adjustment percentage, and Federally-facilitated Exchange user fees: Johanna Lauer, (301) 492-4397.

For matters related to the annual limitation on cost sharing for stand-alone dental plans, privacy and security of personally identifiable information, the annual open enrollment period for the 2015 benefit year, and the meaningful difference standard: Leigha Basini, (301) 492-4380.

For matters related to the Small Business Health Options Program: Scott Dafflito, (301) 492-4198.

For matters related to the actuarial value calculator: Allison Wiley at (410) 786-1740.

For matters related to patient safety standards for issuers of qualified health plans: Nidhi Singh Shah, (301) 492-5110.

For matters related to netting of payments and charges: Pat Meisol, (410) 786-1917.

SUPPLEMENTARY INFORMATION:

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

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

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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

NAIC—National Association of Insurance Commissioners

OMB—Office of Management and Budget

OPM—United States Office of Personnel Management

PHS Act—Public Health Service Act

PII—Personally identifiable information

PSO—Patient Safety Organization

PRA—Paperwork Reduction Act of 1985

PSES—Patient safety evaluation system

QHP—Qualified health plan

SHOP—Small Business Health Options Program

The Code Internal Revenue Code of 1986

I. Executive Summary

Qualified individuals and qualified employers are now able to purchase private health insurance coverage that begins as early as January 1, 2014, 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 receive premium tax credits to make health insurance more affordable and financial assistance to reduce cost sharing for health care services. In 2014, HHS will also operationalize the premium stabilization programs established by the Affordable Care Act—the risk adjustment, reinsurance, and risk corridors programs—which are intended to mitigate the impact of possible 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 proposed rule proposes additional provisions related to the implementation of these programs. Specifically, we propose certain oversight provisions for the premium stabilization programs, as well as key payment parameters for the 2015 benefit year.

The Patient Protection and Affordable Care Act; 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 proposed rule proposes minor updates to this risk adjustment methodology for 2014 to account for certain private market Medicaid expansion plans, and seeks comment on how to adjust the geographic cost factor in the payment transfer formula to account for less populous rating areas in future benefit years. In this proposed rule, we also propose to clarify the counting methods for determining small

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

group size for participation in the risk adjustment and risk corridors programs.

Using the methodology set forth in the 2014 Payment Notice for determining the uniform reinsurance contribution rate and uniform reinsurance payment parameters, we propose in this rule 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 also propose 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 propose that if reinsurance contributions collected for a benefit year exceed the requests for reinsurance payments for the benefit year, we would increase the coinsurance rate on our reinsurance payments, ensuring that all of the contributions collected for a benefit year are expended for claims for that benefit year.

We also propose several provisions related to cost sharing. First, we propose a methodology 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 also propose to set the same reduced maximum annual limitations on cost sharing for the 2015 benefit year as we established for the 2014 benefit year for cost-sharing reduction plan variations. Additionally, we are proposing certain modifications to the methodology for calculating advance payments for cost-sharing reductions for the 2015 benefit year. We also propose standards for updating the actuarial value (AV) calculator.

This proposed rule provides for a 2015 Federally-facilitated Exchange (FFE) user fee rate of 3.5 percent of premium. Additionally, we propose a user fee adjustment allowance for administrative costs in the 2015 benefit year to reimburse third party administrators that provide payment for contraceptive services for enrollees in certain self-insured group health plans that receive an accommodation from the obligation to cover these services in 2014.

On November 14, 2013, the Federal government announced a policy under which it will not consider certain non-grandfathered health insurance coverage in the individual or small group market renewed between January 1, 2014, and

October 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.²

Issuers have set their 2014 premiums for individual and small group market plans by estimating the health risk of enrollees across all of their plans in the respective markets, in accordance with the single risk pool requirement at 45 CFR 156.80. These estimates assumed that individuals currently enrolled in the transitional plans described above would participate in the single risk pools applicable to all non-grandfathered individual and small group plans, respectively (or a merged risk pool, if required by the State). Individuals who elect to continue coverage in a transitional plan (forgoing premium tax credits and cost-sharing reductions that might be available through an Exchange plan, and the essential health benefits package offered by plans compliant with the 2014 market rules, and perhaps taking advantage of the underwritten premiums offered by the transitional plan) may have lower health risk, on average, than enrollees in individual and small group plans subject to the 2014 market rules.

If lower health risk individuals remain in a separate risk pool, the transitional policy could increase an issuer's average expected claims cost for plans that comply with the 2014 market rules. Because issuers would have set premiums for QHPs in accordance with 45 CFR 156.80 based on a risk pool assumed to include the potentially lower health risk individuals that enroll in the transitional plans, an increase in expected claims costs could lead to unexpected losses.

To help address the effects of this transitional policy on the risk pool, we are exploring modifications to a number of programs. We have outlined various options under consideration throughout this proposed rule, including adjustments to the reinsurance and risk corridors programs. We are seeking comment on these proposals, as well as soliciting suggestions for alternate proposals. As the impact of the transitional policy becomes clearer, we will determine what, if any, adjustments are appropriate.

The success of the premium stabilization programs depends on a robust oversight program. This proposed rule expands on 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). In this proposed rule, we propose that HHS may audit State-operated reinsurance programs, contributing entities, and issuers of risk adjustment covered plans and reinsurance eligible-plans. We also clarify participation standards for the risk corridors program, and outline a proposed process for validating risk corridors data submissions and enforcing compliance with the provisions of the risk corridors program.

We also propose several provisions regarding 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"³ 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 proposed rule, we propose standards for risk adjustment data validation, including a sampling methodology for the initial validation audit and detailed audit standards. These proposed standards would be tested for 2 years before they are used as a basis for payment adjustments. This proposed rule also includes a proposal to implement, over time, the requirements related to patient safety standards that QHP issuers must meet, and proposes reducing 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 propose provisions related to the privacy and security of personally identifiable information (PII), the annual open enrollment period for 2015, the annual limitation on cost sharing for stand-alone dental plans, and the meaningful difference standards for QHPs offered through an FFE. We also propose certain standards for the Small Business Health Options Program (SHOP) and for composite rating 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

² Letter to Insurance Commissioners, Center for Consumer Information and Insurance Oversight, November 14, 2013. See <http://www.cms.gov/CCIIO/Resources/Letters/Downloads/commissioner-letter-11-14-2013.PDF>.

³ Available at: https://www.regtap.info/uploads/library/ACA_HHS_OperatedRADVWhitePaper_062213_5CR_062213.pdf

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 proposed rule, we refer to the two statutes collectively as the “Affordable Care Act.”

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 EHBs and provides for cost-sharing limits and AV requirements. Sections 1302(d)(1) and (d)(2) of the Affordable Care Act describe the determination of the 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.

Section 1311(c)(6)(B) of the Affordable Care Act states that the Secretary is to require an Exchange to provide for annual open enrollment periods 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, including use of a patient safety evaluation system, a comprehensive hospital discharge program, and implementation of health care quality improvement activities. 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.

Section 1313 of the Affordable Care Act, combined with section 1321 of the Affordable Care Act, provides 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 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 individuals with lower household income and Indians.

Section 1411(g) of the Affordable Care Act provides that any person who receives information specified in section 1411(b) provided by 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.

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), we published a proposed rule outlining the benefit and payment parameters for 2014 to expand the provisions related to the premium stabilization programs and set forth payment parameters in those programs (proposed 2014 Payment Notice). We published the 2014 Payment Notice in the March 11, 2013 **Federal Register** (78 FR 153410).

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 proposed standards related to the premium adjustment percentage 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 set forth standards related to Exchange user fees in the 2014 Payment Notice. We also established an adjustment to the FFE user fee in the Coverage of Certain Preventive Services Under the Affordable Care Act final rule, published in the July 2, 2013 **Federal Register** (78 FR 39870) (Preventive Services Rule).

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

Provisions relating to the 2014 market reforms and rate review were published in Patient Protection and Affordable Care Act; Health Insurance Market Rules; Rate Review proposed rule in the November 26, 2012 **Federal Register** (77 FR 70584). A final rule implementing these provisions was published 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 (NAIC), regular contact with States through the Exchange Establishment grant and Exchange Blueprint approval processes, and meetings with Tribal leaders and representatives, health insurance issuers, trade groups, consumer advocates, employers, and other interested parties. We considered all of the public input as we developed the policies in this proposed rule.

C. Structure of Proposed Rule

The regulations outlined in this proposed rule would be codified in 45 CFR parts 144, 147, 153, 155 and 156. The proposed regulations in parts 144 and 147 propose amendments relating to student health insurance coverage. The proposed regulations in part 147 also outline market-wide provisions regarding composite rating. The proposed regulations in part 153 outline the 2015 uniform contribution rate and uniform reinsurance payment parameters for the 2015 benefit year and oversight provisions related to the premium stabilization programs, such as provisions related to risk adjustment data validation, risk corridors data validation, and HHS's authority to audit entities participating in these programs. The proposed regulations in part 153 propose that excess reinsurance contributions collected for a benefit year be used for claims for that benefit year.

The proposed regulations in part 155 propose to reduce the time that States that elect to establish and operate an Exchange after 2014 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 effective date of coverage. The proposed regulations also include a change to the annual open enrollment period for the 2015 benefit year and certain proposals related to the SHOP Exchanges, which we discuss in greater detail below. We also propose in part 155 to amend § 155.260 to allow the Secretary to determine that additional uses or disclosures of PII not specifically permitted by § 155.260 ensure the efficient operation of the Exchange. In addition, we propose to establish a process under which Exchanges may seek the Secretary's approval for other uses of applicant PII not specifically permitted by § 155.260. We also propose to amend § 155.260 to more specifically define the term "non-Exchange entity" and to provide a baseline for the privacy

and security standards to which Exchanges must bind non-Exchange entities through written contracts or agreements.

The proposed regulations in part 156 set forth provisions related to cost sharing, including the premium adjustment percentage, the maximum annual limitation on cost sharing, the maximum annual limitation on deductibles for health plans in the small group market, the reductions in the maximum annual limitation for cost sharing plan variations, and the methodology to calculate advance payments of cost-sharing reductions for 2015. They also outline the 2015 FFE user fee rate and propose a user fee adjustment to reimburse third party administrators that pay for contraceptive services for enrollees in certain self-insured group health plans that receive an accommodation from the obligation to cover these services. They also include provisions related to parameters for making updates to the AV calculator in future plan years. The proposed 2015 AV Calculator and a proposed 2015 AV Calculator methodology, which would supersede the 2014 versions of these documents incorporated by reference in the EHB Rule, are being incorporated by reference in this proposed rule. In part 156 we also propose a meaningful difference standard for QHPs offered through an FFE and patient safety standards for issuers of QHPs. Finally, we propose an administrative appeals process applicable to the premium stabilization, cost-sharing reduction, advance payments of the premium tax credit, and FFE user fee programs.

In parts 155 and 156, we also propose the following provisions related to the SHOP:

- We propose to permit all SHOPS performing premium aggregation to establish one or more standard processes for premium calculation, payment, and collection.
- We propose that in the FF-SHOPS, for plan years when premium aggregation is available, employers be required to make premium payments to the FF-SHOP according to a timeline and process established by HHS. We further propose that for plan years beginning on or after January 1, 2015, unless the QHP issuer receives a cancellation notice from the FF-SHOP, the issuer would be required to effectuate coverage.
- We propose a standard premium pro-rating methodology for the FF-SHOPS, for plan years when premium aggregation is available, providing that groups will be charged for the portion

of the month for which an enrollee is enrolled.

- We propose to make explicit our interpretation of current regulations that no SHOPs would be permitted to collect information on a SHOP application unless that information is necessary to determine SHOP eligibility or effectuate enrollment through the SHOP.

- We propose that no SHOPs would be permitted to perform individual market Exchange eligibility determinations or verifications.

- We propose that a qualified employer that becomes a large employer but continues to purchase coverage through a SHOP would continue to be rated as a small employer.

- We propose to limit the employer and employee eligibility adjustment periods to circumstances when the SHOP has an optional verification process, and collects information through that verification process that is inconsistent with the information provided by an employer or employee on a SHOP application.

- We propose for plan years beginning on or after January 1, 2015 to give SHOPs in States that permit this activity under State law, the option of permitting enrollment in a SHOP through the Internet Web site of an agent or broker.

- We propose to limit the availability of composite premiums in the FF-SHOPs after employee choice and premium aggregation become available.

- We propose methods for employers in the FF-SHOPs to offer stand-alone dental coverage after employee choice becomes available in those SHOPs.

- We propose for plan years beginning on or after January 1, 2015 to permit FF-SHOPs to give employers the flexibility to define different premium percentage contributions for full-time employees and non-full-time employees.

We note that nothing in these proposed regulations would limit the authority of the Office of the Inspector General (OIG) as set forth by the Inspector General Act of 1978 or other applicable law.

III. Provisions of the Proposed HHS Notice of Benefit and Payment Parameters for 2015

A. Part 144—Requirements Relating to Health Insurance Coverage

In § 144.103, the term “policy year,” as amended by the second final Program Integrity Rule, is defined as: (1) With respect to a grandfathered health plan offered in the individual health insurance market, the 12-month period that is designated as the policy year in

the policy documents of the individual health insurance coverage. If there is no designation of a policy year in the policy document (or no such policy document is available), then the policy year is the deductible or limit year used under the coverage. If deductibles or other limits are not imposed on a yearly basis, the policy year is the calendar year; and (2) with respect to a non-grandfathered health plan offered in the individual health insurance market, or in a market in which the State has merged the individual and small group risk pools (merged market), for coverage issued or renewed beginning January 1, 2014, a calendar year for which health insurance coverage provides coverage for health benefits. Further, § 147.104, as amended by the second final Program Integrity Rule, establishes individual market open enrollment periods based on a calendar policy year and provides that non-grandfathered coverage in the individual or merged markets must be offered on a calendar year basis, with a policy year beginning on January 1 and ending on December 31 of each year.

Under regulations at § 147.145(a), student health insurance coverage is defined as individual health insurance coverage. Section 147.145(b), however, exempts student health insurance coverage from certain PHS Act and Affordable Care Act requirements that apply to individual health insurance coverage, including certain guaranteed availability provisions of section 2702 of the PHS Act, implemented at § 147.104. As discussed below, because student health insurance coverage is traditionally offered on a school year basis (for example, a policy year beginning on September 1 of each year and ending on August 30 of the following year), we are proposing to modify § 147.145 to exempt student health insurance coverage from the requirement under section 2702 to establish open enrollment periods and coverage effective dates that are based on a calendar policy year, including the requirement that non-grandfathered coverage in the individual and merged markets be offered on a calendar year basis. We are also proposing conforming amendments to the definition of “policy year” to reflect that student health insurance coverage would not be required to be offered on a calendar year basis. We seek comment on this proposal.

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

1. Composite Rating

Section 2701 of the PHS Act, as added by section 1201 of the Affordable Care Act, establishes permissible rating factors that may be used to vary the premium rate charged by a health insurance issuer for non-grandfathered health insurance coverage (including QHPs) in the individual and small group markets beginning in 2014.⁴ The factors are: family size, rating area, age, and tobacco use (within limits). Section 2701(a)(4) of the PHS Act provides that with respect to family coverage under a group health plan or health insurance coverage, any rating variation for age or tobacco use must be applied based on the proportion of the premium attributable to each family member covered under the plan or coverage.

In the Market Reform Rule, we applied the per-member rating requirement of PHS Act section 2701(a)(4) in both the individual and small group markets. Thus, at § 147.102(c), we generally directed that issuers calculate a separate premium for each individual covered under the plan or coverage based on allowable rating factors including age and tobacco use, and sum the individual rates to determine the total premium charged by the issuer to a family or to a group health plan.⁵

We recognized that in the small group market it is common industry billing practice to charge an employer a uniform premium for a given family composition by adding the per-member rates and dividing by the total number of employees covered under the employer's health insurance plan. We indicated that nothing prevents an issuer from converting per-member rates into average enrollee premium amounts (calculated composite premiums), provided that the total group premium is the same total amount derived in accordance with the process established by the regulations.

Because calculated composite premiums are average rates for a particular group, changes in employee

⁴ Beginning in 2017, States will have the option to allow issuers to offer QHPs in the large group market through the SHOP. If a State elects this option, the rating rules in section 2701 and its implementing regulations will apply to all coverage offered in such State's large group market (except for self-insured group health plans) under to section 2701(a)(5) of the PHS Act.

⁵ 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. § 147.102(c)(2).

census would typically cause a change in the average rate. For example, a new average rate per enrollee would typically result from employees adding or dropping coverage during the course of the plan year, causing employer and employee contributions to change as well. We have been asked about such mid-year changes in group composition and how issuers should address the resulting changes in the calculated composite premium for the group.

In this proposed rule, we propose to add a provision at § 147.102(c)(3) clarifying that if an issuer offers a composite premium calculated when the employer obtains or renews coverage, the issuer must ensure that such amount does not vary for any plan participant or beneficiary during the plan year with respect to the particular plan involved. Under this approach, an issuer would be required to accept the group's composite premium, calculated based on applicable employee enrollment at the beginning of the plan year, as the applicable premium rate for any new individual who enrolls in the plan during the plan year.⁶ Terminations of coverage during the plan year also would not change the composite premium. At the time of renewal, the issuer would recalculate a group's composite premium based on plan enrollment at that time for subsequent coverage. This will allow calculated composite premiums, and thus employer and employee contributions to coverage, to remain stable during the plan year, regardless of changes in the group's composition.

This proposed policy would generally apply to health insurance issuers offering non-grandfathered health insurance coverage in the small group market, through a SHOP or outside of a SHOP, for plan years beginning on or after January 1, 2015. However, we encourage issuers to voluntarily adopt this approach for plan years beginning in 2014. As discussed in more detail below, we propose a limited exception to this policy in § 155.705(b)(11)(ii)(D) and § 156.285(a)(4)(ii) of this proposed rule, under which composite rating would not be available when an

employer participating in a Federally-facilitated SHOP elects to offer its employees all QHPs within a single level of coverage under § 155.705(b)(3)(iv)(A).

We are considering establishing a uniform tiered-composite rating structure that would apply market wide unless a State requires and HHS approves an alternate tiered-composite rating methodology. Under the approach we are considering, a small group market issuer offering composite rating would calculate the composite premium for different tiers of enrollees covered under the employer's plan. For example, in a two-tier structure, one composite premium would be calculated for covered adults (employees and adult dependents) and another composite premium would be calculated for covered children. Alternatively, in a three-tier structure, there would be one composite premium for covered employees, a second composite premium for covered adult dependents, and a third composite premium for covered children. The premium for a given family composition would simply be determined by summing the applicable tiered-composite rates. We believe a tiered-composite approach would promote simplicity for issuers and employers, and ensure that premiums for family coverage appropriately reflect the lower rates for children.

We seek comments on all aspects of this approach to composite rating. We also seek comments on whether to establish a default uniform tiered-composite rating structure, including the appropriate number and types of enrollee tiers (for example, an employee-only tier, an adult dependent tier, and a child dependent tier).

2. Student Health Insurance Coverage

As discussed above, under § 147.145(a), student health insurance coverage is defined as a type of individual health insurance coverage. However, § 147.145(b) provides that for purposes of the guaranteed availability requirements of section 2702 of the PHS Act, a health insurance issuer that offers student health insurance coverage is not required to accept individuals who are not students or dependents of student in such coverage. Because student health insurance coverage is traditionally offered on a school year basis that does not align with the calendar year, we do not believe student health insurance should be required to establish open enrollment periods and coverage effective dates under § 147.104(b)(1) and (2) that are based on a calendar policy year, including the requirement that

non-grandfathered coverage in the individual and merged markets be offered on a calendar year basis. Accordingly, we are proposing to amend § 147.145(b)(1)(ii) to exempt student health insurance coverage from these guaranteed availability requirements. We seek comments on this proposal and whether other modifications are necessary for student health insurance coverage.

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

1. Provisions and Parameters for the Permanent Risk Adjustment Program

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

a. Risk Adjustment User Fees

If a State is not approved to operate or chooses to forgo operating its own risk adjustment program, HHS will operate risk adjustment on the State's behalf. As described in the 2014 Payment Notice, HHS's operation of risk adjustment on behalf of States is funded through a risk adjustment user fee. Section 153.610(f)(2) provides that an issuer of a risk adjustment covered plan must remit a user fee to HHS 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

⁶ In cases where the composite premium does not incorporate the age or tobacco use rating factor, an issuer would be required to accept the group's composite premium, calculated based on applicable employee enrollment at the beginning of the plan year, multiplied by any applicable age or tobacco rating factor, as the applicable premium for any new individual who enrolls in the plan during the plan year. Under § 147.102(a)(1)(iv), rating for tobacco use is subject to the nondiscrimination and wellness provisions under section 2705 of the PHS Act and its implementing regulations, regardless of whether the composite premium incorporates the tobacco use rating factor.

adjustment program also will contribute to consumer confidence in the health insurance industry by helping to stabilize premiums across the individual and small group health insurance markets.

In the 2014 Payment Notice, we estimated Federal administrative expenses of operating the risk adjustment program to be \$0.96 per enrollee per year, based on our estimated contract costs for risk adjustment operations. For the 2015 benefit year, we propose to use the same methodology to estimate our administrative expenses to operate the program. These contracts 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 do not propose to set the user fee to cover costs associated with Federal personnel. To calculate the user fee, we would divide 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 (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) in HHS-operated risk adjustment programs for the 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 per capita risk adjustment user fee would be no more than \$1.00 per enrollee per year. We seek comment on this proposed assessment of user fees to support HHS-operated risk adjustment programs.

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 propose to use the same methodology in 2015. In this proposed rule, we propose to clarify the treatment of premium assistance Medicaid alternative plans in this risk adjustment methodology, and seek comment on potential adjustments to the geographic cost factor in the HHS risk adjustment model for future years.

(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 expansion 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, we increase the risk score for individuals in plan variations by a certain factor. We propose to use the same factor for individuals enrolled in the corresponding Medicaid expansion plan variations. 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. We propose to implement these adjustments for 2014. We plan to evaluate these adjustments in the future, after data from the initial years of risk adjustment is available. We seek comment on this approach.

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

(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 geographically 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, several States have defined a large number of rating areas. 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 seek comment on how to best adjust the geographic cost factors or geographic rating areas in future years to address these potential premium distortions. We also seek comments on how this adjustment should be implemented for a separately risk adjusted pool of catastrophic plans. We do not intend to make this adjustment for 2014.

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 limit “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 part-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. Thus, 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 the effects of 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 propose to clarify that in determining which group health plans participate as small group plans in the risk adjustment program, we would apply the applicable State counting method, unless the State counting method does not take into account employees that are not full-time. In that circumstance, we would apply the full-time equivalent method described in section 4980H(c)(2)(E) of the Code.⁷ We believe that this approach defers to State counting methods and aligns with State enforcement of rating rules, within the bounds of what is permissible under the Affordable Care Act. We seek comment on our interpretation of the permissible counting rules for purposes of risk adjustment, the approach described above, and on alternate counting methods that may be preferable. We also seek comment on whether we should codify these risk adjustment counting rules in regulation text.

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, 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. That white paper discussed and sought comments on a number of potential considerations for the development of the risk adjustment data validation methodology. On June 25, 2013, we held a public meeting to discuss the topics considered in the white paper. 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 this proposed rule, we propose 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 note that a State operating a risk adjustment program is not required to adopt these standards. These proposed rules are consistent with the white paper and lessons drawn from our experience with Medicare Advantage risk adjustment data validation and thus should be familiar to issuers.

(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 proposed 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, we propose to use the methodology outlined in the white paper. Our goal in determining the enrollee sample size for the initial 2 years of risk adjustment data validation is to propose a statistically valid sample large enough to inform us to the dynamics of the risk adjustment data validation process in operation and estimation of risk score accuracy. As we established in the 2014 Payment Notice, for 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 general, we propose to select 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. We are proposing that, for the initial 2 years of the risk adjustment data validation program, the initial validation audit sample will consist of 200 enrollees from each issuer. We stated in the 2014 Payment Notice that the overall sample will reflect a disproportionate selection of enrollees with HCCs. Here, we discuss in detail our proposed 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 proposing a simple age and risk score stratification for at least the initial 2 years of the program. Following the division of the relevant population into strata, we propose to use the following formulas to calculate a proposed sample size for the initial validation audit each year. In general, the proposed formula for the overall sample size for an issuer (n) is:

⁷ We note that the IRS has published a proposed regulation that contains further details that would apply to this calculation (54.4980H-2(c)).

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

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).

As noted above, we propose a sample size of 200 enrollees from each issuer for the initial 2 years of the program.

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

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.

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

- Strata 1–3 would include low, medium, and high risk adults with the presence of at least one HCC.
- Strata 4–6 would include low, medium, and high risk children with the presence of at least one HCC.
- Strata 7–9 would 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

The formula above would be used after this initial 2-year period to calculate a more precise, issuer-specific sample size for each issuer.

The proposed formula for calculating the sample size for each stratum is:

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. That program 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 propose to 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 propose to use the lowest error rate across all HCC strata as the error rate for the stratum of enrollees without HCCs, and we propose to 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 used the same risk score error rates and standard

deviation for the age bands for a risk category. Thus, we used 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 made 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, we propose to use 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 $1.96 \cdot \sigma$ 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 proposed 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.

In the proposed rule for the 2014 Payment Notice, we suggested that an issuer's initial validation audit sample for risk adjustment data validation would consist of approximately 300 enrollees. After conducting the calculations described above, we believe that we can achieve acceptable sampling precision with a sample size of 200 enrollees for the initial years of HHS-operated risk adjustment data validation. Therefore, we are proposing a sample size of 200 enrollees in the initial 2 years of the program. As noted above, we may provide for different, or issuer-specific, sample sizes in future years.

When data becomes available from the program's first year, we expect to examine our sampling assumptions

using actual enrollee data. We anticipate that at least in the initial 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 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 seek comments on this approach, including our proposed sample size of 200 enrollees for the initial 2 years of HHS-operated risk adjustment data validation.

(ii) Initial Validation Audit

The second stage of the HHS-operated risk adjustment data validation process is the initial validation audit. In § 153.630(b)(1), we require an issuer of a risk adjustment covered plan to engage one or more independent auditors to perform an initial validation audit of a sample of its risk adjustment data selected by HHS, which will include individually identifiable health information subject to HIPAA.⁹ In this section of this proposed rule, we discuss proposed standards and guidelines regarding the qualifications of the initial validation auditor, including conflict of interest standards, standards for the initial validation audit, rater consistency and reliability, and confirmation of risk adjustment errors. As discussed in the white paper, 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 direct 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 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. We propose certain guidance on these topics here.

We are considering 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

⁸ Critical value for the two-sided 95 percent confidence level.

⁹ Whether any given organization is a HIPAA business associate is a fact-specific inquiry. We expect that most independent auditors operating on behalf of an issuer of a health plan would be performing activities that would render them a business associate of the covered plan, and would be required to enter into and maintain a business associate agreement with the health plan.

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 are considering standards under which issuers would 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 Office of the Inspector General exclusion list, or are under investigation with respect to any HHS programs.

We note 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 note that HHS could gather information through external reporting to support that review. Although we are 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.

We propose 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 propose to consider 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 propose to consider any individual that serves on the governing board of an entity to be a director of the entity. We are 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 expect to identify the enrollee sample for the initial validation audit in the summer of the year following the benefit year. We are contemplating requiring delivery of the initial validation audit findings to HHS in the fourth quarter of that year. We include a proposed schedule of the risk adjustment data validation process at the end of this section.

Once the audit sample is selected by HHS, we expect issuers would 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 data security and privacy requirements, including the applicable provisions of HIPAA, and enables the initial validation auditor to meet HHS established timelines;

- The initial validation auditor would analyze the enrollment and medical record data to validate the demographic information, plan or plan variation enrollment, and health 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 note that § 153.630(f)(2) is not changed by this proposal, and that the issuer would be required to ensure that its initial validation auditor comply with the security standards described at 45 CFR 164.308, 164.310, and 164.312 in connection with the initial validation audit. We seek comments on these proposals.

(2) Standards for the Initial Validation Audit

We propose to add a new paragraph (b)(5) to § 153.630, in which we propose 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 seek comment on other nationally recognized accrediting agencies that may be

appropriate to certify medical coders who are performing the initial validation audit review of enrollee health status.

(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, we propose 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 (defined below) 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 ("data in transit"). We note that existing privacy and security standards, such as standards under HIPAA and those detailed at § 153.630(f)(2), would apply. This information will 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 note that only a very small percentage of an issuer's records containing personally identifiable information 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. As we describe in this section at (viii), regarding data security standards, we are seeking comment on the applicability and effectiveness of current standards, as well as what other standards HHS should promulgate to ensure data security and privacy protections.

We also propose to add paragraph (b)(7) to § 153.630 to describe the standards for validating each factor of an enrollee's risk score. In paragraph (b)(7)(i), we propose that the initial validation auditor must validate demographic data and enrollment information by reviewing plan source enrollment documentation, such as the

834 transaction,¹⁰ 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 note that certain identifying information from these enrollment transactions, such as the enrollee's name, would be used to ensure that the appropriate medical documentation has been provided.

The sample audit pool will consist of enrollees with and without risk adjustment-eligible diagnoses within eligible dates of service. For each enrollee in the sample with risk adjustment HCC scores, the initial validation auditor would validate diagnoses through a review of the relevant risk adjustment-eligible medical records. We 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 must 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.¹¹

Therefore, in § 153.630(b)(7)(ii), we propose 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. In this paragraph, we also propose, for purposes of § 153.630, that "medical record documentation" 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 must 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 propose 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-CM), or the *International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, 4th Edition* (ICD-10-CM) guidelines for coding and reporting.

(4) Confirmation of Risk Adjustment Errors

We note 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, we propose that no risk adjustment error be assessed for the enrollee's HCC. However, if none of the medical record documentation supports a particular HCC diagnosis for an enrollee, we propose that a risk adjustment error be assessed.

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 may 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 propose in § 153.630(b)(7)(iv) that a senior reviewer must confirm any finding of a risk adjustment error. We believe that a senior reviewer is a reviewer with substantial expertise in medical record coding such that the initial validation auditor would consider the senior reviewer to be the standard against which to measure inter-rater reliability and coding consistency. As such, we propose 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. We seek comment on the credentials and expertise that should be required of a senior reviewer.

(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 propose 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. We propose to 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. Reviews should 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.

(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.

We propose 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),

¹⁰ 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.

¹¹ See "HHS-Operated Data Collection Policy FAQ" for a discussion of chart review as an acceptable source of supplemental diagnosis codes. Additional detail will be provided in future guidance. https://www.regtap.info/uploads/library/HHS_OperatedDataCollectionPolicyFAQs_062613.

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, we are considering selecting the second validation audit subsample using a sampling methodology that will allow for pair-wise means testing to establish statistical difference between the initial and second validation audit results. If the pair-wise means test results 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 is 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 is found based on the second validation audit on the larger subsample, HHS would apply the second validation audit error results to modify the risk scores of the issuer's enrollees, as discussed below. We are considering using a 95 percent confidence interval, but seek comment on the appropriate confidence interval to use with respect to these pair-wise means tests.

As discussed in the white paper, we are considering a number of 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. For example, an issuer could allow its initial validation auditor to submit data validation documentation and results a number of months in advance of the HHS established deadline for submission of initial validation audit results. The second validation auditor would thus be able to begin its review earlier, permitting more time to provide feedback to the issuer on the results of that review and allowing for more opportunity for discussion prior to finalizing the second validation audit findings. Prior to finalizing the risk score adjustment based on the second validation audit findings, the second validation auditor may request discussions with the initial validation auditor to identify the source of the differences, or may review the initial validation auditor's processes. If the initial validation audits are substantiated, the second validation auditor may adjust its risk scores accordingly. This process would not allow for any additional documentation to be submitted on those enrollees for which the second validation audit began early. The appeals decision from the expedited, concurrent process would be final and binding, but would provide issuers the opportunity to begin the process earlier. If HHS establishes a concurrent second validation audit and appeals process, we would need to develop intermediate timelines for initial validation auditor submission of audit documentation and data to the second validation auditor. We seek comments on this approach for establishing a concurrent second validation audit and appeals process.

(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 would be used to adjust the average risk score for each risk adjustment eligible plan offered by the issuer. HHS intends to provide each issuer with enrollee-level audit results and the error estimates.

We are proposing 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 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. For phase two, we describe 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, a pair-wise statistical test would be performed 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 observations;

\tilde{y}_i is the i th second validation audit risk score observation in the second validation audit sample of n observations;

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

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

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

From the N enrollees in the initial validation audit sample, HHS selects a smaller second validation audit subsample of n enrollees. For each second validation audit selected record, HHS calculates the difference, $d_i = \tilde{y}_i - \tilde{x}_i$. HHS then conducts 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,

$$\bar{d} \pm 1.96 \left(\frac{S_d}{\sqrt{n}} \right).$$

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 , have the second validation auditor review the enrollee files, and again conduct a pairwise 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 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, we propose that if the difference between the initial and second validation audits is found to be statistically significant, then 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. We also considered another option, as discussed in the white paper and below. Under this alternate approach, we would use the error rate from the larger second validation audit subsample directly in our determination of whether and by how much to adjust the risk scores of all enrollees in the issuer's risk adjustment covered plans. This approach would disregard all enrollees in the initial validation audit sample that were not reviewed as part of the larger second validation audit subsample.

To illustrate these two options under the phase two adjustment process, consider the following notations:

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

N is the initial validation audit sample size;

n is the size of the larger second validation audit subsample;

\bar{y}_N is the mean of the initial validation audit-adjusted risk scores in the initial validation audit sample N ;

\bar{y}_n is the mean of the second validation audit-adjusted risk scores in the second validation audit sample n ;

\bar{x}_N is the mean of the original risk scores in the initial validation audit sample N ;

\bar{x}_n is the mean of the original risk scores in the second validation audit sample n ;

\bar{X}_M is the original risk score total across all M records;

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

$$\hat{Y}_N = \frac{\bar{y}_N}{\bar{x}_N} \bar{X}_M$$

\hat{y}_n is the projected correct risk score across all M records using the error rate from the larger second validation audit subsample.

$$\hat{Y}_n = \frac{\bar{y}_n}{\bar{x}_n} \bar{X}_M$$

Under this proposed approach, 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 records that were sampled from N (one-for-one risk score adjustment).

(2) Apply a uniform adjustment factor,

$$\frac{\hat{Y}_n}{\hat{Y}_N}$$

to the initial validation audit-adjusted risk scores in the $(N-n)$ records not reviewed by the second validation audit.

Under the alternate approach, the second validation audit-adjusted risk scores in the n records in the larger second validation audit subsample would be used as the basis for adjustment of plan-level average risk scores.

Considering the comments in response to the white paper, and in order to estimate error using a narrower confidence interval, we are proposing to use the larger second validation audit subsample to adjust the initial validation audit sample (by direct replacement for enrollees reviewed by the second validation audit, and by proportional adjustment for the other enrollees), whose adjusted error rate could be used as a basis to adjust plan average risk scores for all risk adjustment covered plans of the issuer.

We seek comment on our proposed approach.

Adjusted Risk Score Projections

Based on the proposals described above, the results of the initial or second validation audits could be used as the basis for projecting a corrected risk score for each issuer's population. The projections described above would be performed on a stratum-by-stratum level and weighted accordingly to achieve an estimate of the corrected risk score for each issuer. As described in the white paper, a stratified separate ratio estimator¹² would be used 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 could 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 is calculated using the following equation:

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

Where:

\hat{Y}_R is used to estimate the correct 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 will first estimate the variance within each stratum and then sum the stratum-specific variances for all strata. The estimated variance of the stratified separate ratio estimate for the correct risk score is calculated as follows:

¹² For a discussion of stratified separate ratio estimators, see Cochran, William G., *Sampling Techniques*, third edition, John Wiley & Sons, 1977, at 164.

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

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 are proposing 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 eligible plans within the issuer. We are considering two options for applying the adjustment factor. Under the first option, we are considering directly applying an adjustment factor to all of the issuer's risk adjustment covered plans. Under the second option, we are considering applying this adjustment only if the corrected average risk score and the recorded average risk score are statistically different.

Were we to implement the second option, a critical parameter of the statistical test would be the target confidence interval, which would determine the stringency of the test. For example, we could perform the statistical test at the 90, 95, or 99 percent confidence interval. We note that the HHS Office of the Inspector General 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 also note that even if the statistical test finds the two risk scores to be statistically different, we could apply the adjustment factor to adjust plan average risk scores based upon using the point estimate of the adjusted average risk score, or some other value within an interval around the point estimate, such as the upper or lower bound of a 95 percent confidence interval around the point estimate.

The choice among these options poses a tradeoff between reducing issuers' incentives to aggressively report or code diagnoses, and increasing the variability of issuers' risk adjustment payments. Under the first option, an issuer that reports data that systematically overstates its risk score would, on average, assuming the corrected risk scores are unbiased estimates of the true risk scores, receive a downward adjustment to its reported risk score equal in magnitude to the degree of overstatement. As a result, this option could eliminate an issuer's incentive to overstate its risk score. On the other hand, due to sampling variation, the first option would routinely introduce significant variability in issuers' risk scores (both up and down), even if the issuer was making no attempt to manipulate its risk scores. While these adjustments would make such an issuer's risk adjustment payments less predictable in any given year, they would not introduce systematic bias in risk scores (assuming the corrected risk scores are unbiased estimates of the true risk scores).

The second option, in contrast, would only adjust an issuer's risk scores when it is very likely that the reported risk scores deviated from the true values, so issuers' risk adjustment payments would be more predictable. However, particularly if the confidence level of the statistical test were set at a high threshold, this approach would often fail to make adjustments when an issuer does in fact overstate its risk score.

Based on commenters' feedback on the white paper, we are proposing to use the second approach described above—we would adjust the plan average risk scores of an issuer based upon the ratio between the correct average risk score estimate and recorded average risk score only if the difference between the estimated and recorded average risk scores were determined to be statistically significant. We are proposing to use a 95 percent confidence interval to determine if the adjusted average risk score and the recorded average risk score are statistically different. Nevertheless, we welcome comments on both options discussed above and on the appropriate tradeoff between reducing issuers' incentive to aggressively report or code

diagnoses and increasing the variability of issuers' risk adjustment payments. In addition, regarding the proposed approach in particular, we seek comments on the appropriate confidence interval to apply when determining whether an adjustment to an issuer's plan average risk score is necessary.

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 would 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).¹³ We would then select an expanded subsample from the original sample of 200 enrollees. Assume that the larger sample is a sample of 100 enrollees. Following completion of the larger second validation audit, we would perform the pair-wise means test again. Assume the test fails again (that is, there is a statistically significant difference in the projected risk scores between the sample of 200 and the larger subsample of 100). We would conclude that the risk scores in the sample of 200 enrollees need to be adjusted.

¹³ 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.

In the second step of error estimation, HHS would adjust the risk scores in the sample of 200 using a one-for-one replacement for the risk scores of the 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 larger subsample of 100. The remaining 100 enrollees that were not included in the second validation audit subsample would 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 in the sample of 200 (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 would be increased by 7 percent.

The projected correct population risk score from the revised sample of 200 would therefore be 1.45, with a two-sided 95 percent confidence interval of 1.35 to 1.55.

(v) Appeals

We anticipate that the risk adjustment data validation appeals process would 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 payments and charges would apply would be 2016. Risk scores and initial payments and charges would be calculated in the spring of 2017 for that payment cycle. 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.

(vi) Payment Transfer Adjustments

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

adjust the plan average risk score for each of the issuer's risk adjustment covered plans. This adjustment would 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 seek comment on considerations for reporting error rates and any additional information that could improve transparency in the markets.

(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 market that fail to provide data necessary for risk adjustment. We are proposing to expand on these provisions to include oversight related to risk adjustment data validation when HHS operates risk adjustment on behalf of a State.

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 are proposing 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 civil money penalties. We note 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 would reserve the right to impose penalties up to the maximum amounts proposed in § 156.805(c), as a general principle, we intend to work collaboratively with issuers to address problems in conducting the risk adjustment data validation process. In our application of the proposed 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. 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 also note that HHS will not perform the initial validation audit for an issuer that does not hire an initial validation auditor or otherwise does not submit initial validation audit results that comply with the regulations in subpart G and subpart H of part 153. For these issuers, we propose in § 153.630(b)(10) to assign a default risk adjustment charge. We are considering whether this charge should be the same charge as contemplated in § 153.740(b), should be based on a default error rate, or should be calculated based on some other methodology. We will propose a

methodology for computing the default error rate or default charge in future rulemaking.

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, and user group calls. We welcome comment on these proposals.

(viii) Data Security

We recognize that the risk adjustment data validation process outlined here will require the transmission of sensitive data and documents between the issuer and the initial and second validation auditors. HHS takes seriously the importance of safeguarding protected health information and personally identifiable information. As outlined in the white paper, 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) requires issuers to ensure that it and its initial validation auditor comply with the security standards described at 45 CFR 164.308, 164.310, and 164.312 in connection with the initial validation audit, the second validation audit, and any appeal. In addition to these requirements, we are considering 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 the 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 intend to address these issues and the treatment of initial and second validation auditors under HIPAA in future rulemaking or guidance, and seek comment on the applicability and effectiveness of current standards, as well as what other standards HHS should promulgate to ensure data security and privacy protections.

(ix) Implementation Timeline

For the 2014 benefit year, we expect to implement risk adjustment data validation activities in early 2015. Implementation activities would 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 would 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 would train issuers and initial validation auditors on the risk adjustment data validation process and the applicable standards for performing the initial validation audit, which would begin in the summer of 2015. Once the initial validation audit has concluded in the fall of 2015, HHS would begin the second validation audit process, which would continue into 2016. Risk adjustment data validation implementation activities for the 2014 benefit year data would 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 the risk adjustment data validation implementation activities would follow a similar schedule for each subsequent benefit year. The 2016 benefit year would be the first year when payments and charges are adjusted. Those adjustments would occur after the conclusion of risk adjustment data validation activities for the 2016 benefit year, in the summer of 2018.

e. HHS Audits of Issuers of Risk Adjustment Covered Plans

In order to safeguard Federal funds, we propose 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 must also ensure that its relevant contractors, subcontractors, or agents cooperate with the audit. 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. We will provide further details on this audit program, including timelines, procedures, and substantive requirements, in future rulemaking and guidance. This audit will focus on those aspects of the risk adjustment program that are not validated through the risk adjustment data validation program, described above in this proposed rule. In particular, we anticipate that the audit will focus on records documenting that the plan was a risk adjustment covered plan. For example, the audit might seek to review records evidencing the type of plan at issue (for example, an individual market metal level plan versus a catastrophic plan), the plan renewal date (to ensure the plan was subject to the market reform rules during the time periods for which data was submitted to the dedicated distributed data environment), and, in the case of an insured group health plan, the plan size (to ensure the plan was a small employer plan).

We also propose 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)¹⁴ for compliance with any requirement of subpart G or H of 45 CFR part 153, the issuer: (i) Within 30 calendar days of the issuance of the final audit report, must 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. 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 has received risk adjustment payments to which it was not entitled, it may require the issuer to pay such amounts to the Federal government.

To reduce the burden on issuers and HHS, to the extent practical, we intend to coordinate any audits of issuers of risk adjustment covered plans with related audits of Exchange financial programs and premium stabilization programs, such as reinsurance. We seek comment on this proposal, including

¹⁴ See Government Auditing Standards (2011 Revision), available at: <http://www.gao.gov/yellowbook>. For public companies, the Public Company Accounting Oversight Board (PCAOB) sets audit standards. See <http://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>.

the standards that should govern these audits.

2. Provisions and Parameters for the Transitional Reinsurance Program

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

a. 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 . . .” In the preamble to the 2014 Payment Notice (78 FR 15456), we included a general description of major medical coverage for reinsurance purposes based on the comprehensiveness of the coverage provided (for example, a range of medical, surgical, and preventive services) and the settings in which the coverage is provided (for example, inpatient and outpatient settings). Commenters requested that HHS codify a definition of major medical coverage for purposes of reinsurance contributions in regulation text.

Codification in regulation text of a more specific definition of major medical coverage for reinsurance contributions purposes would provide additional clarification for some contributing entities. Therefore, we propose to add a definition of 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 believe that because minimum value is calculated on a broad set of services—comparable to the essential health benefits applicable to individual and small group coverage—it is a reasonable measure of comprehensiveness of coverage. Minimum essential coverage under an employer-sponsored plan generally will provide minimum value if the plan’s share of total allowed costs of benefits

provided under the plan exceeds 60 percent of such costs (see section 36B(c)(2)(C)(II) of the Code). The minimum value standards established under § 156.145 also deem coverage that meets any of the levels of coverage requirements described in § 156.140 to satisfy this requirement. Because the calculation of minimum value is an objective process, we believe that the use of the concept of 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 stakeholders, and will not add undue burden to the determination of whether a plan offers major medical coverage for reinsurance purposes. It is important to note that this definition of major medical coverage only applies for determining reinsurance contributions under section 1341 of the Affordable Care Act. We seek comment on this proposed definition.

b. Self-insured Plans Without Third Party Administrators

Section 1341(b)(1)(A) of the Affordable Care Act provides that “health insurance issuers and third party administrators on behalf of group health plans” must make reinsurance contributions. We recognize that some self-insured group health plans self-administer the benefits and services provided under the plan, and do not use the services of a third party administrator. We believe that section 1341(b)(1)(A) of the Affordable Care Act clearly applies to both issuers of insured plans as well as to self-insured plans that use third party administrators. However, our continued study of this issue leads us to believe that this provision may reasonably be interpreted in one of two ways—it may be interpreted to mean that self-insured, self-administered plans must make reinsurance contributions, or it may be interpreted to mean that such plans are excluded from the obligation to make reinsurance contributions. For the reasons discussed below, we propose to modify the definition of a “contributing entity” for the 2015 and 2016 benefit years to exclude self-insured group health plans that do not use a third party administrator in connection with claims processing or adjudication (including the management of appeals) or plan enrollment.

Following consideration of the comments submitted with respect to the 2014 Payment Notice and the proposed Program Integrity Rule, we propose that

for the 2015 and 2016 benefit years, the phrase “third party administrators on behalf of group health plans” not include self-insured, self-administered group health plans. An insured plan and a self-insured plan administered by a third party administrator are similar in that each arrangement involves an employer and an outside commercial entity—an issuer or a third party administrator (which is often an insurance company or an affiliate)—for the administration of the core health insurance functions of claims processing and plan enrollment. We note that under section 1341(b)(3)(B) of the Affordable Care Act and § 153.400(a)(1)(ii), reinsurance contribution amounts are to reflect a “commercial book of business.” Our consideration of these comments leads us to believe that a group health plan administered by a third party administrator would normally be viewed as part of the third party administrator’s “commercial book of business,” but that a self-insured, self-administered plan would not normally be viewed as part of any entity’s “commercial book of business.”

Therefore, we propose that for the 2015 and 2016 benefit years, a “contributing entity” would mean: (a) A health insurance issuer; or (b) 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 appeals) or plan enrollment. The proposed modification for the 2015 and 2016 benefit years would exclude from the obligation to make reinsurance contributions those self-insured plans that do not use a third party administrator for their core administrative processing functions—adjudicating, adjusting, and settling claims (including the management of appeals), and processing and communicating enrollment information to plan participants and beneficiaries. This proposed amendment would recognize that some self-insured group health plans, which we believe would generally not be considered to be using the core services of a third party administrator, may use third parties for ancillary administrative support, and we would consider these plans to be self-administered for purposes of the reinsurance program.

For purposes of the definition of “contributing entity,” we propose to consider a third party administrator 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 services to the self-insured group health plan in connection with claims processing or adjudication (including the management of appeals) or plan enrollment. We seek comment on this definition, and whether certain types of service providers, such as an attorney providing legal advice in connection with claims adjudication, or an issuer administering an insured component of a group health plan that is partially self-insured and partially insured should be considered a third party administrator for these purposes.

In addition, we seek comment on whether the core administrative functions that we have described above—claims processing or adjudication (including the management of appeals) and plan enrollment—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 third party administrator. We also seek comment on whether a self-insured plan must perform these core administrative functions for all healthcare benefits and services provided to enrollees under the plan in order not to be considered to be using a third party administrator, or 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. If so, we seek comment on which benefits or services should be excluded from this criterion, or how such a de minimis amount or small percentage should be measured.

While, upon further consideration of the issue, we believe the statutory language can reasonably be read to support the proposition that self-insured group health plans that do not use third

party administrators for the functions described above should not be obligated to make reinsurance contributions, we also recognize, as a public policy matter, that it would be disruptive to plans and issuers to modify the definition of “contributing entity” for the 2014 benefit year at this late date. Health insurance issuers have already set premiums and developed operational processes based on the definition of “contributing entity” that was previously finalized in the 2014 Payment Notice. To prevent lower reinsurance payments, the contribution rate would have to be raised for other contributing entities, many of whom have already set their 2014 premiums based on the contribution rate finalized in March 2013. Excluding self-insured, self-administered group health plans from the set of entities that must provide reinsurance contributions for the 2014 benefit year, without raising the rate on other entities, would decrease the funds available for reinsurance payments for that benefit year, and thus upset settled estimates with respect to expected reinsurance payments that were used to establish premiums.

Therefore, we do not propose to change the definition of a “contributing entity” for the 2014 benefit year. That definition will remain as provided for in the second final Program Integrity Rule—a health insurance issuer or a self-insured group health plan (including a group health plan that is partially self-insured and partially insured, where the health insurance coverage does not constitute major medical coverage), regardless of whether the group health plan uses a third party administrator. The modification to the definition of “contributing entity” described above would be effective only for the 2015 and 2016 benefit years.

Finally, we note that our proposed change to the definition of a contributing entity may have implications for our plan aggregation rules at § 153.405(g), and seek comment on whether a plan sponsor that maintains two or more group health

plans covering the same covered lives, where one or more group health plans are insured and one or more are self-insured and do not use a third party administrator for core administrative functions, should be required to treat the multiple plans as a single group health plan for purposes of calculating any reinsurance contribution amount due.

c. Uniform Reinsurance Contribution Rate

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

Section 153.220(c) provides that HHS is to publish in the annual HHS notice of benefit and payment parameters the uniform reinsurance contribution rate for the upcoming benefit year. Section 1341(b)(3)(B)(iii) of the Affordable Care Act specifies that \$10 billion for reinsurance contributions are to be collected from contributing entities 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 are 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 for each of the 3 years of the reinsurance program under the uniform reinsurance contribution rate.

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

Uniform Reinsurance Contribution Rate

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

As discussed in greater detail below, we are proposing to collect \$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 an annual per

capita contribution rate of \$44 for the 2015 benefit year.

(ii) Timing of Collection of Reinsurance Contributions

As set forth in the 2014 Payment Notice, under § 153.405(b), no later than November 15 of the 2014, 2015, and 2016 benefit years, as applicable, a contributing entity must submit an annual enrollment count of the number of covered lives of reinsurance contribution enrollees for the applicable benefit year to HHS. Under § 153.405(c)(1), HHS is to notify the contributing entity of the reinsurance contribution amount to be paid for the applicable benefit year within 30 days of the submission of the annual enrollment count, or by December 15 of the applicable benefit year. Under § 153.405(c)(2), a contributing entity is to remit reinsurance contributions to HHS within 30 days after the date of the notification.

We recognize that the reinsurance collections provided for in the Affordable Care Act—\$12 billion for 2014, \$8 billion for 2015, and \$5 billion for 2016—will result in substantial upfront payments from contributing entities for the reinsurance program. Therefore, we are proposing to modify our collection schedule for the program, so that we would 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 currently described 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. Therefore, we propose to modify § 153.405(c) so that a contributing entity would make reinsurance contributions in two installments to HHS—one at the beginning of the calendar year following the applicable benefit year, and one at the end. As noted in the second final Program Integrity Rule, the proposed policy is designed to alleviate the upfront burden of the reinsurance contribution, allowing contributing entities additional time to make the payment. We note that the proposed change in the collection schedule would not affect the amount of funds collected for reinsurance payments. Additionally, the amounts allocated to reinsurance payments and administrative expenses are needed to operate the reinsurance program, while the amounts allocated for payments to the U.S. Treasury are not needed for the operation of the

transitional reinsurance program. Therefore, collecting the amounts allocated to payments to the U.S. Treasury later in the calendar year following the applicable benefit year will not affect the reinsurance program, and will alleviate a contributing entity's upfront financial burden.

Under this proposal, the first of the two installments each year would include the reinsurance contribution amounts allocated to reinsurance payments and administrative expenses. We propose in § 153.405(c)(1) that 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 intends to 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)(3), which provides for notification by the later of 30 days of the submission of the annual enrollment count or by December 15. We propose in § 153.405(c)(3) that the contributing entity remit this amount within 30 days after the date of the first notification.

The second installment would cover the portion of the reinsurance contribution amount allocated to the payments for the U.S. Treasury to be paid for a benefit year. We propose in § 153.405(c)(2), that 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. Again, under 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 would be required to submit an annual enrollment count only once for each benefit year under § 153.405(b).

For example, for the 2014 benefit year, of the \$63.00 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. Thus, we contemplate that if a contributing entity submits its

enrollment count for the 2014 benefit year in a timely manner (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.

We propose that for the 2015 benefit year, the proposed \$44 annual per capita contribution rate 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.

We plan to establish the uniform reinsurance contribution rate for the 2016 benefit year in the HHS notice of benefit and payment parameters for 2016.

We seek comment on this proposal. We note that we are considering a variation of this proposal under which contributing entities would be provided the option of paying the entire reinsurance contribution amount with the first installment, at the beginning of the calendar year following the applicable benefit year. We also clarify that the two installment payments (or one, should a contributing entity be permitted and elect to make the entire payment with the first installment) would be reported with 2014 data for purposes of the risk corridors and MLR calculations due July 31, 2015, despite the fact that the later installment would not have been paid at that time. This has the effect of leaving the MLR and risk corridors calculations unchanged.

(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, 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. In Table 2, we specify these proportions (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

Proportion or amount for:	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.
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 propose to 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. We note that the proposed method of collection would not affect the allocation to reinsurance payments, administrative expenses, and payments to the U.S. Treasury.

To provide that all reinsurance contributions collected for a benefit year are paid out for claims for that benefit year, we propose to amend § 153.230(d) to provide that if HHS determines that the amount of 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 (up or down) to be applied to all such requests for reinsurance payments for all States. We propose that 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 that paragraph.

For example, for 2014, if HHS collects \$9 billion for the reinsurance payments pool and \$10 billion in reinsurance payments are requested, HHS and each applicable reinsurance entity would reduce all reinsurance payments by 10 percent (effectively decreasing the coinsurance rate). If HHS collects \$11 billion for the reinsurance payments pool and \$10 billion in reinsurance payments are requested, HHS and each applicable reinsurance entity would increase all reinsurance payments by 10 percent (effectively increasing the coinsurance rate).

We seek comment on this payment proposal, including on 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 proposal above would provide that all reinsurance contributions collected for a benefit year are paid out for claims for that benefit year, we propose 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. For years beyond the 2014 benefit year (for which we propose to pay out all reinsurance contributions collected, as described above), we seek comment on whether we should have the flexibility to use excess contributions collected in the applicable benefit year for that benefit year or in a subsequent benefit year.

(iv) Administrative Expenses

In the 2014 Payment Notice, 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 propose 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 propose to exclude from these administrative expenses the costs associated with work performed by

Federal personnel. To calculate our proposed reinsurance administrative expenses for 2015, we divided HHS's projected total costs for administering the reinsurance programs on behalf of States by the expected number of enrollees in reinsurance-eligible plans for the benefit year.

We estimate this amount to be approximately \$25.4 million for the 2015 benefit year. This estimate has increased for the 2015 benefit year because we will be making reinsurance payments in the 2015 benefit year 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 2015, we are proposing 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 propose to allocate the total administrative expenses equally between these two functions. Therefore, as shown in Table 3, we expect to 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 would 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 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 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.

d. Uniform Reinsurance Payment Parameters

Our goal in setting the reinsurance payment parameters is to achieve the greatest impact on rate setting, and therefore premiums, through reductions in plan risk, while complementing the current commercial reinsurance market. Section 1341(b)(2)(B) of the Affordable Care Act directs the Secretary, in establishing standards for the transitional reinsurance program, to include a formula for determining the amount of reinsurance payments to be made to issuers for high-risk individuals that provides for the equitable allocation of funds. In the Premium Stabilization Rule, we provided that reinsurance payments to eligible issuers will be made for a portion of an enrollee's claims costs paid by the issuer (the coinsurance rate, meant to reimburse a proportion of claims while giving issuers an incentive to contain costs)

that exceeds an attachment point (when reinsurance would begin), subject to a reinsurance cap (when the reinsurance program stops paying claims for a high-cost individual). The coinsurance rate, attachment point, and reinsurance cap together constitute the uniform reinsurance payment parameters.

Given the smaller pool of reinsurance contributions to be collected for the 2015 benefit year, we are proposing that the uniform reinsurance payment parameters for the 2015 benefit year 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. We believe setting the coinsurance rate at 50 percent and increasing the attachment point allows for the reinsurance program to help pay for nearly the same group of high-cost enrollees as was the case for the 2014 benefit year, while still encouraging issuers to contain costs. We believe that maintaining the reinsurance cap for the 2015 benefit year while ensuring that the coinsurance rate sufficiently compensates issuers for high risk individuals will make it easier for issuers to estimate the effects of reinsurance. We believe that these uniform reinsurance payment parameters will support the reinsurance program's goals of promoting nationwide premium stabilization and market stability while providing issuers incentives to continue to effectively manage enrollee costs. We intend to continue to monitor individual market enrollment and claims patterns to appropriately disburse reinsurance payments throughout each of the benefit years of the transitional reinsurance program.

As discussed in the 2014 Payment Notice, 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 uniform reinsurance contribution rate and uniform reinsurance payment parameters proposed in this rule.

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 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.

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 payment parameters may overestimate the total covered claims costs of individuals enrolled in reinsurance-eligible plans in 2014. To account for this, we propose to decrease the 2014 attachment point to \$45,000. We seek comment on this proposal.

f. Deducting Cost-Sharing Reduction Amounts From Reinsurance Payments

Subpart H of 45 CFR part 153 governs the submission of reinsurance claims to an issuer's dedicated distributed data environment. Under § 156.410, if an individual is determined eligible to enroll in a QHP in the individual market offered through an Exchange and elects to do so, the QHP issuer must assign the individual to a standard plan or cost-sharing plan variation based on the enrollment and eligibility information submitted by the Exchange. Issuers of QHPs offered in an individual market through an Exchange will receive cost-sharing reduction payments for enrollees in their 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. Here, we propose to explain the methodology HHS would 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. In this section, we first set forth a methodology for policies that cover only one enrollee, then policies with more than one enrollee, such as family plans,

and finally, for policies under a limited cost sharing plan variation.

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. We believe that the cost-sharing 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"¹⁵ 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, we propose 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 seek to avoid requiring QHP issuers to engage in a complicated re-adjudication of claims to determine cost-sharing reduction amounts multiple times throughout the year. We believe that the proposed methodology set forth below will accurately estimate those cost-sharing reduction payments while also alleviating the burden on both QHP issuers and HHS.

We propose that for each enrollee enrolled in a QHP plan variation, we will subtract from the QHP issuer's total plan paid amounts for the enrollee in a reinsurance-eligible plan the difference between the annual limitation on cost sharing for the standard plan and the annual limitation on cost sharing for the plan variation. Because reinsurance payments are made for enrollees only when the issuer's total plan paid amounts exceeds the attachment point (for example, \$60,000 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.¹⁶ We propose 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 propose 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. We believe that such an approach is intuitive and will be easy to operationalize. We considered an alternative approach that would allocate the difference in annual limitation in cost sharing equally across all enrollees in a family policy, with any difference in annual limitations on cost sharing that exceeds the total plan paid amounts for a particular enrollee to be reallocated equally across the other enrollees. That approach would tend to result in a higher allocation of cost sharing on low-claims-cost individuals, which we believe is unrealistic.

In contrast, we propose 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 note that such enrollees will have the same annual limitation on cost sharing as individuals enrolled in standard plans, and thus, an approach that calculates the difference in annual limitations on cost sharing would yield estimated cost-sharing reductions of zero. We believe that this result is reasonable for individuals with plan paid amounts greater than the attachment point because those individuals are likely to have incurred significant claims costs with providers for which cost sharing is not reduced—that is, providers other

¹⁵ We note an increase in reinsurance claims spread evenly across the individual market may not necessarily result in higher reinsurance payments to all issuers in aggregate. However, increased requests for reinsurance payments may result in a higher pro rata reduction to be applied to all reinsurance payments because total reinsurance payments for a benefit year cannot exceed the reinsurance contributions collected for reinsurance payments (see 45 CFR 153.230(d)).

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.

than the Indian Health Service and facilities operated by an Indian Tribe, Tribal Organization, or Urban Indian Organization. Thus, we believe that these individuals are likely to have reached the full annual limitation on cost sharing for the standard plan.

We also considered an alternative approach that would require issuers to re-adjudicate claims periodically throughout the year to calculate cost-sharing reductions provided to date for an Indian enrolled in a limited cost sharing plan, but believe that such an approach would be burdensome to QHP issuers and only slightly improve the accuracy of cost-sharing reduction estimates. Finally, we considered an approach under which QHP issuers would submit an estimate of the effective annual limitation on cost sharing for limited cost sharing plans. However, we believe that this will be difficult for a QHP issuer to estimate due to the lack of cost-sharing reduction data for the early years of the Exchanges.

g. Audits

(i) HHS Audits of State-Operated Reinsurance Programs

To safeguard the use of Federal funds in the transitional reinsurance program, we propose in § 153.270(a) 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. A State that establishes a reinsurance program must 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.

Under the proposed rule, HHS may conduct 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. Such audits may, for example, examine the receipt and expenditure of reinsurance funds, as well as funds received from HHS for administrative expenses. The audits may also examine the reinsurance program's compliance with the requirements for the State and the program under subparts B and C of 45 CFR part 153. We will provide further details on our audit program, including timelines, procedures, and substantive requirements, in future rulemaking and guidance.

We propose 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)¹⁷) 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 must 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 applicable reinsurance entity must implement the plan and provide to HHS written documentation of the corrective actions once taken. We seek comment on this proposal, including the standards that should govern these audits.

(ii) HHS Audits of Contributing Entities

We propose in § 153.405(i) that HHS or its designee may audit a contributing entity to assess its compliance with the requirements of subpart E of 45 CFR part 153. We anticipate 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 will provide further details on this audit program, including timelines, procedures, and substantive requirements, in future rulemaking and guidance. We anticipate that these audits will focus on records relating to the enrollment of the applicable self-insured or insured plan, to confirm that the number of covered lives was correctly counted and that the correct amount of reinsurance contributions was paid. Audits may also identify entities that were required to but did not make reinsurance contributions. If HHS determines as the result of an audit that a contributing entity was required to pay additional reinsurance contributions, it may require the contributing entity to pay such amounts to the Federal government. If the contributing entity is an issuer subject to an audit for other Exchange financial programs or premium stabilization

programs, such as risk adjustment, we intend to coordinate these audits, to the extent practical, to reduce the burden on both the contributing entity and HHS.

We seek comment on this proposal, including the standards that should govern these audits.

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

We propose in § 153.410(d) that HHS or its designee may 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, and that if an audit results in a finding of material weakness or significant deficiency, the issuer must:

- Within 30 calendar days of the issuance of the final audit report, provide a written corrective action plan to HHS for approval;
- Implement that corrective action plan; and
- Provide to HHS written documentation of the corrective actions once taken.

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, it may require the issuer to pay such amounts back to the Federal government.

We anticipate conducting targeted audits of issuers of reinsurance-eligible plans based on, 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. We will provide further details on this audit program, including timelines, procedures, and substantive requirements, in future rulemaking and guidance. 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. To reduce the burden on issuers and HHS, to the extent practical, we intend to coordinate any audits of issuers of reinsurance-eligible plans with related audits of Exchange financial programs and premium stabilization programs, such as risk adjustment.

We seek comment on this proposal, including the standards that should govern these audits.

h. 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

¹⁷ 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>.

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.

Therefore, we propose to make two changes to § 153.400. In § 153.400(a)(1), we propose to clarify 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 propose to add paragraph (vi) to § 153.400(a)(1), which would provide 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 language would 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, such as if a union offers a plan that supplements a group health plan offered by the employer. It would also address a situation in which two spouses are each covered as dependents by the respective group health plans offered by their two independent employers.

If it is not clear from the terms of the health plans which group health plan is supplemental, we propose, in keeping with § 153.400(a)(3), that the group health plan that offers the greater portion of inpatient hospitalization benefits be 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 propose to defer to the arrangements on primary and secondary liability worked out 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.

We seek comment on these proposals, including which entity should be responsible for the reinsurance contributions, how that responsibility should be determined, and what arrangements should be required between the entities to assure efficient coordination of the responsibility for the reinsurance contributions, and what other situations we should address in which reinsurance contributions might be required to achieve the goal of preventing more than one contribution per covered life.

i. 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 (Territories Letter), 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." The Territories 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.

In this proposed rule, we propose that a contributing entity is not required to make reinsurance contributions on behalf of enrollees who reside in a territory that does not operate a reinsurance program. We propose to add in § 153.400(a)(1)(v) an 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, a contributing entity would not be required to make reinsurance contributions for those enrollees. We believe that this proposal 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.

We propose that a contributing entity may 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 seek comment on other methods that would be acceptable for determining the primary residence of an enrollee, including the principal work location of the principal subscriber on the enrollee's policy.

We note that a contributing entity is 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, only if it wishes to exclude covered lives from reinsurance contributions under proposed § 153.400(a)(1)(v).

j. 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 this proposed rule, we seek to clarify § 153.405(e)(3), by changing the references from "benefit year" to "plan year"¹⁸ 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 other than the benefit year, which is defined in § 153.20 and § 155.20 as a calendar year for which a health plan provides coverage for health benefits. 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.

¹⁸ Plan year as defined in 45 CFR 155.20 as a consecutive 12 month period during which a health plan provides coverage for health benefits. A plan year may be a calendar year or otherwise.

3. 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, premium, provider network 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. We are considering whether a plan that differs from a QHP (as defined at § 155.20) based on these standards would be considered to be “substantially the same” as a QHP for the purposes of participating in the risk corridors program, and are considering amending the definition of a QHP at § 153.500 in response. We seek comment on this approach.

b. Compliance With Risk Corridors Standards

The risk corridors program requires the Federal government and participating plans to share in profits or losses resulting from inaccurate rate setting for benefit years 2014 through 2016. A robust oversight process is critical for this program because risk corridors payments are Federal funds. In this proposed rule, we outline 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 program and the risk corridors program will require similar data, we propose to closely align the data submission, data validation, audit provisions, and sanctions for the two programs. We note that the risk corridors oversight provisions will apply to all plans, including QHPs and plans that are substantially the same as QHPs (as defined in the first final Program Integrity Rule) that are subject to the risk corridors program, whether these

plans are offered through the Exchange or outside of the Exchange.

For the 2014 benefit year, we propose to collect risk corridors data through the same form used for MLR data collection, at the same time (July 31 of the year following the applicable benefit year). We note 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 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 are 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 reported in the dedicated distributed data environment). Similar to the MLR process, we anticipate requiring issuers to resubmit corrected data after risk corridors data errors are identified. We request comment on this approach.

To ensure the integrity of risk corridors data reporting, we propose 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 are considering conducting 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. We are further contemplating conducting risk corridors audits under an overall issuer audit program so that we may simultaneously obtain the financial information necessary to determine compliance with other programs, such as the risk adjustment and reinsurance programs. We believe that this may further reduce the overall audit burden on issuers. Some States already review data and audit issuer information related to MLR reporting and rebate obligations; HHS does not intend to review information that would be duplicative of a review that has been completed by a State. However, because States may not examine all data required to be examined for the risk corridors program, HHS could audit a QHP issuer's risk corridors data to the extent not examined by the State. We request comments on all aspects of this approach, including appropriate criteria

for identifying issuers for audit in any particular benefit year.

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 civil money penalties (CMPs), but does not extend this remedy to a QHP issuer on a State Exchange. State Exchange issuers that fail to submit risk corridors charges, and consequently owe HHS money, would be subject to the Federal debt collection processes; however, without risk corridors data, HHS will be unable to determine whether a debt is owed or the amount of a debt. Therefore, in § 153.540(b) we propose to extend our CMP authority under sections 1321(a)(1) and (c)(2) of the Affordable Care Act to all QHP issuers that fail to provide timely, accurate, and complete data necessary for risk corridors calculations, or that otherwise do not comply with the standards in subpart F of 45 CFR part 153. We propose 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. For purposes of calculating the maximum CMP amount, we may consider using enrollment information acquired from other internal sources (for example, risk adjustment and reinsurance enrollment data from the dedicated distributed data environment). Under this approach, we would either use enrollment information from all of an issuer's non-grandfathered plans within a State market, or would limit calculation of the CMP amount to the number of enrollees in an issuer's QHPs (including enrollees in plans that are substantially the same as a QHP). We note 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 in corrective action plans).¹⁹ We request comments on all aspects of this approach, particularly for the methodology that we should use to determine a CMP amount for a QHP

¹⁹ We note that the good faith provision at § 156.800(c) will not be applicable in this context because risk corridors activities, such as data submission and payment, occur beginning in 2015.

issuer that does not comply with risk corridors data requirements.

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 for plans that are subject to the premium rating rules. Therefore, in the 2014 Payment Notice, we clarified that under the methodology HHS will use when operating risk adjustment on behalf of a State, a plan that is not subject to the market reform rules, including the premium rating rules, is not a risk adjustment covered plan. In the second final Program Integrity Rule, we further clarified that stand-alone dental plans would not be subject to the risk corridors program because they are not subject to the premium rating rules, and therefore do not require the protections of the risk corridors program. In this proposed rule, we are similarly proposing 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 propose to add a paragraph (f) to § 153.510 to provide that the risk corridors program would apply only to qualified health plans, 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 believe that this approach is consistent with how QHPs have determined their pricing for the 2014 benefit year. We note that a QHP that must adhere to the premium rating rules as a condition of participation on the SHOP is a plan that is “subject to the rating rules” for the purposes of this policy.

We are also proposing 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 as small employers that would be large employers under the Federal definition. Given our broad authority to establish the risk corridors program, we believe that we have the discretion to include such employers in the program even if they do not meet the Federal definition of small employer that would apply for other purposes. We believe that the inclusion of such employers in the definition of small employers for purposes of the risk corridors program would maintain consistency between the risk corridors calculation and implementation of the single risk pool provision, which is generally enforced by the State. We further believe that clearly specifying the employee counting method that is specific to the risk corridors program would provide clarity for QHP issuers with plans that could either be excluded from or subject to the risk corridors program, depending on the employee counting method used. We note that permitting the use of a State employee counting method that is inconsistent with Federal law for purposes of the risk corridors program 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 proposed rule. Under these programs, non-full-time employees must be counted. We note 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 would, therefore, be part of a QHP issuer’s risk corridors data submission under § 153.530. We also note that the State’s employee counting method would determine whether any plan offered outside of an Exchange that is the “same” as or “substantially similar” to an Exchange QHP (under the definition set forth in § 153.500) would be part of the individual or small group market for purposes of the risk corridors program, and, therefore whether it is eligible to receive or make risk corridors payments. This proposed approach would serve to align the market-wide rating rules with the protections of the premium stabilization programs. However, the approach could likely lead to a more complex data submission for risk corridors and MLR, because we may not be able to align the market definitions between the two programs.

We seek comment on our proposal that a QHP must be subject to the market reform rules in order to

participate in the risk corridors program. We also seek comment on our proposal to use the State employee counting method to define plans in the small group market for purposes of determining which plans participate in the risk corridors program, even where that would include employers that would be large employers under the Federal definition, or whether we should instead use the counting method used for the MLR program and proposed for risk adjustment purposes. We also seek comments on whether we should explicitly codify the applicable counting rules for each program in regulations text.

d. Adjustment Options for Transitional Policy

As discussed earlier, on November 14, 2013, the Federal government announced a policy under which it will not consider certain health insurance coverage in the individual or small group market between January 1, 2014, and October 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.²⁰ CMS noted in a letter to the insurance commissioners of the 50 States and the District of Columbia that while this transitional policy would not have been anticipated by issuers in setting rates for 2014, the risk corridors program should ameliorate the effect 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.

Therefore, for the 2014 benefit year, we are considering whether we should make an adjustment to the risk corridors formula that would help to further mitigate any unexpected losses for issuers of plans subject to risk corridors that are attributable to the effects of the transition policy. One potential option we are considering would be to implement 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 (that is, a plan with an 80 percent allowable costs-to-premium ratio). This adjustment could serve to

²⁰ Letter to Insurance Commissioners, Center for Consumer Information and Insurance Oversight, November 14, 2013. See <http://www.cms.gov/CCIIO/Resources/Letters/Downloads/commissioner-letter-11-14-2013.PDF>.

increase a QHP issuer's risk corridors ratio and its risk corridors payment amount to help offset the loss in premium revenue and profit that might occur under the transitional policy as a result of predicted increased claims costs that were not accounted for when setting 2014 premiums. We are considering applying this adjustment only to plans whose allowable costs (as defined at 45 CFR 153.500) are at least 80 percent of their after-tax premiums, because issuers under this threshold would generally be required to pay out rebates to consumers. We note that for plans whose ratio of allowable costs to after-tax premium are below 80 percent, the 3 percent risk corridors profit margin and 20 percent allowable administrative cost ceiling would continue to apply for these plans.

The effect on the risk pool of plans compliant with the 2014 market rules may vary significantly from State to State, depending upon the extent to which each State elects not to enforce the 2014 market rules, as recommended under the transition policy, and upon the market dynamics of the health insurance market within the State. We believe that the State-wide effect on this risk pool will increase with the increase in the percentage enrollment in transitional plans in the State, and so we are 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.

We are considering calculating the State-specific percentage adjustment by analyzing the effects of the transitional policy upon a plan with specified characteristics. For example, our actuaries believe the following are reasonable plan assumptions: 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 are considering calculating the State-specific percentage adjustment to the risk corridors profit margin floor and allowable administrative costs ceiling in a manner that would help to offset the effects of the transitional policy upon the model plan's claims costs.

We propose 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. After consulting our actuaries,

we believe that this assumption is a reasonable reflection of the effects of underwriting on the transitional plans. To estimate this State-specific effect of the transitional policy on average claims costs, we propose 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. This submission would occur in 2015 prior to the risk corridors submission. 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.

We have proposed a State-wide adjustment for reasons of administrative simplicity and due to the analytical difficulty in estimating this effect on an issuer-by-issuer basis. Although the adjustment that we are considering would affect each issuer differently, depending on its particular claims experience and administrative cost rate, we believe that, on average, the adjustment would suitably offset the losses that a standard issuer might experience as a result of the transitional policy. We also note that, because the risk corridors program applies only to certain plans defined to be qualified health plans at 45 CFR 153.500, the extent to which an issuer may receive the full effect of this adjustment would depend upon the portion of an issuer's individual and small group enrollees in plans subject to risk corridors.

Another option we are considering would be to make a similar modification to the medical loss ratio formula. We would use our authority under section 2718(c) of the Public Health Service Act to "take into account . . . special circumstances of different types of plans" to ensure that the proposed adjustment to the risk corridor 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 seek comment on the best way to make such a modification, and whether such a modification is required.

We request comment on all aspects of these potential approaches to help mitigate any potential impact of the transitional policy. As we continue to analyze its potential impacts, we will determine whether such approaches and modifications are warranted. We seek comment on alternate ways of implementing adjustments to current risk corridors and reinsurance program policy that would help offset issuers for any unexpected losses that might be

incurred as a result of the transitional policy. In particular, we seek comment on whether this risk corridors adjustment should depend upon State-wide market characteristics, as we have proposed, or whether it should be national, tailored to each issuer, or based upon different State-wide characteristics.

We also seek comment on whether the characteristics of the standard plan we have outlined above are the appropriate characteristics to use for our modeling. We seek comment on the data that we should collect to measure the key characteristics for this adjustment, and who we should collect that data from. We seek comment on whether particular ceilings and floors should be placed upon the amount of the adjustment. We also seek comment on whether the adjustment should apply to QHP issuers with allowable costs that are below 80 percent of after-tax premiums.

4. 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

Because the accuracy of the data on an issuer's dedicated distributed data environment is critical to the accuracy of the HHS-operated risk adjustment and reinsurance calculations, we are proposing an iterative discrepancy reporting process that would allow 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. We anticipate that 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: Beginning 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 also intend to issue these interim reports to issuers of risk adjustment covered plans and reinsurance-eligible plans that do not load data, to verify this result.) We anticipate that issuers of risk adjustment covered plans would receive interim

reports that include preliminary risk scores based on this data. We anticipate that issuers of reinsurance-eligible plans would receive interim reports that include an estimate of the issuer's aggregated total claims eligible for reinsurance payments based on this data. Therefore, we propose in § 153.710(d) that within 30 calendar days of the receipt of an interim dedicated distributed data environment report from HHS, the issuer must either 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 must describe to HHS any discrepancy it identifies in the interim report. Following the identification of a discrepancy in an interim dedicated distributed data environment report, HHS would review the evidence submitted by the issuer, along with any other relevant data, and would determine if the preliminary risk score or estimated payment amount at issue was properly calculated using the applicable data. We believe that the 30-calendar-day timeframe would provide sufficient opportunity for an issuer to verify the preliminary risk scores and estimated reinsurance payment amounts, but note that an issuer may notify HHS of a newly discovered discrepancy in connection with responses to later interim or final dedicated distributed data environment reports until 15 calendar days after the final dedicated distributed data environment report is issued, as discussed below. We anticipate that the interim dedicated distributed data environment reports would allow issuers to proactively address any data discrepancies regarding the data the issuer made accessible to HHS on the dedicated distributed data environment and HHS's analysis of the data.

We note that under § 153.700(a), an issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State where HHS operates the risk adjustment or reinsurance program on behalf of the State, 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 or reinsurance program. For the issuer and HHS to effectively address and resolve discrepancies through the proposed interim reporting process, we propose that once an issuer's dedicated distributed data environment is established, the issuer would be

required, on a quarterly basis, to make a complete and current enrollment file accessible to HHS through the dedicated distributed data environment, and would be required to 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 30 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.

We note that, as part of the process for making these files 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. To fulfill its obligation to make these files available to HHS, an issuer would be required to either correct or accept the rejection of this data for the submission process to be considered complete.

Final dedicated distributed data environment report: We propose that HHS would provide issuers with a final dedicated distributed data environment report following the applicable benefit year, after the April 30 data submission deadline. The final dedicated distributed data environment report would 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 propose in § 153.710(e) that the issuer be required, within 15 calendar days of receipt 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 to describe to HHS any discrepancy it identifies in the final dedicated distributed data environment report. 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 30 of the year following the applicable

benefit year, as required under § 153.310(e) and § 153.240(b)(1)(ii). We seek comment on these proposals.

Notification of payments and charges: Last, as required under § 153.310(e) and § 153.240(b)(1)(ii), HHS will provide issuers a report detailing their final risk adjustment payments and charges and reinsurance payments for the applicable benefit year by June 30 of the year following the applicable benefit year. 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 would permit HHS and issuers to resolve most data and payment discrepancies for risk adjustment and reinsurance before the June 30 report is issued, we recognize that some discrepancies might remain unresolved. Therefore, we propose 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 proposed § 153.710(d)(2) or § 153.710(e)(2) remains unresolved after issuance of the June 30 report, an issuer of a risk adjustment covered plan or reinsurance-eligible plan may make a request for reconsideration using the process proposed 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, HHS would assess charges and make payments based on the amounts listed in the June 30 report, whether or not the issuer had submitted a request for reconsideration under proposed § 156.1220(a), and would later correct any charges or payments determined to be inaccurate under the reconsideration or administrative appeals process.

(ii) Reporting of Payments and Charges Under Reconsideration

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 propose in § 153.710(g)(1) that, notwithstanding any discrepancy report made under paragraph § 153.710(d)(2) or (e)(2), or any request for

reconsideration under § 156.1220(a), unless the dispute has been resolved, an issuer must report, as applicable, for purposes of the risk corridors and the MLR program, 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 30 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 the process proposed in § 156.1220(a), we propose 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, if a QHP issuer requests reconsideration of risk corridors payments or charges under the process proposed in § 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 propose in § 153.710(g)(2) that an issuer must 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 medical loss ratio report, in the next following risk corridors and medical loss ratio report.

We seek comment on these proposals.

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 30 of the year following the applicable benefit year in accordance with §§ 153.610(a), 153.700, 153.710, or 153.730, such that HHS cannot apply its Federally certified risk adjustment methodology to calculate the plan's risk adjustment payment transfer amount in a timely fashion, HHS 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.

$$T_n = C_n \times E_n$$

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 are considering 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 risk adjustment charge, and fail to provide adequate incentive for prompt establishment of a compliant distributed data system.

A second option would be 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*.

A third option would be to assess a charge equal to a fixed percentage of the State-wide weighted average premium, which would be calculated as the enrollment-weighted mean of all plan average premiums of risk adjustment covered plans 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 note the many possible variations of these methods. For example, instead of the highest PMPM amount in the risk pool in the market in the State, the PMPM amount could be a fixed percentile along the distribution of PMPM charges for the risk pool in the market in the State—thus, we could use the 75th percentile or an amount equal to 10 percent above the 100th percentile, for example. Instead of the amount based on the mean PMPM amount and two standard deviations, a different number of standard deviations could be used. Also, instead of using a fixed percentage of the State-wide weighted average premium, a fixed percentage of the plan's premium, or a fixed percentage of the average premium of a subpopulation of risk adjustment covered plans in the State, such as those plans in the applicable risk pool, or those plans paying risk adjustment charges, could be used.

Commenters to the proposed Program Integrity Rule also suggested an approach under which the PMPM amount would be the highest amount calculated under each of the three methods described above. Finally, to ensure that a total default charge is not excessive for a particular plan, we are considering setting an upper limit on the total default charge for a plan based on a percentage of the plan's own total premiums. We seek comment on these methods, or other appropriate methods for calculating a default risk adjustment charge.

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

1. Election to Operate an Exchange After 2014

HHS has learned through the process of approving or conditionally approving

the first generation of State Exchanges that it is challenging to make an accurate assessment of a State's progress and ability to complete an Exchange build 10 months prior to open enrollment and a year prior to the first date that coverage would become effective. We are therefore proposing 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 effective date of coverage. We propose to amend § 155.106(a)(2) by moving the deadline for the approval of the Exchange Blueprint for 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 believe that this proposal will give States more time prior to approval of the Blueprint to prepare for the transition from an FFE or State Partnership Exchange to a State Exchange. It will also enable HHS to gauge the State's actual technical, business and operational progress as more indicative milestones should be reached by June 15th. It should be noted that § 155.106(a)(2) sets the date by which a State electing to operate an Exchange after 2014 must "[h]ave in effect" an "approved, or conditionally approved, Exchange Blueprint and operational readiness assessment" and that the rule is silent about the date by which such a State must submit the Exchange Blueprint. HHS, therefore, proposes to extend the date by which a State must submit the Exchange Blueprint from November 15th to June 1st.

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

In § 155.220, we propose to add new paragraph (i) to provide that current paragraph (c)(3), which addresses enrollment through an Internet Web site of an agent or broker, and currently applies only to the individual market Exchanges, would apply to the SHOPs for plan years beginning on or after January 1, 2015. Agents and brokers have traditionally assisted employers in the small group market, and many of them use Internet Web sites to assist employers. Permitting an employer to complete QHP selection through the Internet Web site of an agent or broker would provide an additional potential SHOP enrollment option for small employers. Under this 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 the SHOPs, in a manner similar to that already available in the current market. We propose to allow SHOPs, in States that allow this activity under State law, to permit enrollment in a SHOP QHP through an Internet Web site of an agent or broker under the standards outlined in § 155.220(c)(3) if a State SHOP or the FF-SHOP has the technical capability to make this possible. We invite comment on this proposal.

3. Privacy and Security of Personally Identifiable Information

Section 1411(g)(2)(A) of the Affordable Care Act provides that Exchanges may use information provided by an applicant ". . . only for the purposes of, and to the extent necessary in, ensuring the efficient operation of the Exchange . . ." Section 155.260(a)(1) provides the specific circumstances under which an Exchange may use or disclose PII the Exchange creates or collects for the purposes of determining eligibility for enrollment in a QHP; determining eligibility for other insurance affordability programs as defined at § 155.20; or determining eligibility for exemptions from the individual responsibility provisions in section 5000A of the Code (collectively referred to as "eligibility and enrollment PII"). We believe, based on considerations that have been brought to our attention by States as we work together to implement the Exchanges, that § 155.260(a)(1) unduly limits the ability of an Exchange to ensure its efficient operation. We therefore propose to amend § 155.260(a)(1) to permit an Exchange to use or disclose eligibility and enrollment PII to ensure the efficient operation of an Exchange through uses or disclosures that may not be directly connected to the Exchange minimum functions described at § 155.200, subject to privacy and security standards.

We anticipate that there may be uses or disclosures of eligibility and enrollment PII that present additional opportunities to ensure the efficient operation of the Exchange, consistent with the strict protections of section 1411(g)(2)(A) of the Affordable Care Act. Therefore, we propose in § 155.260(a)(1)(ii) that the Secretary may approve other uses and disclosures of eligibility and enrollment PII, 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 determines that the use or disclosure is appropriate and permissible under relevant law and policy. In addition, prior to an Exchange using eligibility and enrollment PII for such an approved function, the individual would need to provide consent before his or her eligibility and enrollment PII could be used or disclosed for this additional function. We anticipate providing additional information in future guidance about uses or disclosures determined by the Secretary that ensure the efficient operation of the Exchange while maintaining information privacy and security, and we seek comment on such uses and disclosures.

Further, in § 155.260(a)(1)(iii) we propose a process under which Exchanges may seek approval from the Secretary for uses or disclosures of eligibility and enrollment PII not explicitly described in § 155.260(a)(1)(i) or (ii). Requestors must show that the proposed use or disclosure will ensure the efficient operation of the Exchanges consistent with section 1411(g)(2)(A) of the Affordable Care Act and describe how the information to be used or disclosed will be protected by privacy and security standards that are compliant with § 155.260. In addition, any time an Exchange is using eligibility and enrollment PII for such an approved function, the individual would need to provide consent before his or her eligibility and enrollment PII could be used or disclosed. We anticipate providing additional information in future guidance about this process and about the facts and circumstances that will be considered in determining whether a proposed use or disclosure will ensure the efficient operation of an Exchange while maintaining information privacy and security and is also an appropriate and permissible use or disclosure under relevant law and policy. We seek comment on this proposed process, as well as other factors or information that should be considered when determining whether a proposed use or disclosure should be approved pursuant to this proposed process.

We further recognize the imperative to maintain safeguards for eligibility and enrollment PII when it is used or disclosed to support functions beyond those described in § 155.200. Exchanges would be required to limit the disclosure of eligibility and enrollment PII to the extent necessary to accomplish the proposed function and obtain an individual's consent. The proposed use and disclosure would be

subject to privacy and security standards that § 155.260 requires Exchanges to establish in relation to non-Exchange entities.

In light of the proposed amendments to § 155.260(a)(1), we further propose to amend § 155.260(a)(2) to delete the specific reference to § 155.200 minimum functions and to indicate that all permitted uses under § 155.260(a)(1) must be consistent with § 155.260.

Section 155.260(a)(3) provides that Exchanges must establish and implement privacy and security standards consistent with the eight principles in § 155.260(a)(3)(i) through (a)(3)(viii). Section 155.260(b) addresses situations in which Exchanges share PII with “non-Exchange entities,” including “. . . individuals or entities, such as Navigators, agents, and brokers.” Through public comment to the Program Integrity Proposed Rule, we received requests for clarification on the definition of “non-Exchange entities” and also received questions asking if the regulatory language “individuals or entities, such as Navigators, agents, and brokers,” was meant to be an exhaustive list. In the preamble to the first final Program Integrity Rule (78 FR 54082), we stated that we would issue further guidance on this topic. We now propose to amend the regulation text to address these questions.

In § 155.260(b)(1), we propose that 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, be considered a non-Exchange entity, such that a non-Exchange entity is defined based on access to PII and not based on a representative or exhaustive list of entities. As clarification, we believe that entities that would qualify as “non-Exchange entities” based on this proposed definition include, but are not limited to, Medicaid agencies; CHIP agencies; Certified Application Counselors; in person assistants; agents and brokers, including Web-brokers; QHP issuers; Navigators; and other third party contractors. We feel very strongly about the importance of requiring privacy and security standards and believe that this proposed definition of non-Exchange entity makes even more clear which entities are subject to these standards.

At § 155.260(b)(2), we propose to maintain the existing requirement for Exchanges to enter into a contract or agreement with non-Exchange entities, while providing more details regarding

the required elements of these contracts and agreements. We propose that the contract or agreement between an Exchange and a non-Exchange entity must include at least five elements. First, we believe it is important to define in this contract or agreement the functions that the non-Exchange entity will perform so that both parties agree to the circumstances and tasks during which the privacy and security standards will be applicable, and propose to include this requirement in § 155.260(b)(2)(i). This requirement already exists in § 155.260(b)(2), where reference is made to a non-Exchange entity performing the functions outlined in the agreement with the Exchange. Second, we propose 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. A similar requirement also already exists in the current text of § 155.260(b), where an Exchange must require the same or more stringent privacy and security standards as a condition of contract or agreement with the non-Exchange entity. The nature of these standards will be discussed in greater detail in the next paragraph. Third, we propose in § 155.260(b)(2)(iii) that in the contract or agreement, the Exchange must require 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 § 155.260(a)(5). It is assumed that the Exchange would expect this type of assessment to occur any time the non-Exchange entity has a major change in the operational or technical environment employed to meet the duties outlined in their contracts or agreements with the Exchange, and at the time of renewal of the contract or agreement. Fourth, we propose in § 155.260(b)(2)(iv) that in the contract or agreement, the Exchange must require the non-Exchange entity to inform the Exchange of any change in its administrative, technical, or operational environment defined within the contract that would require an alteration of the standards within the contract or agreement. The intent of this requirement is to provide an opportunity to assess and revise standards to ensure that the standards remain relevant. We seek comment on other mechanisms that could be more

effective in keeping standards aligned with operating environments. Fifth, we propose in § 155.260(b)(2)(iv) that the contract or agreement include a requirement that the non-Exchange entity, in a written contract or agreement, must require any downstream entities that also 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. We feel it is important that the privacy and security standards continue to apply to PII as it moves to additional downstream entities.

Currently, § 155.260(b) states that an Exchange must require the same or more stringent privacy and security standards as a condition of contract or agreement with individuals or entities that gain access to PII submitted to an Exchange. In § 155.260(b)(3), we maintain the specification for an Exchange to require privacy and security standards as a condition of contract or agreement with non-Exchange entities and we propose criteria for the establishment of these standards that allow Exchanges flexibility in setting standards for non-Exchange entities that will provide equivalent or more stringent protection while aligning more closely to the functions the non-Exchange entity is performing and the operating environment under which the non-Exchange entity is performing. Because the definition for non-Exchange entities is broad and includes a variety of entities, we recognize that there can be variation between non-Exchange entities.

Different non-Exchange entity functions can result in variation in both the amount and type of access to PII (as an example, a Certified Application Counselor's access to consumer PII is different than the access a consumer's agent or broker would have) and the technical characteristics of the non-Exchange entity's environment (as an example, some non-Exchange entities, such as Medicaid agencies, may have a connection to the Data Services Hub, whereas others, such as Navigators, do not). Additionally, some non-Exchange entities already are required by law to meet other industry-recognized security standards for the environment in which they will perform Exchange-related functions. Currently there is no mechanism within the regulation to take environment variations or already existing security requirements into account, resulting in an operational burden for non-Exchange entities that does not result in additional protections for applicants.

As applied to non-Exchange entity privacy standards, the introduction of this flexibility is not anticipated to result in any weakening of Exchange privacy standards. Variation is not anticipated in the stringency of the particular privacy standard but in how it is implemented. As an example, a written policy and procedure document as required by § 155.260(d) regarding the collection, use, and disclosure of PII may take a different form based on a non-Exchange entity's duties and operations. A non-Exchange entity that is a QHP issuer currently obligated to follow the HIPAA security rule might seek to negotiate a contract with the Exchange under which it is permitted to follow the HIPAA security rules in place of the specific security standards followed by the Exchange. It would then be incumbent upon the Exchange to evaluate whether this arrangement would meet all of the criteria established for privacy and security standards under § 155.260(b)(3). We intend for these standards to provide the same level of protection and safeguards as the current § 155.260(b) affords.

Currently § 155.280 establishes the regulatory authority for oversight and monitoring of Exchanges and non-Exchange entities with regard to privacy and security standards. We anticipate additional proposed rulemaking on oversight, monitoring and enforcement during 2014. We invite comment on alternative ways to address the challenge of implementing effective enforcement while allowing the proposed flexibility.

These proposed requirements in § 155.260(b)(3) 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 have put forth three criteria that must be met by the privacy and security standards to which an Exchange must bind non-Exchange entities, and require that these standards take into specific consideration the environment in which the non-Exchange entity is operating.

The first criterion is set out in § 155.260(b)(3)(i) and requires that any privacy and security standards must be as protective as the standards that the Exchange sets for itself and must be consistent with all of the principles and requirements listed under § 155.260(a). This includes the principles of (a)(3), as well as the requirements established by (a)(1) through (a)(6).

The second criterion proposed in § 155.260(b)(3)(ii) requires that any privacy and security standards must

also comply with the requirements for workforce compliance, written policies and procedures, compliance with the IRS code, and the consequences of improper use and disclosure of information established by § 155.260(c), (d), (f) and (g).

The third criterion proposed in § 155.260(b)(3)(iii) requires that the privacy and security standards to which non-Exchange entities are bound take several factors into consideration. Section 155.260(b)(3)(iii)(A) requires that an Exchange take into consideration the operational and technical environment in which the non-Exchange entity is operating. These environments, and the standards themselves, should be assessed in light of the requirement established by § 155.260(a)(5) to monitor, periodically assess, and update the security controls and related system risks to ensure the continued effectiveness of those controls. Should the environment change, the standards should change accordingly as required by proposed § 155.260(b)(2)(iii) and § 155.260(b)(2)(iv). We would expect that an Exchange's contracts and agreements with non-Exchange entities provide an opportunity for such changes.

Section 155.260(b)(3)(iii)(B) requires standards be relevant and applicable to the non-Exchange entity's duties and activities in relation to the Exchange. The introduction of the concept of 'relevant and applicable' is intended to address the various responsibilities assumed by non-Exchange entities, and the associated technical infrastructures.

Although the proposed approach affords greater flexibility to Exchanges, this flexibility carries with it an Exchange's responsibility to perform an assessment of the non-Exchange entity's duties, activities, and environment and the standards to which it will bind non-Exchange entities to ensure that the standards satisfy § 155.260 requirements. For example, assuming § 155.260 is finalized as proposed, the FFE will incorporate privacy and security standards into non-Exchange entity contracts and agreements only after determining that the standards satisfy the criteria proposed under § 155.260(b)(3)(i), (ii) and (iii), and thereby meet the requirements of § 155.260 and the Affordable Care Act. We expect to publish guidance to provide additional details regarding the process the FFE will follow to evaluate privacy and security standards to which non-Exchange entities will be bound.

We seek comments on the proposed amendments to § 155.260 and on alternate ways to ensure protection for

information while not imposing irrelevant or unnecessarily burdensome requirements on non-Exchange entities.

4. Annual Open Enrollment Period for 2015

In 45 CFR 155.410, as finalized in the Exchange Establishment Rule, we set forth provisions for initial and annual open enrollment periods. We now propose amending § 155.410(e) and (f), which pertain to the annual open enrollment period and effective date for coverage after the annual open enrollment period.

In paragraph (e), we propose adding a paragraph that would change the annual open enrollment period for the 2015 benefit year. We propose that for all Exchanges, annual open enrollment would begin on November 15, 2014 and extend through January 15, 2015. This proposed change would give health insurance issuers an additional month in 2014 before they would need to begin accepting plan selections for the upcoming plan year. It also 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. 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. First-year challenges in enrolling individuals may mean higher than expected enrollment toward the end of the initial open enrollment period which, under the current schedule, coincides with the first day in which applications for 2015 can be submitted to the FFE. This compressed schedule would add uncertainty to setting rates for 2015 and potentially higher premiums without change. This proposed change is applicable for only the 2015 coverage year. We seek comments on this proposed amendment.

In paragraph (f), we propose adding a paragraph to address coverage effective dates for plan selections made during the annual open enrollment period for the 2015 benefit year. We propose that coverage must be effective January 1, 2015, for plan selections received by the Exchange on or before December 15, 2014. We propose that coverage must be effective February 1, 2015, for plan selections received by the Exchange from December 16, 2014 through January 15, 2015. In accordance with 45 CFR 155.335(j), qualified individuals

already enrolled in a QHP through the Exchange in 2014 who maintain the same eligibility would have their coverage continue into 2015, but they would have the ability to change QHPs until January 15, 2015. We seek comments regarding whether issuers should accept payments up until the 31st of a given month, in order to effectuate coverage by the first of the following month. We also seek 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.

5. Functions of a SHOP

For plan years beginning before January 1, 2015, qualified employers participating in a Federally-facilitated SHOP ("FF-SHOP") are able to select a single QHP to offer to their employees. For plan years beginning on or after January 1, 2015, employers participating in the FF-SHOPS will also have the option to select a level of coverage as described in section 1302(d)(1) of the Affordable Care Act, and make all QHPs within that level available to their qualified employees ("employee choice"). Additionally, the FF-SHOPS will begin performing premium aggregation services under § 155.705(b)(4) for plan years beginning on or after January 1, 2015—corresponding with the beginning of employee choice in the FF-SHOPS. Several of the amendments proposed below would take effect when employee choice and premium aggregation become available, including a requirement that employers make premium payments to the FF-SHOPS according to a timeline and process set by HHS, a standard premium pro-rating methodology in the FF-SHOPS providing that groups will be charged for the portion of the month for which an enrollee is enrolled, a prohibition on composite premiums in the FF-SHOPS when an employer utilizes employee choice, methods for employers in the FF-SHOPS to offer stand-alone dental coverage, and flexibility for employers in the FF-SHOPS to define different premium contributions for full-time employees and non-full-time employees.

We propose revising § 155.705(b)(1), which lists the rules regarding eligibility and enrollment to which the SHOP must adhere, to include mention of additional 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.

This provision would become effective when this proposed rule is finalized and becomes effective.

We also propose 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 propose that for plan years beginning on or after January 1, 2015, a qualified employer participating in an FF-SHOP would have two methods by which to offer stand-alone dental plans (SADPs) to its employees and their dependents. This proposal would provide employers with options for offering SADPs while preserving the flexibility not to contribute to SAMP coverage. For example, an employer that elects to offer a single QHP that lacks the pediatric dental benefit may want to ensure that its employees with child dependents have the option to enroll in pediatric dental coverage.

We considered several options for methods by which a qualified employer participating in an FF-SHOP could offer SADPs to its employees and their dependents: the employer could offer a single SAMP, the employer could offer all SADPs at a given dental AV level (under 45 CFR 156.150(b)), the employer could offer all SADPs in an FF-SHOP, or the employer could offer a subset of SADPs available in an FF-SHOP. All of these options would allow an employer flexibility to provide its employees and their dependents with standalone dental coverage. The single SAMP option would enable an employer to choose the plan offered, and may be more administratively appealing to an employer already used to offering a single plan in the current market. This option would have the benefit of administrative ease for an FF-SHOP and issuer, but it would limit the selection for employees more than other options.

Allowing the option for qualified employers to offer all SADPs at a given dental AV level option would also enable an employer to make decisions about the type of plans offered to employees while retaining some administrative simplicity by only requiring a choice between the two dental AV levels (high and low) that were established for the 2014 benefit year. This option would also help advance the goal of increased choice and competition and is similar to employee choice of QHPs where an employer selects a metal tier and employees may select any QHP within that tier. However, the proposed changes to § 156.150 in this proposed rule would remove the AV standards for stand-alone dental plans; thus, this

option would not be possible if § 156.150 is finalized as proposed.

Allowing qualified employers to offer all SADPs available in an FF-SHOP would provide an employer with maximum flexibility to offer its employees and their dependents the ability to choose an SAMP that best fits their needs. Additionally, it would allow an employer to make an offer of coverage without needing to compare and select among plans or tiers. This approach would most advance the goals of increased choice and competition within the small group market, but might create concerns among issuers about potential adverse selection arising from higher risk employees electing to enroll in certain SADPs.

Finally, we considered an option that would allow an employer to make an offer to its employees and their dependents from a defined subset of SADPs in an FF-SHOP. In this option, an FF-SHOP would define a subset of SADPs from which an employer could choose. For example, an employer might be allowed to offer any two plans from the same issuer. This option would allow an employer additional flexibility in offering dental plans while maintaining some control over the particular plans offered to its employees and their dependents. Although less administratively simple, this option could provide some increased level of choice for employers and their employees.

After considering the options described above, we are proposing that a qualified employer in an FF-SHOP could offer its employees (and, if desired, their dependents) either a single SAMP or a choice of all SADPs available in an FF-SHOP after employee choice becomes available in the FF-SHOPS. We note that an employer could choose either option under this proposal regardless of whether it offers one QHP or all QHPs available in an FF-SHOP to its employees and their dependents under § 155.705(b)(3)(iv). We believe this proposal provides the best balance of advancing the Affordable Care Act's goals of increased choice and competition in the small group market, providing employers with an administratively simple way to offer stand-alone dental coverage, providing employees with increased dental coverage options, and maintaining consistency with employee choice. We seek comment on these options, including on the option of offering all plans at a dental AV level if the proposal to eliminate dental AV levels is not finalized.

We also propose to re-designate § 155.705(b)(4)(ii) as (b)(4)(iii) and to

add new paragraph (b)(4)(ii) to allow all SHOPs, both FF-SHOPs and State SHOPs, to establish one or more standard processes for premium calculation, payment, and collection after the SHOP makes premium aggregation available. Many States do not have standardized prorating, payment, and collection practices, and within a given State, issuers may have varying practices. In this environment, a standard method of handling premiums may be necessary for a SHOP to successfully and efficiently implement and operate the premium aggregation services described in § 155.705(b)(4)(i).

We also propose provisions related to the processes FF-SHOPs would establish for premium calculation, payment, and collection under proposed new § 155.705(b)(4)(ii). Consistent with § 155.720(b), which establishes that all SHOPs must establish a uniform enrollment timeline and process, including 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 are proposing 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 intend for this proposed timeline and process to include all premium payments and considered whether to include “all” in the regulation text, but we decided that including the word “all” would be unnecessary. In developing this 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. We anticipate that this payment timeline would require employers to make an initial premium payment at least two days prior to the employer’s desired coverage effectuation date, in order to provide a reasonable window of time for the relevant banks to process the payment transaction. However, we solicit comments about whether such a 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 considerations HHS should factor into the development

of the payment timeline and process. We are also proposing a conforming amendment to § 156.285(c)(7)(iii), discussed in greater detail below, to establish that an FF-SHOP issuer would be required to effectuate coverage unless it has received an enrollment cancellation from the FF-SHOP, and explain in the preamble discussion related to that proposal that if the FF-SHOP has not received an employer’s initial premium payment in accordance with the payment timeline and process established under proposed § 155.705(b)(4)(ii)(A), the FF-SHOP will send the issuer an enrollment cancellation.

At proposed § 155.705(b)(4)(ii)(B), we also propose 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. Because it would be impractical for FF-SHOPs to accommodate the existing variation in premium methodologies that exists across States and issuers, we propose a standard methodology such that groups will be charged for the portion of the month for which the enrollee is enrolled. We considered several methods for prorating partial month payment in the FF-SHOPs, including not charging for a partial month’s coverage, charging a full month’s premium if coverage is effective prior to the 15th of the month, or not charging any premium if coverage is effective after the 15th of the month. We propose that 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 of days in the month. We believe this approach to be the fairest for both consumers and issuers because the issuer will charge for only the portion of coverage provided for a partial month. We invite comments about this methodology, as well as comments about whether a standardized methodology regarding prorating premiums for partial month enrollment should be adopted across all individual market Exchanges as well.

In the proposed 2014 Payment Notice, we proposed at § 155.705(b)(11)(ii)(D) to permit a qualified employer participating in an FF-SHOP to establish, to the extent allowed by Federal and State law, different premium contribution percentages for different employee categories. In the 2014 Payment Notice, we did not finalize this proposal because we concluded that it would be inconsistent with the uniformity provisions established in Internal Revenue Service

Notice 2010–82, which requires employers to contribute a uniform percentage to all employee premiums in order to claim a small business tax credit for health insurance premiums paid.²¹ In this proposed rule, we propose at paragraph (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 different percentage contribution for full-time employees (as defined in § 155.20 and section 4980H(c)(4) of the Code) from the percentage contribution it defines for employees that are not full-time employees under that definition, to the extent permitted by applicable law. This proposal would also allow a FF-SHOP to permit an employer to define different percentage contributions toward premiums for dependent coverage for full-time and non-full-time employees. We note that, to the extent permitted by applicable law, the percentage contributions established for dependent coverage under this proposal could be different from the premium contribution percentages established for employee-only coverage, consistent with current paragraph (b)(11)(ii)(C). Thus, an FF-SHOP under this proposal could allow an employer 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 note that under this proposal, a decision by an employer to define different contribution levels for full-time and non-full-time employees offered coverage through the SHOP may potentially have small business tax credit implications. However, the IRS, not HHS administers the small business tax credit. Therefore, if the proposal is finalized as proposed, employers considering taking this option should consider consulting with the IRS and/or their tax advisors about the implications of such a decision. Even so, we believe that this proposal would provide employers with additional flexibility to choose whether offering different contribution levels would be in the best interest of the business and its employees. Further, this additional flexibility would bring the FF-SHOP more in line with current small group market practices and provide an additional incentive for small employers to participate in the FF-SHOP. Finally, providing for different contribution

²¹ See 78 FR 15502. IRS recently proposed regulations addressing the uniform premium contribution requirement for 2014 at 78 FR 52719, 52721 (Aug. 26, 2013).

levels based on full-time or non-full-time status may encourage some employers to offer coverage to employees who do not meet the Exchange definition of a “full-time employee.”

We also propose amending § 155.705(b)(11)(ii)(D). When an employer offering SHOP coverage elects to base premium contributions on a composite premium, that premium is calculated based on the average per-member premiums for the employees who initially enroll in coverage. Under § 155.705(b)(6)(ii), the average employee premium rate is locked in for the entire plan year, regardless of whether any employees enter or leave the group during the plan year. Additionally, as described above, we are proposing in this rulemaking to amend § 147.102(c) to establish that if an issuer offers a composite premium, the premium amount would not be permitted to vary for any participant during the plan year with respect to a particular plan, even if the composition of the group changes. For example, if several older employees joined the group or several employees terminated their coverage, the composite premium would remain the same until renewal. After employee choice becomes effective in the FF-SHOPs, if an employer participating in an FF-SHOP elects to offer employees all plans at a single metal level of coverage, that employer might have employees enrolled in several different plans. In that circumstance, mid-year changes to the group’s composition without a corresponding change to the composite rate may adversely affect issuers that gain a significant number of older employees once a plan year has started, without a resulting change in premiums to reflect the potentially higher risk. 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. We believe this uncertainty may make issuers more hesitant to offer QHPs in FF-SHOPs after employee choice is available in them—which risks undermining the Affordable Care Act’s goals of increased choice and competition in the small group market. Accordingly, we propose a limited scope prohibition on composite rating in the FF-SHOPs when an employer elects to select a level of coverage and make all QHPs within that level available to its employees. 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 rating 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. Therefore, we propose amending § 155.705(b)(11)(ii)(D) to not allow an employer or State to require that employer premium contributions in an FF-SHOP be based on a calculated composite premium if the employer elects to offer its employees all QHPs within the employer’s selected level of coverage under § 155.705(b)(3)(iv)(A), that is, after employee choice is available in the FF-SHOPs and when an employer elects that option. State-based SHOPs may set their own policies. We are considering extending the prohibition on composite rating to SADPs in the FF-SHOPs, and we invite comment on whether such a prohibition should be adopted, how this policy might affect current market practices on composite rating of dental plans, whether a prohibition on composite rating should apply to all SAMP offering methods or just when an employer chooses to offer more than a single SAMP, and how such a prohibition would affect choice and competition in the small group dental market. Finally, we seek comment on whether the calculation of user fees for the FF-SHOP should be calculated based upon composite premiums or premiums calculated on per-member buildup.

6. Eligibility Determination Process for SHOP

We propose to 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 proposed changes would prohibit a SHOP 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. HHS already interprets existing regulations at § 155.715(c)(3) and (4) and § 155.730 to prohibit SHOPs from performing these types of determinations or verifications and from collecting through the SHOP application process any information other than what is required to make

SHOP eligibility determinations or effectuate enrollment through the SHOP. However, we wish to make the prohibitions explicit in regulation text. We propose this amendment because the SHOPs are designed to assist small employers and employees of small businesses in accessing health insurance coverage, whereas the individual market Exchanges are designed to assist individual consumers. We believe that this proposal would create efficiencies for the SHOP and enable it to focus solely on small businesses. Additionally, we believe the prohibitions in this proposal, in conjunction with the proposed amendments to § 155.730, would help to protect SHOP consumers’ privacy. This provision would become effective when this proposed rule is finalized and becomes effective.

We propose amending paragraph (d) to address when SHOP eligibility adjustment periods would be triggered. Under current paragraph (d)(1), an eligibility adjustment period for an employer would be triggered whenever the employer submits information on the SHOP single employer application that is inconsistent with the eligibility standards described in § 155.710, which effectively means that the inconsistency period is triggered whenever an employer would be determined ineligible. Under current paragraph (d)(2), an eligibility adjustment period would be triggered for employees if the SHOP receives information on the employee’s application that is inconsistent with the information provided by the employer. We are proposing to provide instead for 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).

A SHOP applicant who is determined ineligible could always resolve the reasons for that negative eligibility determination and re-file the application to obtain a favorable eligibility determination. As written, the current eligibility adjustment periods could delay this process in ways that might complicate the enrollment of all employees being offered coverage by an employer, because they could delay the SHOP’s final eligibility determination for an employer or for individual employees, in order to give the SHOP time to resolve issues that may be relatively straightforward for employers or employees to address without the SHOP’s intervention, in a newly filed application. However, if the SHOP has

opted, under § 155.715(c)(2), to establish additional verification methods, and has, as part of that process, decided to verify SHOP applicant eligibility by checking applicant-provided information against information obtained from a trusted third-party data source (such as quarterly wage report data), the applicant might be denied eligibility because of an inconsistency between the information the SHOP received from that applicant and information contained in a third-party data source. Such inconsistencies might be difficult for applicants to identify and resolve on their own.

Our proposed amendments to the eligibility adjustment periods 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). Under the proposal, 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. For example, if an employer provided its commonly used business name on the application but that name varies slightly from the registered business name listed in an unemployment insurance data source used by a SHOP to verify eligibility under § 155.715(c)(2), or if an employee provides a nickname on an application that differs from his or her formal name in quarterly wage report data source used by a SHOP to verify eligibility under § 155.715(c)(2), the applicants would be able to use the adjustment period to address the inconsistencies between their applications and the third-party data sources. If a SHOP does not collect information through optional verification methods under § 155.715(c)(2), the employer and employee would not have to go through the eligibility adjustment period before re-filing their applications, but would still have the right to appeal an adverse eligibility determination under § 155.740. Accordingly, we propose 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). This provision would become effective when this proposed rule is finalized and becomes effective. We seek comments on this proposal, including comments on whether the current eligibility adjustment periods should remain in place.

7. Application Standards for SHOP

HHS already interprets existing regulations at § 155.715(c)(3) and (c)(4) and § 155.730 to prohibit SHOPS from collecting through the SHOP application process any information other than what is required to make SHOP eligibility determinations or effectuate enrollment through the SHOP. We propose amendments to § 155.730 that would expressly state this prohibition in regulation text. Specifically, we propose to re-designate paragraph (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. In conjunction with the amendments we are proposing to § 155.715(c)(4), which would prohibit a SHOP from performing any individual market eligibility determinations or verifications as described in Subpart D of 45 CFR part 155, this proposal seeks to ensure that SHOPS are not collecting information on the single employer or single employee applications that is not pertinent to a determination of SHOP eligibility or effectuation of enrollment. For example, a SHOP could not request through the single employee application the income information necessary for determining eligibility for advance payments of the premium tax credit in the individual market Exchange. Limiting the information required of an applicant helps to protect privacy and promote efficiency and streamlining of the SHOP application process. This provision would become effective when this proposed rule is finalized and becomes effective.

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

1. Provisions Related to Cost Sharing

In this section, we propose several provisions and parameters for the 2015 benefit year related to cost sharing.

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 (proposed at 26 CFR 54.4980H in the “Shared Responsibility for Employers Regarding Health Coverage,” published in the January 2, 2013 **Federal Register** (78 FR 218)). Section 156.130(e) provides that the premium adjustment percentage is the percentage (if any) by which the average per capita premium for health insurance coverage for the preceding calendar year exceeds such average per capita premium for health insurance for 2013, and that this percentage will be published annually in the HHS notice of benefit and payment parameters.

We propose 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 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 propose 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 calculated by the CMS Office of the Actuary. We considered several other sources of premium data, including the Medical Expenditure Panel Survey (administered by the Agency for Healthcare Research and Quality), the Employer Health Benefits Survey (administered by the Kaiser

Family Foundation and the Health Research and Educational Trust), and the Federal Employees Health Benefits Program. However, we believe the NHEA projections, which are partially based on several of the other data sources that we considered, best meet the selection criteria described above and will provide the most accurate estimate of the average per capita premium for the entire health insurance market. We welcome comment on the criteria for selecting a methodology, any additional sources of premium data that we should consider, and the choice of methodology. As additional data on health insurance premiums become available through the Exchanges and other sources, we plan to review the accuracy of the NHEA projections, and if necessary, propose any changes to the methodology for estimating the average premium through the annual Payment Notice.

To calculate the premium adjustment percentage for the 2015 calendar year, we propose to use the most recent NHEA projections of average per enrollee private health insurance spending for 2013 and 2014 (\$5,128 and \$5,435, respectively).²² Therefore, we are proposing that the premium adjustment percentage for 2015 be $(5,435 - 5,128) / 5,128$, and we propose to round the result of this formula to the nearest decimal point, which, in this case, would be 6.0 percent. We are also proposing the following cost-sharing parameters for calendar year 2015, based on our proposed premium adjustment percentage for 2015.

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 product of the maximum annual limitation on cost sharing for calendar year 2014 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. Under § 156.130(d), these amounts must be rounded to the next lowest multiple of 50. Using the proposed premium adjustment percentage of 6.0 percent 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, 2013,²³ we propose that the 2015 maximum annual limitation on cost sharing be \$6,750 for self-only coverage and \$13,500 for other than self-only coverage.

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 product of the maximum annual limitation on deductibles for calendar year 2014 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. Under § 156.130(d), these amounts must be rounded to the next lowest multiple of 50. Using the proposed premium adjustment percentage of 6.0 percent and the 2014 maximum annual limitation on deductibles of \$2,000 for self-only coverage, as specified in § 156.130(b)(1)(i), we propose that the 2015 maximum annual limitation on deductibles be \$2,150 for self-only coverage and \$4,300 for other than self-only coverage.

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 set forth 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 set forth 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. As noted above, we propose the 2015 maximum annual limitation on cost sharing be \$6,750 for self-only coverage and \$13,500 for other than self-only coverage. 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 proposed results.

Reduced Maximum Annual Limitation on Cost Sharing for Benefit Year 2015. Consistent with our analysis in the 2014 Payment Notice, we developed three model silver level QHPs and analyzed the impact on their AVs of the reductions described in the Affordable Care Act to the estimated maximum annual limitation on cost sharing for self-only coverage (\$6,750). However, using data collected for QHP certification for 2014, we updated the model plan designs to ensure that they continue to 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 would include a PPO with a typical cost-sharing structure (\$6,750 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 (\$6,750 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 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 proposed 2015 AV calculator developed by HHS and observed how

²² 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.

²³ See <http://www.irs.gov/pub/irs-drop/rp-13-25.pdf>.

the reductions in the maximum annual limitation on cost sharing specified in the Affordable Care Act affected the AVs of the plans. We found that the reduction in the maximum annual limitation on cost sharing specified in the Affordable Care Act for enrollees with a household income between 100 and 150 percent of the Federal poverty line (FPL) (2/3 reduction in the maximum annual limitation on cost sharing), and 150 and 200 percent of the FPL (2/3 reduction), would not cause the AV of any of the model QHPs to exceed the statutorily specified AV level (94 and 87 percent, respectively). In contrast, the reduction in the maximum annual limitation on cost sharing specified in the Affordable Care Act for enrollees with a household income between 200 and 250 percent of FPL (1/2 reduction), would cause the AVs of two of the model QHPs to exceed the specified AV level of 73 percent. As a result, we propose 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. We further propose that the maximum annual limitation on cost sharing for enrollees with a household income between 100 and 200 percent of the FPL be reduced by 2/3, as specified in the statute, and as shown in Table 4. These proposed 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 would reduce the administrative burden for issuers related to designing new plans, and provide greater continuity for enrollees. Furthermore, as noted in the preamble to the 2014 Payment Notice, selecting a reduction for the maximum annual limitation on cost sharing that is

less than the reduction specified in the statute would not reduce the benefit afforded to enrollees in aggregate because QHP issuers are required to further reduce their annual limitation on cost sharing, or reduce other types of cost sharing, if the required reduction does not cause the AV of the QHP to meet the specified level. We welcome comment on this analysis and the proposed reductions in the maximum annual limitation on cost sharing for 2015. We note that for 2015, as described in § 156.135(d), States are permitted to submit for approval by HHS State-specific data sets for use as the standard population to calculate AV. If States submit such data sets, we intend to analyze their effects on the reductions we propose here, and we will adjust the reductions in the maximum annual limitation on cost sharing if necessary in the final rule.

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

c. Design of Cost-sharing Reduction Plan Variations

In the 2014 Payment Notice, we established standards in § 156.420(c)–(e) to ensure that each cost-sharing reduction plan variation would always provide the most cost savings for which an enrollee is eligible while providing the same benefits and provider network as a plan without cost-sharing reductions. In this proposed rule, we are proposing certain modifications to clarify how these standards would apply to out-of-pocket spending required of an enrollee for benefits other than essential health benefits (EHBs).

Following our implementation of Exchange operations for 2014, we have 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. We are

proposing 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 propose that the standard in § 156.420(e)—that cost sharing for an essential health benefit 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 propose 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

required in the QHP with no cost-sharing reductions.

We believe these proposed modifications strike the appropriate balance between protecting consumers and providing QHP issuers with flexibility. Each cost-sharing reduction plan variation would continue to provide the most cost savings for which an enrollee is eligible; however, QHP issuers would be able to reduce out-of-pocket spending for benefits that are not EHB for enrollees in plan variations. We believe some issuers may want to provide such reductions so as to offer a simpler cost-sharing design that is consistent across EHB and benefits that are not EHBs. 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 would not be reimbursed by the Federal government because payments for cost-sharing reductions only apply to EHB.

We seek comment on this proposal, including on whether our proposal should offer less flexibility.

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, for approval by HHS, 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. In the 2014 Payment Notice, we specified that the estimates of the cost-sharing reductions must be calculated using data that issuers submit 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. If an issuer seeks advance

payments for the cost-sharing reductions provided under the limited cost sharing plan variation of a health plan it offers, we specified that the issuer must submit an estimate of the dollar value of the cost-sharing reductions to be provided. As described in § 156.430(b)(1), HHS uses these estimates to determine the monthly advance payments for cost-sharing reductions.

Based on our experience implementing this process for the 2014 benefit year, we propose 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 are proposing 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 propose to modify § 155.1030(b)(3) to specify that 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). We anticipate that this transmission would occur using the 834 enrollment transaction. As proposed in § 156.430(b)(1), HHS will provide periodic advance payments to QHP issuers based on the amounts transmitted by the Exchange.

For the 2015 benefit year, we are proposing that the Exchanges use a

methodology for calculating the advance payment amounts that will not require QHP issuers to submit an estimate of the value of cost-sharing reductions to be provided or the EHB portion of expected allowed claims costs, as previously required under § 156.470(a), nor will it require Exchanges to transfer data on advance payment amounts to HHS prior to the start of the benefit year.

Specifically, we propose that Exchanges calculate the monthly advance payment amount for a specific policy as the product of (x) the total monthly premium for the specific policy, and (y) a cost-sharing reduction plan variation multiplier. The cost-sharing reduction plan variation multiplier would convert the monthly premium into the appropriate monthly advance payment amount, based on the following formula:

Cost-Sharing Reduction Plan Variation Multiplier = Factor to Remove Administrative Costs * Factor to Convert to Allowed Claims Cost * Induced Utilization Factor * (Plan Variation AV—Standard Plan AV)

Where,

Factor to Remove Administrative Costs = 0.8 for all plan variations, because issuers in the individual market must have a medical loss ratio of at least 80 percent, under § 158.210(c);

Factor to Convert to Allowed Claims Costs = the quotient of 1 and the AV for the standard plan, not accounting for 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
73 percent AV silver plan variation.	73 percent
87 percent AV silver plan variation.	87 percent

TABLE 6—ACTUARIAL VALUES FOR PLAN VARIATIONS—Continued

Cost-Sharing Reduction Plan Variation	Plan Variation AV
94 percent AV silver plan variation.	94 percent
Limited cost sharing plan variation of bronze QHP.	87 percent

TABLE 6—ACTUARIAL VALUES FOR PLAN VARIATIONS—Continued

Cost-Sharing Reduction Plan Variation	Plan Variation AV
Limited cost sharing plan variation of silver QHP.	87 percent
Limited cost sharing plan variation of gold QHP.	94 percent
Limited cost sharing plan variation of platinum QHP.	94 percent
Zero cost sharing plan variation of bronze QHP.	100 percent
Zero cost sharing plan variation of silver QHP.	100 percent
Zero cost sharing plan variation of gold QHP.	100 percent
Zero cost sharing plan variation of platinum QHP.	100 percent

The proposed induced utilization factors are consistent with those 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 will propose updates to the induced utilization factors for all plan variations in future rulemaking as more data becomes available, and at that time will consider applying them to the risk adjustment methodology that HHS will use when operating risk adjustment on behalf of a State. We welcome comment on these induced utilization factors.

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 administrative burden on Exchanges because Exchanges will not need to develop specific multipliers for each QHP and associated plan variations. However, this approach would require us to estimate an actuarial value for each type of limited cost sharing plan variation. We estimate that on average, the AV of the limited cost sharing plan variations of bronze and silver QHPs will be 87 percent, and the AV of the limited cost sharing plan variations of gold and platinum QHPs will 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 welcome comment on these actuarial values.

Overall, we believe this proposed methodology would 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. Although we acknowledge that there may be some limitations to the multiplier (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. We welcome comment on this proposed methodology for the 2015 benefit year, and suggestions for alternative methodologies, including whether the methodology for the 2014 benefit year would be more appropriate.

We are also proposing conforming modifications to §§ 155.1030(b)(1) and 156.470(a), to delete the obligation for QHP issuers to submit, and Exchanges to review, the EHB allocation of the expected allowed claims costs for the plans, because this data would not be used in the proposed 2015 methodology for calculating cost-sharing reduction advance payments.

Lastly, we are proposing to modify § 155.1030(b)(4) to clarify that in accordance with the proposed paragraph (b)(3), the Exchange would not be required to submit issuers' advance payment estimates to HHS for approval prior to the start of the benefit year. We believe such an approval process would no longer be necessary because under the proposed approach, the advance payments will be calculated based on the cost-sharing reduction plan variation multiplier specified by HHS, and the premium for the policy, which is reviewed by the Exchange, in accordance with § 155.1020. HHS would simply validate that the advance payment amounts were calculated in accordance with the methodology specified by HHS, prior to providing advance payments to QHP issuers. This process will ensure the protection of Federal funds, while also limiting the administrative burden on QHP issuers and Exchanges. We welcome comment on these proposed modifications. In future years, as more data becomes available, we will review the methodology for calculating advance payments of cost-sharing reductions,

and will propose additional modifications if necessary.

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–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. These special benefits are provided to participating issuers through the following Federal activities in connection with the operation of FFEs:

- Provision of consumer assistance tools.
- Consumer outreach and education.
- Management of a Navigator program.
- Regulation of agents and brokers.
- Eligibility determinations.
- Administration of advance payments of the premium tax credit and cost-sharing reductions.
- Enrollment processes.
- Certification processes for QHPs (including ongoing compliance verification, recertification and decertification).
- Administration of a SHOP Exchange.

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.

OMB 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). Accordingly, we propose 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.²⁴ Because we expect enrollment to increase in 2015 as awareness of the Exchanges grows, and costs to decrease as operations become more efficient, we believe this user fee rate may allow HHS to recover the full cost to the Federal government of providing the special benefits to issuers participating in an FFE in 2015.

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 Employee Retirement Income Security Act (ERISA) and the Code, requires that non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage provide benefits for certain women's preventive health services without cost sharing.²⁵ 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.²⁶

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, the self-certification must be provided to the plan's third party administrator. A third party administrator that receives a copy of the self-certification 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 third party administrator can provide such payments on its own, or it can arrange for an issuer or other entity to provide such payments. In either case, the third party administrator can make arrangements with an issuer offering coverage through an FFE to obtain reimbursement for its costs (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 propose an allowance for administrative costs and margin that is equal to 15 percent of the total dollar amount of the payments for contraceptive services defined in § 156.50(d)(3)(i).²⁷ We propose this allowance based on our analysis of the administrative costs that we expect each entity involved in the arrangement to incur. For example, the third party administrator will likely incur certain variable administrative costs, including the cost of provider and medical management, and the cost of processing payments to providers of the contraceptive services. However, because payments for contraceptive services are not a separate insurance product and because the third party administrator will have an existing arrangement with the self-insured group health plan of the eligible organization,

we do not expect any additional costs related to marketing, broker fees, enrollment, or billing. We accounted for the cost of submitting data to HHS under § 156.50(d)(2), and the cost of exchanging data between entities involved in the arrangement. We also added an allowance for margin in proportion to the total costs that we expect each entity to incur. We seek comment on the allowance for administrative costs and margin, including the appropriate percentage and alternative methods for future determinations of the allowance.

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 coverage 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.

The AV Calculator uses national claims data to reflect plans of various levels of generosity as the underlying standard population. This standard population is represented in the calculator as tables of aggregated data called continuance tables. The AV methodology document that was incorporated by reference in the EHB Rule provides an overview of the development of these continuance tables and the AV Calculator logic.

As stated in the EHB Rule, HHS does not anticipate making annual changes to the AV Calculator logic or the underlying standard population reflected in the continuance tables. However, 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 can accommodate changes in the marketplace or product design over time and due to the changing cost of providing health care services. Here, we propose to provide for authority to update certain aspects of the AV Calculator on a regular basis, but no more frequently than annually, based on changes to applicable standards or the availability of new data that could

²⁴ 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-based Exchanges.

²⁵ 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.

²⁶ 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.

²⁷ 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.

make the AV Calculator more accurate. These types of changes include:

(1) *Updating the annual limit on cost sharing and related functions in the calculator:* Section 1302(c) of the Affordable Care Act, codified at § 156.130, imposes an annual limit on cost sharing on non-grandfathered plans in the individual and small group markets. We note that, in accordance with section 1302(c)(4) of the Affordable Care Act and § 156.130(e), starting in 2015, HHS will publish the premium adjustment percentage in the annual HHS notice of benefit and payment parameters for purposes of calculating the required indexing of the annual limit on cost sharing. Because this limit is included in the AV Calculator and impacts the range of the AV Calculator, we propose to update the AV Calculator to include an estimated annual limit on cost sharing. In order to allow issuers the most time possible to develop plans, HHS may make available prior to the annual HHS notice of benefit and payment parameters the AV Calculator that would project an estimated annual limit on cost sharing for the given plan year. Issuers would still be required to adhere to the annual limit on cost sharing that is published in the applicable HHS notice of benefit and payment parameters. The intention in using an estimated annual limit on cost sharing in the AV Calculator is to ensure flexibility of the AV Calculator for issuers. Since we may make the AV Calculator available prior to the finalization of the annual limit on cost sharing for a given plan year, we are proposing to use an estimated annual limit on cost sharing in the AV Calculator, to ensure that the final AV Calculator does not contain an annual limit on cost sharing that is lower than the finalized one. Accordingly, in the proposed 2015 AV Calculator, we propose an estimated annual limit on cost sharing of \$6,850, compared to the proposed annual limit for cost sharing for 2015, which is \$6,750.

(2) *Updating the continuance tables to reflect more current enrollment data:* Starting in 2016, HHS expects to have sets of actual enrollment data from 2014 and to receive the subsequent year's data on an annual basis thereafter. These data could be used to reweight the standard population in the continuance tables that run the AV Calculator to more accurately reflect true enrollment trends and as a result project claims spending. We anticipate that during the first several years of operation, the demographic mix of the enrolled population will likely change and may need to be reweighted in the AV Calculator annually. After a few

years, the population may stabilize and begin matching the claims data to the point where reweighting the AV Calculator may not be necessary on an annual basis.

We propose to analyze the most recently available data on the enrolled population every year, starting in 2016, and in cases where we determine that the enrolled population has materially changed, we propose to reweight the continuance tables in the AV Calculator to continue to accurately reflect enrollment data. We are proposing to consider a material change in gender or age in the enrolled population as more than a 5 percent change. We propose to determine this change based on a combined measurement of the effects of shifts in gender or age statistics. We solicit comment on this 5 percent standard and whether it should be a higher or lower percentage, as well as how this change should be determined. For the proposed 2015 AV Calculator, we did not have actual enrollment data to analyze and therefore, we are not proposing to reweight the calculator based on enrollment data at this time.

(3) *Updating the algorithms behind the AV Calculator to adapt to new industry practices and plan designs:* As discussed in the EHB Rule, because the AV Calculator is intended to account for the vast majority of plan designs in the market, in order to ensure that the AV Calculator will be available to plans and issuers, it will likely need to be periodically adapted. To do this, we are proposing to make technical, non-substantive updates to the AV Calculator algorithms as industry practices change and as technology advances, including adding features to the AV Calculator. For example, for the proposed 2015 AV Calculator, we are able to make improvements to the algorithms to allow for additional functionality to apply the deductible first and then copayments. Adding this feature would allow the calculator to be applicable for more types of plans and would not substantively affect other plan designs using the AV calculator. Such an adaptation of the AV Calculator to allow more types of plan designs to use the calculator without adjustment and to accommodate new types of plan designs in the market would be the basis for making these non-substantive changes. The standard that we propose to apply in making such adaptations would 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. We propose to make such

adaptations under the provisions of this proposed rule if the adaptations can be based on actuarially sound principles and these adaptations would only involve minor modifications to the AV Calculator that would result in only a limited or no impact on the majority of plan designs that use the AV Calculator. We invite public comment on suggestions for ways in which this standard could best be achieved.

To identify new industry practices and technical advances, we propose to consult annually with the American Academy of Actuaries to determine what new adaptations are needed in the AV Calculator as the basis for those changes. Under § 156.135(b), the American Academy of Actuaries' members play a critical role in determining the AV of plan designs that are not compatible with the AV Calculator and would have insight into adjustments that are needed in the AV Calculator to meet the needs of the involving market and to allow more plan designs to use the AV Calculator. We also propose taking into consideration stakeholder feedback on adjustments to the AV Calculator that are submitted to the CMS Actuarial Value email address at actuarialvalue@cms.hhs.gov. To accomplish this goal, we propose aggregating this information annually and assessing which modifications would benefit the most issuers, are feasible in the AV Calculator, and will not substantively impact other functions of the calculator. If an algorithm change meets these criteria, and standards set forth above, we would consider incorporating it into the AV Calculator's algorithms. Changes that are made to the algorithms would be described in the AV Calculator Methodology that would be released with any updated AV Calculator.

(4) *Updating the continuance tables to reflect more current claims data:* HHS is proposing to update the claims data underlying the continuance tables, including refreshing the national claims database data with new data, as well as trending the AV Calculator to account for changes in the unit prices, utilization and intensity of services used. A trending factor could be a historical trend factor making use of actual premiums that reflect utilization and unit price increases, a factor based on emerging trends changing the demographic, or be based on the premiums of the new product designs with unique features. Data on these changes in insurance could be used to develop a trending factor that could be applied to the claims data to make adjustments in the continuance tables of the AV Calculator. For future plan years,

we propose to 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. For the individual market, we propose to use the premium rate data and/or the standard population data compared from year to year, and for the small group market, we proposed to use similar premium rate data and/or the standard population data compared from year to year to develop a trending factor that we could apply to the claims data in the AV Calculator, adjusted for key changes, such as the reduction in transitional reinsurance that will occur from 2014 through 2016. In years when we are planning to update the claims data from the national claims database system in the AV Calculator, we are proposing to trend the AV Calculator based on the new claims data with the dataset currently being used in the calculator to ensure that the trend factor and claims data are reconciled.

In considering the factors in adjusting the claims data and trending the calculator, we recognize the importance of market stability for both issuers and consumers from year-to-year. At the same time, we recognize the importance of the AV Calculator reflecting the current market. By pursuing the approach of not updating the claims data every year, we would be providing greater stability in an emerging market. For these reasons, we are proposing to update the baseline claims data no more than every 3 and no less than every 5 years. This proposal of no more than every 3 years reflects the duration of the transitional reinsurance program and the temporary risk corridors program.

We are also proposing to 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. By considering whether to trend the AV Calculator every year, we would be helping to ensure that the AV Calculator more accurately reflects the current market and to avoid having any steep "cliff" changes in the AV Calculator every few years. Under the methodology proposed above, we are proposing to trend the AV Calculator on premium data and/or the 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 are proposing to trend the calculator based on the updated claims data. We seek comments on this proposed approach, including our proposed approach to

updating the claims data. We are proposing to provide details of our consideration of the trending factor each year in the AV Methodology. For 2015, we do not propose to trend the AV Calculator since the necessary 2 years of data were not available to make the adjustment per our proposed policy.

(5) *Updating the AV Calculator user interface:* HHS is proposing to update the AV Calculator user interface as needed to improve the user's experience. An example of this type of change, which we included in the proposed 2015 AV Calculator, is adding the ability for the user to save AV calculations. The 2014 AV Calculator did not incorporate this function, but based on comments received, we recognized the importance for users to have this feature. In the future, we anticipate that there will be other ways in which we could continue to make improvements to the AV Calculator's user interface to assist users and we anticipate that we will continue to receive feedback from various stakeholders to inform future proposed improvements to the AV Calculator user experience. HHS may consider making changes when an improvement 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. These changes would simplify the process for providing users with features that could help save time and improve processes.

When making updates to the AV Calculator in accordance with this proposed rule, we propose to update the AV Calculator through guidance that will be posted on our CCIIO Web site. This guidance will include an updated AV Calculator Methodology to explain the changes that were made to the AV Calculator, along with the updated AV Calculator. We also expect that we would make any updates that will affect the AV Calculator in advance of the benefit year for which issuers are using the AV Calculator, with the intention of making the AV Calculator available no later than the end of the first quarter of the preceding the benefit year.

We are soliciting comments on all of the above types of updates and the accompanying criteria that would be used to identify the need for and to implement these updates. Outside of the above types of updates, we are also soliciting comments on whether other types of updates should be considered routinely for the AV calculator. To clarify, we are proposing that, to comply with § 156.135(a), 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). The purpose of requiring that the issuers use the AV Calculator of the given benefit year or the State AV Calculator is to ensure that the AV calculation is being more accurately calculated on the most recent data each year and that there is only one AV Calculator (or State AV Calculator) applicable for each benefit year. We are also soliciting comments on the proposed 2015 AV Calculator and AV Calculator methodology that would supersede the 2014 versions of these documents. In accordance with our proposed policy, we provide an explanation of the changes that were made in the proposed 2015 AV Calculator in the proposed 2015 AV Methodology. For the 2015 AV Calculator, HHS is only proposing to make minor changes to the design and inputs into the AV Calculator. While plans' AV calculations may be impacted by the updated AV Calculator, our testing has shown that this impact will be limited for the vast majority of plans and that only in certain cases will plans see a significant change in AV. We encourage stakeholders to test the proposed 2015 AV Calculator and submit technical comments on it during the comment period.

In the preamble to the EHB Rule, we discussed the calculation of AV for health plans with family cost-sharing features. In addition we provided guidance in the "2014 Letter to Issuers on Federally-facilitated and State Partnership Exchanges"²⁸ on accounting for family plans for 2014. Since the AV Calculator claims data are based on individual claims data that did not include family cost-sharing information, HHS is seeking the necessary empirical data to develop the code that can incorporate family plans into future versions of the AV Calculator. We are now seeking comment on how to account for these family plan designs and we are particularly interested in information regarding potential data source options.

4. National Annual Limit on Cost Sharing for Stand-Alone Dental Plans in an Exchange

The EHB Rule established an annual limit on cost sharing for the pediatric dental essential health benefit offered by

²⁸ "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.

stand-alone dental plans (SADPs) in the Exchanges that is separate from the annual limit on cost sharing that applies to QHPs that offer comprehensive medical benefits. The EHB Rule established that Exchanges should set a “reasonable” annual limit on cost sharing for SADPs. The CMS Letter to Issuers on Federally-facilitated and State Partnership Exchanges, published on April 5, 2013, established that CMS’s interpretation of a reasonable SAMP annual limit on cost sharing for the FFEs is \$700 for an SAMP with one child enrollee and \$1,400 for an SAMP with two or more children enrollees.

We propose a revised policy for the 2015 benefit year and beyond in response to significant public interest in establishing a policy that is consistent across Exchanges and that minimizes a consumer’s total annual limit on cost sharing. HHS also seeks to minimize the differences between a consumer’s total annual limit on cost sharing when purchasing essential health benefits through a QHP that includes coverage of the pediatric dental essential health benefits or through a combination of a QHP and an SAMP. Thus, we are proposing in this rule an amendment to § 156.150 that would establish an annual limit on cost sharing for SADPs that would be applicable in all Exchanges. For the 2015 benefit year, the new proposed paragraph (a)(1) would impose an annual limit on cost sharing for the pediatric dental EHB when offered through an SAMP of \$300 for one covered child and \$400 for two or more covered children. We request 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. Further, due to the limited variation in cost sharing with a decreased annual limit on cost sharing, we propose removing the actuarial value requirement SADPs offered through the Exchanges by deleting paragraph (b) of § 156.150. We request comment on the removal of the AV standard as well.

We understand that under the current rules, some State Exchanges have interpreted a reasonable annual limit on cost sharing to be higher than what is proposed in this proposed rule. For example, at least two State Exchanges have established an annual limit on cost sharing for SADPs of \$1,000 for one covered child and \$2,000 for two or more covered children. We therefore request comment on whether the annual limit on cost sharing should be consistent nationally, which would be more straightforward for consumers and issuers, or set by each Exchange, which allows for State flexibility to adjust to

specific market standards and whether the limits proposed here are appropriate. As stated above, we propose to establish the \$300/\$400 annual limit on cost-sharing as a national maximum annual limit on cost sharing applicable in all Exchanges. For those States that currently have annual limits on cost sharing of \$1,000/\$2,000, we request comment on whether there should be a more gradual decrease in the annual limit in cost sharing that would ultimately reach the national level, but would result in a less significant one-time decrease.

HHS considered several other alternatives to minimize a consumer’s total annual limit on cost sharing when purchasing the pediatric dental EHB through a SAMP, including: Requiring issuers of SADPs to consider the annual limit on cost sharing to be met once the consumer reaches the annual limit on cost sharing for the QHP; requiring issuers of QHPs without the pediatric dental EHB to reduce the annual limit on cost sharing by the amount of annual limit on cost sharing permitted for SADPs; and, requiring issuers of QHPs and SADPs to track out of pocket costs for a shared consumer and jointly consider a consumer’s out of pocket commitments to be met once a total number has been reached. We note that HHS is generally concerned with the administrative costs of implementing a policy that requires coordination of claims to a single annual limit on cost sharing. We seek comments on these alternatives.

5. Additional Standards Specific to SHOP

We propose to add new 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. Under section 1304(b)(4)(D) of the Affordable Care Act, a small employer that ceases to be a small employer by reason of an increase in the number of employees continues to be treated as a small employer for purposes of Subtitle D of Title I of the statute. Included within Subtitle D are the provisions governing the SHOP and the premium stabilization rules. However, the fair health insurance premium provisions at section 2701 are not contained in Title D. To assure consistency of pricing within the SHOP,²⁹ we propose to require a QHP

offered through the SHOP to comply with the rating rules described in § 147.102. We note that 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 believe that, when employee choice becomes available in FF-SHOPs for plan years beginning on or after January 1, 2015, allowing composite rating when an employer chooses to offer all plans within a metal tier under § 155.705(b)(3)(iv)(A) could result in issuers becoming more hesitant to offer QHPs in an employee choice environment—undermining the ACA’s goals of increased choice and competition. As discussed in more detail above with regard to proposed § 155.705(b)(11)(ii)(D), composite rating when an employer takes advantage of employee choice could result in an issuer taking on proportionately more risk from mid-year changes to the employer’s roster than in a single plan environment and, therefore, deny an issuer the premiums that would otherwise be due in a per-member premium calculation for the group. We proposed in § 155.705(b)(11)(ii)(D) to prohibit composite rating in the FF-SHOPs when an employer chooses a level of coverage and make all QHPs within that level available to its employees, and we propose in § 156.285(a)(4)(ii) to subject issuers to the same prohibition, to assure that issuers understand that composite billing is not allowed in the FF-SHOPs when employee choice becomes available and an employer selects a level of coverage and not a single plan. As with proposed § 155.705(b)(11)(ii)(D), we are considering extending the prohibition on composite rating to SADPs in the FF-SHOPs, and we invite comment on whether such a prohibition should be adopted, how this policy might affect current market practices on composite rating of dental plans, whether a prohibition on composite rating should apply to all SAMP offering methods or just when an employer chooses to offer more than a single SAMP, and how such a prohibition would affect choice and competition in the small group dental market. We acknowledge that this proposal provides a limited exception to § 147.102(c)(3) and note that this proposal would preempt State law in

²⁹ In the 2014 Payment Notice (78 FR 15418), we provided that risk adjustment would not apply to a plan unless it was subject to certain market reform rules, including the rating rules. Elsewhere in this proposed rule, at § 153.510(f), we propose a similar approach with respect to risk corridors. Our

proposed approach here for the SHOP would provide that a SHOP QHP that grows into a large group plan would continue to receive the protections of the risk adjustment and risk corridors programs.

this context, 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.

If the proposed amendments to § 155.705(b)(4) summarized above are finalized as proposed, all SHOPs would 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 would 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 recognize that under this approach, an issuer might not receive an employer's initial premium payment from the FF-SHOP prior to the coverage effective date even though the employer has remitted payment to the FF-SHOP consistent with the HHS-established timeline. We understand that issuers may be concerned about effectuating coverage prior to receiving payment from a FF-SHOP. To address this concern, if the FF-SHOP has not received the initial premium payment in accordance with the payment timeline and process established in accordance with proposed § 155.705(b)(4)(ii)(A), the FF-SHOP will send an enrollment cancellation transaction to the issuer to ensure that coverage is not effectuated. Accordingly, we propose that if the issuer does not receive an enrollment cancellation transaction, it should effectuate coverage. We considered whether an FF-SHOP could, alternatively, send an issuer a notice confirming that it should effectuate coverage when the FF-SHOP received an employer's initial premium payment but the issuer would not receive that payment prior to the coverage effective date. However, it would be simpler administratively and operationally for issuers to assume they should effectuate coverage and proceed to effectuate coverage unless an FF-SHOP cancels the enrollment. Therefore, we propose adding § 156.285(c)(7)(iii) 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 from the

FF-SHOP. We note that 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 proposed § 155.705(b)(4)(ii)(A) and the termination provisions of § 155.735 would apply. We seek through this proposal to balance issuers' concerns about receiving payment with the need for timely FF-SHOP enrollment and operational efficiency. We welcome comment on the proposed approach, as well as on the alternative approach discussed above which we considered but rejected, and encourage commenters to suggest additional alternatives.

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 propose 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 propose a standard for what is meant by the term "meaningfully different."

Based on feedback from stakeholders and HHS' experience from administering the Medicare program, HHS believes that it is in the interests of consumers to have an Exchange with meaningfully different plan choices, as meaningful difference has important benefits to consumers, such as ensuring the ability to readily differentiate and compare plan choices, leading to informed decisions.³⁰ A single issuer offering a number of plans that lack meaningful difference could take virtual "shelf space" from other competitors and stifle competition. Therefore, conducting a review for meaningful difference will ensure that consumers are able to make informed selections among an ample—but manageable—number of QHPs, while allowing for plan innovation. The approach outlined

below for a meaningful difference requirement would allow time for HHS to see how the market develops, assess the consumer need for a more specific meaningful difference standard, and consider options to meet this potential need. HHS does not intend to set numerical limits on the number of QHPs that may be offered; rather, the proposed approach would serve to avoid having an issuer offering multiple QHPs that appear the same through an Exchange.

In § 156.298(a), we propose that the FFEs and FF-SHOPs will 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 stand-alone dental plan market, HHS proposes not to require meaningful difference as a condition for certification among stand-alone dental plans at this time. HHS seeks comment on this approach. We propose, in § 156.298(b), that a plan within a service area and metal tier (bronze, silver, gold, or platinum, and catastrophic coverage) is 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 eight key characteristics between the plan and other plans to be offered by the same issuer. The key characteristics are proposed in paragraphs (b)(1)–(b)(7), and would 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. At a minimum, two or more of the characteristics proposed at § 156.298(b) must be different in order to pass the meaningful difference test. Therefore, within a service area and level of coverage in an Exchange, if two 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 may 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 propose 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 will not be subject to the meaningful difference requirement.

³⁰ Research suggests that consumers may prefer more limited arrays of choices. See Iyengar, S.; Lepper, M. *Journal of Personality and Social Psychology*, Vol. 79(6), Dec 2000, 995–1006.

To provide flexibility for issuers that merge with or acquire another issuer that is a separate legal entity, HHS proposes 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 propose 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. After the 2-year transition period, HHS may approve a QHP application for certification that is being offered by the acquiring entity only if HHS finds that the plan's benefit package or costs are meaningfully different from other QHPs offered by the acquiring entity and the plan meets all other certification requirements. We believe that this transition timeframe provides ample time for issuers to ensure that benefit packages being offered are meaningfully different without stifling market transactions.

We seek comment on the proposed approach to reviewing meaningful difference for QHP certification and whether this standard should be expanded to all Exchanges, including State Exchanges. We also seek comment on whether this authority granted to the Exchange by section 1311(e)(1) of the Affordable Care Act, to act in the interests of qualified individuals and qualified employers, should be used by the Secretary, in conjunction with the authority granted by section 1311(e)(2) of the Affordable Care Act, to limit an issuer's participation in the FFEs should there be significantly different rate increases for its QHPs and non-QHPs. While the transitional policy regarding renewals of certain coverage announced in November 2013 and described earlier in this preamble was intended to allow for continuity of coverage, it was not intended to promote adverse selection through significantly higher rates for QHPs.

7. Quality Standards: Establishment of Patient Safety Standards for QHP Issuers

Section 1311(h)(1)(A) of the Affordable Care Act specifies that, beginning on January 1, 2015, a QHP may contract with hospitals with greater than 50 beds only if the hospitals meet certain patient safety standards, including use of a patient safety evaluation system (PSES) as described in part C of Title IX of the PHS Act, and a comprehensive hospital discharge program. A PSES means the collection, management, or analysis of information for reporting to or by a patient safety

organization (PSO).³¹ Section 1311(h)(1)(B) of the Affordable Care Act specifies that a QHP may contract with health care providers that implement health care quality mechanisms, if any are required by the Secretary in regulations. Section 1311(h)(2) of the Affordable Care Act provides the Secretary with the authority and flexibility to establish reasonable exceptions to these requirements and section 1311(h)(3) of the Affordable Care Act allows the Secretary to issue regulations to modify the number of beds described in section 1311(h)(1)(A).

As discussed in the National Strategy for Quality Improvement in Health Care (National Quality Strategy), HHS seeks to improve the overall quality of health care by making health care more patient-centered, reliable, accessible, and safe.³² One of the main priorities of the National Quality Strategy is making care safer by reducing harm caused in the delivery of care. In addition, section 1311(h) of the Affordable Care Act aims to strengthen quality improvement and patient safety for consumers in Exchanges. To effectively balance the priorities for making quality health care accessible and safe in the Exchanges, we propose to implement these patient safety standards for QHP issuers over time, under the Secretary's authority in section 1311(h)(2) of the Affordable Care Act. We believe 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.

Currently, there are 79 listed PSOs nationwide operating in 29 States and the District of Columbia.³³ PSOs carry out a variety of patient safety activities with the goal to improve patient safety and the quality of health care delivery. PSOs are able to collect, aggregate, and analyze patient safety events and information that is protected under privilege and confidentiality standards. However, it is not entirely clear that there is sufficient capacity to enable all hospitals subject to this provision to contract with a PSO at this time. HHS recognizes the continuously-growing capacity of the PSO program and the potential to accommodate U.S. hospitals subject to § 156.1110 within the proposed phase-in period. HHS recognizes the significant burden and

time constraints for hospitals to enter into agreements with PSOs for appropriate services to improve patient safety, especially for particular hospital settings and populations. HHS also recognizes the significant resources that QHP issuers would need to invest to track such initiatives, such as ensuring that the hospitals and health care providers the QHP issuer contracts with have appropriate agreements with PSOs and adequate hospital discharge planning activities. Consequently, we believe that this proposed rule would provide an opportunity for QHP issuers to meaningfully comply with section 1311(h) of the Affordable Care Act and consider how PSOs will work with their network hospitals and health care providers. This proposal would also provide time for hospitals and healthcare providers to demonstrate to a QHP issuer that they meet the patient safety standards in accordance with section 1311(h). Moreover, we believe that this proposed 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.

In phase one, which would become effective for QHP issuer plan years beginning on or after January 1, 2015, the patient safety standards proposed in § 156.1110 would apply to hospitals, as defined in section 1861(e) of the Social Security Act,³⁴ that are Medicare-certified, and to Medicaid-only hospitals which have been issued a Medicaid-only CMS Certification Number (CCN). These standards would apply to such hospitals that have been certified for greater than 50 beds. For the reasons described above, HHS is not proposing requirements regarding the patient safety standards described in section 1311(h)(1)(B) at this time. HHS is currently in the process of researching the establishment of appropriate quality and patient safety standards for QHP issuers contracting with health care providers as described in section 1311(h)(1)(B).

In § 156.1110(a), we propose that a QHP issuer may contract with hospitals that have more than 50 beds, only if they are Medicare-certified or have been issued a Medicaid-only CCN, both of which are subject to Medicare Hospital Conditions of Participation (CoPs)

³¹ See <http://www.pso.ahrq.gov/regulations/fnlrule01.pdf>.

³² See Report to Congress: National Strategy for Quality Improvement in Health Care available at <http://www.healthcare.gov/law/resources/reports/quality03212011a.html>.

³³ See <http://www.pso.ahrq.gov/listing/geolist.htm>.

³⁴ Section 1861(e) of the Social Security Act: http://www.ssa.gov/OP_Home/ssact/title18/1861.htm.

standards found in 42 CFR part 482.³⁵ Specifically, such hospitals must develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement (QAPI) program, as described in 42 CFR 482.21. In addition, a hospital that is Medicare-certified or participates in the Medicaid program must have in effect a discharge planning process that applies to all patients, as described in 42 CFR 482.43. HHS believes that the standards of QAPI and discharge planning in the Medicare hospital CoPs represent the most efficient way to balance the need to have a sufficient number of hospitals available for QHP issuers to contract with, and the statutory intent of section 1311(h) to provide for adequate patient safety standards. In addition, based on our preliminary research, the vast majority of hospitals with greater than 50 beds are Medicare-certified or are Medicaid-only hospitals and must comply with the health and patient safety standards in the Medicare hospital CoPs. Hospitals may be deemed to meet the CoP standards if accredited per section 1865 of the Social Security Act. Therefore, the proposed approach would not significantly limit hospital participation in QHP networks and would provide consumers access to health care services from an adequate number of hospitals through QHPs in the Exchanges.

In § 156.1110(b), we propose to direct QHP issuers to maintain documentation, including but not limited to the CCN for each hospital. Since both Medicare-certified hospitals and Medicaid-only hospitals are issued CCNs, such documentation would demonstrate that a QHP issuer's contracted hospital is Medicare-certified or has a Medicaid-only CCN and are subject to the Medicare hospital CoP standards as required in paragraph (a). We believe that collecting and maintaining data such as the CCN would not be burdensome for QHP issuers. In § 156.1110(c), we propose 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. We intend to include all Exchange types when referring to the Exchange in § 156.1110, including a State-based Exchange. We anticipate using the data collected as part of information used to evaluate and oversee QHP issuers in FFEs. We note that multi-State plans, as defined in § 155.1000(a), are subject to

these provisions. OPM would determine the time and manner for multi-State plans to submit the documentation.

In § 156.1110(d), we propose that a QHP issuer must ensure that each of its QHPs meets the patient safety standards in accordance with paragraph (a) of this section for plan or policy years beginning on or after January 1, 2015. We anticipate that this first phase of implementation of QHP-related quality standards 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 seek comment regarding our proposal to apply Medicare hospital CoP standards for implementation of section 1311(h) of the Affordable Care Act. We also request comment on the proposed 2-year time period for the first phase of implementation. Additionally, we propose to maintain the statutory distinction between hospitals with 50 or fewer beds and hospitals with more than 50 beds, but we request comment for phase one implementation on whether HHS should adjust the number of hospital beds to be greater or less than the standard under section 1311(h)(3) of the Affordable Care Act. We also seek comment regarding whether the proposed standards in § 156.1110 should be applicable to hospitals other than Medicare-certified and Medicaid-only hospitals. We further request comment on whether any other documentation would be reasonable to require QHP issuers to collect and maintain to meet the proposed standards described in § 156.1110(c).

For the next phase of implementation, we are considering requiring QHP issuers to ensure that their contracted hospitals have agreements with PSOs and comprehensive hospital discharge programs, and that their health care providers implement health care quality activities. We recognize the various important patient safety initiatives, including discharge planning activities, with which hospitals, health care providers, and issuers are already involved. In future rulemaking, we intend to consider whether and which reasonable exceptions under section 1311(h)(2) of the Affordable Care Act should be made. We seek comment on:

- What core aspects should be included in hospital patient safety programs.
- What a comprehensive hospital discharge planning program should require for each patient.
- What health care quality improvement activities should be implemented by health care providers.

Specifically, we request comment on how QHP issuers could effectively track patient safety information, such as hospital agreements with a PSO, related to their contracted hospitals and provider networks. We also seek comment regarding specific, comparable activities that may be included as reasonable exceptions to the patient safety standards, in accordance with section 1311(h)(2) of the Affordable Care Act.

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 propose in § 156.1215(a) that each month we would 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 would also reflect current information related to enrollment for past months, including information related to excess payments previously made. Finally, we propose that amounts owed to or by a QHP issuer would be netted across all entities operating under the same taxpayer identification number (TIN). This process would permit HHS to calculate amounts owed each month, and pay or collect those amounts from issuers more efficiently. When netting occurs, HHS would demand amounts due only when there is a balance due to the Federal government.

In addition to the monthly payment flows under the programs described above, 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 propose in § 156.1215(b)

³⁵ Hospital Conditions of Participation: <http://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/Hospitals.html>.

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 propose 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 after netting be the basis for calculating a debt owed to the Federal government. We propose that payments and collections under all of these programs would occur under an integrated monthly payment and collection cycle.

We seek comment on these proposals, including on the appropriate payment timeframes for these charges so that amounts may be netted and invoiced as part of an orderly, monthly payment cycle.

b. Confirmation of HHS Payment and Collections Reports

As discussed in the preamble to § 156.1210 of the second final Program Integrity Rule, HHS anticipates sending a monthly payment and collections report—the HIX 820—to issuers describing the advance payments of the premium tax credit and advance payments of cost-sharing reductions that an issuer is to receive on behalf of eligible enrollees, and the FFE user fee charges that the issuer must pay. These amounts are based on enrollments previously confirmed by the issuer as part of the enrollment transaction process and the resultant HIX 820 discrepancy reporting process described in § 156.1210. Under § 156.1210 (a), an issuer must respond to the payment and collections report 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. As described below, any resolution to such an identified discrepancy would be reflected in a later payment and collections report and the invoice generated under that later report would not affect the debt established by the

invoice generated in connection with the earlier report.

We propose that an issuer that notifies HHS of a discrepancy under § 156.1210 will trigger an administrative discrepancy resolution process. 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 as proposed below in § 156.1220(a).

We intend that this discrepancy resolution process would permit HHS to work with issuers to resolve outstanding discrepancies in a cooperative manner. Because of the number and timing of the daily flows of enrollment and premium-related data and confirmations between HHS, the Exchange, and the issuer, we anticipate that there would be frequent adjustments to the enrollment counts and therefore the amounts of the advance payments of the premium tax credit, advance payments of cost-sharing reductions, and FFE user fees. 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 propose not to retroactively adjust previous months' payment and collections reports and amounts previously due. Consistent with our approach in the Medicare Advantage program, the invoice for a particular month would be calculated on the monthly payment cycle. We propose that the amount thus invoiced for a particular month, which would reflect netted amounts as described above, constitute an amount owed to the Federal government. As more accurate data become available to HHS, the Exchange, and the issuer, we propose that this later information not reduce or increase the previous determination of an amount owed. Rather, the information would be 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 propose to add paragraph (c) to § 156.1210 to provide that discrepancies in payment and collections reports identified to HHS under that section would 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.

We seek comment on this approach.

c. Administrative Appeals

We propose an administrative appeals process designed to address any unresolved discrepancies for advance payments of the premium tax credit, advance payments of cost-sharing reductions, FFE user fee payments, payments and charges for the premium stabilization programs, cost-sharing reduction reconciliation payments and charges, and any assessments under § 153.740(b) of a default risk adjustment charge. This administrative appeals process is similar to that utilized to address payment disputes in the Medicare Part D program, in which an appeal to a CMS hearing officer, and then the Administrator of CMS, if desired, may be filed after a request for reconsideration.

In § 156.1220(a), we propose that an issuer may file a request for reconsideration of what the issuer believes is a processing error by HHS,³⁶ 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 propose that a request for reconsideration must 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 anticipate that this final reconsideration notification would be provided in the summer of the year following the benefit year. We believe that the constant flow of enrollment data for payments under these programs will lead to difficulty in finalizing a precise, final calculation for a benefit year, and propose to finalize payments under these programs

³⁶ We note that under proposed § 156.1220(a)(3)(i)–(ii), an issuer may not submit data for consideration in the appeal if the data was not submitted prior to the applicable data submission deadline, but may submit documentary evidence that certain data was timely submitted.

including for purposes of appeal by the late summer of the following year. We are considering permitting reconsideration only for material errors. We seek comment on this proposal, including on the minimum materiality threshold that should be required to seek reconsideration. For example, we are considering a minimum materiality threshold of 1 percent or 5 percent of total payments made to the issuer for the year for advance payments of the premium tax credit, advance payments of cost-sharing reductions, and FFE user fees, or a minimum dollar amount such as \$10,000.

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 propose that a request for reconsideration must be filed within 30 calendar days of receipt of the applicable notification of payments and charges provided by HHS. We believe that because the interim and final dedicated distributed data environment reporting process proposed at § 153.710(d) and (e) would permit an issuer an extended period of time in which to review risk adjustment and reinsurance data and because the cost-sharing reduction reconciliation and risk corridors payments or charges are based on data provided by the issuer, 30 calendar days should be sufficient for an issuer to review the notification and make a request for reconsideration. We seek comment on this timeline.

In § 156.1220(a)(3)(i), we propose that the request for reconsideration specify the findings or issues that the issuer challenges and the reasons for the challenge. In § 156.1220(a)(3)(ii), we propose that 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), it was so identified and remains unresolved. Similarly, in § 156.1220(a)(3)(iii), we propose that a reconsideration with respect to advance payments of the premium tax credit, advance payments of cost-sharing reductions, and FFE user fees may 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 propose to clarify that 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.

In § 156.1220(a)(3)(iv), we propose that 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 the timely submission of such documents.

In § 156.1220(a)(4), we propose 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 propose 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), we propose 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). Because the monthly iterative discrepancy report process is available until the reconsideration notice is sent and because of the simplicity of the calculation of advance payments of the premium tax credit, advance payments of cost-sharing reductions, or FFE user fees, 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 is sufficient. We propose 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 proposed § 156.1220 would be entitled to an informal hearing before a

CMS hearing officer. In § 156.1220(b)(1), we propose 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 propose that the request for an informal hearing must include a copy of the reconsideration decision and must specify the findings or issues in the decision that the issuer is challenging and its reasons for the challenge. We also propose that HHS may submit for review by the CMS hearing officer a statement of the reasons supporting the reconsideration decision.

In § 156.1220(b)(3)(i), we propose that the issuer 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 propose 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. We propose that the scope of the CMS hearing officer's review would be limited to the statements provided by the issuer and HHS and the 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 propose that, following the informal hearing, the CMS hearing officer would send the decision and the reasons for the decision to the issuer. We propose that this decision would be final and binding, but subject to any Administrator's review initiated in accordance with proposed § 156.1220(c).

We propose in § 156.1220(c)(1) that if the CMS hearing officer upholds the reconsideration decision, the issuer may request a review by the Administrator of CMS within 15 calendar days of receipt of the CMS hearing officer's decision. The request for a review by the Administrator of CMS must specify the findings or issues in the decision that the issuer is challenging, and the reasons for the challenge. We propose that HHS may submit for review by the Administrator of CMS a statement supporting the decision of the CMS hearing officer.

In § 156.1220(c)(2), we propose that the Administrator of CMS or a delegate would 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 would determine whether to uphold, reverse, or modify the CMS hearing officer's decision. We propose that the issuer would be required to prove its case by clear and convincing evidence with respect to issues of fact. We propose that the Administrator's determination would be considered final and binding.

We believe that the administrative appeals process outlined above would give issuers reasonable opportunity for reconsideration and review of their payments and charges. Furthermore, building on established procedures utilized by HHS in Medicare Part D will provide a structure for administrative appeals with which issuers are already familiar. We seek comment on the proposed reconsideration and administrative appeals process.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. This proposed rule contains information collection requirements (ICRs) that are subject to review by OMB. A description of these provisions is given in the following paragraphs with an estimate of the annual burden, summarized in Table 6. 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 are soliciting public comment on each of these issues for the following sections of this proposed rule that contain ICRs. 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)

In § 153.270, we propose that HHS or its designee may conduct a financial

and programmatic audit of a State-operated reinsurance program to assess compliance with reinsurance program requirements. We also propose that, 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 two States 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 are not seeking 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 proposed 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))

We propose that HHS or its designee would have 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 proposed 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.

For issuers of risk adjustment covered plans and issuers of reinsurance-eligible plans, these provisions would result in a third party disclosure requirement for issuers to prepare and compile the financial and programmatic information necessary to comply with the audit. For each onsite review, we estimate that it will take an average of 40 hours for administrative work to assemble the requested information, 19.5 hours to review the information for

completeness, and 30 minutes to submit the information to HHS in preparation for an onsite review. We estimate that an onsite review would require an additional 2 hours to schedule the onsite activities with the compliance reviewer (at an hourly wage rate of \$53.75), 4 hours for introductory meeting, 8 hours to tour reviewers onsite, 10 hours of interview time, 2 hours to walk through processes with the reviewer, and 4 hours for concluding meetings, resulting in a total of approximately 60 hours of preparation time and an additional 30 hours of onsite time for each issuer. We estimate that it will take 90 hours at a cost of approximately \$4,838 for each issuer to make information available to HHS for an onsite review. Because we have not finalized our audit protocols, it is difficult to accurately estimate an audit rate. However, we believe that it would be 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 estimate an aggregate burden of 10,800 hours and \$580,500 for issuers as a result of this requirement.

For contributing entities, we estimate that the disclosure burden would be substantially less because the audit would be simpler. We estimate 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 a cost of approximately \$1,209 for each contributing entity. Similarly, because we have not finalized the audit protocols, it is difficult to accurately estimate an audit rate. However, we estimate that approximately 1 percent of contributing entities would be audited, representing 226 contributing entities. Therefore, we estimate an aggregate burden of 5,085 hours, or \$273,319, as a result of this proposed 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)

For the 2014 benefit year, we are considering adjustments to the premium stabilization programs that would help to further mitigate any unexpected losses for QHP issuers with plans that are affected by the transitional policy. To effectuate potential adjustments, we must estimate the State-specific effect on average claims costs. We therefore

propose 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. This submission would occur in 2015 prior to the risk corridors July 31, 2015 data submission deadline. HHS would 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 request comment on data collection methods and the potential effect on issuers' administrative costs.

We estimate that there will be approximately 2,400 issuers in the individual and small group market in the 2014 benefit year, and that it would take an insurance analyst approximately 30 minutes (at an hourly wage rate 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 2015, and because we expect to issue additional clarifying guidance on this proposed policy, will seek OMB approval and solicit public comment on this information collection requirement at a future date.

D. ICRs Regarding Risk Corridors Data Validation (§ 153.530 and § 153.540)

For the 2014 benefit year, we propose to collect risk corridors data by 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 under § 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 program and the risk corridors program 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 wage rate of \$38.49) and 30 minutes for a senior manager (at an hourly wage rate 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. We estimate that 1,200 QHP issuers will submit risk corridors data for the 2014 benefit year in the 2015 risk corridors and MLR reporting cycle. Therefore, we estimate an aggregate burden of 1,800 hours (at a total cost of approximately \$92,394) for QHP issuers as a result of this requirement. 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 § 153.540(b), we propose that HHS may impose CMPs on QHP issuers on a State Exchange that do not comply with the risk corridors requirements in Subpart F. We note that we would impose any CMP in accordance with the procedures set forth in 45 CFR 156.805. Although the processes set forth in § 156.805 would result in information collection requirements that are subject to PRA, we expect to impose CMPs on fewer than 10 entities in a year. Therefore, we believe that this collection is exempt from the PRA under 44 U.S.C. 3502(3)(A)(i).

E. ICRs Regarding Data Validation Requirements When HHS Operates Risk Adjustment (§ 153.630)

In § 153.630(b)(1), we propose that 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 proposes that the issuer 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 wage rate of \$38.49) and a senior manager (at an hourly wage rate of \$77) each approximately 15 minutes to prepare and send an electronic report to HHS. Therefore, for 2,400 risk adjustment covered issuers, the aggregate burden associated with this requirement is 1,200 hours, at an approximate cost of \$69,300.

In § 153.630(b)(8), we propose that the initial validation auditor 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 propose that the initial validation auditor to achieve a minimum consistency measure of 95 percent for demographic, enrollment, and health status review outcomes. 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 wage rate of \$38.49) and a senior manager (at an hourly wage rate 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 proposed rule, we clarify this timeframe, proposing 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 we are clarifying in this proposed rule that issuers must make this data available to HHS on a quarterly basis, 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))

We propose in § 153.710(d) 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 reflect 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, we propose in § 153.710(e) 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 wage rate 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 propose that an Exchange may submit to the Secretary a proposed use or disclosure of eligibility and enrollment PII. The Exchange submitting such a request must provide a detailed description of the use or disclosure and how the proposed use or disclosure will ensure the efficient operation of the Exchanges consistent with section 1411(g)(2)(A) of the Affordable Care Act. The requesting Exchange must also describe how the information to be used or disclosed will be protected in compliance with the privacy and security standards established by the Exchange. We estimate fewer than 10 states will submit such proposals on a yearly basis. While this reporting requirement is subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.3(c)(4) and 44 U.S.C. 3502(3)(A)(i), since fewer than 10 entities would be affected. Therefore, we are not seeking approval from OMB for these information collection requirements. We seek comment on this estimate from states that are contemplating any uses of eligibility and enrollment PII for which they would submit such a proposal.

I. 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 these proposed patient safety standards. The burden estimate associated with these standards includes the time and effort required for QHPs to maintain and submit hospital CMS Certification Numbers and any other information to the Exchange 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. Until that time, we are soliciting comments on the burden for QHPs to maintain and submit such documentation to demonstrate meeting the patient safety standards proposed here.

J. ICRs Regarding Administrative Appeals (§ 156.1220)

In § 156.1220, we propose 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), we propose that 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 Federally-facilitated user fees 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 the purpose of this burden estimate we estimate that it will take an insurance operations analyst 1 hour (at an hourly wage rate 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), we propose that 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 15 calendar days of the date the issuer receives 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 are not seeking 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	22.50	5,085	53.75	273,319	0	273,319
§ 153.410; § 153.620	120	120	90.00	10,800	53.75	580,500	0	580,500
§ 153.500– § 153.540– ..	2,400	2,400	0.50	1,200	38.49	46,200	46,200
§ 153.540	1,200	1,200	1.50	1,200	51.33	92,394	0	92,394
§ 153.630(b)(1)	2,400	2,400	0.50	1,200	57.75	69,300	0	69,300
§ 153.630(b)(8)	2,400	2,400	0.50	1,200	57.75	69,300	0	69,300
(§ 153.700(d) and (e))	2,400	2,400	8.00	19,200	38.49	739,008	0	739,008
§ 156.1220	24	24	1.00	24	38.49	924	0	924
Total	^a 3,970	1,870,945	0	1,870,945

^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 proposed 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.

V. Response to Comments

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

VI. Regulatory Impact Statement (or Analysis)

A. Statement of Need

This proposed rule proposes 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 2014 Payment Notice provided detail on the implementation of these programs, including the specific parameters applicable to these programs. This proposed rule also proposes additional standards with respect to composite rating, privacy and security of personally identifiable information, the open enrollment period for 2015, the

actuarial value calculator, the annual limitation on 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, 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 1 year).

OMB has determined that this proposed rule is “economically significant” within the meaning of section 3(f)(1) of Executive Order 12866, because it is likely to have an annual effect of \$100 million in any 1 year. Accordingly, we have prepared a RIA that presents the costs and benefits of this proposed rule.

Although it is difficult to discuss the wide-ranging effects of these provisions in isolation, the overarching goal of the premium stabilization and Exchange-related provisions and policies in the Affordable Care Act is to make affordable health insurance available to individuals who do not have access to affordable employer-sponsored coverage. The provisions within this proposed rule are integral to the goal of expanding 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 proposed rule related to cost sharing and FFE user fees, as well as new oversight provisions for the premium stabilization programs.

C. Impact Estimates of the Payment Notice Provisions and Accounting Table

In accordance with OMB Circular A–4, Table 8 below depicts an accounting statement summarizing HHS’s assessment of the benefits, costs, and transfers associated with this regulatory action.

This proposed 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 proposed 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 proposed 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 proposed provisions, and include administrative costs estimated in the Collection of Information section of this proposed rule. We note 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 we are proposing a 2015 reinsurance contribution rate that is lower than the 2014 reinsurance contribution rate, total reinsurance administrative expenses, including the reinsurance contribution rate, 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 (in millions)	Year dollar	Discount rate (percent)	Period covered
Annualized Monetized (\$/year)	1.75	2013	7	2014–2017
	1.82	2013	3	2014–2017

Qualitative:

- *Costs incurred by issuers and contributing entities to comply with provisions in the proposed rule.
- *Costs incurred by States for complying with audits of State-operated reinsurance programs.

Transfers:	Estimate (in millions)	Year dollar	Discount rate (percent)	Period covered
Annualized Monetized (\$/year)	11.59	2013	7	2014–2017
	12.04	2013	3	2014–2017

TABLE 8—ACCOUNTING TABLE—Continued

*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 Congressional Budget Office's (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 May 2013 baseline projections estimated that 22 million enrollees will enroll in Exchange coverage by 2016, including approximately 18 million Exchange enrollees who will be receiving subsidies.³⁷ 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 from fiscal years 2014 through 2017, with the additional, societal effects of this proposed rule discussed in this RIA. We do not expect the provisions of this proposed rule to significantly alter CBO's estimates of the budget impact of the risk adjustment and reinsurance programs that are described in Table 9. For this RIA, we are shifting the estimates for the risk adjustment and reinsurance programs to reflect the 4-year period from fiscal years 2014 through 2017, because CBO's scoring of the risk adjustment and reinsurance programs assumed that payments and charges would begin in 2014, when in fact these payments and charges will begin in 2015. CBO did not separately estimate the program costs of risk corridors, but assumed aggregate collections from some issuers would offset payments made to other issuers. 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 proposed 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 proposed 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.

TABLE 9—ESTIMATED FEDERAL GOVERNMENT OUTLAYS AND RECEIPTS FOR THE RISK ADJUSTMENT AND REINSURANCE PROGRAMS FROM FY 2013–2017, IN BILLIONS OF DOLLARS

Year	2013	2014	2015	2016	2017	2013–2017
Risk Adjustment and Reinsurance Program Payments	—	6	17	18	20	61
Risk Adjustment and Reinsurance Program Collections *	—	13	16	18	18	65

*Risk adjustment program payments and receipts lag by one quarter. Receipt will fully offset payments over time. Source: Congressional Budget Office. 2012. *Letter to Hon. John Boehner*. July 24, 2012.

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 and 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 per capita risk adjustment user fee would be less than \$1.00 per year for HHS to operate the risk adjustment program on behalf of States for 2015.

In this proposed rule, we propose 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. 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 proposed rule would be covered through the risk adjustment user fee, and that there would be no impact for the Federal government as a result of the proposed audit provisions. The proposed 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 proposed requirement for issuers in the Collection of Information section of this proposed rule.

³⁷ "Updated Estimates for the Insurance Coverage Provisions of the Affordable Care Act," Congressional Budget Office, May 2013.

Although this proposed rule would result in some additional administrative burden for issuers of risk adjustment covered plans as a result of the proposed 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 proposed rule substantially alter the previous estimates. We describe these administrative costs in the Collection of Information Requirements section of this proposed 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 and established the 2014 uniform reinsurance payment parameters and national contribution rate. In this proposed rule, we set forth the 2015 uniform reinsurance payment parameters and contribution rate, and 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 for each of the 3 years of the reinsurance program under the uniform per capita contribution rate.

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 propose in § 153.270(a) 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 proposed 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 proposed audit provisions. Because this proposed 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 proposed requirement would impose a cost on States operating reinsurance. 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 wage rate 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 the

corrective actions taken if necessary. We also estimate a senior manager (at an hourly wage rate 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 proposed audit requirement. For the two States that will operate reinsurance for the 2014 benefit year, we estimate an aggregate burden of approximately \$14,952 as a result of this requirement. Although we have estimated the cost of a potential audit in this RIA, we note that we will not audit all State-operated reinsurance programs, and may not audit any of these programs.

In § 153.405(i) and § 153.410(d), we propose 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 proposed 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.

Risk Corridors

The Affordable Care Act creates a temporary risk corridors program for the years 2014, 2015, and 2016 that applies to QHPs, as defined in § 153.500. The risk corridors program creates a mechanism for sharing risk for allowable costs between the Federal government and QHP issuers. The Affordable Care Act establishes the risk corridors program as a Federal program; consequently, HHS will operate the risk corridors program under Federal rules with no State variation. The risk corridors program will help protect against inaccurate rate setting in the early years of the Exchanges by limiting the extent of issuer losses and gains.

As mentioned elsewhere in this proposed rule, for the 2014 benefit year, we are proposing an adjustment to the risk corridors formula that would help

to further mitigate potential QHP issuers' unexpected losses that are attributable to the effects of the transition policy. This proposed adjustment may increase the total amount of risk corridors payments that the Federal government will make to QHP issuers, and reduce the amount of risk corridors receipts; however, we are considering a number of approaches that would limit the impact of the policy on the Federal budget. Because of the difficulty associated with predicting State enforcement of 2014 market rules and estimating the enrollment in transitional plans and in QHPs, we cannot estimate the magnitude of this impact on aggregate risk corridors payments and charges at this time. We also estimate that this proposed 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 proposed rule.

To ensure the integrity of risk corridors data reporting, we propose in § 153.540(a) to establish HHS authority 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 proposed rule, we believe that the cost for issuers that would result from this proposed audit requirement is already accounted for as part of the MLR audit process.

We also propose in § 153.540(c) to extend our CMP authority under sections 1321(a)(1) and (c)(2) of the Affordable Care Act to all QHP issuers that fail to provide timely, accurate, and complete data necessary for risk corridors calculations, or that otherwise do not comply with the standards in subpart F of 45 CFR part 153. We propose to assess CMPs on QHP issuers in State Exchanges in accordance with the same enforcement and sanction procedures that apply to QHP issuers on an FFE under § 156.805.

As set forth in § 156.805(c), HHS will impose a maximum penalty amount of \$100 per day on a QHP issuer for each violation, for each individual adversely affected by the non-compliance. As noted in the preamble to § 153.540 in this proposed rule, for violations of subpart F where the number of individuals adversely affected by the non-compliance cannot be determined, we propose giving HHS the authority to estimate the number of individuals likely to be adversely affected by the

non-compliance. We note that CMPs will be imposed only for serious issues of non-compliance. We expect to provide technical assistance to issuers, as appropriate, to assist them in maintaining compliance with the applicable standards. We also plan to coordinate with States and the MLR program in our oversight and enforcement activities to avoid inappropriately duplicating enforcement efforts. Consequently, we anticipate that CMPs will be rare, and that the impact of this proposed requirement on QHP issuers will be negligible.

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.³⁸

To support the administration of the cost-sharing reduction program, we set forth in this proposed rule the reductions in the maximum annual limitation on cost sharing for silver plan variations and a modified methodology for calculating advance payments for cost-sharing reductions. For benefit year 2015, we propose to require the same reductions in the maximum annual limitation on cost sharing as were finalized for benefit year 2014. We note that we are proposing certain modifications to the methodology for calculating advance payments for cost-sharing reductions, but 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 proposed rule will have an impact on the program established by and described in the 2014 Payment Notice.

We also proposed a methodology for estimating average per capita premium, and proposed 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 proposed premium adjustment percentage is well within the parameters used in the modeling of the Affordable Care Act, and do not expect that these proposed provisions will alter CBO's May 2013 baseline estimates of the budget impact.

Annual Open Enrollment Period

We propose amendments to § 155.410(e) and (f) to amend the dates for the annual open enrollment period and related coverage effective dates. These proposed amendments would benefit issuers at no additional cost, as Exchanges would delay their QHP certification dates by at least one month, giving issuers additional time. Because open enrollment dates would be moved forward, Exchanges would still have the same amount of time for the QHP certification process, and we do not anticipate that this would come 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 are established in the EHB Rule and are in accordance with the proposed provisions in this proposed 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.

³⁸ 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>.

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 propose 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.³⁹ This RIA addresses the additional costs and benefits of the proposed modifications in this proposed rule to the SHOP sections of the Exchange Establishment Rule.

In this proposed rule, we propose revising paragraph § 155.705(b)(1), which lists the rules regarding eligibility and enrollment to which the SHOPS must adhere, to include mention of 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. We propose that an employer in the FF-SHOPS would have the option to offer its employees either a single SADP or a choice of all SADPs available in an FF-SHOP for plan years beginning on or after January 1, 2015. In § 155.705(b)(11)(ii)(D) we propose prohibiting an employer in an FF-SHOP from basing its contribution on composite rates when employee choice becomes available and the employer elects to offer its employees all plans in a metal tier selected by the employer.

We also propose amendments to § 155.705(b)(4) that would allow SHOPS performing premium aggregation to establish a standard method for premium calculation, payment, and collection. We propose that in the FF-SHOPS, after premium aggregation

becomes available in plan years beginning on or after January 1, 2015, employers would 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 would 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. 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. We believe the proposed 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.

We also propose amendments to § 155.705(b)(11) that would provide additional flexibility 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 would be in the best interest of the business and its employees. We believe that this additional flexibility would 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 would allow different contribution levels based on full-time or non-full-time status may encourage some employers to offer coverage to non-full-time employees.

In § 155.715, we propose amendments that would provide for 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 propose to 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 proposed changes would 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 propose to provide that SHOPS are not permitted to collect information from applicants, employers, or employees in the SHOP if that information 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 propose for plan years beginning on or after January 1, 2015 to allow SHOPS, in States that permit this activity under State law, to 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.

In § 156.285, we propose 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 propose that a qualified employer in the SHOP that becomes a large employer would continue to be rated as a small employer and propose to prohibit issuers from composite billing in the FF-SHOPS when employee choice becomes available and an employer selects a level of coverage and not a single plan.

We do not expect the proposed policies related to the SHOP to create

³⁹ Available at: <http://ccio.cms.gov/resources/files/Files2/03162012/hie3r-ria-032012.pdf>

any new significant costs for small businesses, employees, or the FF-SHOPs.

Patient Safety

The proposed patient safety requirements would be implemented in phases, to ensure that QHP issuers contract with hospitals that meet adequate safety and quality standards in their networks. The proposed rule would require QHP issuers to collect and maintain CCNs for each of its contracted hospitals that are certified for more than 50 beds. It also would require that this documentation, if requested by the Exchange, be submitted in a form and manner specified by the Exchange. QHP issuers would already have established procedures and relationships to contract with hospitals including obtaining hospital identification information. Therefore, HHS believes that there would not be a significant additional cost for a QHP issuer to collect and maintain CCNs. QHP issuers would 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 proposed rule.

D. Regulatory Alternatives Considered

We considered a number of alternatives to our proposed 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 proposed rule discusses and seeks comment on a number of alternative approaches to the detailed methodology proposed here. For example, we have suggested a number of options for confidence intervals and whether to use tests of statistical significance in determining plan average risk score adjustments. We have also suggested an expedited second validation audit approach to permit more time for inter-auditor discussions and appeals. We have 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 risk in

those plans, potentially leading to higher premiums in those plans.

In § 153.270, we propose 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.

We considered not proposing that HHS have the authority to assess CMPs on QHP issuers for non-compliance with the risk corridors standards. This would reduce the burden on QHP issuers on State Exchanges and would have reduced Federal oversight costs. However, we determined that similar standards and oversight were appropriate for all issuers of QHPs, regardless of whether the QHPs were offered through FFEs or State Exchanges, in order to ensure compliance with the risk corridors program and the proper use of Federal funds.

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 uniform reinsurance payment parameters that would have substantially raised the attachment point or lowered the reinsurance cap, but believe those uniform reinsurance payment parameters would have 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 are discussed in detail above.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of the proposed rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The RFA generally defines a “small entity” as (1) A proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of “small entity.” HHS uses a change in revenues of more than 3 to 5 percent as its measure of significant economic impact on a substantial number of small entities.

In this proposed rule, we propose 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 firms offering comprehensive health insurance policies generally exceed the size thresholds for “small entities” established by the SBA, we do not believe that an initial regulatory flexibility analysis is required for such firms.

For purposes of the RFA, we expect the following types of entities to be affected by this 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 proposed rule, we proposed requirements on employers that choose to participate in a SHOP Exchange. The SHOPS are limited by statute to employers with at least one but not more than 100 employees. For this reason, we expect that many employers who would be affected by the proposals would meet the SBA standard for small entities. We do not believe that the proposals 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 proposed policy will provide greater choice for both employees and employers. We believe the processes that we have established constitute the minimum amount of requirements necessary to implement the SHOP program and accomplish our policy goals, and that no appropriate regulatory alternatives could be developed to further lessen the compliance burden.

We believe that a substantial number of sponsors of self-insured group health plans could qualify as “small entities.” This proposed 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 proposed rule that includes any Federal mandate that may result in expenditures in any 1 year by a State, local, or Tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. In 2013, that threshold is approximately \$141 million. Although we have not been able to quantify the user fees that will be associated with this proposed 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 proposed rule that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications. Because States have flexibility in designing their Exchange and Exchange-related programs, State decisions will ultimately influence both administrative expenses and overall premiums. States are not required to establish an Exchange or risk adjustment or reinsurance program. For States electing to operate an Exchange, risk adjustment or reinsurance program, much of the initial cost of creating these programs will be funded by Exchange Planning and Establishment Grants. After establishment, Exchanges will be financially self-sustaining, with revenue sources at the discretion of the State. Current State Exchanges charge user fees to issuers.

In HHS’s view, while this proposed rule did 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 proposed rule, or have in effect a State law or regulation that implements these Federal standards. However, HHS anticipates that the Federalism implications (if any) are substantially mitigated because under the statute, States have choices regarding the structure and governance of their Exchanges and risk adjustment and reinsurance programs. Additionally, the Affordable Care Act does not require States to establish these programs; if a State elects not to establish any of these programs or is not approved to do so, HHS must establish and operate the programs in that State.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have Federalism implications or limit the policy making discretion of the States, HHS has engaged in efforts to

consult with and work cooperatively with affected States, including participating in conference calls with and attending conferences of the National Association of Insurance Commissioners, and consulting with State insurance officials on an individual basis.

Throughout the process of developing this proposed rule, HHS has attempted to balance the States’ interests in regulating health insurance issuers, and Congress’ intent to provide access to Affordable Insurance Exchanges for consumers in every State. By doing so, it is HHS’s view that we have complied with the requirements of Executive Order 13132.

H. Congressional Review Act

This proposed 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.

For the reasons set forth in the preamble, the Department of Health and Human Services proposes to amend 45 CFR parts 147, 153, 155, and 156, and proposes to further amend 45 CFR parts 144, 153, and 156, as amended October 30, 2013, at 78 FR 65091, effective December 30, 2013, 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 individual health insurance coverage.

* * *

* * * * *

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

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

Authority: Secs. 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42

U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

■ 4. Section 147.102 is amended by revising paragraph (c)(3) to read as follows:

§ 147.102 Fair health insurance premiums.

* * * * *

(c) * * *

(3) *Application to small group market.*

In the case of the small group market, the total premium charged to the group is determined by summing the premiums of covered participants and beneficiaries in accordance with paragraph (c)(1) or (2) of this section, as applicable. Nothing in this section precludes a State from requiring issuers to offer, or an issuer from voluntarily offering, to a group premiums that are based on average enrollee premium amounts, provided that the total group premium is the same total amount derived in accordance with paragraph (c)(1) or (2) of this section, as applicable. In such case, effective for plan years beginning on or after January 1, 2015, an issuer must ensure that average enrollee premium amounts calculated based on applicable employee enrollment at the beginning of the plan year do not vary for any participant or beneficiary during the plan year.

* * * * *

■ 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 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 appeals) or plan enrollment. 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, health coverage for a broad range of services and treatments provided in various settings that provides minimum value in accordance with § 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 153.235 is amended by removing and reserving paragraph (b).

§ 153.235 Allocation and distribution of reinsurance contributions.

* * * * *

(b) [Reserved]

■ 10. 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.

■ 11. 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.

* * * * *

■ 12. 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.

■ 13. 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. 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.

■ 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 153.540 is added to subpart F to read as follows:

§ 153.540 Compliance with risk corridors standards.

(a) *Audits.* 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.

(b) *Enforcement actions.* If an issuer of a QHP on a State-based Exchange fails to comply with the requirements of this subpart, HHS may impose civil money penalties in accordance with the procedures set forth in § 156.805 of this subchapter.

■ 16. 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.

■ 17. 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), 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 validator 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 through review of source enrollment documentation;

(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.

(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 demographic, enrollment, and health status 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.

* * * * *

■ 18. 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).

(g) *Risk corridors and medical loss ratio 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) 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 medical loss ratio 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) 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

■ 19. Authority citation for part 155 is revised to read as follows:

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

■ 20. 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

* * * * *

■ 21. Section 155.220 is amended by adding paragraph (i) 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) 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.

■ 22. Section 155.260 is amended by revising paragraphs (a)(1), (a)(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 (a)(1)(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 (a)(1)(ii), 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 (a)(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.

* * * * *

■ 23. 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 benefit years beginning—

(1) On January 1, 2015, the annual open enrollment period begins November 15 of 2014, and extends through January 15 of 2015.

(2) On or after January 1, 2016, the annual open enrollment period begins October 15 of the preceding calendar year, and extends through December 7 of the preceding calendar year.

(f) *Effective date for coverage after the annual open enrollment period.* For the benefit years beginning—

(1) On January 1, 2015, the Exchange must ensure coverage is effective—

(i) January 1, 2015, for plan selections received by the Exchange on or before December 15, 2014.

(ii) February 1, 2015, for plan selections received by the Exchange from December 16, 2015 through January 15, 2015.

(2) On or after January 1, 2016, the Exchange must ensure coverage is effective as of the first day of the following benefit year for a qualified

individual who has made a QHP selection during the annual open enrollment period.

* * * * *

■ 24. 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); and

■ e. Revising paragraphs (b)(11)(ii)(C) and (D).

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 §§ 155.710, 155.715, 155.720, 155.725, 155.730, 155.735, and 155.740.

* * * * *

(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 the Federally-facilitated SHOP.

(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.

* * * * *

(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, the 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.

(D) In a Federally-facilitated SHOP, for plan years beginning on or after January 1, 2015, if the employer elects to offer coverage to its employees under § 155.705(b)(3)(iv)(A), neither State law nor the employer may require that employer contributions be based on a calculated composite premium for the reference plan for employees, for adult dependents of employees, and for dependents of employees under age 21.

* * * * *

■ 25. 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—

* * * * *

■ 26. Section 155.730 is amended by redesignating paragraph (g) as paragraph (g)(1) and by adding paragraph (g)(2) to read as follows:

§ 155.730 Application standards for SHOP.

* * * * *

(g) * * *

(1) * * *

(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.

■ 27. 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).

* * * * *

(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).

(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

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

Authority: Title I of the Affordable Care Act, sections 1301–1304, 1311–1312, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, and 1412, Pub. L. 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

■ 29. 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.

■ 30. Section 156.150 is revised 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 \$300 for one covered child and \$400 for two or more covered children.

(b) [Reserved]

■ 31. 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 regardless of whether the QHP 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 amounts under § 147.102(c)(3), if the employer

elects to offer coverage to its employees under § 155.705(b)(3)(iv)(A).

* * * * *

(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.

* * * * *

■ 32. 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 two 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) Premiums;
- (6) Health Savings Account eligibility;

or

(7) Self-only, non-self-only, or child-only coverage 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.

■ 33. 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 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.

* * * * *

■ 34. 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).

* * * * *

■ 35. 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.

* * * * *

■ 36. 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 Condition 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, from each of its contracted hospitals with greater than 50 beds, information that demonstrates that those hospitals meet patient safety standards required in paragraph (a) of this section including, but not limited to, the CCN.

(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.

■ 37. 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.

■ 38. 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.

■ 39. 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) *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 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 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 30 calendar days of receipt of the notification provided by HHS under § 153.310(e);

(iii) For a reinsurance payment, within 30 calendar days of receipt of the notification provided by HHS under § 153.240(b)(1)(ii);

(iv) For a default risk adjustment charge, within 30 calendar days of receipt of the notification of the default risk adjustment charge;

(v) For reconciliation of cost-sharing reductions, within 30 calendar days of receipt 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 30 calendar days of receipt of the notification provided by HHS under § 153.510(d).

(3) *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)(3)(i) 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)(3)(i) 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 of this subpart, it was so identified and remains unresolved. An issuer may request reconsideration if it previously identified an issue under § 156.1210 of this subpart 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.

(4) *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.

(5) *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 15 calendar days of the date the issuer receives 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 receipt 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.

Dated: November 21, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Approved: November 21, 2013.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

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