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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 144, 146, 147, 148, 153, 154, 155, 156 and 158

[CMS-9944-P]

RIN 0938-AS19

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

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would set forth payment parameters and provisions related to the risk adjustment, reinsurance, and risk corridors programs; cost sharing parameters and cost-sharing reductions; and user fees for Federally-facilitated Exchanges. It would also provide additional standards for the annual open enrollment period for the individual market for benefit years beginning on or after January 1, 2016, essential health benefits, qualified health plans, network adequacy, quality improvement strategies, the Small Business Health Options Program, guaranteed availability, guaranteed renewability, minimum essential coverage, the rate review program, the medical loss ratio program, and other related topics.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 22, 2014.

ADDRESSES: In commenting, please refer to file code CMS-9944-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-9944-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-9944-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: Laurie McWright, (301) 492-4311; or Jeff Wu, (301) 492-4305. For matters related to guaranteed availability, guaranteed renewability, rate review, and the U.S. territories: Jacob Ackerman, (301) 492-4179.

For matters related to the risk adjustment program generally, 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, distributed data collection good faith compliance policy, and administrative appeals: Adrienne Glasgow, (410) 786-0686.

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

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

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

For matters related to essential health benefits, network adequacy, essential community providers, and other standards for QHP issuers: Leigha Basini, (301) 492-4380.

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For matters related to special enrollment periods under part 155: Spencer Manasse, (301) 492-5141.

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

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

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

For matters related to meaningful access to QHP information and consumer assistance tools and programs of an Exchange under part 155, and cost-sharing reduction notices under part 156: Tricia Beckmann, (301) 492-4328.

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), as amended

AHFS—American hospital formulary system

AV—Actuarial value

CFR—Code of Federal Regulations

CMS—Centers for Medicare & Medicaid Services

ECP—Essential community provider

EHB—Essential health benefits

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

FFE—Federally-facilitated Exchange

FF-SHOP—Federally-facilitated Small Business Health Options Program

FPL—Federal poverty level

FQHC—Federally qualified health center

HCC—Hierarchical condition category

HHS—United States Department of Health and Human Services

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

IRS—Internal Revenue Service

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

PRA—Paperwork Reduction Act of 1995

P&T committee—Pharmacy and therapeutics committee

QHP—Qualified health plan

QIS—Quality improvement strategy

SHOP—Small Business Health Options Program

The Code—Internal Revenue Code of 1986

TPA—Third-party administrator

URL—Uniform resource locator

USP—United States Pharmacopeia

I. Executive Summary

Qualified individuals and qualified employers are now able to purchase private health insurance coverage through competitive marketplaces called Affordable Insurance Exchanges, or “Exchanges” (also called Health Insurance Marketplaces, or “Marketplaces”). Individuals who enroll in qualified health plans (QHPs) through individual market Exchanges may be eligible to receive the premium tax credit to make health insurance more affordable and reductions in cost-sharing payments to reduce out-of-pocket expenses for health care services. Additionally, in 2014, HHS began

operationalizing the premium stabilization programs established by the Affordable Care Act. These programs—the risk adjustment, reinsurance, and risk corridors programs—are intended to mitigate the potential impact of adverse selection and stabilize the price of health insurance in the individual and small group markets. These programs, together with other reforms of the Affordable Care Act, are making high-quality health insurance affordable and accessible to millions of Americans.

We have previously outlined the major provisions and parameters related to the advance payments of the premium tax credit, cost-sharing reductions, and premium stabilization programs. This rule proposes additional provisions and modifications related to the implementation of these premium stabilization programs, as well as key payment parameters for the 2016 benefit year.

The HHS Notice of Benefit and Payment Parameters for 2014 (78 FR 15410) (2014 Payment Notice) finalized the risk adjustment methodology that HHS will use when it operates risk adjustment on behalf of a State. Risk adjustment factors reflect enrollee health risk and the costs of a given disease relative to average spending. This proposed rule proposes to recalibrate the HHS risk adjustment models for 2016 by using 2010, 2011, and 2012 claims data from the Truven Health Analytics 2010 MarketScan® Commercial Claims and Encounters database (MarketScan) to develop updated risk factors. We also propose that when 2013 MarketScan data become available, we may recalculate these factors for publication in the final rule. We also seek comment on whether the recalculated risk factors should apply for 2015.

Using the methodology set forth in the 2014 Payment Notice and the HHS Notice of Benefit and Payment Parameters for 2015 (79 FR 13744) (2015 Payment Notice), we propose a 2016 uniform reinsurance contribution rate of \$27 annually per enrollee, and the 2016 uniform reinsurance payment parameters—a \$90,000 attachment point, a \$250,000 reinsurance cap, and a 50 percent coinsurance rate. We also propose to decrease the attachment point for the 2015 benefit year from \$70,000 to \$45,000, while retaining the \$250,000 reinsurance cap and a 50 percent coinsurance rate. We include proposals regarding the definition of “common ownership” for purposes of determining whether a contributing entity uses a third-party administrator for core administrative functions. In

addition, this proposed rule discusses the reinsurance contribution payment schedule and accompanying notifications.

We also propose a clarification and a modification to the risk corridors program. We clarify that the risk corridors transitional adjustment policy established in the 2015 Payment Notice does not adjust the risk corridors calculation based on enrollment in a so-called “early renewal plan” (a plan that renewed before January 1, 2014 and before the end of its 12-month term) unless and until the plan renews in 2014 and becomes a transitional plan. Additionally, for the 2016 benefit year, we are proposing an approach for the treatment of risk corridors collections under the policy set forth in our April 11, 2014 FAQ on Risk Corridors and Budget Neutrality, if risk corridors collections available in 2016 exceed risk corridors payment requests from QHP issuers. We reiterate our previous guidance that in the unlikely event of a shortfall in the 2016 benefit year, HHS will use other sources of funding, subject to availability of appropriations. We also propose to extend the good faith safe harbor for non-compliance with the HHS-operated risk adjustment and reinsurance data requirements through the 2015 calendar year.

We also propose several provisions related to cost sharing. First, we propose the premium adjustment percentage for 2016, which is used to set the rate of increase for several parameters detailed in the Affordable Care Act, including the maximum annual limitation on cost sharing for 2016. We propose the maximum annual limitations on cost sharing for the 2016 benefit year for cost-sharing reduction plan variations. For reconciliation of 2014 cost-sharing reductions, we propose to permit issuers whose plan variations meet certain criteria to estimate the portion of claims attributable to non-essential health benefits to calculate cost-sharing reductions provided.

For 2016, we are proposing a Federally-facilitated Exchange (FFE) user fee rate of 3.5 percent of premium. This rule also proposes provisions to enhance the transparency and effectiveness of the rate review program. It also proposes standards related to minimum essential coverage, the individual market annual open enrollment period for benefit years beginning on or after January 1, 2016, and proposes minor amendments to a number of SHOP provisions to clarify how certain Exchange provisions apply to qualified employers and qualified employees. This rule proposes provisions relating to the treatment of

cost-sharing reductions and certain taxes in medical loss ratio (MLR) and rebate calculations, as well as the distribution of rebates by group health plans not subject to Employee Retirement Income Security Act of 1974 (Pub. L. 93-406) (ERISA). The proposed rule would provide more specificity about the meaningful access requirements applicable to an Exchange and to QHP issuers related to access for individuals with disabilities and individuals with limited English proficiency. This proposed rule would require issuers to provide a summary of benefits and coverage (SBC) for each plan variation of the standard QHP and to provide adequate notice to enrollees of changes in cost-sharing reduction eligibility. This proposed rule also includes additional quality improvement strategy reporting provisions for QHP issuers. Finally, this proposed rule specifies the circumstances that may lead an Exchange to suppress a QHP from being offered to new enrollees through an Exchange, and would extend the good faith compliance policy for QHP issuers through the 2015 calendar year.

We propose several provisions relating to essential health benefits (EHBs). This proposed rule proposes a definition of habilitative services, and provides examples of discriminatory plan designs. This proposed rule would also change existing EHB standards regarding coverage of prescription drugs by proposing that formularies be established by issuers' pharmacy and therapeutics committees (P&T committees). In addition, this proposed rule would amend requirements for essential community providers and network adequacy.

II. Background

A. Legislative and Regulatory Overview

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

Subtitles A and C of title I of the Affordable Care Act reorganized, amended, and added to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets.

Section 2701 of the PHS Act, as added by the Affordable Care Act, restricts the variation in premium rates charged by a health insurance issuer for non-grandfathered health insurance coverage in the individual or small group market to certain specified factors. The factors are: family size, rating area, and age and tobacco use (within specified limits).

Section 2701 of the PHS Act operates in coordination with section 1312(c) of the Affordable Care Act. Section 1312(c) of the Affordable Care Act generally requires a health insurance issuer to consider all enrollees in all health plans (except for grandfathered health plans) offered by such issuer to be members of a single risk pool for each of its individual and small group markets. States have the option to merge the individual market and small group market risk pools under section 1312(c)(3) of the Affordable Care Act.

Section 2702 of the PHS Act, as added by the Affordable Care Act, requires health insurance issuers that offer health insurance coverage in the group or individual market in a State to offer coverage to and accept every employer and individual in the State that applies for such coverage unless an exception applies.

Section 2703 of the PHS Act, as added by the Affordable Care Act, and sections 2712 and 2741 of the PHS Act, as added by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and codified prior to the enactment of the Affordable Care Act, require health insurance issuers that offer health insurance coverage in the group or individual market to renew or continue in force such coverage at the option of the plan sponsor or individual unless an exception applies.

Section 2718 of the PHS Act, as added by the Affordable Care Act, generally requires health insurance issuers to submit an annual MLR report to HHS and provide rebates to enrollees if they do not achieve specified MLR thresholds.

Section 2794 of the PHS Act, as added by the Affordable Care Act, directs the Secretary of HHS (the Secretary), in conjunction with the States, to establish a process for the annual review of "unreasonable increases in premiums for health insurance coverage."¹ The law also requires health insurance issuers to submit to the Secretary and the applicable State justifications for

unreasonable premium increases prior to the implementation of the increases. Section 2794(b)(2) further specifies that beginning with plan years beginning in 2014, the Secretary, in conjunction with the States, will monitor premium increases of health insurance coverage offered through an Exchange and outside of an Exchange.

Section 1302 of the Affordable Care Act provides for the establishment of an essential health benefits (EHB) package that includes coverage of EHB (as defined by the Secretary), cost-sharing limits, and actuarial value (AV) requirements. The law directs that EHBs be equal in scope to the benefits covered by a typical employer plan and that they cover at least the following 10 general categories: Ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care.

Sections 1302(b)(4)(A) through (D) establish that the Secretary must define EHB in a manner that: (1) Reflects appropriate balance among the 10 categories; (2) is not designed in such a way as to discriminate based on age, disability, or expected length of life; (3) takes into account the health care needs of diverse segments of the population; and (4) does not allow denials of EHBs based on age, life expectancy, disability, degree of medical dependency, or quality of life.

Section 1302(d) of the Affordable Care Act describes the various levels of coverage based on actuarial value (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. Sections 1312(f)(1) and (2) of the Affordable Care Act define qualified individuals and qualified employers. Under section 1312(f)(2)(B) of the Affordable Care Act, beginning in 2017, States will have the option to

¹ The implementing regulations in part 154 limit the scope of the requirements under section 2794 of the PHS Act to health insurance issuers offering health insurance coverage in the individual market or small group market. See Rate Increase Disclosure and Review; Final Rule, 76 FR 29964, 29966 (May 23, 2011).

allow issuers to offer QHPs in the large group market through the SHOP.²

Section 1311(c)(1)(B) of the Affordable Care Act requires the Secretary to establish minimum criteria for provider network adequacy that a health plan must meet to be certified as a QHP. Section 1311(c)(1)(E) of the Affordable Care Act specifies that, to be certified as a QHP participating in Exchanges, each health plan must implement a quality improvement strategy (QIS), which is described in section 1311(g)(1) of the Affordable Care Act.

Section 1311(c)(5) of the Affordable Care Act requires the Secretary to continue to operate, maintain and update the Internet portal developed under section 1103 of the Affordable Care Act to provide information to consumers and small businesses on affordable health insurance coverage options.

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

Section 1301(a)(1)(B) of the Affordable Care Act directs all issuers of QHPs to cover the EHB package described in section 1302(a) of the Affordable Care Act, including coverage of the services described in section 1302(b) of the Affordable Care Act, to adhere to the cost-sharing limits described in section 1302(c) of the Affordable Care Act and to meet the AV levels established in section 1302(d) of the Affordable Care Act. Section 2707(a) of the PHS Act, which is effective for plan or policy years beginning on or after January 1, 2014, extends the coverage of the EHB package to non-grandfathered individual and small group coverage, irrespective of whether such coverage is offered through an Exchange. In addition, section 2707(b) of the PHS Act directs non-grandfathered group health plans to ensure that cost sharing under the plan does not exceed the limitations described in sections 1302(c)(1) and (2) of the Affordable Care Act.

Sections 1313 and 1321 of the Affordable Care Act provide the Secretary with the authority to oversee the financial integrity of State Exchanges, their compliance with HHS standards, and the efficient and non-discriminatory administration of State

Exchange activities. Section 1321 of the Affordable Care Act provides for State flexibility in the operation and enforcement of Exchanges and related requirements.

Section 1321(a) of the Affordable Care Act provides the Secretary with broad authority to establish standards and regulations to implement statutory requirements related to Exchanges, QHPs and other components of title I of the Affordable Care Act. Under the authority established in section 1321(a)(1) of the Affordable Care Act, the Secretary promulgated the regulations at § 155.205(d) and (e). Section 155.205 authorizes Exchanges to perform certain consumer service functions, including the Navigator program described in § 155.210. Section 155.205(d) provides that each Exchange must conduct consumer assistance activities, and § 155.205(e) provides that each Exchange must conduct outreach and education activities to inform consumers about the Exchange and insurance affordability programs to encourage participation. Section 155.205(d) and (e) also allow for the establishment of a non-Navigator consumer assistance program. Section 155.215 establishes standards for Navigators and non-Navigator assistance personnel in Federally-facilitated Exchanges and for non-Navigator assistance personnel that are funded with Exchange establishment grant funds under section 1311(a) of the Affordable Care Act.

When operating an FFE under section 1321(c)(1) of the Affordable Care Act, HHS has the authority under sections 1321(c)(1) and 1311(d)(5)(A) of the Affordable Care Act to collect and spend user fees. In addition, 31 U.S.C. 9701 permits a Federal agency to establish a charge for a service provided by the agency. Office of Management and Budget (OMB) Circular A-25 Revised establishes Federal policy regarding user fees and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public.

Section 1321(c)(2) of the Affordable Care Act authorizes the Secretary to enforce the Exchange standards using civil money penalties (CMPs) on the same basis as detailed in section 2723(b) of the PHS Act. Section 2723(b) of the PHS Act authorizes the Secretary to impose CMPs as a means of enforcing the individual and group market reforms contained in Part A of title XXVII of the PHS Act when a State fails to substantially enforce these provisions.

Section 1321(d) of the Affordable Care Act provides that nothing in title I of the Affordable Care Act should be construed to preempt any State law that does not prevent the application of title I of the Affordable Care Act. Section 1311(k) of the Affordable Care Act specifies that Exchanges may not establish rules that conflict with or prevent the application of regulations issued by the Secretary.

Section 1341 of the Affordable Care Act 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 in benefit years 2014 through 2016. Section 1342 of the Affordable Care Act directs the Secretary to establish a temporary risk corridors program that protects against inaccurate rate setting from 2014 through 2016. Section 1343 of the Affordable Care Act establishes a permanent risk adjustment program that is intended to provide increased payments to health insurance issuers that attract higher-risk populations, such as those with chronic conditions, funded by payments from those that attract lower-risk populations, thereby reducing incentives for issuers to avoid higher-risk enrollees.

Sections 1402 and 1412 of the Affordable Care Act provide for reductions in cost sharing for essential health benefits for qualified low- and moderate-income enrollees in silver level health plans offered through the individual market Exchanges. These sections also provide for reductions in cost sharing for Indians enrolled in QHPs at any metal level.

Section 5000A of the Code, as added by section 1501(b) of the Affordable Care Act, requires all non-exempt individuals to maintain minimum essential coverage or make the individual shared responsibility payment. Section 5000A(f) of the Code defines minimum essential coverage as any of the following: (1) Coverage under a specified government sponsored program; (2) coverage under an eligible employer-sponsored plan; (3) coverage under a health plan offered in the individual market within a State; and (4) coverage under a grandfathered health plan. Section 5000A(f)(1)(E) of the Code authorizes the Secretary of HHS, in coordination with the Secretary of the Treasury, to designate other health benefits coverage as minimum essential coverage.

1. Premium Stabilization Programs

In the July 15, 2011 **Federal Register** (76 FR 41930), we published a proposed rule outlining the framework for the premium stabilization programs. We

² If a State elects this option, the rating rules in section 2701 of the PHS Act and its implementing regulations will apply to all coverage offered in such State's large group market (except for self-insured group health plans) pursuant to section 2701(a)(5) of the PHS Act.

implemented the premium stabilization programs in a final rule, published in the March 23, 2012 **Federal Register** (77 FR 17220) (Premium Stabilization Rule). In the December 7, 2012 **Federal Register** (77 FR 73118), we published a proposed rule outlining the benefit and payment parameters for the 2014 benefit year to expand the provisions related to the premium stabilization programs and set forth payment parameters in those programs (proposed 2014 Payment Notice). We published the 2014 Payment Notice final rule in the March 11, 2013 **Federal Register** (78 FR 15410).

In the December 2, 2013 **Federal Register** (78 FR 72322), we published a proposed rule outlining the benefit and payment parameters for the 2015 benefit year to expand the provisions related to the premium stabilization programs, setting forth certain oversight provisions and establishing the payment parameters in those programs (proposed 2015 Payment Notice). We published the 2015 Payment Notice final rule in the March 11, 2014 **Federal Register** (79 FR 13744).

2. Program Integrity

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

3. Exchanges

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

We established standards for the administration and payment of cost-sharing reductions and the SHOP in the

2014 Payment Notice and in the Amendments to the HHS Notice of Benefit and Payment Parameters for 2014 interim final rule, published in the March 11, 2013 **Federal Register** (78 FR 15541). The provisions established in the interim final rule were finalized in the second Program Integrity Rule. We also set forth standards related to Exchange user fees in the 2014 Payment Notice. We also established an adjustment to the FFE user fee in the Coverage of Certain Preventive Services Under the Affordable Care Act final rule, published in the July 2, 2013 **Federal Register** (78 FR 39870) (Preventive Services Rule).

In a final rule published in the July 17, 2013 **Federal Register** (78 FR 42859), we established standards for Navigators and non-Navigator assistance personnel in Federally-facilitated Exchanges and for non-Navigator assistance personnel funded through an Exchange establishment grant.

4. Essential Health Benefits, Actuarial Value

We established requirements relating to EHBs and AVs in the Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation Final Rule, which was published in the February 25, 2013 **Federal Register** (78 FR 12834) (EHB Rule).

5. Market Rules

A proposed rule relating to the 2014 health insurance market rules was published in the November 26, 2012 **Federal Register** (77 FR 70584). A final rule implementing the market rules was published in the February 27, 2013 **Federal Register** (78 FR 13406) (2014 Market Rules).

A proposed rule relating to Exchanges and Insurance Market Standards for 2015 and Beyond was published in the March 21, 2014 **Federal Register** (79 FR 15808) (2015 Market Standards Proposed Rule). A final rule implementing the Exchange and Insurance Market Standards for 2015 and Beyond was published in the May 27, 2014 **Federal Register** (79 FR 30240) (2015 Market Standards Rule).

6. Rate Review

A proposed rule to establish the rate review program was published in the December 23, 2010 **Federal Register** (75 FR 81004). A final rule with comment period implementing the rate review program was published in the May 23, 2011 **Federal Register** (76 FR 29964) (Rate Review Rule). The provisions of the Rate Review Rule were amended in a final rule published in the September 6, 2011 **Federal Register** (76 FR 54969)

and in the proposed and final 2014 Market Rules.

7. Medical Loss Ratio (MLR)

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 MLR program on December 1, 2010 (75 FR 74864). A final rule with a 30-day comment period was published in the December 7, 2011 **Federal Register** (76 FR 76574). An interim final rule with a 60-day comment period was published in the December 7, 2011 **Federal Register** (76 FR 76596).

B. Stakeholder Consultation and Input

HHS has consulted with stakeholders on policies related to the operation of Exchanges, including the SHOP and the premium stabilization programs. HHS has held a number of listening sessions with consumers, providers, employers, health plans, the actuarial community, and State representatives to gather public input. HHS consulted with stakeholders through regular meetings with the National Association of Insurance Commissioners (NAIC), regular contact with States through the Exchange Establishment grant and Exchange Blueprint approval processes, and meetings with Tribal leaders and representatives, health insurance issuers, trade groups, consumer advocates, employers, and other interested parties. We considered all of the public input as we developed the policies in this proposed rule.

C. Structure of Proposed Rule

The regulations outlined in this proposed rule would be codified in 45 CFR parts 144, 146, 147, 148, 153, 154, 155, 156 and 158. The proposed regulations in parts 144 propose a revised definition of the term “plan” and amendments relating to the definition of “State” for purposes of the group and individual market reforms added by the Affordable Care Act.

The proposed regulations in parts 146, 147, and 148 would establish parallel provisions in the guaranteed renewability regulations that prohibit an issuer that is discontinuing a product from automatically enrolling plan sponsors or individuals into a product of another licensed health insurance issuer.

The proposed regulations in part 153 outline the 2016 uniform reinsurance contribution rate, the uniform reinsurance payment parameters for the 2016 benefit year, and a modification to the attachment point for the 2015

benefit year. We propose an approach with respect to the transitional reinsurance program and the definition of “common ownership” for purposes of determining whether a contributing entity uses a third-party administrator for core administrative functions. The proposed regulations also propose the risk adjustment user fee for 2016 and outline certain modifications to the HHS risk adjustment methodology. We propose to clarify that the risk corridors transitional adjustment policy does not adjust the risk corridors calculation based on enrollment in early renewal plans (plans that renewed before January 1, 2014 and before the end of their 12-month term) unless and until the plan renews in late 2014 and becomes a transitional plan, and propose how to distribute any excess risk corridors funds at the end of the 3-year program. We also propose to extend the good faith safe harbor for non-compliance with the HHS-operated risk adjustment and reinsurance data requirements into the 2015 calendar year.

The proposed regulations in part 154 outline certain modifications to enhance the transparency and effectiveness of the rate review process. We propose to consider the impact of rate increases at the “plan” level as opposed to the “product” level when determining whether a rate increase in the individual or small group market is subject to review. Part 154 also includes related revisions to the definition of “rate increase” and a new definition of “plan.” We further propose an approach to ensure that all rate increases in the individual and small group market—for both QHPs and non-QHPs—are filed on a uniform timeline, and that States with Effective Rate Review Programs provide public access from their Web site to information about proposed and final rate increases in the individual and small group markets by consistent times for every relevant State market.

The proposed regulations in part 155 include a clarification related to the functions of an Exchange, and would establish the individual market open enrollment period for benefit years beginning on or after January 1, 2016. They also make certain proposals related to the SHOP Exchanges, which we discuss in greater detail below. We also propose to specify oral interpretation services standards for Exchanges and for QHP issuers offering coverage through Exchanges and certain agents and brokers. We propose to clarify the scope of the physical presence requirement at § 155.215(h) with regard to non-Navigator assistance personnel in State Exchanges that are

funded with section 1311(a) Exchange Establishment grants.

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, and the reductions in the maximum annual limitation for cost-sharing plan variations for 2016. They describe a limited exception to the process issuers are required to use to estimate the portion of claims for non-essential health benefits when calculating 2014 cost-sharing reductions provided. They also outline the 2016 FFE user fee rate, and include provisions related to the essential health benefits and the calculation of AV.

In part 156, we also propose a clarification to the administrative appeals process applicable to the premium stabilization, cost-sharing reduction, advance payments of the premium tax credit, and FFE user fee programs. Part 156 also outlines health insurance issuer responsibilities, including consumer disclosure requirements in the summary of benefits and coverage (SBC) related to plan variations and changes in eligibility for cost-sharing reductions. Part 156 also includes proposals related to essential health benefits, including proposed collection of new benchmark plan information, clarification of habilitative services coverage, and examples of possible discriminatory plan designs. We also propose a change in the EHB prescription drug standard, amendments to network adequacy requirements, and amendments to essential community provider requirements. Part 156 also contains a proposal relating to the recognition of State high risk pool coverage as minimum essential coverage.

The proposed regulations in part 158 propose clarifications regarding the treatment of cost-sharing reductions in MLR calculations, and amendments regarding the treatment of payroll taxes in MLR and rebate calculations, and relating to the distribution of rebates to group enrollees in non-Federal governmental and other group health plans not subject to ERISA.

III. Provisions of the Proposed HHS Notice of Benefit and Payment Parameters for 2016

A. Part 144—Requirements Relating to Health Insurance Coverage

1. Definitions (§ 144.103)

a. Plan

In the 2015 Market Standards Rule, we codified a definition of “plan” at

§ 144.103. Under that definition, the term “plan” means, with respect to an issuer and a product, the pairing of the health insurance coverage benefits under the product with a metal tier level (as described in sections 1302(d) and (e) of the Affordable Care Act) and service area. The product comprises all plans offered within the product, and the combination of all plans offered within a product constitutes the total service area of the product.

We propose to amend this definition to provide further specificity about the characteristics that distinguish a plan. Specifically, we propose that the term “plan” mean, with respect to an issuer and a product, the pairing of the health insurance coverage benefits under the product with a particular cost-sharing structure, provider network, and service area. This definition would make clear that plans that differ in their cost-sharing requirements (such as copayments, coinsurance or deductibles), or that have different networks of contracted providers or different service areas, are considered to be different plans. This would be true even if the plans are offered at the same metal tier level.

This definition is consistent with our approach for determining whether a plan offered outside the Exchange is the same plan as one that is certified as a QHP and offered through the Exchange.³ It is also consistent with the standards for determining whether a plan is the “same” or “substantially the same” as a QHP under § 153.500 and will therefore participate in the risk corridors program.⁴ The proposed amendments would also better align the defining features of a plan with the permitted plan-level adjustments under the single risk pool provision at § 156.80. For these reasons, we are also proposing the same definition apply for purposes of part 154, rate review program, and part 156, health insurance issuer standards.

We recognize that an issuer may, at the time of coverage renewal, make uniform modifications to a product, including modifying the cost sharing, provider network, and service area of a plan. We seek comment on when a plan should be considered the same plan for purposes of review for unreasonable rate increases, plan identification in the Health Insurance Oversight System (HIOS), and other programs based on changes in these characteristics. For instance, we seek comment on whether to adopt standards, similar to the

³ Patient Protection and Affordable Care Act; Program Integrity: Exchange, SHOP, and Eligibility Appeals, 78 FR at 54074 (August 30, 2013).

⁴ *Id.*, at 78 FR 54073.

product-level standards for uniform modification of coverage at § 147.106(e), for identifying when plan-level modifications constitute the same or different plan, and the particular form such standards should take.

b. State

On July 16, 2014, we issued letters to the Insurance Commissioners of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands clarifying the applicability of certain Affordable Care Act provisions to health insurance issuers in the U.S. territories.⁵ We had been informed by representatives of the territories that subjecting issuers in the territories to the new market reforms in the PHS Act was undermining the stability of the territories' health insurance markets. Accordingly, the letters explained that, in HHS's determination, the new provisions of the PHS Act enacted in title I of the Affordable Care Act are appropriately governed by the definition of "State" set forth in that title, and therefore do not apply to group and individual health insurance issuers in the territories. The portions of the PHS Act that will not apply to group or individual health insurance issuers in the U.S. territories are sections 2701 through 2719A and 2794. As explained in the letters, this analysis applies only to health insurance that is governed by the PHS Act. It does not affect the PHS Act requirements that were enacted in the Affordable Care Act and incorporated into ERISA and the Internal Revenue Code (the Code) and apply to group health plans (whether insured or self-insured), because such applicability does not rely upon the term "State" as it is defined in either the PHS Act or in the Affordable Care Act. Similarly, it also does not affect the PHS Act requirements that were enacted in the Affordable Care Act and apply to non-Federal governmental plans. As a practical matter, therefore, PHS Act, ERISA, and the Code requirements applicable to group health plans continue to apply to such coverage, and issuers selling policies to both private sector and public sector employers in the territories will want to make certain that their products comply with the relevant Affordable Care Act amendments to the PHS Act applicable to group health plans since their customers—the group health plans—are still subject to those provisions of the

PHS Act that were enacted in the Affordable Care Act including the prohibition on lifetime and annual limits (PHS Act section 2711), the prohibition on rescissions (PHS Act section 2712), coverage of preventive health services (PHS Act section 2713), and the revised internal and external appeals process (PHS Act section 2719), among other provisions.

We propose to codify this interpretation in § 144.103. The proposed amendments would provide that, for purposes of the Affordable Care Act requirements implemented in part 147, the term "State" does not include the U.S. territories of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands. The term "State" would continue to include the territories for purposes of parts 146, 148, and 150. Furthermore, part 147 requirements would continue to apply to non-Federal governmental plans, consistent with the analysis in the letters to the territories. In proposing this amendment, we are also proposing a minor modification to the definition of "State" to replace the words "several States" with "50 States," so that the definition of "State" will read, "State means each of the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands; except that for purposes of part 147, the term does not include Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands."

We also propose to amend the regulations regarding rate review (§ 154.102) and EHB (§ 156.100) to reflect this interpretation. For a discussion of those provisions, see sections III.F.1.a and III.H.2.a of this preamble.

B. Part 146—Requirements for the Group Health Insurance Market

For a discussion of the provisions of this proposed rule related to part 146, see section III.C.2 of this preamble.

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

1. Guaranteed Availability of Coverage (§ 147.104)

Section 147.104(b)(2) incorporates certain triggering events for special enrollment periods described in the Exchange regulations at § 155.420(d), and applies them to health insurance issuers offering non-grandfathered coverage in the individual market through or outside the Exchange. Sections 147.104(b)(2) and 155.420(d)(1)(ii) also establish a special

enrollment period (also referred to as a limited open enrollment period) for individuals enrolled in non-calendar year individual health insurance policies when their policy year ends in 2014.

In this proposed rule, as described below, we propose to modify § 155.420(d)(1)(ii) to extend the availability of the special enrollment period for a qualified individual and his or her dependent who, in any year, has coverage under a group health plan or individual health insurance coverage that is offered on a non-calendar year basis. Because the special enrollment period in § 155.420(d)(1)(ii) is cross-referenced in § 147.104(b)(2), the parallel regulation text in § 147.104(b)(2) is no longer necessary, and we propose to remove it.

We also propose to move the related regulation text in § 147.104(b)(2) that requires individual market and merged market plans to be offered on a calendar year basis. We propose to redesignate existing paragraphs (f) through (h) as paragraphs (g) through (i) and to codify the calendar-year requirement in new paragraph (f), with minor modifications for clarity.

To further ensure consistency between plans offered through or outside the individual market Exchange, we also propose to amend § 147.104(b)(4) by cross-referencing § 155.420(c)(2). Section 147.104(b)(4) provides that an individual has 60 days from the date of a triggering event to select an individual market plan during a special enrollment period. This amendment would apply the advance availability provisions in § 155.420(c)(2) to the broader individual market, allowing an individual 60 days before and after certain triggering events to make a plan selection through or outside the individual market Exchange.

Finally, we propose to update the cross-reference in § 147.104(b)(1)(i)(C) to refer to § 155.725 rather than § 155.725(a)(2), to conform with proposed amendments in § 155.725 described later in this preamble.

2. Guaranteed Renewability of Coverage (§ 147.106)

The guaranteed renewability provisions of title XXVII of the PHS Act provide that an issuer may discontinue a product offered in the group or individual market if the issuer offers to each plan sponsor or individual who is enrolled in that particular product the option to purchase all (or, in the case of the large group market, any) other health insurance coverage currently being offered by the issuer in that market, and complies with other

⁵ See for example, Letter to Virgin Islands on the Definition of State (July 16, 2014). Available at: <http://www.cms.gov/CCIIO/Resources/Letters/Downloads/letter-to-Francis.pdf>.

requirements of those sections, as well as with any applicable State law.

In previous guidance outlining our current regulatory interpretation of the product discontinuation provisions, we explained that an issuer does not satisfy the requirement to offer other coverage currently being offered “by the issuer” in the applicable market if it automatically enrolls a plan sponsor or individual into a product of another issuer that is separately licensed to engage in the business of insurance in a State.⁶ We propose to codify that interpretation by amending the guaranteed renewability regulations at § 146.152(c)(2), § 147.106(c)(2), and § 148.122(d)(2).

We note that this proposal would not prevent an issuer that decides to discontinue all health insurance coverage in a market (market withdrawal) from automatically enrolling plan sponsors or individuals into a product of another licensed issuer, to the extent permitted by applicable State law. However, if the issuer terminates all coverage in a market or markets, it is subject to certain requirements outlined in § 146.152(d), § 147.106(d), and § 148.122(e), as applicable. In particular, the issuer must provide at least 180 days’ notice to the applicable State authority and to each plan sponsor or individual, as applicable, (and participants and beneficiaries covered under such coverage), and it is prohibited from issuing coverage in the market(s) or State involved for 5 years following the date of discontinuation. The issuer must also comply with any applicable State law.

In instances when an issuer is not withdrawing from the market, we note that permitting the purchase and sale of products between issuers, whether through acquisitions of the product, statutory mergers of the issuers, or other corporate combinations, could create an opportunity for insurance holding companies to segment risk on the basis of health status between their subsidiary companies. However, we also do not want to impose undue constraints on standard corporate reorganization practices. Where an issuer may wish to

transfer its product(s) to another issuer, it is not clear whether the purposes of the guaranteed renewability provisions are better served by requiring the ceding issuer to offer the consumer enrollment in a different product offered by that issuer, or by having the acquiring issuer automatically enroll the consumer in the transferred product, which may have the same benefits, cost sharing, and other plan features.

We are considering how to interpret the guaranteed renewability provisions in the context of various corporate transactions involving a change of ownership, such as mergers, acquisitions, and similar business restructuring, as well as particular standards that may be necessary to ensure seamless coverage for enrollees and to facilitate the ongoing operational processes of HHS-administered programs. For example, we could allow for the retention of enrollees under a product that is being transferred to another issuer under certain types of transactions as permitted by applicable State law, but only if the same benefits, network, and other coverage features remain in place and the acquiring issuer agrees to accept liability for any payments and charges for the advance payments for the premium tax credit, cost-sharing reductions, the FFE user fee, and the HHS-operated risk adjustment, reinsurance, and risk corridors programs. We believe that this allocation of liability would accord with many parties’ expectations upon entering into such a transaction. We seek comment on such a standard, or what other allocation of liability should apply following such a transaction for each of these programs.

In addition to interpretations of the guaranteed renewability provisions in this context, mid-year changes in ownership affect operational processes, in particular for the data and payment processes associated with the programs listed above. These programs utilize plan identification in the Health Insurance Oversight System (HIOS), and at this time, cannot easily accommodate changes in such identification that would result from certain mid-year changes in ownership. Therefore issuers subject to these programs must continue data and payment processes under the original HIOS identifying information for affected programs until operations for the coverage year are complete. Operational guidance addressing data submissions and payments and charges when an issuer participating in the programs listed above experiences a change of ownership will be forthcoming.

To facilitate these operational processes, we propose to impose a notification requirement on issuers of a QHP, a plan otherwise subject to risk corridors, or a reinsurance-eligible plan or a risk adjustment covered plan, in cases of changes of ownership, as recognized by the State in which the issuer offers coverage. As an alternative, we also are considering defining a change of ownership for these purposes as a transaction that would cause a change in an issuer’s tax identification number, or any change in legal ownership of an issuer’s plan, for example through an asset sale or transfer or change in holding company ownership. We propose to require the post-transaction issuer to notify HHS of the transaction in the manner specified by HHS, by the later of the date the transaction is entered into or the 30th day prior to the effective date of the transaction. We anticipate that these timelines will not interfere with the negotiation and consummation of the transaction, but will permit the parties and HHS to clarify operational payment processes in a timely manner.

We seek comment on how the guaranteed renewability provisions should be interpreted as related to the transfer of products or corporate transformations of issuers. In particular, we seek comment on what, if any, types of automatic enrollment practices should be permitted in connection with specific types of corporate transactions and whether the regulations should be amended to create an exception to the prohibition on auto-enrollment with a different issuer in certain situations involving changes of ownership; how common such transactions are and how they are typically structured; the extent to which State laws and regulations impose restrictions on such transactions, and how our interpretation of the guaranteed renewability provisions would best protect the interests of consumers. We also seek comment on how the timing of such transactions may interact with other applicable market reforms in the relevant market segment, such as the timing of index rate updates under the single risk pool provision at § 156.80. We additionally seek comment on whether particular disclosure or special enrollment period provisions are necessary to ensure consumers are timely notified of a transaction affecting their coverage and given options for electing other coverage.

Finally, we seek comment on all aspects of proposed notification to HHS, including the identity of the notifying issuer, the timing of the proposed notification, types of transactions for

⁶ See Insurance Standards Bulletin, Form and Manner of Notices When Discontinuing or Renewing a Product in the Group or Individual Market, section IV (September 2, 2014). Available at: <http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Renewal-Notices-9-3-14-FINAL.PDF>. See also Patient Protection and Affordable Care Act; Annual Eligibility Redeterminations for Exchange Participation and Insurance Affordability Programs; Health Insurance Issuer Standards under the Affordable Care Act, Including Standards Related to Exchanges, 79 FR at 53000 (September 5, 2014).

which notification should be required, operational guidance that should be offered, and which issuer should be liable for payments and charges for the advance payments for the premium tax credit, cost-sharing reductions, the Federally-facilitated Exchange user fees, and the HHS-operated risk adjustment, reinsurance, and risk corridors programs. We also seek comment on whether the notification requirement should apply to issuers of all plans subject to the guaranteed renewability requirements, including, for example, grandfathered health plans.

D. Part 148—Requirements for the Individual Health Insurance Market

For a discussion of the provisions of this proposed rule related to part 148, see section III.C.2 of this preamble.

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

1. Provisions for the State Notice of Benefit and Payment Parameters (§ 153.100)

In § 153.100(c), we established a deadline of March 1 of the calendar year prior to the applicable benefit year for a State to publish a State notice of benefit and payment parameters if the State is required to do so under § 153.100(a) or (b)—that is, if the State is operating a risk adjustment program, or if the State is establishing a reinsurance program and wishes to modify the data requirements for issuers to receive reinsurance payments from those specified in the HHS notice of benefit and payment parameters for the benefit year, wishes to collect additional reinsurance contributions or use additional funds for reinsurance payments, or elects to use more than one applicable reinsurance entity. As of the date of publication of this proposed rulemaking, Connecticut is the only State that has elected to establish a transitional reinsurance program and Massachusetts is the only State that has elected to operate a risk-adjustment program.

We have previously recognized in the 2014 and 2015 Payment Notices that it may be difficult for States to publish such a notice by the required deadline if the final HHS notice of benefit and payment parameters for the applicable benefit year has not yet been published. Therefore, we propose to modify § 153.100(c) so that the publication deadline for the State notice of benefit and payment parameters would be the later of March 1 of the calendar year prior to the applicable benefit year, or

the 30th day following publication of the final HHS notice of benefit and payment parameters for that benefit year. This deadline corresponds to the extended deadlines we implemented for the 2014 and 2015 benefit years in the 2014 and 2015 Payment Notices, respectively. We seek comment on this proposal.

2. Provisions and Parameters for the Permanent Risk Adjustment Program

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

a. Risk Adjustment User Fee

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

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

In the 2015 Payment Notice, we estimated Federal administrative expenses of operating the risk adjustment program to be \$0.96 per enrollee-per-year, based on our estimated contract costs for risk adjustment operations. For the 2016 benefit year, we 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. 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 2016 will be approximately \$50 million, and that the risk adjustment user fee would be \$1.75 per enrollee per year. The increased risk adjustment user fee for 2016 is the result of the increased contract costs to support the risk adjustment data validation process, which will be administered for the first time in 2016. We seek comment on this proposed risk adjustment user fee rate.

b. Overview of the HHS Risk Adjustment Model

The HHS risk adjustment model predicts plan liability for an average enrollee based on that person's age, sex, and diagnoses (risk factors), producing a risk score. The HHS risk adjustment methodology utilizes separate models for adults, children, and infants to account for cost differences in each of these age groups. In each of the adult and child models, the relative costs assigned to an individual's age, sex, and diagnoses are added together to produce a risk score. Infant risk scores are determined by inclusion in one of 25 mutually exclusive groups based on the infant's maturity and the severity of its diagnoses. If applicable, the risk score is multiplied by a cost-sharing reduction adjustment.

The enrollment-weighted average risk score of all enrollees in a particular risk

adjustment-covered plan, or the plan liability risk score, within a geographic rating area is one input into the payment transfer formula, which determines an issuer's transfer (payment or charge) for that plan. Thus, the HHS risk adjustment model predicts individual-level risk scores, but is designed to predict average group costs to account for risk across plans, which, as we stated in the 2014 Payment Notice, accords with the Actuarial Standards Board's Actuarial Standards of Practice for risk classification.

c. Proposed Updates to Risk Adjustment Model

We propose to continue to use the same risk adjustment methodology finalized in the 2014 Payment Notice, with changes to reflect more current data, as described here. As we stated above, in the adult and child models, enrollee health risks are estimated using the HHS risk adjustment model, which assigns a set of additive factors that reflect the relative costs of demographics and diagnoses. Risk adjustment factors are developed using claims data and reflect the costs of a given disease relative to average spending. The longer the lag in data used to develop the risk factors, the greater the potential that the costs of treating one disease versus another have changed in a manner not fully reflected in the risk factors.

To provide risk adjustment factors that best reflect more recent treatment patterns and costs, we propose to recalibrate the HHS risk adjustment models for 2016 by using more recent claims data to develop updated risk factors. The risk factors published in the 2014 Payment Notice for use in 2014 and 2015 were developed using the Truven Health Analytics 2010 MarketScan® Commercial Claims and Encounters database (MarketScan); we are proposing to update the risk factors in the HHS risk adjustment model using 2010, 2011, and 2012 MarketScan data. We seek comment on this proposal.

We propose to implement the recalibrated risk adjustment factors in 2016 to provide sufficient time for issuers to account for risk adjustment model changes. However, we also seek comment on making the recalibrated HHS risk adjustment models effective beginning for the 2015 benefit year instead of the 2016 benefit year.

We also propose that if 2013 MarketScan data becomes available after the publication of this proposed rule, we would update the risk factors in the

HHS risk adjustment model using the 3 most recent years of data available—MarketScan 2011, 2012, and 2013 data. These updated risk factors would be published and finalized in this final rule. We seek comment on this approach, including whether we should update risk factors based on 2013 MarketScan data when it becomes available after publication of this proposed rule, and whether the updated risk factors should be implemented for 2015, or 2016.

We believe that using multiple years of data will promote market stability and minimize volatility in coefficients for certain rare diagnoses. In using multiple years of data to recalibrate the risk adjustment model, we considered either pooling data from 3 sample years or blending coefficients from three separately estimated calibrations, based on the 2010, 2011, and 2012 data. We examined the effects of pooling data and blending separate calibrations, and did not find a significant difference between the resulting coefficients. However, we believe that blending coefficients offers the advantage of transparency and ease in future recalibrations. Blending coefficients using the 3 most recent years of separately estimated calibrations allows for most recent data to be incorporated into the model, while ensuring that coefficients remain relatively stable. We would publish the R-squared statistics of the 3 separately-estimated sample years and the blended coefficient for each risk adjustment factor. We seek comment on this approach.

We made minor refinements to the underlying MarketScan recalibration samples from which the risk adjustment factors are derived. In particular, we changed our treatment of Age 0 infants without birth hierarchical condition categories (HCCs). There may be cases in which there is no separate infant birth claim from which to gather diagnoses. For example, at an operational level, mother and infant claims may be bundled such that infant diagnoses appear on the mother's record. Where newborn diagnoses appear on the mother's claims, HHS has issued operational guidance on how best to associate those codes with the appropriate infant.⁷ This assumes that the mother and infant enrollment records exist and can be matched.

However, we are proposing a change in how we categorize age 0 infants who do not have birth codes. We previously stated in the operational guidance referenced above that infants without

birth codes would be assigned an "Age 0, Term" factor in risk adjustment operations. We did so under the assumption that issuers paid the birth costs, yet the birth HCCs were missing (perhaps because claims were bundled with the mother's, whose claims were excluded). Upon further analysis of age 0 and age 1 claims, we found that age 0 infants without birth HCCs had costs more similar to age 1 infants by severity level. We believe that these infants should be assigned to age 1 in situations where the issuer did not pay the birth costs during the plan year. For many age 0 infants without birth HCCs, the birth could have occurred in the prior year or was paid by a different issuer. We are proposing that age 0 infants without birth HCCs be assigned to "Age 1" by severity level. We have made this change in the recalibration samples that we are using to calculate risk factors for proposed implementation in the 2016 benefit year. We are also proposing to make this change in the operation of the risk adjustment methodology for the year in which we would implement the recalibrated risk adjustment factors. We seek comment on this approach.

d. List of Factors To Be Employed in the Model

The HHS risk adjustment models predict annualized plan liability expenditures using age and sex categories and the HHS HCCs included in the HHS risk adjustment model. Dollar coefficients were estimated for these factors using weighted least squares regression, where the weight was the fraction of the year enrolled.

We are including the same HCCs that were included in the original risk adjustment calibration in the 2014 Payment Notice. For each model, the factors are the statistical regression dollar values for each HCC in the model divided by a weighted average plan liability for the full modeling sample. The factors represent the predicted relative incremental expenditures for each HCC. The proposed factors resulting from the blended factors from the 2010, 2011, and 2012 separately solved models are shown in the tables below. For a given enrollee, the sums of the factors for the enrollee's HCCs are the total relative predicted expenditures for that enrollee. Table 1 contains factors for each adult model, including the interactions. Table 3 contains the factors for each child model. Table 4 contains the factors for each infant model.

⁷ HHS-Developed Risk Adjustment Model Algorithm Software Instructions. June 2, 2014.

<http://www.cms.gov/CCIIO/Resources/Regulations->

<and-Guidance/Downloads/DIY-instructions-5-20-14.pdf>.

TABLE 1—ADULT RISK ADJUSTMENT MODEL FACTORS

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors					
Age 21–24, Male	0.245	0.197	0.139	0.079	0.063
Age 25–29, Male	0.259	0.207	0.144	0.079	0.062
Age 30–34, Male	0.314	0.252	0.176	0.095	0.074
Age 35–39, Male	0.379	0.307	0.220	0.125	0.099
Age 40–44, Male	0.464	0.379	0.281	0.169	0.138
Age 45–49, Male	0.553	0.456	0.347	0.219	0.183
Age 50–54, Male	0.711	0.593	0.464	0.305	0.257
Age 55–59, Male	0.834	0.698	0.556	0.379	0.325
Age 60–64, Male	1.005	0.844	0.681	0.475	0.412
Age 21–24, Female	0.408	0.327	0.216	0.102	0.072
Age 25–29, Female	0.516	0.417	0.289	0.153	0.117
Age 30–34, Female	0.635	0.521	0.387	0.240	0.201
Age 35–39, Female	0.738	0.615	0.479	0.329	0.288
Age 40–44, Female	0.824	0.691	0.545	0.381	0.335
Age 45–49, Female	0.858	0.718	0.567	0.393	0.343
Age 50–54, Female	0.983	0.828	0.667	0.467	0.407
Age 55–59, Female	1.019	0.856	0.690	0.481	0.418
Age 60–64, Female	1.126	0.945	0.766	0.538	0.468
Diagnosis Factors					
HIV/AIDS	5.788	5.291	4.962	4.962	4.971
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	13.018	12.842	12.720	12.792	12.820
Central Nervous System Infections, Except Viral Meningitis	7.352	7.230	7.147	7.178	7.190
Viral or Unspecified Meningitis	5.066	4.796	4.649	4.590	4.578
Opportunistic Infections	10.028	9.915	9.848	9.852	9.851
Metastatic Cancer	25.642	25.144	24.784	24.890	24.924
Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	11.814	11.428	11.169	11.196	11.204
Non-Hodgkin's Lymphomas and Other Cancers and Tumors	6.522	6.247	6.069	6.030	6.015
Colorectal, Breast (Age <50), Kidney, and Other Cancers	5.935	5.661	5.483	5.439	5.421
Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors	3.467	3.259	3.129	3.075	3.055
Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors	1.693	1.516	1.407	1.296	1.258
Pancreas Transplant Status/Complications	7.981	7.895	7.819	7.841	7.845
Diabetes with Acute Complications	1.333	1.184	1.095	0.977	0.933
Diabetes with Chronic Complications	1.333	1.184	1.095	0.977	0.933
Diabetes without Complication	1.333	1.184	1.095	0.977	0.933
Protein-Calorie Malnutrition	14.895	14.913	14.901	14.977	15.000
Mucopolysaccharidosis	2.334	2.196	2.112	2.052	2.032
Lipidoses and Glycogenosis	2.334	2.196	2.112	2.052	2.032
Amyloidosis, Porphyria, and Other Metabolic Disorders	2.334	2.196	2.112	2.052	2.032
Adrenal, Pituitary, and Other Significant Endocrine Disorders	2.334	2.196	2.112	2.052	2.032
Liver Transplant Status/Complications	17.442	17.225	17.090	17.131	17.150
End-Stage Liver Disease	6.311	6.031	5.853	5.879	5.890
Cirrhosis of Liver	2.591	2.399	2.290	2.258	2.247
Chronic Hepatitis	2.134	1.970	1.871	1.799	1.776
Acute Liver Failure/Disease, Including Neonatal Hepatitis	4.501	4.322	4.209	4.201	4.202
Intestine Transplant Status/Complications	53.540	53.545	53.543	53.563	53.571
Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	13.301	13.001	12.793	12.848	12.867
Intestinal Obstruction	7.360	7.048	6.853	6.898	6.917
Chronic Pancreatitis	6.620	6.343	6.171	6.209	6.227
Acute Pancreatitis/Other Pancreatic Disorders and Intestinal Malabsorption	3.357	3.132	2.999	2.956	2.944
Inflammatory Bowel Disease	3.091	2.816	2.655	2.539	2.495
Necrotizing Fasciitis	7.589	7.358	7.198	7.230	7.242
Bone/Joint/Muscle Infections/Necrosis	7.589	7.358	7.198	7.230	7.242
Rheumatoid Arthritis and Specified Autoimmune Disorders	3.565	3.292	3.116	3.094	3.089
Systemic Lupus Erythematosus and Other Autoimmune Disorders	1.289	1.138	1.050	0.952	0.917
Osteogenesis Imperfecta and Other Osteodystrophies	3.519	3.299	3.151	3.092	3.071
Congenital/Developmental Skeletal and Connective Tissue Disorders	3.519	3.299	3.151	3.092	3.071
Cleft Lip/Cleft Palate	1.728	1.545	1.437	1.349	1.322
Hemophilia	46.995	46.679	46.437	46.451	46.455
Myelodysplastic Syndromes and Myelofibrosis	14.398	14.258	14.158	14.185	14.194
Aplastic Anemia	14.398	14.258	14.158	14.185	14.194
Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	9.323	9.130	8.996	8.989	8.989
Sickle Cell Anemia (Hb-SS)	9.323	9.130	8.996	8.989	8.989
Thalassemia Major	9.323	9.130	8.996	8.989	8.989
Combined and Other Severe Immunodeficiencies	5.539	5.361	5.242	5.258	5.263
Disorders of the Immune Mechanism	5.539	5.361	5.242	5.258	5.263

TABLE 1—ADULT RISK ADJUSTMENT MODEL FACTORS—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Coagulation Defects and Other Specified Hematological Disorders	3.167	3.053	2.976	2.952	2.943
Drug Psychosis	3.735	3.469	3.306	3.209	3.176
Drug Dependence	3.735	3.469	3.306	3.209	3.176
Schizophrenia	3.199	2.922	2.760	2.675	2.649
Major Depressive and Bipolar Disorders	1.857	1.674	1.561	1.439	1.397
Reactive and Unspecified Psychosis, Delusional Disorders	1.857	1.674	1.561	1.439	1.397
Personality Disorders	1.187	1.051	0.955	0.821	0.774
Anorexia/Bulimia Nervosa	2.779	2.599	2.483	2.406	2.378
Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	3.815	3.668	3.574	3.532	3.516
Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Con- genital Malformation Syndromes	1.384	1.280	1.203	1.120	1.090
Autistic Disorder	1.187	1.051	0.955	0.821	0.774
Pervasive Developmental Disorders, Except Autistic Disorder	1.187	1.051	0.955	0.821	0.774
Traumatic Complete Lesion Cervical Spinal Cord	13.467	13.285	13.155	13.164	13.167
Quadriplegia	13.467	13.285	13.155	13.164	13.167
Traumatic Complete Lesion Dorsal Spinal Cord	9.938	9.745	9.616	9.614	9.613
Paraplegia	9.938	9.745	9.616	9.614	9.613
Spinal Cord Disorders/Injuries	6.268	6.031	5.883	5.864	5.857
Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	4.060	3.784	3.618	3.579	3.571
Quadriplegic Cerebral Palsy	1.208	0.961	0.825	0.753	0.731
Cerebral Palsy, Except Quadriplegic	0.372	0.280	0.220	0.167	0.148
Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/In- flammatory and Toxic Neuropathy	5.313	5.145	5.041	5.017	5.008
Muscular Dystrophy	2.201	2.008	1.906	1.832	1.806
Multiple Sclerosis	8.413	7.975	7.673	7.736	7.756
Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders	2.201	2.008	1.906	1.832	1.806
Seizure Disorders and Convulsions	1.578	1.403	1.296	1.207	1.177
Hydrocephalus	7.868	7.733	7.636	7.623	7.615
Non-Traumatic Coma, and Brain Compression/Anoxic Damage	10.042	9.885	9.770	9.773	9.772
Respirator Dependence/Tracheostomy Status	39.643	39.644	39.620	39.697	39.721
Respiratory Arrest	12.584	12.408	12.271	12.354	12.383
Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syn- dromes	12.584	12.408	12.271	12.354	12.383
Heart Assistive Device/Artificial Heart	35.480	35.184	34.977	35.065	35.099
Heart Transplant	35.480	35.184	34.977	35.065	35.099
Congestive Heart Failure	3.651	3.522	3.438	3.440	3.441
Acute Myocardial Infarction	11.824	11.431	11.143	11.303	11.358
Unstable Angina and Other Acute Ischemic Heart Disease	6.167	5.830	5.628	5.667	5.686
Heart Infection/Inflammation, Except Rheumatic	7.052	6.895	6.793	6.780	6.775
Specified Heart Arrhythmias	3.369	3.197	3.091	3.039	3.020
Intracranial Hemorrhage	10.890	10.560	10.343	10.374	10.388
Ischemic or Unspecified Stroke	4.214	3.985	3.856	3.877	3.890
Cerebral Aneurysm and Arteriovenous Malformation	4.887	4.638	4.491	4.462	4.452
Hemiplegia/Hemiparesis	6.179	6.069	5.988	6.049	6.071
Monoplegia, Other Paralytic Syndromes	3.942	3.789	3.697	3.675	3.668
Atherosclerosis of the Extremities with Ulceration or Gangrene	12.276	12.162	12.073	12.166	12.198
Vascular Disease with Complications	8.278	8.061	7.919	7.940	7.948
Pulmonary Embolism and Deep Vein Thrombosis	4.709	4.510	4.386	4.372	4.369
Lung Transplant Status/Complications	34.373	34.131	33.949	34.046	34.078
Cystic Fibrosis	11.033	10.684	10.430	10.438	10.440
Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	1.101	0.970	0.884	0.791	0.759
Asthma	1.101	0.970	0.884	0.791	0.759
Fibrosis of Lung and Other Lung Disorders	2.568	2.426	2.343	2.310	2.299
Aspiration and Specified Bacterial Pneumonias and Other Severe Lung In- fections	8.848	8.747	8.678	8.703	8.713
Kidney Transplant Status	11.117	10.782	10.581	10.596	10.608
End Stage Renal Disease	40.465	40.171	39.935	40.097	40.149
Chronic Kidney Disease, Stage 5	2.400	2.272	2.200	2.193	2.194
Chronic Kidney Disease, Severe (Stage 4)	2.400	2.272	2.200	2.193	2.194
Ectopic and Molar Pregnancy, Except with Renal Failure, Shock, or Embo- lism	1.430	1.234	1.123	0.918	0.831
Miscarriage with Complications	1.430	1.234	1.123	0.918	0.831
Miscarriage with No or Minor Complications	1.430	1.234	1.123	0.918	0.831
Completed Pregnancy With Major Complications	3.914	3.381	3.175	2.970	2.940
Completed Pregnancy With Complications	3.914	3.381	3.175	2.970	2.940
Completed Pregnancy with No or Minor Complications	3.914	3.381	3.175	2.970	2.940
Chronic Ulcer of Skin, Except Pressure	2.554	2.413	2.332	2.320	2.318
Hip Fractures and Pathological Vertebral or Humerus Fractures	10.056	9.807	9.634	9.697	9.719
Pathological Fractures, Except of Vertebrae, Hip, or Humerus	1.860	1.725	1.640	1.554	1.522
Stem Cell, Including Bone Marrow, Transplant Status/Complications	32.497	32.482	32.463	32.490	32.499

TABLE 1—ADULT RISK ADJUSTMENT MODEL FACTORS—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Artificial Openings for Feeding or Elimination	11.444	11.324	11.232	11.295	11.316
Amputation Status, Lower Limb/Amputation Complications	6.152	5.974	5.855	5.894	5.910
Interaction Factors					
Severe illness x Opportunistic Infections	12.052	12.304	12.437	12.542	12.573
Severe illness x Metastatic Cancer	12.052	12.304	12.437	12.542	12.573
Severe illness x Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	12.052	12.304	12.437	12.542	12.573
Severe illness x Non-Hodgkin's Lymphomas and Other Cancers and Tu- mors	12.052	12.304	12.437	12.542	12.573
Severe illness x Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	12.052	12.304	12.437	12.542	12.573
Severe illness x Heart Infection/Inflammation, Except Rheumatic	12.052	12.304	12.437	12.542	12.573
Severe illness x Intracranial Hemorrhage	12.052	12.304	12.437	12.542	12.573
Severe illness x HCC group G06 (G06 is HCC Group 6 which includes the following HCCs in the blood disease category: 67, 68)	12.052	12.304	12.437	12.542	12.573
Severe illness x HCC group G08 (G08 is HCC Group 8 which includes the following HCCs in the blood disease category: 73, 74)	12.052	12.304	12.437	12.542	12.573
Severe illness x End-Stage Liver Disease	2.611	2.768	2.841	2.942	2.971
Severe illness x Acute Liver Failure/Disease, Including Neonatal Hepatitis ...	2.611	2.768	2.841	2.942	2.971
Severe illness x Atherosclerosis of the Extremities with Ulceration or Gan- grene	2.611	2.768	2.841	2.942	2.971
Severe illness x Vascular Disease with Complications	2.611	2.768	2.841	2.942	2.971
Severe illness x Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	2.611	2.768	2.841	2.942	2.971
Severe illness x Artificial Openings for Feeding or Elimination	2.611	2.768	2.841	2.942	2.971
Severe illness x HCC group G03 (G03 is HCC Group 3 which includes the following HCCs in the musculoskeletal disease category: 54, 55)	2.611	2.768	2.841	2.942	2.971

TABLE 2—HHS HCCs IN THE SEVERITY ILLNESS INDICATOR VARIABLE

Description
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock.
Peritonitis/Gastrointestinal Perforation/Necrotizing Enter colitis.
Seizure Disorders and Convulsions.
Non-Traumatic Coma, Brain Compression/Anoxic Damage.
Respirator Dependence/Tracheostomy Status.
Respiratory Arrest.
Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes.
Pulmonary Embolism and Deep Vein Thrombosis.

TABLE 3—CHILD RISK ADJUSTMENT MODEL FACTORS

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors					
Age 2–4, Male	0.264	0.196	0.108	0.031	0.010
Age 5–9, Male	0.179	0.130	0.065	0.003	0.000
Age 10–14, Male	0.228	0.177	0.107	0.044	0.030
Age 15–20, Male	0.306	0.247	0.174	0.100	0.080
Age 2–4, Female	0.211	0.152	0.072	0.010	0.002
Age 5–9, Female	0.142	0.100	0.044	0.001	0.000
Age 10–14, Female	0.207	0.160	0.095	0.043	0.031
Age 15–20, Female	0.358	0.285	0.191	0.096	0.072
Diagnosis Factors					
HIV/AIDS	3.508	3.108	2.862	2.709	2.665
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	18.633	18.476	18.371	18.395	18.404
Central Nervous System Infections, Except Viral Meningitis	12.297	12.095	11.951	11.964	11.969
Viral or Unspecified Meningitis	3.643	3.409	3.280	3.134	3.084
Opportunistic Infections	23.813	23.736	23.693	23.677	23.669
Metastatic Cancer	38.610	38.324	38.101	38.102	38.101
Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymph- oid Leukemia	12.521	12.200	11.971	11.895	11.867
Non-Hodgkin's Lymphomas and Other Cancers and Tumors	9.945	9.655	9.451	9.349	9.314
Colorectal, Breast (Age < 50), Kidney, and Other Cancers	3.870	3.641	3.473	3.332	3.282

TABLE 3—CHILD RISK ADJUSTMENT MODEL FACTORS—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors	3.276	3.046	2.896	2.764	2.715
Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors	1.665	1.482	1.354	1.217	1.169
Pancreas Transplant Status/Complications	33.090	32.913	32.794	32.834	32.845
Diabetes with Acute Complications	2.668	2.335	2.166	1.882	1.777
Diabetes with Chronic Complications	2.668	2.335	2.166	1.882	1.777
Diabetes without Complication	2.668	2.335	2.166	1.882	1.777
Protein-Calorie Malnutrition	15.118	15.003	14.912	14.952	14.964
Mucopolysaccharidosis	6.331	6.034	5.820	5.764	5.746
Lipidoses and Glycogenosis	6.331	6.034	5.820	5.764	5.746
Congenital Metabolic Disorders, Not Elsewhere Classified	6.331	6.034	5.820	5.764	5.746
Amyloidosis, Porphyria, and Other Metabolic Disorders	6.331	6.034	5.820	5.764	5.746
Adrenal, Pituitary, and Other Significant Endocrine Disorders	6.331	6.034	5.820	5.764	5.746
Liver Transplant Status/Complications	33.090	32.913	32.794	32.834	32.845
End-Stage Liver Disease	14.421	14.253	14.144	14.137	14.138
Cirrhosis of Liver	5.357	5.183	5.063	5.006	4.989
Chronic Hepatitis	0.950	0.790	0.664	0.562	0.533
Acute Liver Failure/Disease, Including Neonatal Hepatitis	7.729	7.577	7.462	7.433	7.425
Intestine Transplant Status/Complications	33.090	32.913	32.794	32.834	32.845
Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	17.127	16.729	16.447	16.473	16.483
Intestinal Obstruction	6.086	5.815	5.635	5.538	5.504
Chronic Pancreatitis	13.304	12.986	12.777	12.788	12.793
Acute Pancreatitis/Other Pancreatic Disorders and Intestinal Malabsorption	3.572	3.410	3.300	3.189	3.148
Inflammatory Bowel Disease	5.553	5.157	4.899	4.761	4.714
Necrotizing Fasciitis	5.393	5.116	4.925	4.851	4.829
Bone/Joint/Muscle Infections/Necrosis	5.393	5.116	4.925	4.851	4.829
Rheumatoid Arthritis and Specified Autoimmune Disorders	3.062	2.821	2.650	2.510	2.465
Systemic Lupus Erythematosus and Other Autoimmune Disorders	1.260	1.087	0.966	0.819	0.772
Osteogenesis Imperfecta and Other Osteodystrophies	1.645	1.510	1.401	1.305	1.273
Congenital/Developmental Skeletal and Connective Tissue Disorders	1.645	1.510	1.401	1.305	1.273
Cleft Lip/Cleft Palate	1.858	1.622	1.473	1.321	1.267
Hemophilia	54.299	53.777	53.390	53.377	53.370
Myelodysplastic Syndromes and Myelofibrosis	24.525	24.330	24.187	24.183	24.182
Aplastic Anemia	24.525	24.330	24.187	24.183	24.182
Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	8.038	7.730	7.520	7.441	7.414
Sickle Cell Anemia (Hb-SS)	8.038	7.730	7.520	7.441	7.414
Thalassemia Major	8.038	7.730	7.520	7.441	7.414
Combined and Other Severe Immunodeficiencies	6.604	6.386	6.246	6.182	6.157
Disorders of the Immune Mechanism	6.604	6.386	6.246	6.182	6.157
Coagulation Defects and Other Specified Hematological Disorders	4.878	4.716	4.596	4.498	4.464
Drug Psychosis	4.456	4.181	4.016	3.931	3.905
Drug Dependence	4.456	4.181	4.016	3.931	3.905
Schizophrenia	5.488	5.073	4.812	4.681	4.640
Major Depressive and Bipolar Disorders	1.856	1.641	1.494	1.301	1.236
Reactive and Unspecified Psychosis, Delusional Disorders	1.856	1.641	1.494	1.301	1.236
Personality Disorders	0.948	0.810	0.694	0.491	0.417
Anorexia/Bulimia Nervosa	2.504	2.293	2.144	2.047	2.014
Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	3.328	3.078	2.933	2.900	2.887
Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes	2.003	1.795	1.668	1.558	1.518
Autistic Disorder	1.824	1.614	1.470	1.278	1.213
Pervasive Developmental Disorders, Except Autistic Disorder	0.961	0.818	0.696	0.491	0.417
Traumatic Complete Lesion Cervical Spinal Cord	15.854	15.746	15.662	15.736	15.762
Quadriplegia	15.854	15.746	15.662	15.736	15.762
Traumatic Complete Lesion Dorsal Spinal Cord	14.020	13.813	13.675	13.699	13.708
Paraplegia	14.020	13.813	13.675	13.699	13.708
Spinal Cord Disorders/Injuries	5.531	5.265	5.099	5.009	4.980
Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	11.987	11.687	11.485	11.444	11.427
Quadriplegic Cerebral Palsy	4.773	4.463	4.269	4.294	4.304
Cerebral Palsy, Except Quadriplegic	1.400	1.172	1.037	0.931	0.896
Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies	1.252	1.089	0.976	0.888	0.858
Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	8.606	8.390	8.246	8.178	8.151
Muscular Dystrophy	3.364	3.138	2.992	2.896	2.864
Multiple Sclerosis	5.914	5.555	5.304	5.274	5.264
Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders	3.364	3.138	2.992	2.896	2.864
Seizure Disorders and Convulsions	2.314	2.115	1.976	1.803	1.744
Hydrocephalus	6.470	6.320	6.219	6.207	6.203
Non-Traumatic Coma, and Brain Compression/Anoxic Damage	9.166	8.977	8.853	8.819	8.804
Respirator Dependence/Tracheostomy Status	40.570	40.448	40.351	40.512	40.563

TABLE 3—CHILD RISK ADJUSTMENT MODEL FACTORS—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Respiratory Arrest	14.474	14.256	14.114	14.125	14.126
Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes	14.474	14.256	14.114	14.125	14.126
Heart Assistive Device/Artificial Heart	33.090	32.913	32.794	32.834	32.845
Heart Transplant	33.090	32.913	32.794	32.834	32.845
Congestive Heart Failure	6.832	6.704	6.609	6.562	6.545
Acute Myocardial Infarction	4.876	4.783	4.725	4.727	4.734
Unstable Angina and Other Acute Ischemic Heart Disease	4.876	4.783	4.725	4.727	4.734
Heart Infection/Inflammation, Except Rheumatic	16.293	16.130	16.019	16.019	16.020
Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders	7.938	7.710	7.527	7.384	7.334
Major Congenital Heart/Circulatory Disorders	2.264	2.133	2.003	1.855	1.810
Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders	1.312	1.203	1.088	0.961	0.926
Specified Heart Arrhythmias	5.180	4.968	4.808	4.726	4.699
Intracranial Hemorrhage	20.007	19.725	19.533	19.542	19.545
Ischemic or Unspecified Stroke	7.836	7.690	7.592	7.643	7.657
Cerebral Aneurysm and Arteriovenous Malformation	4.674	4.421	4.264	4.194	4.161
Hemiplegia/Hemiparesis	6.060	5.920	5.837	5.815	5.807
Monoplegia, Other Paralytic Syndromes	5.353	5.170	5.061	5.033	5.026
Atherosclerosis of the Extremities with Ulceration or Gangrene	10.802	10.595	10.455	10.343	10.292
Vascular Disease with Complications	15.629	15.437	15.310	15.322	15.331
Pulmonary Embolism and Deep Vein Thrombosis	14.822	14.613	14.473	14.504	14.515
Lung Transplant Status/Complications	33.090	32.913	32.794	32.834	32.845
Cystic Fibrosis	13.994	13.502	13.147	13.156	13.161
Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	0.524	0.443	0.345	0.210	0.168
Asthma	0.524	0.443	0.345	0.210	0.168
Fibrosis of Lung and Other Lung Disorders	5.214	5.066	4.954	4.868	4.840
Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	9.469	9.373	9.291	9.304	9.308
Kidney Transplant Status	17.992	17.577	17.297	17.316	17.326
End Stage Renal Disease	38.852	38.586	38.382	38.492	38.527
Chronic Kidney Disease, Stage 5	11.138	10.943	10.809	10.718	10.690
Chronic Kidney Disease, Severe (Stage 4)	11.138	10.943	10.809	10.718	10.690
Ectopic and Molar Pregnancy, Except with Renal Failure, Shock, or Embolism	1.276	1.084	0.957	0.719	0.629
Miscarriage with Complications	1.276	1.084	0.957	0.719	0.629
Miscarriage with No or Minor Complications	1.276	1.084	0.957	0.719	0.629
Completed Pregnancy With Major Complications	3.462	2.960	2.749	2.485	2.425
Completed Pregnancy With Complications	3.462	2.960	2.749	2.485	2.425
Completed Pregnancy with No or Minor Complications	3.462	2.960	2.749	2.485	2.425
Chronic Ulcer of Skin, Except Pressure	1.579	1.481	1.390	1.310	1.284
Hip Fractures and Pathological Vertebral or Humerus Fractures	6.169	5.861	5.643	5.527	5.491
Pathological Fractures, Except of Vertebrae, Hip, or Humerus	2.058	1.921	1.798	1.635	1.582
Stem Cell, Including Bone Marrow, Transplant Status/Complications	33.090	32.913	32.794	32.834	32.845
Artificial Openings for Feeding or Elimination	15.660	15.540	15.451	15.602	15.651
Amputation Status, Lower Limb/Amputation Complications	10.245	9.973	9.802	9.701	9.658

TABLE 4—INFANT RISK ADJUSTMENT MODELS FACTORS

Group	Platinum	Gold	Silver	Bronze	Catastrophic
Extremely Immature * Severity Level 5 (Highest)	410.348	408.872	407.691	407.693	407.703
Extremely Immature * Severity Level 4	218.224	216.730	215.551	215.509	215.506
Extremely Immature * Severity Level 3	62.449	61.375	60.541	60.202	60.106
Extremely Immature * Severity Level 2	62.449	61.375	60.541	60.202	60.106
Extremely Immature * Severity Level 1 (Lowest)	62.449	61.375	60.541	60.202	60.106
Immature * Severity Level 5 (Highest)	217.679	216.228	215.075	215.072	215.086
Immature * Severity Level 4	93.597	92.104	90.918	90.899	90.906
Immature * Severity Level 3	50.841	49.478	48.421	48.331	48.317
Immature * Severity Level 2	33.561	32.279	31.304	31.068	31.006
Immature * Severity Level 1 (Lowest)	33.561	32.279	31.304	31.068	31.006
Premature/Multiples * Severity Level 5 (Highest)	168.945	167.526	166.408	166.364	166.363
Premature/Multiples * Severity Level 4	34.579	33.195	32.161	31.973	31.939
Premature/Multiples * Severity Level 3	19.070	17.942	17.128	16.748	16.633
Premature/Multiples * Severity Level 2	10.224	9.307	8.652	8.095	7.907
Premature/Multiples * Severity Level 1 (Lowest)	6.921	6.234	5.664	5.018	4.810
Term * Severity Level 5 (Highest)	144.955	143.654	142.633	142.485	142.440
Term * Severity Level 4	19.307	18.234	17.478	17.000	16.862
Term * Severity Level 3	6.881	6.181	5.640	4.964	4.724
Term * Severity Level 2	4.010	3.481	3.021	2.286	2.029

TABLE 4—INFANT RISK ADJUSTMENT MODELS FACTORS—Continued

Group	Platinum	Gold	Silver	Bronze	Catastrophic
Term * Severity Level 1 (Lowest)	1.718	1.442	1.026	0.349	0.176
Age1 * Severity Level 5 (Highest)	63.225	62.492	61.921	61.814	61.786
Age1 * Severity Level 4	10.493	9.956	9.554	9.291	9.218
Age1 * Severity Level 3	3.645	3.281	2.973	2.642	2.549
Age1 * Severity Level 2	2.286	2.001	1.735	1.383	1.281
Age1 * Severity Level 1 (Lowest)	0.623	0.518	0.334	0.161	0.125
Age 0 Male	0.695	0.642	0.625	0.587	0.557
Age 1 Male	0.147	0.125	0.117	0.089	0.077

TABLE 5—HHS HCCS INCLUDED IN INFANT MODEL MATURITY CATEGORIES

Maturity category	HCC/description
Extremely Immature	Extremely Immature Newborns, Birthweight <500 Grams.
Extremely Immature	Extremely Immature Newborns, Including Birthweight 500–749 Grams.
Extremely Immature	Extremely Immature Newborns, Including Birthweight 750–999 Grams.
Immature	Premature Newborns, Including Birthweight 1000–1499 Grams.
Immature	Premature Newborns, Including Birthweight 1500–1999 Grams.
Premature/Multiples	Premature Newborns, Including Birthweight 2000–2499 Grams.
Premature/Multiples	Other Premature, Low Birthweight, Malnourished, or Multiple Birth Newborns.
Term	Term or Post-Term Singleton Newborn, Normal or High Birthweight.
Age 1	All age 1 infants.

TABLE 6—HHS HCCS INCLUDED IN INFANT MODEL SEVERITY CATEGORIES

Severity category	HCC
Severity Level 5 (Highest)	Metastatic Cancer.
Severity Level 5	Pancreas Transplant Status/Complications.
Severity Level 5	Liver Transplant Status/Complications.
Severity Level 5	End-Stage Liver Disease.
Severity Level 5	Intestine Transplant Status/Complications.
Severity Level 5	Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis.
Severity Level 5	Respirator Dependence/Tracheostomy Status.
Severity Level 5	Heart Assistive Device/Artificial Heart.
Severity Level 5	Heart Transplant.
Severity Level 5	Congestive Heart Failure.
Severity Level 5	Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders.
Severity Level 5	Lung Transplant Status/Complications.
Severity Level 5	Kidney Transplant Status.
Severity Level 5	End Stage Renal Disease.
Severity Level 5	Stem Cell, Including Bone Marrow, Transplant Status/Complications.
Severity Level 4	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock.
Severity Level 4	Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia.
Severity Level 4	Mucopolysaccharidosis.
Severity Level 4	Major Congenital Anomalies of Diaphragm, Abdominal Wall, and Esophagus, Age <2.
Severity Level 4	Myelodysplastic Syndromes and Myelofibrosis.
Severity Level 4	Aplastic Anemia.
Severity Level 4	Combined and Other Severe Immunodeficiencies.
Severity Level 4	Traumatic Complete Lesion Cervical Spinal Cord.
Severity Level 4	Quadriplegia.
Severity Level 4	Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease.
Severity Level 4	Quadriplegic Cerebral Palsy.
Severity Level 4	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy.
Severity Level 4	Non-Traumatic Coma, Brain Compression/Anoxic Damage.
Severity Level 4	Respiratory Arrest.
Severity Level 4	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes.
Severity Level 4	Acute Myocardial Infarction.
Severity Level 4	Heart Infection/Inflammation, Except Rheumatic.
Severity Level 4	Major Congenital Heart/Circulatory Disorders.
Severity Level 4	Intracranial Hemorrhage.
Severity Level 4	Ischemic or Unspecified Stroke.
Severity Level 4	Vascular Disease with Complications.
Severity Level 4	Pulmonary Embolism and Deep Vein Thrombosis.
Severity Level 4	Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections.
Severity Level 4	Chronic Kidney Disease, Stage 5.
Severity Level 4	Hip Fractures and Pathological Vertebral or Humerus Fractures.
Severity Level 4	Artificial Openings for Feeding or Elimination.
Severity Level 3	HIV/AIDS.
Severity Level 3	Central Nervous System Infections, Except Viral Meningitis.

TABLE 6—HHS HCCs INCLUDED IN INFANT MODEL SEVERITY CATEGORIES—Continued

Severity category	HCC
Severity Level 3	Opportunistic Infections.
Severity Level 3	Non-Hodgkin's Lymphomas and Other Cancers and Tumors.
Severity Level 3	Colorectal, Breast (Age <50), Kidney and Other Cancers.
Severity Level 3	Breast (Age 50+), Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors.
Severity Level 3	Lipidoses and Glycogenosis.
Severity Level 3	Adrenal, Pituitary, and Other Significant Endocrine Disorders.
Severity Level 3	Acute Liver Failure/Disease, Including Neonatal Hepatitis.
Severity Level 3	Intestinal Obstruction.
Severity Level 3	Necrotizing Fasciitis.
Severity Level 3	Bone/Joint/Muscle Infections/Necrosis.
Severity Level 3	Osteogenesis Imperfecta and Other Osteodystrophies.
Severity Level 3	Cleft Lip/Cleft Palate.
Severity Level 3	Hemophilia.
Severity Level 3	Disorders of the Immune Mechanism.
Severity Level 3	Coagulation Defects and Other Specified Hematological Disorders.
Severity Level 3	Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes.
Severity Level 3	Traumatic Complete Lesion Dorsal Spinal Cord.
Severity Level 3	Paraplegia.
Severity Level 3	Spinal Cord Disorders/Injuries.
Severity Level 3	Cerebral Palsy, Except Quadriplegic.
Severity Level 3	Muscular Dystrophy.
Severity Level 3	Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders.
Severity Level 3	Hydrocephalus.
Severity Level 3	Unstable Angina and Other Acute Ischemic Heart Disease.
Severity Level 3	Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders.
Severity Level 3	Specified Heart Arrhythmias.
Severity Level 3	Cerebral Aneurysm and Arteriovenous Malformation.
Severity Level 3	Hemiplegia/Hemiparesis.
Severity Level 3	Cystic Fibrosis.
Severity Level 3	Fibrosis of Lung and Other Lung Disorders.
Severity Level 3	Pathological Fractures, Except of Vertebrae, Hip, or Humerus.
Severity Level 2	Viral or Unspecified Meningitis.
Severity Level 2	Thyroid, Melanoma, Neurofibromatosis, and Other Cancers and Tumors.
Severity Level 2	Diabetes with Acute Complications.
Severity Level 2	Diabetes with Chronic Complications.
Severity Level 2	Diabetes without Complication.
Severity Level 2	Protein-Calorie Malnutrition.
Severity Level 2	Congenital Metabolic Disorders, Not Elsewhere Classified.
Severity Level 2	Amyloidosis, Porphyria, and Other Metabolic Disorders.
Severity Level 2	Cirrhosis of Liver.
Severity Level 2	Chronic Pancreatitis.
Severity Level 2	Inflammatory Bowel Disease.
Severity Level 2	Rheumatoid Arthritis and Specified Autoimmune Disorders.
Severity Level 2	Systemic Lupus Erythematosus and Other Autoimmune Disorders.
Severity Level 2	Congenital/Developmental Skeletal and Connective Tissue Disorders.
Severity Level 2	Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn.
Severity Level 2	Sickle Cell Anemia (Hb-SS).
Severity Level 2	Drug Psychosis.
Severity Level 2	Drug Dependence.
Severity Level 2	Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes.
Severity Level 2	Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies.
Severity Level 2	Seizure Disorders and Convulsions.
Severity Level 2	Monoplegia, Other Paralytic Syndromes.
Severity Level 2	Atherosclerosis of the Extremities with Ulceration or Gangrene.
Severity Level 2	Chronic Obstructive Pulmonary Disease, Including Bronchiectasis.
Severity Level 2	Chronic Ulcer of Skin, Except Pressure.
Severity Level 1 (Lowest)	Chronic Hepatitis.
Severity Level 1	Acute Pancreatitis/Other Pancreatic Disorders and Intestinal Malabsorption.
Severity Level 1	Thalassemia Major.
Severity Level 1	Autistic Disorder.
Severity Level 1	Pervasive Developmental Disorders, Except Autistic Disorder.
Severity Level 1	Multiple Sclerosis.
Severity Level 1	Asthma.
Severity Level 1	Chronic Kidney Disease, Severe (Stage 4).
Severity Level 1	Amputation Status, Lower Limb/Amputation Complications.
Severity Level 1	No Severity HCCs.

e. Cost-Sharing Reductions Adjustments

We propose to continue to include an adjustment for the receipt of cost-sharing reductions in the model, and propose to continue not to adjust for receipt of reinsurance payments in the model. We have updated the adjustments to the HHS risk adjustment

models for individuals who receive cost-sharing reductions to be consistent with the cost-sharing reductions advance payment formula finalized in the 2015 Payment Notice, for implementation in 2015 benefit year risk adjustment. We note that the silver plan variant and zero cost-sharing factors are unchanged from those

finalized in the 2014 Payment Notice. The adjustment factors are set forth in Table 7. These adjustments are multiplied against the sum of the demographic, diagnosis, and interaction factors. We will continue to evaluate this adjustment as more data becomes available. We seek comment on this approach.

TABLE 7—COST-SHARING REDUCTION ADJUSTMENT

Household income	Plan AV	Induced utilization factor
Silver Plan Variant Recipients		
100–150% of FPL	Plan Variation 94%	1.12
150–200% of FPL	Plan Variation 87%	1.12
200–250% of FPL	Plan Variation 73%	1.00
>250% of FPL	Standard Plan 70%	1.00
Zero Cost-Sharing Recipients		
<300% of FPL	Platinum (90%)	1.00
<300% of FPL	Gold (80%)	1.07
<300% of FPL	Silver (70%)	1.12
<300% of FPL	Bronze (60%)	1.15
Limited Cost-Sharing Recipients		
>300% of FPL	Platinum (90%)	1.00
>300% of FPL	Gold (80%)	1.07
>300% of FPL	Silver (70%)	1.12
>300% of FPL	Bronze (60%)	1.15

f. Model Performance Statistics

To evaluate model performance, we examined its R-squared and predictive ratios. The R-squared statistic, which calculates the percentage of individual variation explained by a model, measures the predictive accuracy of the model overall. The predictive ratios measure the predictive accuracy of a model for different validation groups or subpopulations. The predictive ratio for

each of the HHS risk adjustment models is the ratio of the weighted mean predicted plan liability for the model sample population to the weighted mean actual plan liability for the model sample population. The predictive ratio represents how well the model does on average at predicting plan liability for that subpopulation. A subpopulation that is predicted perfectly would have a predictive ratio of 1.0. For each of the HHS risk adjustment models, the R-

squared statistic and the predictive ratio are in the range of published estimates for concurrent risk adjustment models.⁸ Because we are proposing to blend the coefficients from separately solved models based on MarketScan 2010, 2011 and 2012 data, we are publishing the R-squared statistic for each model and year separately to verify their statistical validity. The R-squared statistic for each model is shown in Table 8.

TABLE 8—R-SQUARED STATISTIC FOR HHS RISK ADJUSTMENT MODELS

Risk adjustment model	R-squared statistic		
	2010	2011	2012
Platinum Adult	0.3619	0.3684	0.3937
Platinum Child	0.3030	0.2835	0.2856
Platinum Infant	0.2892	0.3371	0.2845
Gold Adult	0.3572	0.3636	0.3896
Gold Child	0.2985	0.2786	0.2805
Gold Infant	0.2871	0.3351	0.2821
Silver Adult	0.3537	0.3602	0.3865
Silver Child	0.2949	0.2749	0.2767
Silver Infant	0.2858	0.3339	0.2807
Bronze Adult	0.3519	0.3582	0.3842
Bronze Child	0.2919	0.2721	0.2737
Bronze Infant	0.2859	0.3341	0.2808
Catastrophic Adult	0.3511	0.3574	0.3833

⁸ Winkleman, Ross and Syed Mehmud. “A Comparative Analysis of Claims-Based Tools for

Health Risk Assessment.” Society of Actuaries. April 2007.

TABLE 8—R-SQUARED STATISTIC FOR HHS RISK ADJUSTMENT MODELS—Continued

Risk adjustment model	R-squared statistic		
	2010	2011	2012
Catastrophic Child	0.2907	0.2710	0.2726
Catastrophic Infant	0.2859	0.3340	0.2808

g. Overview of the Payment Transfer Formula

We do not propose to alter our payment transfer methodology. Plan average risk scores would be calculated as the member month-weighted average of individual enrollee risk scores. We defined the calculation of plan average actuarial risk and the calculation of payments and charges in the Premium Stabilization Rule. In the 2014 Payment Notice, we combined those concepts into a risk adjustment payment transfer formula. Risk adjustment transfers (payments and charges) would be calculated following the completion of issuer risk adjustment data reporting.

The payment transfer formula includes a set of cost adjustment terms that require transfers to be calculated at the geographic rating area level for each plan (that is, HHS would calculate two separate transfer amounts for a plan that operates in two rating areas).

The payment transfer formula is designed to provide a per member per month (PMPM) transfer amount. The PMPM transfer amount derived from the payment transfer formula would be multiplied by each plan’s total member months for the benefit year to determine the total payment due or charge owed by the issuer for that plan in a rating area.

(1) Overview of the Payment Transfer Formula

Though we do not propose to change the payment transfer formula from what was finalized in the 2014 Payment Notice (78 FR 15430–15434), we believe it would be useful to republish the formula in its entirety, since we are proposing to recalibrate the HHS risk adjustment model. Transfers (payments and charges) will be calculated as the difference between the plan premium estimate reflecting risk selection and the plan premium estimate not reflecting risk selection. As finalized in the 2014 Payment Notice, the HHS risk adjustment payment transfer formula is:

$$T_i = \left[\frac{PLRS_i \cdot IDF_i \cdot GCF_i}{\sum_i (s_i \cdot PLRS_i \cdot IDF_i \cdot GCF_i)} - \frac{AV_i \cdot ARF_i \cdot IDF_i \cdot GCF_i}{\sum_i (s_i \cdot AV_i \cdot ARF_i \cdot IDF_i \cdot GCF_i)} \right] \bar{P}_s$$

Where:

\bar{P}_s = State average premium;
 $PLRS_i$ = plan i 's plan liability risk score;
 AV_i = plan i 's metal level AV;
 ARF_i = allowable rating factor;
 IDF_i = plan i 's induced demand factor;
 GCF_i = plan i 's geographic cost factor;
 s_i = plan i 's share of State enrollment;
 and the denominator is summed across all plans in the risk pool in the market in the State.

The difference between the two premium estimates in the payment transfer formula determines whether a plan pays a risk transfer charge or receives a risk transfer payment. Note that the value of the plan average risk score by itself does not determine whether a plan would be assessed a charge or receive a payment—even if the risk score is greater than 1.0, it is possible that the plan would be assessed a charge if the premium compensation that the plan may receive through its rating practices (as measured through the allowable rating factor) exceeds the plan’s predicted liability associated with risk selection. Risk adjustment transfers are calculated at the risk pool level and catastrophic plans are treated as a separate risk pool for purposes of risk adjustment.

h. HHS Risk Adjustment Methodology Considerations

In the 2014 Payment Notice, we finalized the methodology that HHS will use when operating a risk adjustment program on behalf of a State. In the second Program Integrity Rule (78 FR 65046), we clarified the modification to the transfer formula to accommodate community rated States that utilize family tiering rating factors. We are further clarifying this formula to ensure that the allowable rating factor (ARF) is appropriately applied in the transfer formula in community rated States for 2014 risk adjustment. In the second Program Integrity rule, we stated that the ARF formula should be modified so that the numerator is a summation over all subscribers of the product of the family tiering factor and the subscriber member months, and the denominator the sum of billable member months. However, we do not believe the formula accurately reflects that description, as it does not distinguish between subscriber months (months attributed to the sole subscriber) and billable member months (months attributed to all allowable members of the family factored into the community rating). The calculation of ARF for family tiering States that was published in the second Program Integrity rule that would be calculated

at the level of the subscriber, was as follows:

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

Where:

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

While the preamble description in the second Program Integrity rule is correct, as we noted, the formula itself is incorrect in that it does not distinguish between billable member months and subscriber months by using the same variable for both. Therefore, we are proposing a technical change to the ARF calculation for family tiering States, as follows:

$$ARF_i = \frac{\sum_s (ARF_s \cdot MS_s)}{\sum_s (MB_s)}$$

Where:

ARF_i is the allowable rating factor for plan i ,
 ARF_s is the allowable rating factor—also known as the family rating tier—for subscriber (family) s in plan i ,
 MS_s is the number of subscriber months for subscriber s , and
 MB_s is the number of billable member months for subscriber (family) s .

The numerator is summed over the product of the allowable rating factor and the number of subscriber months (that is, months of family subscription), and the denominator is the sum over all billable members. Each family unit covered under a single contract is considered a single “subscriber.” Therefore, a family of four that purchases coverage for a period from January through December will accumulate 12 subscriber months (*MS*_s), although coverage is being provided for 48 member months (both billable and non-billable). Billable members are individuals who are counted for purposes of placing the subscriber in a family tier. For example, in a community rated State that rates based on two adults and one or more children with one full year of enrollment, the family of four would have 36 billable member months (*MB*_s), (12 billable member months for the subscriber, 12 billable member months for the second adult, and 12 billable months for the first child). We seek comment on this proposed clarification.

3. Provisions and Parameters for the Transitional Reinsurance Program

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

a. Common Ownership Clarification

The definition of a “contributing entity” at § 153.20 provides that for the 2015 and 2016 benefit years, a contributing entity is (i) a health insurance issuer or (ii) a self-insured group health plan, including a group health plan that is partially self-insured and partially insured, where the health insurance coverage does not constitute major medical coverage, that uses a third party administrator (TPA) in connection with claims processing or adjudication, including the management of internal appeals, or plan enrollment for services other than for pharmacy benefits or excepted benefits within the meaning of section 2791(c) of the PHS Act. A self-insured group health plan

will not be deemed to use a TPA for this purpose if it uses an unrelated third party: (a) To obtain a provider network and related claims repricing services; or (b) for up to 5 percent of claims processing or adjudication or plan enrollment, based on either the number of transactions processed by the third party, or the value of the claims processing and adjudication and plan enrollment services provided by the third party.

The definition of a “contributing entity” does not include qualifying self-administered, self-insured group health plans for the purpose of the requirement to make reinsurance contributions for the 2015 and 2016 benefit years. In the preamble to the 2015 Payment Notice, we indicated that we consider a TPA to be, with respect to a self-insured group health plan, an entity that is not under common ownership or control with the self-insured group health plan or its plan sponsor that provides the specified core administrative services (79 FR 13773).

We have received a number of inquiries seeking clarification on how to determine common ownership or control for purposes of the definition of a “contributing entity” in § 153.20. In response, we propose to clarify that principles similar to the controlled group rules of section 414(b) and (c) of the Code should be used to determine whether the TPA is under common ownership or control with the self-insured group health plan or the plan sponsor.

We believe that applying principles similar to the controlled group rules under the Code are appropriate for use in determining whether a TPA is under common ownership or control with the self-insured group health plan or plan sponsor for purposes of the definition of a “contributing entity” under § 153.20 because they are familiar to many stakeholders. We also note that similar common ownership or control rules apply for other purposes under the Affordable Care Act, such as the shared responsibility payment for applicable large employers that do not offer full-time employees and dependents the opportunity to enroll in minimum essential coverage. See, for example, section 4980H(c)(2)(C)(i) of the Code, which states that all persons treated as a single employer under section 414 are to be treated as one employer. Additionally, section 9010(c)(3) of the Affordable Act applies similar controlled group rules for purposes of the annual fee on health insurance issuers.

We seek comment on this proposal and on alternative definitions that are

based on existing standards that would be familiar to stakeholders for determining whether a TPA is under common ownership or control with the self-insured group health plan or its sponsor for purposes of the definition of “contributing entity” at § 153.20.

b. Self-Insured Expatriate Plans (§ 153.400(a)(1)(iii))

Section 1341(b)(3)(B) of the Affordable Care Act and the implementing regulations at § 153.400(a)(1) require contributing entities to make reinsurance contributions for major medical coverage that is considered to be part of a commercial book of business. In the 2014 Payment Notice (78 FR 15457), we stated that we interpret this language to exclude expatriate health coverage, as defined by the Secretary, and we codified this approach in regulatory text at § 153.400(a)(1)(iii). In the March 8, 2013, FAQs about the Affordable Care Act Implementation Part XIII,⁹ an expatriate health plan is defined as an *insured* group health plan with respect to which enrollment is limited to primary insured who reside outside of their home country for at least 6 months of the plan year and any covered dependents, and its associated group health insurance coverage. Therefore, under our current regulation, *self-insured* expatriate plans that would otherwise meet the conditions outlined in the March 2013 FAQ are required to make reinsurance contributions if these plans provide major medical coverage, unless another exemption in § 153.400(a) applies, because the definition in the FAQ applies only to *insured* expatriate plans.

We propose to amend § 153.400(a)(1)(iii), which currently exempts expatriate health coverage, as defined by the Secretary, from reinsurance contributions, so that it also exempts, beginning for the 2015 benefit year, any self-insured group health plan with respect to which enrollment is limited to participants who reside outside of their home country for at least 6 months of the plan year, and any covered dependents. This approach and definition, applicable solely to this program, is consistent with FAQs discussed above for insured expatriate health plans and aligns the definition for this time-limited program. We seek comment on this proposed amendment.

⁹ Available at: http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs13.html.

c. Determination of Debt (§ 153.400(c))

Consistent with the determination of debt provision set forth in § 156.1215(c), we propose to clarify in a new § 153.400(c) that any amount owed to the Federal government by a self-insured group health plan (including a group health plan that is partially self-insured and partially insured, where the health insurance coverage does not constitute major medical coverage), including reinsurance contributions that are not remitted in full in a timely manner, would be a determination of a debt. We seek comment on this proposal.

d. Reinsurance Contribution Submission Process

On May 22, 2014, we released an FAQ about the reinsurance contribution submission process.¹⁰ As detailed in this FAQ, we have implemented a streamlined process for the collection of reinsurance contributions. A contributing entity, or a TPA or administrative services-only (ASO) contractor on behalf of the contributing entity, will complete all required steps for the reinsurance contribution submission process on www.pay.gov (Pay.gov). The “ACA Transitional Reinsurance Program Annual Enrollment and Contributions Submission Form” available on Pay.gov must be completed and submitted by a contributing entity or a TPA or ASO contractor on its behalf no later than November 15, 2014, 2015, or 2016, as applicable, under § 153.405(b). The form includes basic company and contact information, and the annual enrollment count for the applicable benefit year. The form will auto-calculate the contribution amounts owed.

We propose to amend § 153.405(b), requiring a contributing entity to submit its annual enrollment count of the number of covered lives of reinsurance contribution enrollees for the applicable benefit year to HHS no later than November 15 of benefit year 2014, 2015, or 2016. When November 15 does not fall on a business day, we propose that a contributing entity submit its annual enrollment count of the number of covered lives of reinsurance contribution enrollees for the applicable benefit year to HHS no later than November 15, 2014, 2015, or 2016, or if such date is not a business day, the next business day. Similarly, because November 15, 2015 and January 15, 2017 do not fall on a business day, we

propose in § 153.405(c)(2) that a contributing entity must remit reinsurance contributions to HHS no later than January 15, 2015, 2016, or 2017, as applicable, or, if such date is not a business day, the next applicable business day, if making a combined contribution or the first payment of the bifurcated contribution; and no later than November 15, 2015, 2016, or 2017, as applicable, or, if such date is not a business day, the next applicable business day, if making the second payment of the bifurcated contribution.

Although we stated in the 2015 Payment Notice (79 FR 13776) that, for operational reasons, HHS would not permit contributing entities to elect to make the entire benefit year’s reinsurance contribution by January 15, 2015, 2016, or 2017, as applicable, we have resolved those operational difficulties, and will offer contributing entities the option to pay: (1) the entire 2014, 2015, or 2016 benefit year contribution in one payment no later than January 15, 2015, 2016, or 2017, as applicable (or, if such date is not a business day, the next applicable business day), reflecting the entire uniform contribution rate applicable to each benefit year (that is, \$63 per covered life for 2014, \$44 per covered life for 2015, and a proposed \$27 per covered life for 2016); or (2) in two separate payments for the 2014, 2015, or 2016 benefit years, with the first remittance due by January 15, 2015, 2016, and 2017, as applicable (or, if such date is not a business day, the next applicable business day), reflecting the first payment of the bifurcated contribution (that is, \$52.50 per covered life for 2014, \$33.00 per covered life for 2015, and a proposed \$21.60 per covered life for 2016); and the second remittance due by November 15, 2015, 2016, or 2017, as applicable (or, if such date is not a business day, the next applicable business day) reflecting the second payment of the bifurcated contribution (that is, \$10.50 reinsurance fee per covered life for 2014, \$11.00 per covered life for 2015, and a proposed \$5.40 per covered life for 2016).

Under § 153.405(c)(1), HHS must notify the contributing entity of the reinsurance contribution amount allocated to reinsurance payments and administrative expenses to be paid for the applicable benefit year following submission of the annual enrollment count. We clarify that this notification will occur when the contributing entity enters the gross annual enrollment count into the Pay.gov form and the form auto-calculates the contribution amount owed. No separate notification or invoice will be sent to a contributing

entity, unless a discrepancy in data or payment has been identified after the form is submitted. In addition, we propose to delete § 153.405(c)(2), to be consistent with HHS permitting flexibility for a contributing entity (or the TPA or ASO contractor on its behalf) to remit the entire contribution in one payment, rather than requiring a bifurcated payment. Notification of the reinsurance contribution amount related to the allocation for reinsurance payments, administrative expenses, and payments to the U.S. Treasury for the applicable benefit year will also be made through the automatic calculation of this amount when a contributing entity (or the TPA or ASO contractor on its behalf) completes the reinsurance contribution submission process and submits the Form through Pay.gov.

We also propose to amend and redesignate § 153.405(c)(3) to (c)(2) to clarify that a contributing entity must remit its contribution payment for the applicable benefit year to occur no later than January 15, 2015, 2016, or 2017, as applicable (or, if such date is not a business day, the next applicable business day) if making a combined payment or the first payment of the bifurcated payment, and no later than November 15, 2015, 2016, or 2017, as applicable (or, if such date is not a business day, the next applicable business day) if making the second payment of the bifurcated payment. However, we note that the form must be completed and the reinsurance contribution payment(s) must be *scheduled* no later than November 15, 2014, 2015, or 2016, as applicable, to successfully comply with the deadline set forth in § 153.405(b) and complete the reinsurance contribution submission process through Pay.gov. The reinsurance contribution payments must be scheduled by this deadline regardless of whether the contributing entity (or the TPA or ASO contractor on its behalf) is remitting a single combined payment or two payments under the bifurcated schedule.

We note that under certain circumstances, if a contributing entity elects to follow the bifurcated schedule, then the contributing entity would be required to submit two separate forms through Pay.gov. However, in this circumstance, the annual enrollment count reported on both forms must be the same. This is consistent with § 153.405(b) and previous guidance, which provide that no later than November 15 of benefit year 2014, 2015, or 2016, as applicable, a contributing entity must submit an annual enrollment count of the number of covered lives of reinsurance

¹⁰ Available at: <http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/Reinsurance-contributions-process-FAQ-5-22-14.pdf>.

contribution enrollees one time for the applicable benefit year to HHS.

Finally, we propose to amend § 153.405(g)(4)(1)(i) and (ii), which require a plan sponsor who maintains multiple group health plans to report to HHS the average number of covered lives calculated, the counting method used, and the names of the multiple plans being treated as a single group health plan as determined by the plan sponsor. A plan sponsor will continue to be required to determine this information, but will only need to report to HHS the average number of covered lives calculated and the other data elements required through the Pay.gov reinsurance contribution submission process. Under § 153.405(h), plan sponsors should retain this additional information (that is, the counting method used and the names of the multiple plans being treated as a single group health plan), as this information may be requested to assess the plan sponsor's compliance with the reinsurance contribution requirements, if necessary. We seek comment on these proposals.

e. Consistency in Counting Methods for Health Insurance Issuers (§ 153.405(d))

As noted in the 2014 Payment Notice (78 FR15462), the counting methods for the transitional reinsurance program are designed to align with the methods permitted for purposes of the fee to fund the Patient-Centered Outcomes Research Trust Fund (PCORTF). The PCORTF Final Rule (77 FR 72729) requires consistency in the use of counting methods for calculating covered lives for the duration of the year. In response to stakeholder questions, to promote administrative efficiencies, and to minimize the potential for strategic reporting of enrollment counts for reinsurance purposes, we propose to amend § 153.405(d) to similarly require a contributing entity that is a health insurance issuer to use the same counting method to calculate its annual enrollment count of covered lives of reinsurance contribution enrollees in a State (including both the individual and group markets) for a benefit year even if the fully insured major medical plans for which reinsurance contributions are required enroll different covered lives. If a health insurance issuer has multiple major medical plans covering different lives in different States, the issuer may use different counting methods for all major medical plans in each State (including both the individual and group markets). We note that this consistency requirement, if finalized as proposed, would be required for the 2015 and 2016 benefit years. As noted

in an FAQ issued on October 21, 2014,¹¹ we also encourage this approach for the 2014 benefit year. This proposal would not prevent an issuer from using different counting methods for different benefit years. We do not propose a similar requirement for self-insured group health plans because we believe in many instances, a plan sponsor's multiple group health plans may be administered by different entities, making uniformity of counting method potentially more difficult. We seek comment on this proposal, including with respect to whether such uniformity of counting method is more difficult for self-insured group health plans.

f. Snapshot Count and Snapshot Factor Counting Methods (§§ 153.405(d)(2) and (e)(2))

Under § 153.400(a)(1), reinsurance contributions are generally required for major medical coverage that is considered to be part of a commercial book of business, but contributions are not required to be paid more than once with respect to the same covered life. Reinsurance contributions are generally calculated based on the number of covered lives covered by a plan or coverage that provides major medical coverage. The reinsurance contribution required from a contributing entity is calculated by multiplying the number of covered lives (determined under a permitted counting method set forth in § 153.405(d) through § 153.405(g)) during the applicable calendar year for all applicable plans and coverage of the contributing entity by the applicable contribution rate for the respective benefit year.

We seek to clarify how two of the counting methods set forth in §§ 153.405(d)(2) and (e)(2) are to be used in those situations when a plan terminates or is established in the middle of a quarter to effectuate the principle that contributions are required to be paid once with respect to the same covered life. Under the snapshot count method, described at § 153.405(d)(2), to determine the number of covered lives for the purposes of reinsurance contributions, the issuer or self-insured group health plan must add the total number of lives covered on any date (or more dates, if an equal number of dates are used for each quarter) during the same corresponding month in each of the first 3 quarters of the benefit year, and divide that total by the number of dates on which a count was made. Under the snapshot factor method, described at § 153.405(e)(2), to

determine the number of covered lives for the purposes of reinsurance contributions, the self-insured group health plan must add the total number of lives covered on any date (or more dates, if an equal number of dates are used for each quarter) during the same corresponding month in each of the first 3 quarters of the benefit year (provided that the date used for the second and third quarters must fall within the same week of the quarter as the corresponding date used for the first quarter), and divide that total by the number of dates on which a count was made, except that the number of lives covered on a date is calculated by adding the number of participants with self-only coverage on the date to the product of the number of participants with coverage other than self-only coverage on the date and a factor of 2.35. For each of these counting methods, the same months must be used for each quarter (for example, January, April, July), and the date used for the second and third quarter must fall within the same week of the quarter as the corresponding date used for the first quarter.

We understand that a health insurance plan or coverage may be established, terminated, or change funding mechanisms (that is, from fully insured to self-insured or self-insured to fully insured), in the middle of a quarter. In these circumstances, it is possible that the new plan or coverage would not have covered lives enrolled in the plan or coverage for the entire quarter. If this occurs, a contributing entity could, due to its selection of dates, be required to pay an amount significantly greater or lesser than the amount that would be due based on its average count of covered lives over the course of the 9-month counting period. To avoid this result, we clarify that, if the plan or coverage in question had enrollees on any day during a quarter and if the contributing entity elects to (and is permitted to) use either the snapshot count or snapshot factor method, it must choose a set of counting dates for the 9-month counting period such that the plan or coverage has enrollees on each of the dates, if possible. However, the enrollment count for a date during a quarter in which the plan or coverage was in existence for only part of the quarter can be reduced by a factor reflecting the amount of time during the quarter for which the plan or coverage was not in existence. This approach is intended to accurately capture the amount of time during the quarter for which major medical coverage that is part of a commercial book of business and subject to

¹¹ Available at: <https://www.regtagp.info/>, FAQ #6037.

reinsurance contributions was provided to enrollees, while not requiring contributions to be paid more than once with respect to the same covered life. For example, a contributing entity that has a plan that terminates on August 31st (that is, 62 days into the third quarter) would not be permitted to use September 1st as the date for the third quarter under the snapshot count or snapshot factor methods because this would not properly reflect the number of covered lives of reinsurance contribution enrollees under the plan in the third quarter of the benefit year. However, it would be entitled to reduce its count of covered lives during that quarter by 30/92, the proportion of the quarter during which the plan had no enrollment. This reduction factor would only be applicable for the snapshot count and snapshot factor methods set

forth in §§ 153.405(d)(2) and (e)(2), respectively, as all of the other permitted counting methods automatically account for partial year enrollment.

g. Uniform Reinsurance Contribution Rate for 2016

Section 153.220(c) provides that HHS is to publish in the annual HHS notice of benefit and payment parameters the uniform reinsurance contribution rate for the upcoming benefit year. Section 1341(b)(3)(B)(iii) of the Affordable Care Act specifies that \$10 billion for reinsurance contributions are to be collected from contributing entities 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 2014, 2015, and 2016 benefit years under the uniform reinsurance contribution rate.

As discussed in the 2014 and 2015 Payment Notices, each year, the uniform reinsurance contribution rate will be calculated by dividing the sum of the three amounts (the reinsurance payment pool, the U.S. Treasury contribution, and administrative costs) by the estimated number of enrollees in plans that must make reinsurance contributions:

Uniform Reinsurance Contribution Rate

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

As discussed in greater detail below, we are proposing to collect \$32 million for administrative expenses for the 2016 benefit year. Therefore, the total amount to be collected would be approximately \$5.032 billion. Our estimate of the number of enrollees in plans that must make reinsurance contributions yields an annual per capita contribution rate of \$27 for the 2016 benefit year.

(1) Allocation of Uniform Reinsurance Contribution Rate

Section 153.220(c) provides that HHS is to establish in the annual HHS notice of benefit and payment parameters for the applicable benefit year the proportion of contributions collected under the uniform reinsurance contribution rate to be allocated to reinsurance payments, payments to the U.S. Treasury, and administrative expenses. In the 2014 and 2015 Payment Notices, we stated that reinsurance contributions collected for the 2014 and 2015 benefit years would be allocated pro rata to the reinsurance payment pool, administrative expenses, and the U.S. Treasury, up to \$12.02 billion for 2014 and up to \$8.025 billion for 2015. However, we amended this approach in the 2015 Market Standards Rule,¹² such that, if reinsurance collections fall short of our estimates for a particular benefit year, we will allocate reinsurance

contributions collected first to the reinsurance payment pool, with any remaining amounts being then allocated to the U.S. Treasury and administrative expenses, on a pro rata basis. We propose to follow a similar approach for the 2016 benefit year, such that if reinsurance contributions fall short of our estimates, contributions collected will first be allocated to the reinsurance payment pool, with any remaining allocated on a pro rata basis to administrative expenses and payments to the U.S. Treasury. We note that consistent with the statement in the 2015 Payment Notice (79 FR 13777), if we collect more than the statutorily required amount in the 2016 benefit year we propose to use any excess contributions for reinsurance payments for the current benefit year by increasing the coinsurance rate for the 2016 benefit year up to 100 percent before rolling over any remaining funds to the next year. Additionally, we anticipate expending all reinsurance contributions collected for the 2016 benefit year for 2016 requests for reinsurance payments rather than reserving any of the excess funds rolled over or collected for the 2016 benefit year in future years. However, because allowing excess funds to roll over for the 2017 benefit year could help stabilize 2017 premiums, we seek comment on rolling over any

excess funds to the 2017 benefit year as an alternative to this approach.

(2) Administrative Expenses

In the 2015 Payment Notice, we estimated that the Federal administrative expenses of operating the reinsurance program would be \$25.4 million, based on our estimated contract and operational costs. We propose to use the same methodology to estimate the administrative expenses for the 2016 benefit year. These estimated costs would cover the costs related to contracts for developing the uniform reinsurance payment parameters and the uniform reinsurance contribution rate, collecting reinsurance contributions, making reinsurance payments, and conducting account management, data collection, program integrity and audit functions, operational and fraud analytics, training for entities involved in the reinsurance program, and general operational support. To calculate our proposed reinsurance administrative expenses for 2016, we divided HHS's projected total costs for administering the reinsurance programs on behalf of States by the expected number of covered lives for which reinsurance contributions are to be made for 2016.

We estimate this amount to be approximately \$32 million for the 2016 benefit year. This estimate increased for the 2016 benefit year due to increased

¹² 79 FR 20557–59.

audit and data validation contract costs. We believe that this amount reflects the Federal government’s significant economies of scale, which helps to decrease the costs associated with operating the reinsurance program. Based on our estimate of covered lives for which reinsurance contributions are to be made for 2016, we are proposing a uniform reinsurance contribution rate of \$0.17 annually per capita for HHS administrative expenses. We provide details below on the methodology we

used to develop the 2016 enrollment estimates.

Similar to the allocation for 2015, for the 2016 benefit year, we allocated the administrative expenses equally between contribution and payment-related activities. Because we anticipate that our additional activities in the 2016 benefit year, including our program integrity and audit activities, will also be divided approximately equally between contribution and payment-related activities, we again propose to allocate the total administrative

expenses equally between these two functions. Therefore, as shown in Table 9, we expect to apportion the annual per capita amount of \$0.17 of administrative expenses as follows: (a) \$0.085 of the total amount collected per capita for administrative expenses for the collection of contributions from contributing entities; and (b) \$0.085 of the total amount collected per capita for administrative expenses for reinsurance payment activities, supporting the administration of payments to issuers of reinsurance-eligible plans.

TABLE 9—BREAKDOWN OF ADMINISTRATIVE EXPENSES

[Annual, per capita]

Activities	Estimated expenses
Collecting reinsurance contributions from health insurance issuers and certain self-insured group health plans	\$0.085
Calculation and disbursement of reinsurance payments	0.085
Total annual per capita expenses for HHS to perform all reinsurance functions	0.17

If HHS operates the reinsurance program on behalf of a State, HHS would retain the annual per capita fee to fund HHS’s performance of all reinsurance functions, which would be \$0.17. If a State establishes its own reinsurance program, HHS would transfer \$0.085 of the per capita administrative fee to the State for purposes of administrative expenses incurred in making reinsurance payments, and retain the remaining \$0.085 to offset HHS’s costs of collecting contributions. We note that the administrative expenses for reinsurance payments will be distributed to those States that operate their own reinsurance program in proportion to the State-by-State total requests for reinsurance payments made under the uniform reinsurance payment parameters.

h. Uniform Reinsurance Payment Parameters for 2016

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 minimizing interference with 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 2016 benefit year, we are proposing that the uniform reinsurance payment parameters for the 2016 benefit year be established at an attachment point of \$90,000, a reinsurance cap of \$250,000, and a coinsurance rate of 50 percent. We estimate that these uniform reinsurance payment parameters will result in total requests for reinsurance payments of approximately \$4 billion for the 2016 benefit year. We believe setting the coinsurance rate at 50 percent and increasing the attachment point allows for the reinsurance program to help pay for nearly the same group of high-cost enrollees as was the case for the 2014 and 2015 benefit years, while still encouraging issuers to contain costs. We believe that maintaining the reinsurance cap for the 2016 benefit year while ensuring that the coinsurance rate sufficiently compensates issuers for high-risk individuals will make it easier for issuers to estimate the effects of reinsurance. 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 seek comment on this proposal.

As discussed in the 2014 and 2015 Payment Notices, to assist with the development of the uniform reinsurance payment parameters and the premium adjustment percentage index, HHS developed the Affordable Care Act Health Insurance Model (ACA-HIM). The ACA-HIM generates a range of national and State-level outputs for 2016, using updated assumptions reflecting more recent data, but using the same methodology described in the 2014 and 2015 Payment Notices.¹³

Specifically, the ACA-HIM uses the Health Intelligence Company, LLC (HIC) database from calendar year 2010, with the claims data trended to 2016 to estimate total medical expenditures per enrollee by age, gender, and area of residence. The expenditure distributions are further adjusted to take into account plan benefit design, or “metal” level (that is, “level of coverage,” as defined in § 156.20) and other characteristics of individual insurance coverage in an Exchange. To describe a State’s coverage market, the ACA-HIM computes the pattern of enrollment using the model’s predicted number and composition of participants in a coverage market. These estimated

¹³ See the proposed 2014 Payment Notice (77 FR 73160) and the proposed 2015 Payment Notice (78 FR 72344) for more information on the ACA-HIM methodology.

expenditure distributions were the basis for the uniform reinsurance payment parameters.

i. Uniform Reinsurance Payment Parameters for 2015

In the 2015 Market Standards Rule,¹⁴ we stated that we intended to propose to lower the 2015 attachment point from \$70,000 to \$45,000 for the 2015 benefit year. We believe that lowering the attachment point to \$45,000 would allow the reinsurance program to make more payments for high-cost enrollees in individual market reinsurance-eligible plans without increasing the contribution rate. We do not propose to adjust the 2015 coinsurance rate of 50 percent or reinsurance cap of \$250,000. We seek comment on this proposal.

j. Deducting Cost-Sharing Reduction Amounts From Reinsurance Payments

We propose to modify the methodology finalized in the 2015 Payment Notice (79 FR 13780) regarding the deduction of cost-sharing reduction amounts from reinsurance payments. Under § 156.410, if an individual is determined eligible to enroll in an individual market Exchange QHP and elects to do so, the QHP issuer must assign the individual to a standard plan or cost-sharing plan variation based on the enrollment and eligibility information submitted by the Exchange. Issuers of individual market Exchange QHPs will receive cost-sharing reduction payments for enrollees that have effectuated coverage in cost-sharing plan variations. To avoid double payment by the Federal government, we indicated in the 2014 Payment Notice (78 FR 15499) that the enrollee-level claims data submitted by an issuer of a reinsurance-eligible plan should be net of cost-sharing reductions provided through a cost-sharing plan variation (which are reimbursed by the Federal government).

In the 2015 Payment Notice (79 FR 13780), we explained the methodology HHS will use to deduct the amount of cost-sharing reductions paid on behalf of an enrollee enrolled in a QHP in an individual market through an Exchange. For each enrollee enrolled in a QHP plan variation,¹⁵ we will subtract from the QHP issuer's total plan paid amounts for the enrollee in a reinsurance-eligible plan the difference between the annual limitation on cost sharing for the standard plan and the annual limitation on cost sharing for the

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

We also stated that for an enrollee who is assigned to different plan variations during the benefit year, we would calculate the adjustment for cost-sharing reductions based on the annual limitation on cost sharing applicable to the plan variation in which the enrollee was last enrolled during the benefit year, because cost sharing accumulates over the benefit year across plan variations of the same standard plan.

We are proposing to modify this policy; we propose that if an enrollee is assigned to different plan variations during the benefit year, we would calculate the adjustment for cost-sharing reductions based on the difference between the annual limitation on cost sharing for the standard plan and the average annual limitation on cost sharing in the plan variations (including any standard plan), weighted by the number of months the enrollee is enrolled in each plan variation during the benefit year. This approach will also permit us to allocate the difference in annual limitations in a family policy to individual family members when a member exits or enters the policy mid-year, or if there are other changes in circumstances that impact the cost-sharing reductions provided to enrollees covered by the family policy. We are not proposing any changes to the approach finalized in the 2015 Payment Notice with respect to the QHP issuer's plan paid amounts for purposes of calculating reinsurance payments for an Indian in a limited cost-sharing plan variation. We seek comment on this proposed modification, as well as alternative approaches to deducting CSR amounts from reinsurance payments.

4. Provisions for the Temporary Risk Corridors Program

a. Application of the Transitional Policy Adjustment in Early Renewal States

On November 14, 2013, the Federal government announced a transitional policy under which it will not consider certain health insurance coverage in the individual or small group markets that is renewed for a policy year starting after January 1, 2014, under certain conditions to be out of compliance with specified 2014 market rules, and requested that States adopt a similar

non-enforcement policy.¹⁶ HHS extended this transitional policy on March 5, 2014, permitting issuers to renew transitional policies through policy years beginning on or before October 1, 2016.¹⁷ In the 2015 Payment Notice, HHS implemented an adjustment to the risk corridors formula for the 2014 benefit year to help further mitigate any unexpected losses attributable to the effects of the transitional policy for QHP issuers in a State that adopts the transitional policy. Under § 153.500, we will effectuate this adjustment to the risk corridors formula 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) to help offset losses that might occur under the transitional policy as a result of increased claims costs not accounted for when setting 2014 premiums. Because we believe that the Statewide effect on this risk pool would increase with an increase in the percentage enrollment in transitional plans in the State, we stated that we would vary the State-specific percentage adjustment to the risk corridors formula with the percentage of member-months enrollment in these transitional plans in the State.¹⁸

In response to stakeholder questions, we propose to clarify that the transitional adjustment applies only with respect to plans under the transitional policy—that is, plans that renew after January 1, 2014 for which HHS and the applicable State are not enforcing market rules. We would further clarify that member-months of enrollees in early renewal plans will not be counted towards the risk corridors transitional policy adjustment (that is, unless and until the plan becomes a transitional plan in a transitional State upon renewal in 2014).¹⁹ We believe

¹⁶ Letter to Insurance Commissioners, Center for Consumer Information and Insurance Oversight, November 14, 2013. Available at: <http://www.cms.gov/CCIIO/Resources/Letters/Downloads/commissioner-letter-11-14-2013.PDF>.

¹⁷ Insurance Standards Bulletin Series—Extension of Transitional Policy through October 1, 2016. Center for Consumer Information and Insurance Oversight, March 5, 2014. Available at: <http://www.cms.gov/CCIIO/Resources/Letters/Downloads/commissioner-letter-11-14-2013.PDF>.

¹⁸ As stated in the 2015 Payment Notice, HHS will calculate the amount of the adjustment that applies to each State based on the State's member-month enrollment count for transitional plans and non-transitional plans in the individual and small group markets.

¹⁹ Title 45 Part 153, Section 530 of the Code of Federal Regulations (CFR) sets forth the data requirements for this information collection. A notice was published in the **Federal Register** on September 5, 2014, providing the public with a 60-

¹⁴ 79 FR 30259.

¹⁵ Except for limited cost-sharing plan variations, for which we stated we would not reduce the QHP issuer's plan paid amounts.

that this approach for counting member months towards the risk corridors transitional adjustment is consistent with the intent of the transitional policy adjustment set forth in the 2015 Payment Notice because issuers could have been able to account for the risk of early renewals in their 2014 rate setting. We request comment on this approach.

b. Risk Corridors Payments for 2016

To provide greater clarity on how risk corridors payments will be made, we issued a bulletin on April 11, 2014, titled "Risk Corridors and Budget Neutrality," which described how we intend to administer risk corridors in a budget neutral way over the 3-year life of the program.²⁰ Specifically, we stated that if risk corridors collections in the first or second year are insufficient to make risk corridors payments as prescribed by the regulations, risk corridors collections received for the next year will first be used to pay off the payment reductions issuers experienced in the previous year in a proportional manner, up to the point where issuers are reimbursed in full for the previous year, and remaining funds will then be used to fund current year payments. If any risk corridors funds remain after prior and current year payment obligations have been met, we stated that they will be held to offset potential insufficiencies in risk corridors collections in the next year. Our April 11, 2014 bulletin stated that we would establish in future guidance how we would calculate risk corridors payments in the event that cumulative risk corridors collections do not equal cumulative risk corridors payment requests.

We now propose that if, for the 2016 benefit year, cumulative risk corridors collections exceed cumulative risk corridors payment requests, we would make an adjustment to our administrative expense definitions (that is, the profit margin floor and the ceiling for allowable administrative costs) to account for the excess funds. That is to say, if, when the risk corridors program concludes, cumulative risk corridors collections exceed both 2016 payment requests under the risk corridors formula and any unpaid risk corridors amounts from previous years,²¹ we

would increase the administrative cost ceiling and the profit floor in the risk corridors formula by a percentage calculated to pay out all collections to QHP issuers. The administrative cost ceiling and the profit floor would be adjusted by the same percentage.

We propose to determine the percentage adjustment to the administrative cost ceiling and profit margin floor by evaluating the amount of excess risk corridors collections (if any) available after risk corridors payments for benefit year 2016 have been calculated. As stated in our bulletin on risk corridors budget neutrality, after receiving charges from issuers for the 2016 benefit year, we would first prioritize payments to any unpaid risk corridors payments remaining from the 2015 benefit year. We would then calculate benefit year 2016 risk corridors payments for eligible issuers based on the 3 percent profit floor and 20 percent allowable administrative cost ceiling, as required by regulation. If, after making 2015 payments and calculating (but not paying) risk corridors payments for benefit year 2016, we determine that the aggregate amount of collections (including any amounts collected for 2016 and any amounts remaining from benefit years 2014 and 2015) exceed what is needed to make 2016 risk corridors payments, we would implement an adjustment to the profit floor and administrative cost ceiling to increase risk corridors payments for eligible issuers for benefit year 2016. We would examine data that issuers have submitted for calculation of their 2016 risk corridors ratios (that is, allowable costs and target amount) and determine, based on the amount of collections available, what percentage increase to the administrative cost ceiling and profit floor could be implemented for eligible issuers while maintaining budget neutrality for the program overall. Although all eligible issuers would receive the same percentage adjustment, the amount of additional payment made to each issuer would vary based on the issuer's allowable costs and target amount. Once HHS has calculated the adjustment and applied it to eligible issuers' risk corridors formulas, it would make a single risk corridors payment for benefit year 2016 that would include any additional, adjusted payment amount.

Because risk corridors collections are a user fee to be used to fund premium

in 2014 or 2015, requests for risk corridors payments exceed risk corridors collections, we would reduce risk corridors payments pro rata, but would make up those deficiencies to the extent collections exceed payment requests in later years.

stabilization under risk corridors and because we intend to implement the risk corridors program in a budget neutral manner, we propose to limit this adjustment to excess amounts collected. We propose to apply this adjustment to allowable administrative costs and profits for the 2016 benefit year only to plans whose allowable costs (as defined at § 153.500) are at least 80 percent of their after-tax premiums, because issuers under this threshold would generally be required to pay out MLR rebates to consumers.²² In the past, we have sought to align the definitions we use for the risk corridors program, including those of "allowable administrative costs" and "profits," with the manner in which these concepts are treated in the MLR program, to ensure that the programs are consistent in their effects. 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. Furthermore, we propose that, to the extent that applying the proposed adjustment to a plan could increase its risk corridors payment and affect its MLR calculation, the MLR calculation will ignore these adjustments. This is consistent with our previous policy with respect to the adjustments to these definitions for 2014 and 2015 in the 2015 Payment Notice and the 2015 Market Standards Rule. We request comment on this approach.

As previously stated, we anticipate that risk corridors collections will be sufficient to pay for all risk corridors payments. HHS recognizes that the Affordable Care Act requires the Secretary to make full payments to issuers. In the unlikely event that risk corridors collections, including any potential carryover from the prior years, are insufficient to make risk corridors payments for the 2016 program year, HHS will use other sources of funding for the risk corridors payments, subject to the availability of appropriations.

²² Because of some differences in the MLR numerator and the definition of allowable costs that applies with respect to the risk corridors formula, in a small number of cases, an issuer with allowable costs that are at least 80 percent of after-tax premium, may be required to pay MLR rebates to consumers.

day period to submit written comments on the information collection requirement associated with the Transitional Adjustment Reporting form.

²⁰ The Centers for Medicare and Medicaid Services, Center for Consumer Information and Insurance Oversight. "Risk Corridors and Budget Neutrality". April 11, 2014. Available at: <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/fq-risk-corridors-04-11-2014.pdf>.

²¹ In our bulletin on "Risk Corridors and Budget Neutrality" dated April 11, 2014, we stated that if,

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

a. Good Faith Safe Harbor (§ 153.740(a))

In the second Program Integrity rule,²³ HHS finalized a good faith safe harbor policy which provided that civil money penalties (CMPs) will not be imposed for non-compliance with the HHS-operated risk adjustment and reinsurance data requirements during 2014, if the issuer has made good faith efforts to comply with these requirements.²⁴ That safe harbor parallels a similar safe harbor for QHP issuers in FFEs under § 156.800.

We propose to amend § 153.740(a) to extend the safe harbor for non-compliance with the HHS-operated risk adjustment and reinsurance data requirements during the 2015 calendar year if the issuer has made good faith efforts to comply with these requirements. This proposal acknowledges that the distributed data collection requirements have been the subject of modifications through the 2014 calendar year, including the introduction of cloud-based virtual options for the distributed data environments. We note that good faith efforts could include notifying, communicating with, and cooperating with HHS with respect to issues that arise with the establishment and provisioning of the issuers' dedicated distributed data environment.

The extension of this good faith safe harbor will not affect HHS's ability to assess issuers of risk adjustment covered plans a default risk adjustment charge under § 153.740(b).²⁵ Additionally, we

note that the good faith safe harbor does not apply to non-compliance with dedicated distributed data environment standards applicable during 2016, even if the non-compliance in the 2016 calendar year relates to data for the 2015 benefit year. Issuers of risk adjustment covered plans and reinsurance-eligible plans must establish dedicated distributed data environments in 2014 and begin loading data according to a quarterly schedule provided by HHS. The good faith safe harbor would apply, for example, to noncompliance with the 2015 benefit year schedule for loading data to the dedicated distributed data environment during the 2015 calendar year. However, the data loading schedule applicable to the 2015 benefit year for risk adjustment and reinsurance data extends into the 2016 calendar year (the final loading deadline is April 30, 2016, which will enable HHS to calculate risk adjustment payments and charges and reinsurance payments for the 2015 benefit year by June 30, 2016). The good faith safe harbor would not extend to non-compliance with any 2016 calendar year obligations, even if those 2016 obligations apply for 2015 benefit year data. We seek comment on this proposal.

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

In the second Program Integrity Rule and the 2015 Payment Notice, HHS indicated that a default risk adjustment charge will be assessed if an issuer does not establish a dedicated distributed data environment or submits inadequate risk adjustment data. However, we did not establish how the money collected

from the default charge will be allocated among risk adjustment covered plans.

We are proposing to allocate collected per member per month default charge funds proportional to each plan's relative revenue requirement, the product of $PLRS_i \cdot IDF_i \cdot GCF_i$ (Plan Liability Risk Score * Induced Demand Factor * Geographic Cost Factor) relative to the market average of these products, across all risk adjustment covered plans in the market in the State. This approach would allocate funds proportionally to a plan's enrollment, adjusted for factors such as health risk, actuarial value, and geographic cost differences. This approach would also allocate the default charge funds in accordance with plans' expected revenue requirements as calculated in the transfer formula. By contrast, an approach that allocates risk adjustment default charge funds in accordance with enrollment or premiums, for example, would favor plans with lower metal levels, low risk selection, or lower geographic costs.

This allocation would occur only in risk adjustment markets with at least one noncompliant plan, and these steps would be used to calculate each compliant plan's allocation of the default charges collected from the noncompliant plan(s). We would calculate risk transfers among the compliant plans only and exclude all data from noncompliant plans. Using the same inputs of the compliant plans as used in the transfer formula, we would calculate the distribution of default charges paid by noncompliant plans among the compliant plans using the following formula:

$$DC_i = \text{total default charges collected} \times s_i \left[\frac{PLRS_i \cdot IDF_i \cdot GCF_i}{\sum (s_i \cdot PLRS_i \cdot IDF_i \cdot GCF_i)} \right]$$

Where:

DC_i is the total amount of default charges allocated to plan i ;

"Total default charges collected" is the sum, in dollars, collected from all noncompliant plans (aggregate dollars, that is, *not* on a per member per month basis); Other terms are as defined in the usual risk transfer calculations, and restricted to compliant plans only (s_i = plan i 's share of State enrollment; $PLRS_i$ = plan i 's plan liability risk score,

IDF_i = plan i 's induced demand factor, GCF_i = plan i 's geographic cost factor); and

i indexes compliant plans, and the summation in the denominator is over compliant plans only.

We seek comment on this approach.

c. Information Sharing (§ 153.740(c))

In § 153.740, we established the enforcement remedies available to HHS

for an issuer of a risk adjustment covered plan or a reinsurance-eligible plan's failure to comply with HHS-operated risk adjustment and reinsurance data requirements. Consistent with the policy set forth at § 156.800(d), as finalized in the 2015 Market Standards Rule,²⁶ we propose adding paragraph (c) to clarify that HHS may consult and share information about issuers of a risk adjustment

²³ Patient Protection and Affordable Care Act; Program Integrity: Exchange, Premium Stabilization Programs and Market Standards, 78 FR 65046 (October 30, 2013).

²⁴ We note that HHS also clarified in a March 28, 2014 FAQ that CMPs would not be imposed on an issuer for non-compliance during the 2014 calendar year, if the issuer made good efforts to comply with

these requirements. See, FAQ 1212, published March 28, 2014. https://www.regtap.info/faq_viewu.php?id=1212.

²⁵ According to 45 CFR 153.740(b), "If an issuer of a risk adjustment covered plan fails to establish a dedicated distributed data environment or fails to provide HHS with access to the required data in such environment in accordance with § 153.610(a),

§ 153.700, § 153.710, or § 153.730 such that HHS cannot apply the applicable Federally certified risk adjustment methodology to calculate the risk adjustment payment transfer amount for the risk adjustment covered plan in a timely fashion, HHS will assess a default risk adjustment charge."

²⁶ 79 FR 30240.

covered plan or a reinsurance-eligible plan with other Federal and State regulatory and enforcement entities to the extent that the consultation and information is necessary for HHS to determine whether an enforcement remedy against the issuer of the risk adjustment covered plan or reinsurance-eligible plan under § 153.740 is appropriate. For example, HHS may consult other Federal and State regulatory and enforcement entities to identify issuers within a State who have failed to establish a dedicated distributed data environment. No personally identifiable information would be transferred as part of such a consultation. We seek comment on this proposal.

F. Part 154—Health Insurance Issuer Rate Increases: Disclosure and Review Requirements

1. General Provisions

This section includes proposals related to the rate review program under part 154. Unless otherwise specified, the amendments in this part would apply beginning with rates filed during the 2015 calendar year for coverage effective on or after January 1, 2016. We seek comment on whether the proposal provides States and issuers sufficient time to transition to the new rate review timeframe.

a. Definitions (§ 154.102)

Section 154.102 sets forth definitions used for purposes of the rate review provisions in part 154. In this proposed rule, we propose to add a definition “plan” and to amend the definitions of “individual market,” “small group market,” “rate increase” and “State.” We propose that these definitions would become effective for rate filings submitted during the 2015 calendar year for coverage effective January 1, 2016.

We propose that the term “plan” have the meaning given the term in § 144.103. For a discussion of the proposed amendments related to the term “plan,” see section III.A.1.a of this preamble.

We propose amending the terms “individual market” and “small group market” to also have the meaning given such terms in § 144.103. Under that section, the term “individual market” means the market for health insurance coverage offered to individuals other than in connection with a group health plan. The term “small group market” means the health insurance market under which individuals obtain health insurance coverage (directly or through any arrangement) on behalf of themselves (and their dependents) through a group health plan maintained

by a small employer. By incorporating the definition of small group market in § 144.103, we are also incorporating the definition of small employer in § 144.103. We are also incorporating all aspects of the individual market and small group market definitions as described in § 144.102, including § 144.102(c), with respect to coverage provided through associations. These proposed changes will more fully harmonize the applicability of the rate review provisions with the rating reforms under the Affordable Care Act, including the premium rating and single risk requirements.

We propose amending the term “rate increase” to mean any increase of the rates for a specific product or plan within a product offered in the individual or small group market. This change is for consistency with our proposal in § 154.200, discussed below, to require the consideration of rate increases at the plan level as opposed to the product level when determining whether a rate increase is subject to review.

We lastly propose amending the definition of “State” to exclude the U.S. territories of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands. The change reflects HHS’s determination, described in more detail in section III.A.1.b of this preamble, that certain provisions of the PHS Act enacted in title I of the Affordable Care Act that apply to health insurance issuers are appropriately governed by the definition of “State” set forth in that title. This proposed amendment would codify the approach that the rate review provisions (section 2794 of the PHS Act) do not apply to health insurance issuers in the U.S. territories.²⁷

2. Disclosure and Review Provisions

a. Rate Increases Subject to Review (§ 154.200)

In § 154.200, we propose to make technical corrections to the text of paragraphs (a)(1) and (2) to clarify that rate increases are applicable to a 12-month period that begins on January 1 rather than September 1 as currently specified in those paragraphs. The proposed corrections are necessary to align the text of the rate review regulation with rate effective dates under § 156.80, which requires a single risk pool index rate to be established and effective for a State market by January 1 of each calendar year.

²⁷ See e.g., Letter to Virgin Islands on the Definition of State (July 16, 2014). Available at: <http://www.cms.gov/CCIIO/Resources/Letters/Downloads/letter-to-Francis.pdf>.

In paragraph (c), we propose to modify the standard for determining whether a rate increase is subject to review. Under the current regulations, a rate increase in the individual or small group market is subject to review if the rate increase is 10 percent or more, or the increase meets or exceeds an applicable State-specific threshold established in accordance with § 154.200. The percent increase is calculated as the average increase for all enrollees with coverage under the product weighted by premium volume.

We propose to amend paragraph (c) to require the consideration of rate increases at the plan level (as that term is proposed to be defined in § 154.102) as opposed to the product level when determining whether the increase is subject to review. Under this approach, if an increase in the plan-adjusted index rate (as described in the single risk pool provision at § 156.80) for any plan within a product in the individual or small group market meets or exceeds the applicable threshold, the product (including all plans within the product) would be subject to review to determine whether the rate increase is unreasonable. The rate increase would trigger review even if the average increase for the product itself did not meet or exceed the applicable threshold.

We believe considering the impact of rate increases at the plan level is the appropriate level of aggregation when determining whether an increase is subject to review, because consumers are affected by rate increases at the plan level. This approach would ensure that all rate increases at or above the specified threshold in the individual or small group market are reviewed by the applicable State or CMS to determine whether the rate increase is unreasonable. This will further help protect consumers against unreasonable rate increases, eliminating the possibility that a plan could experience a significant rate increase and still avoid review because the average increase for the product does not meet or exceed the applicable threshold.

We seek comment on this proposal, including on the benefits and costs to States of carrying out the plan-level trigger for review.

b. Submission of Rate Filing Justification (§ 154.215)

Under § 154.215, health insurance issuers are required to submit a Rate Filing Justification for all products in the issuer’s single risk pool, on a form and in a manner prescribed by the Secretary, when any product in the individual or small group market is subject to a rate increase. This

requirement was finalized in the 2014 Market Rules to carry out the Secretary's responsibility, in conjunction with the States, under PHS Act section 2794(b)(2)(A) to monitor premium increases of health insurance coverage offered through an Exchange and outside of an Exchange beginning in 2014.

We explained in the preamble to the 2014 Market Rules this provision requires the completion of a Rate Filing Justification for all proposed rate increases, whether or not the rate increase meets or exceeds the subject to review threshold (78 FR 13420). To better reflect the intent of this requirement, we are proposing to modify the text of paragraph (a) of § 154.215 to expressly state that "all" proposed rate increases includes a rate increase with respect to "any plan within a product" in the individual or small group market that is subject to a rate increase. This clarification would become effective with the effective date of the final rule.

c. Timing of Providing the Rate Filing Justification (§ 154.220)

Section 154.220 provides that if a State requires a proposed rate increase to be filed with the State prior to implementation of the increase, the health insurance issuer must send CMS and the applicable State the Rate Filing Justification on the date the issuer submits the proposed rate increase to the State. For all other States, the health insurance issuer must send CMS and the applicable State the Rate Filing Justification prior to the implementation of the rate increase.

There is currently wide variation in State submission timelines and practices for reviewing proposed rate increases. Some States require that all rates must be filed at the same time. Others require rate filings after the date the QHP submissions are required to be made, creating a situation in which QHPs must file rates before non-QHPs. Some States have not adopted specific rate filing timeframes but instead rely on "file and use" laws, which provide that a rate (or rate increase) may go into effect as soon as it is filed with the State. Others prohibit posting of final rates until the date that the coverage begins.

We propose to modify § 154.220 to establish a uniform timeline by which health insurance issuers must submit a completed Rate Filing Justification to CMS and, when applicable, to the State. We propose that a health insurance issuer must submit the Rate Filing Justification by the earlier of the following: (1) The date by which the State requires that a proposed rate

increase be filed with the State; or (2) the date specified by the Secretary in guidance. We are considering specifying in future guidance a deadline to coincide with the end of the QHP application window for the FFE for issuers to complete and submit the Rate Filing Justification for proposed rate increases in the individual and small group markets for both QHPs and non-QHPs. We seek comments on this date.

The proposed approach would assure that all rate increases in every relevant State market for both QHPs and non-QHPs are filed by a consistent time each year. This would improve predictability and transparency, reduce the opportunity for anti-competitive behavior, and establish a more meaningful opportunity for consumers and other stakeholders to comment on proposed rate increases before rates are finalized. It would also ensure that State and Federal regulators have adequate time for review prior to implementation of a rate increase. We note that States would have flexibility to impose earlier rate filing deadlines to meet their specific State needs.

We seek comment on all aspects of this proposal.

d. CMS's Determinations of Effective Rate Review Programs (§ 154.301)

Section 154.301 sets forth criteria for evaluating whether a State has an Effective Rate Review Program in the individual and small group markets. If a State meets the criteria to have an Effective Rate Review Program, CMS adopts the State's determination as to whether a rate increase that is subject to review is unreasonable. If a State does not meet the criteria to have an Effective Rate Review Program, then CMS conducts the review and makes a determination about whether a rate increase is unreasonable.

We propose to amend § 154.301(b) to specify the timeframe and manner for a State with an Effective Rate Review Program to provide public access to information about proposed and final rate increases if the State elects to make such information available to the public.

In paragraph (b)(1)(i), we propose that, for proposed rate increases subject to review, the State must provide access from its Web site to at least the information contained in Parts I, II, and III of the Rate Filing Justification that CMS makes available on its Web site (or provide CMS's web address for such information) and have a mechanism for receiving public comments on those proposed rate increases.²⁸ If a State

elects to post information about proposed rate increases on its Web site, the information would be required to be posted no later than the date specified by the Secretary in guidance. We are considering specifying in future guidance a deadline of 10 business days after receipt of all rate filings in the relevant State market for information to be posted about proposed rate increases that are subject to review. We seek comment on this proposed deadline.

In paragraph (b)(1)(ii), we propose that, for all final rate increases, the State must provide access from its Web site to at least the information contained in Parts I, II, and III of the Rate Filing Justification that CMS makes available on its Web site (or provide CMS's web address for such information). This would include information about rate increases that both meet or exceed the review threshold and those not subject to review. The information would be required to be posted no later than the first day of the annual open enrollment period. States could make additional information available to the public or make the information available earlier than this deadline at their option. We seek comment on this proposed deadline.

In paragraph (b)(2), we propose that if a State intends to make the information about proposed rate increases in paragraph (b)(1)(i) available to the public prior to the date specified by the Secretary, or if it intends to make the information about final rate increases in paragraph (b)(1)(ii) available to the public prior to the first day of the annual open enrollment period, the State must notify CMS in writing, no later than 30 days prior to the date it intends to make the information public, of its intent to do so and the date it intends to make the information public. This information will enable CMS to better coordinate and manage public expectations regarding the availability of the rate information, increasing transparency nationally into the rate-setting process.

Finally, we propose in paragraph (b)(3) that the State must ensure the information it posts on its Web site under proposed paragraphs (b)(1)(i) and (b)(1)(ii) (or in addition to the information required under those paragraphs) is made available to the public at a uniform time for all proposed or final rate increases, as applicable, in the relevant market segment and without regard to whether

²⁸ Pursuant to § 154.215(h)(2), CMS posts on its Web site the information contained in Parts I and

III of each Rate Filing Justification that is not a trade secret or confidential commercial or financial information as defined in HHS's Freedom of Information Act regulations, 45 CFR 5.65.

coverage is offered through or outside an Exchange. These provisions would provide consumers with timely access to information about proposed and final rate increases in States that elect to make such information available to the public. They would also promote fair market competition between issuers in the Exchange and non-Exchange markets and further enhance transparency of the rate-setting process.

We are considering establishing as a condition of an Effective Rate Review Program that the State post on its Web site information about proposed and final rate increases, rather than providing the option to simply provide CMS's web address for such information. We seek comment on this proposal. We also seek comments on the timeframes for making proposed and final rate information available to the public, including how the timeframes may interact with current State rate review practices and might affect the State's workload.

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

1. General Provisions

a. Definitions (§ 155.20)

In § 155.20, we propose to amend the definitions of “applicant,” “enrollee,” and “qualified employee.” First, the proposed amendments to applicant, enrollee, and qualified employee would specify that a qualified employer could elect to offer coverage through a SHOP to its former employees that may include retirees, as well as former employees to whom an employer might be obligated to provide continuation coverage under applicable State or Federal law. Second, the proposed amendments specify that a qualified employer could also elect to offer coverage through the SHOP to dependents of employees or former employees. Third, the proposed amendments specify that business owners may enroll in SHOP coverage provided that at least one employee enrolls. We propose to amend these definitions to make it clear that SHOPS may allow small group enrollment practices that were in place before the Affordable Care Act to continue, to preserve continuity for issuers and employers, and to reduce the administrative complexity involved with transitioning to SHOP coverage for qualified employers.

We propose to amend the definition of “applicant” with respect to the group market so that it would include not only an employer or employee seeking eligibility for enrollment in a QHP

through the SHOP, but also a former employee seeking eligibility for enrollment in a QHP through the SHOP. We are also proposing to amend the definition of applicant so that it would reflect that an employer, employee, or former employee could seek eligibility to enroll his or her dependents in a QHP through the SHOP, if the qualified employer offers dependent coverage through the SHOP.

We propose to define “qualified employee” as any employee or former employee of a qualified employer who has been offered health insurance coverage by such qualified employer through the SHOP for himself or herself and, if the qualified employer offers dependent coverage through the SHOP, for his or her dependents.

We note that we would not consider dependents to be applicants or qualified employees—rather, dependents' eligibility to participate in SHOP is linked to the eligibility of the qualified employee. Similarly, we would not consider business owners (including sole proprietors, owners of more than 2 percent of an S corporation or of more than 5 percent of a C corporation, partners owning more than 5 percent of a partnership, or members owning more than 5 percent of a limited liability company (LLC), or working spouses, domestic partners, and other family members of these types of business owners) to be qualified employees. Consistent with current market practice, these types of business owners may, however, enroll in coverage through the SHOP if at least one employee has enrolled in such coverage through the SHOP. We also note that under our interpretation of the definition of employee at § 155.20, a qualified employer may not offer SHOP coverage exclusively to former employees. A qualified employer must have at least one employee who enrolls in order for the coverage to be issued through the SHOP to a former employee.

We propose to amend the definition of “enrollee” so that the term would include not only qualified individuals and qualified employees (as that term would be amended as proposed in this rulemaking), but also dependents of qualified employees. The proposed amendments to enrollee would also establish that business owners and their dependents could also enroll in coverage through the SHOP, provided that at least one employee enrolls in coverage through the SHOP. Including these individuals in the definition of enrollee would mean that where these individuals are permitted to enroll in coverage through the SHOP, the SHOP and QHPs must provide them with the

same rights and privileges as qualified employees who are enrollees, such as timely notice of changes in coverage as described in subpart H of part 155 and § 156.285. We note that this has no impact on the tax treatment of premiums paid by the business owner for coverage for themselves and their dependents.

While we have attempted to ensure that the modifications of these definitions are consistent with the intended usage of these terms throughout subpart H, we seek comment on all aspects of the proposed modifications to these definitions, including comments on any perceived unintended consequences resulting from the proposed modifications of these terms, and comments on whether other provisions of the Exchange rules in part 155 and 156 would also need to be amended to implement the changes proposed in these definitions. We note that these definitions apply only with respect to the provisions of 45 CFR, and should not be read as interpreting these terms for any purposes under Title I of ERISA.

2. General Functions of an Exchange

a. Consumer Assistance Tools and Programs of an Exchange (§ 155.205)

Section 155.205(c) sets forth standards applicable to consumer assistance tools and programs of Exchanges for providing meaningful access to information for individuals with disabilities and individuals with limited English proficiency. Currently, these provisions also apply through § 155.230(b) to applications, forms, and notices used or provided by the Exchange, and through a cross-reference to § 155.230(b) in § 156.250, to QHP issuer applications and notices. Information provided as part of any consumer assistance functions under § 155.205(d) and (e), including the Navigator program described in § 155.210, must meet the standards of § 155.205(c). In addition, if an Internet Web site of an agent or broker (referred to in this section as a “web-broker”) is used by a consumer to complete a QHP selection, that Web site must disclose and display all QHP information provided by the Exchange or directly by QHP issuers consistent with the requirements of § 155.205(c), under § 155.220(c)(3)(i). We propose to amend § 155.205(c) to specify the oral interpretation services that are required for certain entities subject to § 155.205(c). Specifically, with respect to Exchanges, QHP issuers, and web-brokers only, we propose that the requirement to provide oral

interpretation services under § 155.205(c)(2)(i) would include making available telephonic interpreters in at least 150 languages. We propose this specific standard so that in every Exchange consumers with limited English proficiency would have greater access to essential information provided by Exchanges, web-brokers, and QHP issuers when shopping for and accessing health coverage. In addition, this proposed standard would detail for Exchanges, web-brokers, and QHP issuers how they must provide meaningful access to information to individuals with limited English proficiency. We also propose amendments to § 156.250 that are discussed below, and that would require QHP issuers to provide all information that is critical for obtaining health insurance coverage or access to health care services through the QHP, including applications, forms, and notices, to qualified individuals, applicants, qualified employers, qualified employees, and enrollees in accordance with the standards described in § 155.205(c), including the provision of telephonic interpretive services in at least 150 languages.

We are proposing to limit the applicability of the proposed 150 languages standard to Exchanges, web-brokers, and QHP issuers. These groups, in many cases, already maintain a call center with language line capacity in 150 or more languages, which we believe to be the industry standard for language line services. We do not propose that this standard would apply to Navigators and non-Navigator assistance personnel because the smaller non-profit organizations that frequently make up the bulk of these consumer assistance entities have limited resources. For example, small entities and individuals are encouraged to apply for Navigator grants in the FFEs, particularly by partnering with other entities or individuals to form a consortium, and these entities frequently lack the infrastructure to support telephonic interpreter services in multiple languages.

We solicit comment on all aspects of this proposal. In particular, we seek specific comment on whether Navigators and non-Navigator assistance personnel should be required to meet the proposed standard, whether directly or through referral, such as through a referral to the Exchange call center. We also seek specific comment on whether requiring web-brokers to provide telephonic interpretive services in 150 languages would have an adverse impact on them, as well as on whether there are alternative means that should

be provided to web-brokers by which they can meet their existing obligations to provide oral interpretation services (such as through referral to the Exchange call center).

We also solicit specific comments on whether we should consider more or different language accessibility standards in § 155.205(c). For instance, some stakeholders have suggested ideas such as requiring written translations in the languages spoken by the applicable State's top ten Limited English Proficiency (LEP) groups or spoken by 10,000 persons or greater, whichever yields the greater number of languages; oral interpretation in as many languages as are generally available by telephonic interpreter services (which we understand is at least 150 languages); taglines (short statements informing individuals of the availability of language access services) in the top 30 non-English languages spoken nationwide on documents required by State or Federal law or containing information that is critical to obtaining health insurance coverage or access to health care services through a QHP; Web site content translated in each non-English language spoken by an LEP population that reaches 10 percent of the State population; and a uniform requirement that written translations, taglines on notices and Web site content, and oral interpretation services must be provided in the top 15 languages spoken by LEP individuals in the United States. We note that taglines in 15 languages are generally contained in all standard notices sent by the FFE. We solicit comments on these suggestions.

We also solicit comment on whether we should require more specific accessibility standards under other requirements under § 155.205(c), such as the requirement to provide written translations for individuals with limited English proficiency, and auxiliary aids and services to individuals with disabilities, and taglines indicating the availability of language services or auxiliary aids and services. We remind relevant covered entities of the obligations they might have under other Federal laws to meet existing effective communication requirements for individuals with disabilities, as such obligations are independent of the responsibilities they may have under § 155.205(c), § 155.230(b), § 156.200(e), and § 156.250. Finally, we solicit comment on whether this proposal would present implementation challenges for Exchanges, web-brokers, and QHP issuers if it becomes effective before the beginning of the open

enrollment period in the individual market for the 2016 benefit year.

b. Standards Applicable to Navigators and Non-Navigator Assistance Personnel Carrying Out Consumer Assistance Functions Under §§ 155.205(d) and (e) and 155.210 in a Federally-Facilitated Exchange and to Non-Navigator Assistance Personnel Funded Through an Exchange Establishment Grant (§ 155.215)

In the 2015 Market Standards Rule, we added regulatory language at § 155.215(h), which states in relevant part that "all non-Navigator assistance personnel funded through an Exchange Establishment Grant under section 1311(a) of the Affordable Care Act must maintain a physical presence in the Exchange service area, so that face-to-face assistance can be provided to applicants and enrollees." We have since recognized that this wording could create confusion about whether the requirement applies to the non-Navigator entity receiving funding through an Exchange Establishment grant, or whether it applies to each individual providing non-Navigator assistance. CMS currently interprets the provision as applying only to non-Navigator assistance personnel entities, such that only the entity must maintain a physical presence in the Exchange service area, consistent with our application of the requirement to non-Navigator assistance personnel in an Exchange operated by HHS under its authority under § 155.105(f). To make this policy clear, we propose to amend § 155.215(h) to limit it to entities, so it would read "all non-Navigator entities funded through an Exchange Establishment Grant under section 1311(a) of the Affordable Care Act must maintain a physical presence in the Exchange service area, so that face-to-face assistance can be provided to applicants and enrollees." We believe that this amendment strikes an appropriate balance in allowing individuals providing non-Navigator assistance subject to § 155.215 to provide assistance via the telephone, Internet, or through other remote means, particularly in circumstances in which remote assistance would be more effective or practical than face-to-face assistance, while also ensuring that the organization with which they are affiliated is in a position to understand and meet the specific needs of the communities they serve and to facilitate consumer protection efforts, as applicable, in their State. If the non-Navigator is not affiliated with a larger entity, we would consider the individual to be the entity specified in

the amended language under proposed § 155.215(h). We are also proposing to add the title “Physical presence” to paragraph (h) for improved clarity.

c. Standards for HHS Approved Vendors of Federally-Facilitated Exchange Training for Agents and Brokers (§ 155.222)

Section 1312(e) of the Affordable Care Act directs the Secretary of HHS to establish procedures under which a State may allow agents and brokers to enroll individuals and employers in any QHP in the individual or small group market offered through an Exchange, and to assist individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs sold through an Exchange. Under § 155.220, we established procedures to support the State’s ability to permit agents and brokers to assist individuals, employers or employees with enrollment in QHPs offered through an Exchange, subject to applicable Federal and State requirements. As described at § 155.220(d), an agent or broker that enrolls qualified individuals through an Exchange, or assists individuals in applying for advance payments of the premium tax credit or cost-sharing reductions, must comply with the terms of the agreement between the agent or broker and the Exchange. Under the terms of this general agreement, agents and brokers must register with the Exchange, and must receive training in the range of QHP options and insurance affordability programs. In addition, all agents and brokers must execute the applicable privacy and security agreement(s) required by § 155.260(b).

For plan years 2014 and 2015, the procedures established under section 1312(e) of the Affordable Care Act involved HHS implementation of FFE training of agents and brokers. HHS also provided technical support and help desk services to agents and brokers with questions related to that training. In this rule, for 2016 and future plan years, we propose changing the procedures related to FFE agent and broker training so that the certain training and information verification functions could also be provided by HHS-approved vendors. Under this proposal, HHS would provide an additional avenue by which agents and brokers could complete the training requirements necessary to work with consumers seeking coverage through the FFE. HHS would recognize the successful completion of an Exchange training program from an HHS-approved vendor as sufficient to satisfy the requirement to receive training in the range of QHP options and the insurance affordability programs.

We propose that to become an HHS-approved vendor, the organization must demonstrate that it meets the standards in § 155.222(b), under an approval process established by HHS. We further propose that no training program would be recognized unless it included an information verification component under which the vendor confirms the identity and applicable State licensure of the person who is credited with successful completion of the training program. Organizations interested in becoming HHS-approved vendors must have HHS approval by the applicable deadline. In our proposed standards for HHS-approved vendors of an alternative training and information verification process, we seek to make FFE training and registration process easier for agents and broker, and attract greater agent and broker participation in the FFEs through partnership with vendors.

In § 155.222(a), we propose an application and approval process for vendors seeking recognition as HHS-approved vendors for FFE training and information verification for agents and brokers. As part of an approved training and information verification program, we propose that the vendor must require agents and brokers to complete identity proofing, provide identifying information, and successfully complete the required curriculum. We propose that only HHS-approved vendors that meet the designated standards will have their training and information verification programs recognized. We believe that under this approach, we will be able to leverage the experience, contacts, and networks of approved vendors while ensuring that the training and information verification programs adhere to uniform standards for content, format, and delivery. We propose that vendors be approved for one-year terms, and that vendors seeking to continue their recognition as HHS-approved vendors for FFE agent and broker training and information verification the following year must be re-approved through a process to be determined by HHS. If this proposal is finalized, we anticipate developing vendor application forms. We seek comment on the proposed approach outlined above. We also seek comment on what additional components a training program should include in order to qualify for HHS approval (for example, facilitating agent and broker creation of FFE accounts).

In paragraph (b), we propose the standards that a vendor must meet to be approved by HHS to offer FFE training and information verification to agents and brokers. These standards are based on the approval criteria for Enrollee

Satisfaction Survey vendors at § 156.1105. We believe that the establishment of these standards will help ensure that vendors are approved using an objective methodology, and that approved vendors will successfully carry out the agent and broker FFE training and information verification and safeguard the data related to these functions. We seek comment on these proposals.

In paragraph (b)(1) we propose that the vendor submit a complete and accurate application by the deadline established by HHS. We propose that, as part of the application, the vendor must demonstrate prior experience with successfully conducting online training and identity proofing, as well as providing technical support to a large customer base. HHS would only approve vendors with no current or past regulatory, enforcement, or legal actions taken against the vendor by a State or Federal regulator in the last 3 years, beginning from the application or renewal application deadline under this section.

We propose in paragraph (b)(2) that the vendor be required to adhere to HHS specifications for content, format, and delivery of training and information verification. Training includes developing and hosting FFE courses, exams, and curriculums for agents and brokers. HHS would require vendors to have their training approved for continuing education units accepted by State regulatory entities.

In paragraph (b)(3) we propose that vendors be required to collect, store, and share with HHS all data from agent and broker users of the vendor’s training and information verification in a manner specified by HHS, and protect the data in accordance with applicable privacy and security laws and regulations. HHS would expect vendors to be able to securely receive and transfer large data files in formats commonly used in the information technology industry.

In paragraph (b)(4), we propose that the vendor be required to execute an agreement with HHS, in a form and manner to be determined by HHS, which requires the vendor to comply with HHS guidelines for interfacing with HHS data systems, the implementation of the training and information verification processes, and the use of all data collected. In addition to executing the agreement, vendors would be required to comply with all applicable State and Federal laws, including applicable privacy and security standards. HHS would require that the vendor adopt a fee structure that is generally consistent with the fee

structure for comparable trainings offered by the vendor to comparable audiences.

In paragraph (b)(5), we propose that the vendor be required to permit any individual who holds a valid license or equivalent State authority to sell health insurance products to access the vendor's training and information verification process. HHS is considering whether vendors should be permitted to offer the training to other members of the public who are interested in learning about the Exchanges.

In paragraph (c), we propose that once HHS has completed the approval process for vendors for a given year, HHS would publish a list of approved entities on an HHS Web site. In paragraph (d), we propose that HHS may monitor and audit approved vendors and their records related to the FFE training and information verification functions to ensure the approved vendors' ongoing compliance with the standards outlined in paragraph (b). We propose that if HHS determines that the approved vendor is no longer in compliance with standards under paragraph (b), HHS may remove the vendor from the list described in this section, and may direct the vendor to cease performing the training and information verification functions described in this subpart. We propose that the vendor may invoke the appeals process proposed in paragraph (e) if its approval has been revoked. We seek comment on this process.

In paragraph (e), we propose an appeals process for a vendor whose application is denied, or whose approval to offer training and information verification is revoked. Specifically, we propose that such a vendor may appeal HHS's decision by notifying HHS in writing within 15 days of receipt of the notification by HHS of not being approved or having its approval revoked, and submitting additional documentation demonstrating how the vendor meets the standards in paragraph (b) and (if applicable) the terms of their agreement with HHS. HHS will review the submitted documentation and make a final determination within 30 days from receipt of the submission of the additional documentation. A vendor that gains approval via the appeals process would be included in the approved list, described in paragraph (c). We seek comment on this proposed appeals process.

3. Exchange Functions in the Individual Market: Eligibility Determinations for Exchange Participation and Insurance Affordability Programs

a. Annual Eligibility Redetermination (§ 155.335)

The current re-enrollment provisions codified at § 155.335(j) prioritize re-enrollment with the same issuer in the same or a similar plan with the goal of maximizing continuity of coverage and care. However, because premiums may change significantly from one year to the next, the plans that are most competitively priced in one year may not continue to be the most competitively priced in subsequent years. For this reason, default enrollment in the same or similar plan may sometimes encourage consumers to remain in plans that are significantly more expensive than the lowest cost plans in the market. Because we believe that many consumers place a high value on low premiums when selecting a plan, we believe that consumers could benefit from alternative re-enrollment hierarchies.

In particular, we are exploring implementing in the FFE an approach under which an enrollee, at the time of initial enrollment, would be offered a choice of re-enrollment hierarchies and could opt into being re-enrolled by default for the subsequent year into a low-cost plan (such as the QHP of the same metal level with the lowest premium in the enrollee's service area, or one of the three such QHPs with the lowest premiums by random allocation), rather than his or her current plan or the plan specified in the current re-enrollment hierarchy. This alternative enrollment hierarchy could be triggered if the enrollee's current plan's premium increased from the prior year, or increased relative to the premium of other similar plans (such as plans of the same metal tier), by more than a threshold amount, such as 5 percent or 10 percent. As is the case under the existing approach, a consumer would retain the option to take action to enroll in a different plan during open enrollment if he or she wished to do so. We are considering applying an alternative hierarchy for the first time when re-enrolling consumers for the 2017 coverage year. On this timeline, consumers could opt in to the alternative hierarchy during open enrollment in 2015 (or during special enrollment periods occurring during 2016).

We seek comment on such an approach, including with respect to how to ensure that consumers understand the risk of being default re-enrolled in

a plan with a significantly different provider network, benefits, cost-sharing structure, or service area; what premium growth in the current plan (or what growth relative to other similar plans) would trigger re-enrollment into a low-cost plan, and how to determine which enrollees get assigned to which plans, if random enrollment into one of the three lowest cost QHPs of the metal level in the enrollee's service area is implemented. We also seek comment on how these types of default re-enrollment procedures have functioned in other programs and settings, and what lessons can be drawn from those experiences. Finally, we seek comment on whether such approaches may influence issuers' pricing decisions, such as by causing them to price more competitively in order to retain or attract enrollees who have opted to be re-enrolled into a low-cost plan.

We are also considering providing this flexibility to State-based Exchanges to implement alternative re-enrollment hierarchies such as the one described above, beginning in 2016, at their option. We believe that providing this flexibility could offer an opportunity to gather valuable information about alternative re-enrollment structures and share lessons learned across Exchanges in hopes of improving the re-enrollment process and the consumer experience.

We seek comment on whether to permit State-based Exchanges the flexibility to implement these alternative re-enrollment hierarchies beginning with 2016 open enrollment, whether to provide flexibility to SBEs to establish other hierarchies, and whether to adopt any such alternatives in the FFE for 2017 open enrollment.

4. Exchange Functions in the Individual Market: Enrollment in Qualified Health Plans

a. Enrollment of Qualified Individuals Into QHPs (§ 155.400)

We propose to amend § 155.400(e) to explicitly provide for an Exchange to establish a standard policy for setting deadlines for payment of the first month's premium. We recognize that decisions regarding payment of the first month's premium have traditionally been business decisions made by issuers, subject to State rules. However, we believe that having uniform deadlines for all issuers for payment of a first month's premium to effectuate enrollments could benefit issuers and consumers by ensuring a consistent operational procedure.

In the Federally-facilitated Exchanges, we are considering payment deadlines tied to the coverage effective date for

regular effective dates (meaning coverage effective the first day of the following month for plan selections made between the first and fifteenth of the month, and coverage effective the first day of the second month following a plan selection made between the 16th and the end of the month). Some options we are considering would be to provide consumers until the coverage effective date, or the day before the coverage effective date, to make their first month premium payment. Alternatively, we could provide consumers additional time after the coverage effective date to make their premium payment. For example, we could provide 5 days, 10 days, or 30 days after the coverage effective date, or something in between. We seek comment on the period of time following the coverage effective date an issuer could be required or permitted to accept a first month's premium payment for that coverage.

With respect to effective dates other than regular effective dates, meaning retroactive or accelerated coverage effective dates resulting from enrollment under certain special enrollment periods (including birth and marriage), resulting from the resolution of appeals, or resulting from amounts newly due for prior coverage based on issuer corrections of under-billing, we are considering a premium payment deadline of 10–15 business days from when the issuer receives the enrollment transaction.

We seek comment on which proposed premium payment deadlines give issuers an acceptable amount of time to send an invoice and allow for timely payment by the consumer, and give consumers sufficient time to make the payment. It is our expectation that QHP issuers will send the consumer the bill within one to two business days after receiving the enrollment transaction to accomplish this goal. We also seek comment on how such a policy would likely affect issuer operations and consumers' ability to obtain coverage.

We note that because this rulemaking will likely not be finalized until after open enrollment for 2015, any such deadlines would not be applicable for that open enrollment period. We anticipate providing flexibility to issuers on premium payment deadlines for this open enrollment period to account for the timing of default re-enrollments this year.

b. Annual Open Enrollment Period (§ 155.410)

In § 155.410, we propose to amend paragraph (e), which provides the dates for the annual open enrollment period

in which qualified individuals and enrollees may apply for or change coverage in a QHP. We propose to restructure paragraph (e) by placing the current provision regarding the 2015 benefit year in paragraph (e)(1) and the proposed requirement for all benefit years beginning on or after 2016 in paragraph (e)(2). Specifically, in paragraph (e)(2), we propose that for benefit years beginning on or after January 1, 2016, the annual open enrollment period begins on October 1 and extends through December 15 of the calendar year preceding the benefit year. We also propose to redesignate the annual open enrollment coverage effective date provisions in paragraphs (f) and (f)(1) through (3) as (f)(1) and (f)(1)(i) through (iii), and to add a new (f)(2), which would specify that, for enrollments made under any annual open enrollment periods for benefit years beginning on or after January 1, 2016, coverage would be effective on January 1 of the year following the open enrollment period. For example, for any enrollment completed under the open enrollment period between October 1 and December 15, 2015, coverage would be effective on January 1, 2016.

We propose this time period and coverage effective date for several reasons. First, because of increasing consumer familiarity with the Exchange, we believe that the proposed open enrollment period, which is shorter than prior open enrollment periods, will still provide consumers sufficient time to enroll or change coverage in a QHP. Second, the proposed open enrollment period does not cross calendar years, which we anticipate will reduce consumer confusion regarding effective dates for coverage because all coverage would be effective on January 1 of the following year. This will be less complicated for Exchanges and issuers to implement. Finally, we anticipate that the proposed open enrollment period will provide consumers with sufficient time to review changes to their current plans, take advantage of consumer assistance resources, and compare plans and complete plan selection as needed. We note the annual open enrollment period and coverage effective dates will also apply to non-grandfathered policies in the individual market outside the Exchange through the cross-reference at § 147.104(b)(1)(ii). We seek comment on this proposal, including whether the open enrollment period should end earlier in December to ensure sufficient time for issuers and Exchanges to accommodate current enrollees switching plans or being enrolled through the default re-

enrollment hierarchy for coverage effective January 1.

c. Special Enrollment Periods (§ 155.420)

In § 155.420, we make certain proposals relating to special enrollment periods. We propose to revise paragraphs (b)(2)(i), (b)(2)(ii), (b)(2)(iv), and add paragraphs (b)(2)(v), (b)(2)(vi), and (b)(2)(vii), which pertain to effective dates for special enrollment periods; to amend paragraphs (c)(2)(i) and (c)(2)(ii), which pertain to availability and length of special enrollment periods, and to revise paragraphs (d)(1)(ii), (d)(1)(v), (d)(2), (d)(4), and remove paragraph (d)(10), which pertain to specific types of special enrollment periods. We also propose to delete the option for consumers to choose a coverage effective date of the first of the month following the birth, adoption, placement for adoption, or placement in foster care. We seek comment on these proposed changes, including whether we should retain the ability for consumers to choose the first of the month following the birth, adoption, placement for adoption, or placement in foster care in addition to providing for regular coverage effective dates.

In paragraph (b)(2)(i), we propose to change one of the options for coverage effective dates in the case of birth, adoption, placement for adoption, or placement in foster care. Currently, a consumer may choose between the date of the birth, adoption, placement for adoption, or placement in foster care; and, if permitted by the Exchange, the first of the month following the birth, adoption, placement for adoption, or placement in foster care. We continue to require the Exchange to allow for coverage to be effective for a qualified individual or enrollee on the date of birth, adoption, placement for adoption, or placement in foster care, but propose to permit the Exchange to allow a qualified individual or enrollee to elect a regular coverage effective date in accordance with paragraph (b)(1) of this section. We seek comment on this proposal.

We propose to amend paragraphs (b)(2)(iv) and (c)(2). The proposed change to (c)(2) would become effective January 1, 2016, and would allow consumers advanced access to the special enrollment period where a qualified individual or enrollee, or his or her dependent, gains access to new QHPs due to a permanent move under (d)(7). Prior to January 1, 2016, consumers who gain access to new QHPs as described under (d)(7) would continue to select a QHP in accordance with paragraph (c)(1). The proposed

changes to (b)(2)(iv) also would allow these persons to have a coverage effective date of the first day of the month following the move if plan selection is made before or on the day of the loss of coverage. If plan selection is made after the loss of coverage, the Exchange must ensure that coverage is effective in accordance with the regular effective dates under paragraph (b)(1) or on the first day of the following month, at the option of the Exchange. Current regulations require consumers to complete their permanent move before they are granted a special enrollment period, creating potential gaps in coverage. This amendment would help prevent such gaps. We seek comment on this proposal.

In addition, we propose to add new paragraphs (b)(2)(v) and (b)(2)(vi), which pertain to effective dates for coverage that must be obtained under court orders, including child support orders, and the death of an enrollee or his or her dependent. In paragraph (b)(2)(vi), we propose to require an Exchange to make coverage effective the first day the court order is effective to minimize any gap in coverage the individual may experience. We would allow Exchanges to provide consumers with a choice for regular effective dates under paragraph (b)(1) of this section to minimize duplicative coverage the child may have. We seek comment on this proposal, and other policies that would provide consumers who must obtain coverage for an individual under a court order the most protective effective date.

In paragraph (b)(2)(vi), we propose to require that an Exchange ensure coverage is effective the first day of the month following a death of the enrollee or his or her dependent, and at the option of the Exchange and the consumer, allow for regular effective dates under paragraph (b)(1) of this section. The effective date of the coverage under this special enrollment period is intended to work in conjunction with the effective date for termination due to death provided in § 155.430(d)(7). When a consumer dies in the middle of the month, and the enrollment group is no longer valid, our expectation is that issuers would continue coverage for the enrollment group through the end of the month. The alternative would be to align the effective date of coverage with the date of death which would require proration of premiums and advance payments of the premium tax credit. We seek comment on which proposal is most beneficial to the consumer.

We propose to combine paragraphs (c)(2)(i) and (c)(2)(ii) to a new paragraph (c)(2) to simplify the regulatory text. In

addition, we propose to allow consumers to report a permanent move 60 days in advance of the move for the purposes of receiving special enrollment period to reduce the likelihood of a gap in coverage. We understand this requirement may not be operationally feasible for the 2015 benefit year and, as such, propose to not require Exchanges to meet this requirement prior to January 1, 2016.

We seek comment on these proposed amendments.

We propose to amend paragraph (d)(1)(ii) which provides a special enrollment period for individuals enrolled in non-calendar year individual health insurance coverage when their policy year ends in 2014. We propose that this special enrollment period be available with respect to a qualified individual or his or her dependent who, in any year, has coverage under a group health plan or an individual plan with a plan or policy year that is not offered on a calendar year basis. We recognize that group health plans as well as grandfathered and transitional individual market plans are not required to be offered on a calendar year basis and may, therefore, come up for renewal outside of the annual open enrollment period for the individual market. This special enrollment period would give individuals enrolled in such plans the opportunity to enroll in an individual market QHP through the Exchange when their plan renews without having to wait until the next available open enrollment period. We seek comments on this proposal.

We propose to amend paragraph (d)(2) to include new paragraphs (i) and (ii). Paragraph (i) is changed from the original paragraph (d)(2) to include situations where a court order requires a qualified individual to cover a dependent or other person. We are adding this provision to allow for situations where a qualified individual is required to cover a dependent or other person who either was not previously covered under the qualified individual's health plan, or where a dependent voluntarily terminates coverage, in order to be added to the qualified individual's health plan and therefore, would not qualify for a special enrollment period under paragraph (d)(1)(i) of this section. We seek comment on this addition.

We propose to amend paragraph (d)(2) to add a new paragraph (ii) to allow enrollees who experience a loss of a dependent or lose dependent status through legal separation, divorce, or death to be determined eligible for a special enrollment period. The special

enrollment period will be available to all enrollees who lose a dependent or are no longer considered a dependent on the application. Currently, depending on the circumstances surrounding the divorce, legal separation, or death, the applicant may be determined eligible for a special enrollment period. This amendment would ensure that when an applicant experiences a life event that changes their familial structure such that their current plan no longer fits their needs, they are able to switch plans. We seek comment on the proposed amendments.

We propose to amend paragraph (d)(4), which allows a special enrollment period where enrollment or non-enrollment in a QHP is unintentional, inadvertent, or erroneous, and is the result of the error, misrepresentation, or inaction of an officer, employee, or agent of the Exchange or HHS, or its instrumentalities as evaluated and determined by the Exchange, to also include situations where a non-Exchange entity is providing enrollment assistance. Concurrently, we propose to strike paragraph (d)(10) which provides a separate special enrollment period for non-Exchange entity misconduct. We believe this modification, which would allow the Exchange to correct its own errors as well as errors of non-Exchange entities, will give the Exchange the authority to remedy these errors. For purposes of this section, non-Exchange entities include, all those entities listed at 78 FR 65064 as possible non-Exchange entities in the final rulemaking for § 155.420(d)(10): Agents and brokers assisting consumers in an Exchange under § 155.220, certified application counselors, as described in § 155.225, and navigators as described in § 155.210, issuer application assisters as described in § 155.415; a QHP as described in § 155.20, or non-Navigator assistance personnel as authorized by §§ 155.205(d) and (e) and 155.215. The current special enrollment period for misconduct of non-Exchange entities provided in paragraph (d)(10) of this section is limited to those situations where the consumer either: (1) Was not enrolled in a QHP; (2) was not enrolled in the QHP selected by the individual; or (3) is eligible for but is not receiving advance payments of the premium tax credit or cost-sharing reductions. During our first year of operations, we have learned that errors can arise involving non-Exchange entities that would be most sufficiently addressed by modifying paragraph (d)(4) of this section, as discussed above, to allow the Exchange to take appropriate action to

correct or eliminate the effects of misconduct or error on behalf of a non-Exchange entity. We seek comment on this proposal.

We propose to amend paragraph (d)(6) to create a special enrollment period for a qualified individual in a non-Medicaid expansion State who was previously ineligible for advance payments of the premium tax credit solely because the qualified individual had a household income below 100 percent FPL, who was ineligible for Medicaid during that same timeframe, and experiences a change in household income that makes the individual newly eligible for advance payments of the premium tax credit. Prior to the change in household income, such an individual had no option for affordable health insurance coverage, and we believe it is appropriate to provide an opportunity for enrollment when changed circumstances make coverage accessible to them. We seek comments on this proposal.

We also seek comments on other situations that may warrant a special enrollment period, particularly situations specific to the initial years in which consumers have an opportunity to purchase coverage through an Exchange.

d. Termination of Coverage (§ 155.430)

Under our current rules, § 155.430(b)(1) requires an Exchange to permit an enrollee to terminate his or her coverage in a qualified health plan (QHP) following appropriate notice to the Exchange or the QHP. We propose to amend this paragraph by adding a sentence to clarify that, to the extent the enrollee has the right to cancel the coverage under applicable State laws, including “free look” cancellation laws—that is, laws permitting cancellation within a certain period of time, even following effectuation of the enrollment, the enrollee may do so, in accordance with the requirements of such laws. Furthermore, we propose to amend § 155.430(d)(2) to add a new paragraph (d)(2)(v) allowing a retroactive termination effective date when an enrollee initiates the termination, if specified by applicable State laws, such as “free look” provisions.

We also invite comments on further standardization that may be needed with § 147.106.

Additionally, we propose to amend § 155.430(b)(1) by removing the language requiring the appropriate notice to the Exchange or QHP since the notice requirement is addressed in § 155.430(d) and this would give greater flexibility for other enrollee initiated

terminations where appropriate notice is not defined. For example, in the case of death, we state that the last day of coverage is the date of death, but we do not require a specific amount of notice of death to the Exchange or QHP.

We also propose to explicitly state that the requirement for Exchanges to ensure appropriate actions are taken in connection with retroactive terminations, currently set forth in paragraph (d)(6) regarding special enrollment periods, applies to all retroactive terminations, including valid cancellations of coverage under a “free look” law. To do so, we propose to move the applicable language to a new paragraph (d)(8). We also propose to add reconciliation of Exchange user fees to the list of items Exchanges would need to address. Under that requirement, the Exchange will ensure that appropriate actions are taken to make necessary adjustments to advance payments of the premium tax credit, cost-sharing reductions, Exchange user fees, premiums, and claims, while adhering to any State law. For example, this would mean that the QHP issuer would be required to return any premium paid by the enrollee, and to refund to HHS any advance payment of the premium tax credit or cost-sharing reductions paid for that enrollee for the period after the termination effective date (and the Exchange would refund any user fee paid on behalf of the enrollee for the period after the termination effective date). We note that, under our proposal, the enrollee would not become eligible to receive a special enrollment period as a direct result of the “free look” cancellation.

We also propose to add a new paragraph (b)(1)(iii) which would require Exchanges to establish processes for a third party to report the death of a consumer. We propose that, as part of these processes, an Exchange must allow a third party, including a consumer’s authorized representative, to report the death of a consumer for purposes of initiating termination of the deceased consumer’s enrollment. To substantiate a report of the death of an enrollee, the Exchange may, but is not required to, request documentation. This process will provide more flexibility for consumers to initiate the termination of Exchange enrollment of an enrollee who has not selected an authorized representative. We seek comment on this proposal.

Sections 2702 and 2703 of the PHS Act, as added by the Affordable Care Act, and their implementing regulations at §§ 147.104 and 147.106, generally require health insurance issuers offering non-grandfathered group or individual

health insurance coverage to guarantee the availability and renewability of the coverage unless an exception applies. QHPs offered through the Exchange or SHOP are health insurance coverage in the individual and small group markets, respectively. Accordingly, QHPs are subject to market-wide requirements in title XXVII of the PHS Act, including guaranteed availability and guaranteed renewability.

Under guaranteed availability requirements, an issuer may not refuse to accept individuals or employers who apply for such coverage unless an exception applies. Under guaranteed renewability requirements, an issuer must offer to renew or continue in force coverage at the option of the individual or employer and may not non-renew or discontinue the individual’s or employer’s coverage unless an exception applies. There are several exceptions to these requirements,²⁹ but whether a consumer is determined to be a qualified individual or qualified employer for purposes of enrollment through the Exchange is not one of them. For these reasons, we have interpreted the guaranteed availability requirements to mean that a QHP offered through the Exchange generally must be available outside the Exchange.³⁰ We have similarly interpreted the guaranteed renewability requirements to mean that a QHP offered through the Exchange generally must be renewable outside the Exchange.³¹

²⁹ The statutory exceptions to guaranteed availability include special rules for network plans, limited network capacity, and limited financial capacity. The statutory exceptions to guaranteed renewability include non-payment of premiums, fraud, violation of participation or contribution rules, termination of coverage, movement outside service area, association membership ceases.

³⁰ See e.g., “Frequently Asked Questions on Health Insurance Market Reforms and Marketplace Standards,” May 16, 2014. Available at <http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/Final-Master-FAQs-5-16-14.pdf>. See also “Frequently Asked Question on Qualified Health Plans and Guaranteed Availability Standards,” June 3, 2014. Available at: http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/faq_on_qhps_and_guaranteed_availability_6314.pdf.

³¹ We note that an exception to the requirement that QHP must be guaranteed available and renewable outside the Exchange arises from the statutory permission for QHPs offered through the Exchange or SHOP to omit coverage of the pediatric dental EHB where a stand-alone dental plan offering the pediatric dental EHB is offered through the Exchange or SHOP. This is not similarly permitted when the plan is offered outside the Exchange or SHOP. This results in certain QHPs only being legally available in the market when offered through the Exchange or SHOP. If the QHP omits coverage of the pediatric dental EHB, the issuer would not be required to offer, renew, or continue enrollment in the QHP outside the Exchange, but could do so, at the enrollee’s option,

We have identified certain aspects of the Exchange and SHOP regulations, particularly relating to termination of coverage, that could be interpreted as being inconsistent with the guaranteed availability right of consumers to purchase QHPs outside the Exchanges, and with the guaranteed renewability right of consumers to retain QHP coverage outside the Exchange. For example, the Exchange regulations list several circumstances under which the Exchange “may initiate termination of an enrollee’s coverage in a QHP, and must permit a QHP issuer to terminate such coverage.”³² Among these listed circumstances are cases in which “[t]he enrollee is no longer eligible for coverage in a QHP through the Exchange,” and in which “[t]he QHP . . . is decertified.”³³ While these two situations would make the individual ineligible to enroll in a QHP through the Exchange, and therefore ineligible for the premium tax credit or cost-sharing reductions, issuers cannot necessarily terminate coverage under the guaranteed renewability provisions.

To better align with market-wide guaranteed availability and guaranteed renewability requirements, we propose to amend the Exchange regulations in parts 155 and 156 that could be construed as limiting coverage in a QHP to coverage through the Exchange. For example, we intend to revise certain references to “termination of coverage,” so that they refer to termination of an individual’s enrollment status as a qualified individual receiving coverage “through the Exchange,” not termination of the coverage altogether, where applicable. Specifically, we intend in the final rule to modify the following provisions that may be viewed as inconsistent with our interpretations of guaranteed availability and guaranteed renewability: §§ 155.430, 155.735, 156.270, 156.285, and 156.290. We anticipate there may be other provisions of the Exchange and SHOP regulations for which conforming amendments may also be necessary. These amendments would become effective with the effective date of the final rule.

We seek comment on these proposals.

if the issuer is “reasonably assured” that the enrollee has obtained such coverage through an Exchange-certified stand-alone dental plan. Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation, 78 FR at 12834, 12853 (February 25, 2013).

³² 45 CFR 155.430(b)(2); with respect to SHOP coverage see also 45 CFR 156.285, 156.270, 155.735.

³³ 45 CFR 155.430(b)(2)(i) and part of (b)(2)(iv).

5. Exchange Functions in the Individual Market: Eligibility Determinations for Exemptions

a. Eligibility Standards for Exemptions (§ 155.605)

In § 155.605, we propose amendments to two hardship exemptions and a correction to a cross-reference. First, we propose to amend § 155.605(g)(3) to provide a hardship exemption to an individual who is not a dependent of another taxpayer and whose gross income is less than the individual’s minimum threshold for filing a Federal income tax return. We expect that the Internal Revenue Service (IRS) and the Department of the Treasury will publish guidance allowing individuals who are eligible for this exemption to claim it on their tax returns without obtaining a hardship exemption certificate number from the Exchange. It is further anticipated that the IRS and the Department of the Treasury will provide that individuals who are eligible for this exemption are not required to file Federal income tax returns to claim the exemption. We expect that the IRS and the Department of Treasury will finalize these policies in time for consumers filing 2014 Federal income taxes. We anticipate that this proposed change will affect a small group of people, and will greatly simplify the process for claiming this exemption on a Federal tax return. We seek comment on this proposal.

Second, we propose amending § 155.605(g)(6)(i) to correct the citation to 42 CFR 447.50 by changing it to 42 CFR 447.51, which cross-references the Medicaid definition for Indian.

Third, we propose new paragraph § 155.605(g)(6)(iii) that will align the exemption process for members of Federally-recognized Tribes and those individuals who are eligible for services through the Indian Health Service (IHS), a Tribal health facility, or an Urban Indian organization (ITU). Under current regulations, members of Federally-recognized Tribes may apply for an exemption from the shared responsibility payment directly with the Exchange, or they may claim the exemption when they file their tax returns without applying for an exemption from the Exchange. However, those who are applying for a hardship exemption based on their eligibility to receive services from an ITU are required to submit an exemption application to the Exchange. These varying application requirements cause confusion for American Indian and Alaska Native families. The proposed amendment will provide individuals who are eligible for services through an

ITU with the same exemption process available to tribal members by permitting them to claim the exemption on their Federal income tax returns without obtaining an exemption certificate number. We expect that the IRS and the Department of Treasury will finalize policies to accommodate this proposal for consumers filing 2014 Federal income taxes. We seek comment on this proposal.

b. Required Contribution Percentage (§ 155.605)

Under section 5000A of the Code, an individual must have minimum essential coverage for each month, qualify for an exemption, or make a shared responsibility payment with his or her Federal income tax return. Section 5000A of the Code and section 1311(d)(4)(H) of the Affordable Care Act authorizes the Secretary to determine individuals’ eligibility for exemptions, including the hardship exemption. Under section 5000A(e)(1) of the Code, an individual is exempt if the amount that he or she would be required to pay for minimum essential coverage (required contribution) exceeds a particular percentage (the required contribution percentage) of his or her actual household income for a taxable year. In addition, under § 155.605(g)(2) an individual is exempt if his or her required contribution exceeds the required contribution percentage of his or her projected household income for a year. Finally, under § 155.605(g)(5) certain employed individuals are exempt if, on an individual basis, the cost of self-only coverage is less than the required contribution percentage but the aggregate cost of self-only coverage through employers exceeds the required contribution percentage and no family coverage is available through an employer at a cost less than the required contribution percentage.

The required contribution percentage for 2014 is 8 percent under section 5000A(e)(1)(A) of the Code. Section 5000A(e)(1)(D) of the Code and 26 CFR 1.5000A-3(e)(2)(ii) provide that for plan years after 2014, the required contribution percentage is the percentage determined by the Secretary that reflects the excess of the rate of premium growth between the preceding calendar year and 2013, over the rate of income growth for that period. In the 2015 Market Standards Rule, we established a method for determining the excess of the rate of premium growth over the rate of income growth each year, and published the 2015 rate. We stated that future adjustments would be published annually in the HHS

notice of benefit and payment parameters.

Under the method previously established, the rate of premium growth over the rate of income growth for 2016 is determined by (x) one plus the premium growth between the preceding year (in this case, 2015), and 2013, carried out to ten significant digits, divided by (y) one plus the rate of income growth between the preceding year (2015), and 2013, carried out to ten significant digits.³⁴ The result of this calculation is carried out to ten significant digits and multiplied by the required contribution percentage specified in section 5000A(e)(1)(A) of the Code (8.00 percent). The result is then rounded to the nearest hundredth of a percent, to yield the required contribution percentage for 2016.

Under the methodology described above, the total rate of premium growth for the two-year period from 2013–2015 is 1.0831604752, or 8.3 percent. We describe the methodology for obtaining this number below in § 156.130(e). In the 2015 Market Standards rule, we also established a methodology for calculating the rate of income growth for the purpose of calculating the annual adjustment to the required contribution percentage.

The measure of income growth is based on projections of per capita Gross Domestic Product (GDP) used for the National Health Expenditure Accounts (NHEA), which is calculated by the CMS Office of the Actuary. Accordingly, using the NHEA data, the rate of income growth for 2016 is the percentage (if any) by which the most recent projection of per capita GDP for the preceding calendar year (\$56,660 for 2015) exceeds the per capita GDP for 2013, (\$53,186), carried out to ten significant digits. The total rate of income growth for the two-year period from 2013–2015 is estimated to be 1.0653179408 or 6.5 percent. We note that the 2013 per capita GDP used for this calculation has been updated to reflect the latest NHEA data.

Thus, the excess of the rate of premium growth over the rate of income growth for 2013–2015 is 1.0831604752/1.0653179408, or 1.0167485534, or 1.7 percent. This results in a required contribution percentage for 2016 of 8.00*1.0167485534, or 8.13 percent, when rounded to the nearest one-hundredth of one percent.

³⁴ We defined premium growth for this measure as the same annually adjusted measure of premium growth used below in this rule to establish the annual maximum and reduced maximum limitations on cost sharing for plan benefit designs. That is, the premium adjustment percentage.

6. Exchange Functions: Small Business Health Options Program (SHOP)

a. Standards for the Establishment of a SHOP (§ 155.700)

We propose to amend § 155.700(b) such that the previous definition of “group participation rule” would conform with the terminology we propose to use in § 155.705(b)(10). Specifically, we propose to modify the term to refer to a “group participation rate,” which is a minimum percentage of all eligible individuals or employees of an employer that must be enrolled.

b. Functions of a SHOP (§ 155.705)

Section 155.705 was amended in the 2015 Market Standards Rule. In § 155.705, we propose to redesignate paragraph (b)(4)(ii)(B) as new paragraph (b)(4)(ii)(C), redesignate paragraph (b)(4)(ii)(A) as new paragraph (b)(4)(ii)(B), add new paragraph (b)(4)(ii)(A), and amend paragraphs (b)(4)(i)(B), (b)(7), and (b)(10).

In the proposed amendment to paragraph (b)(4)(i)(B) and proposed new (b)(4)(ii)(A), we propose to permit the SHOP to assist a qualified employer in the administration of continuation coverage in which former employees seek to enroll through the SHOP. The proposed amendment to paragraph (b)(4)(i)(B) would modify the requirement that the total amount of all premiums due from a given qualified employer must be collected from the qualified employer by the SHOP. This is because, at new paragraph (b)(4)(ii)(A), we propose that where a qualified employer is offering Federal or State continuation coverage³⁵ under 29 U.S.C. 1161 *et seq.* or any applicable State law, and where a SHOP has entered into an agreement with a qualified employer to provide this service, the SHOP may assist the employer in administration of such coverage by billing for and collecting premiums for the continuation coverage directly from the former employee, rather than the employer, if the qualified employer elects to have the SHOP carry out this function. The SHOP would then remit the premium payments to the issuers offering the continuation coverage. We propose this policy to reduce the burden on small businesses related to the administration of continuation coverage in which former employees seek to enroll through the SHOP. A qualified employer may find it difficult to harmonize the timeline for the collection of

³⁵ Consolidated Omnibus Budget Reconciliation Act of 1985 (Pub. L. 99–272) (“COBRA”), or applicable State law.

continuation coverage premiums and the timeline for the collection of premiums in the SHOP. Permitting the SHOP to collect continuation coverage premiums directly from the former employee ensures that both the employer and the former employee may fully exercise their payment grace periods while reducing the likelihood of complex billing problems. We are not proposing that SHOPS, including the Federally-facilitated SHOP, take on other functions related to the administration of continuation coverage, such as administration of required notices. Additionally, in light of the administrative complexities associated with administering payments for State-mandated continuation coverage across all States with an FF–SHOP, we propose that an FF–SHOP may elect to limit this service to the billing and collection of premiums related to Federally mandated (“COBRA”) continuation coverage.

We also note that the IRS has promulgated specific standards regarding payments for COBRA continuation coverage at 26 CFR 54.4980B–8. We note that where such standards and any other applicable COBRA standards in 26 CFR part 54 are more protective than the standards the SHOP has established for administration of payment (such as, for example, grace periods) the IRS rules must apply. We seek comment on all aspects of this proposal, including the interaction of the FF–SHOP’s payment grace periods and termination policies at § 155.735 with the COBRA rules IRS has codified in 26 CFR part 54.

We are considering whether to permit the Federally-facilitated SHOP to accept premium payment using a credit card, and seek comment on whether to do so. Currently, qualified employers participating in the Federally-facilitated SHOP may only pay premiums to the Federally-facilitated SHOP using a check or bank draft. While HHS has received comments from stakeholders urging it to permit qualified employers to pay premiums using a credit card, we seek comment on the extent to which employers would utilize this option. These stakeholders stated, and we agree, that it may be more convenient for a small employer to pay by credit card than by check or bank draft. Additionally, we note that an employer that finances its premium payment with a credit card may be able to better align its premium payments with its monthly receipts. We seek comment on all aspects of this potential policy, including how many FF–SHOP employers expect to use credit cards for payment, whether they would use this

method of payment every month or only for their initial payment, and what credit and debit cards the FF-SHOP should consider accepting.

We also propose to revise paragraph (b)(7) to align the SHOP regulations with the Protecting Access to Medicare Act of 2014 (Pub. L. 113-93), which repealed requirements related to deductible maximums for employer-sponsored coverage at section 1302(c)(2) of the Affordable Care Act. This proposal would remove the only reference in the SHOP regulations to the requirements of Affordable Care Act section 1302(c)(2).

In paragraph (b)(10), we propose to modify the calculation of minimum participation rates in the SHOP. We propose that a SHOP (both a State-based and a Federally-facilitated SHOP) that elects to establish a minimum participation rate would be required to establish a single, uniform rate that applies to all groups and issuers in the SHOP, rather than establishing general rules about minimum participation rates or a threshold over which the minimum percentage may not be raised. Therefore, if the SHOP authorizes a minimum participation rate, such a rate would have to be based on the rate of employee participation in the SHOP and in coverage through another group health plan; governmental coverage such as Medicare, Medicaid, or TRICARE; coverage sold through the individual market; or in other minimum essential coverage, and not on the rate of employee participation in any particular QHP or QHPs of any particular issuer. If this proposal is finalized, State-based SHOPs would be expected to conform to it by its effective date.

In section (b)(10)(i), we propose to amend existing language about employees “accepting coverage under the employer’s group health plan” to instead refer to employees “accepting coverage offered by a qualified employer” to better account for employee choice.

We also propose to amend section (b)(10) regarding how the minimum participation rate would be calculated in the SHOP and how it would be calculated in the Federally-facilitated SHOP. In many States, when an issuer calculates the group’s minimum participation rate, the issuer includes employees who enroll in coverage through sources other than the group health plan being insured. Essentially, under this approach, “participation” is interpreted to refer to participation in health coverage, rather than participation in the specific coverage offered through the SHOP. For this reason, we propose to calculate the

minimum participation rate as the number of full-time employees accepting coverage offered by the qualified employer through the SHOP plus the number of full-time employees who are enrolled in coverage through another group health plan, in governmental coverage (such as Medicare, Medicaid or TRICARE), in coverage sold through the individual market, or in other minimum essential coverage, divided by the number of full-time employees offered coverage through the SHOP. Additionally, we believe that references to coverage offered “through another group health plan” would also include coverage offered in connection with an employee organization and joint board comprised of equal employer and employee representatives (multiemployer plan). Because minimum participation rates were designed to reduce the likelihood that a significant percentage of employees might wait to get coverage until they are sick, this policy objective would be met with respect to employees having any existing coverage, not just coverage under their employer’s group health plan.

The effect of this approach to calculating minimum participation rates would be an increased likelihood the group would meet the issuer’s minimum participation rate even if a significant proportion of the group’s employees enroll in other coverage. While the Federally-facilitated SHOP’s minimum participation rate was established to accommodate the variety of minimum participation rates that exist across States, it relied upon a uniform definition of who was included in the rate’s calculation that did not include certain other forms of coverage in which an employee might enroll. Therefore, this proposal would align the Federally-facilitated SHOP’s minimum participation rate methodology with the current practice of issuers in many States. We note that certain types of coverage, such as excepted benefits, were, and would continue to be, excluded from other permissible coverage used in the calculation of the minimum participation rate because the coverage provided through the purchase of an excepted benefit is not the type of coverage purchased through the SHOP and subject to the minimum participation requirement. We seek comment on whether this definition of which employees would be included in the calculation should be extended beyond the SHOP to the entire small-group market in order to create uniformity among issuer practices and prevent further gaming by issuers

through their use of non-standard definitions for other acceptable coverage.

c. Eligibility Standards for SHOP (§ 155.710)

In § 155.710, we propose to amend paragraph (e) to specify that where an employer has offered dependent coverage, a qualified employee would be eligible to enroll his or her dependents in coverage through the SHOP.

d. Enrollment of Employees Into QHPs Under SHOP (§ 155.720 and § 156.285)

In § 155.720, we propose to amend the list structure of paragraph (b) by replacing the “; and” in (b)(6) with a period, and adding an “and” at the end of (b)(5). We also propose to remove paragraph (b)(7), which requires all SHOPs to establish effective dates for employee coverage in the SHOP. Current § 155.720(b)(7) would be redundant if the proposed requirements to establish effective dates under § 155.725 are finalized as proposed.

We propose to amend paragraph (e) to refer to enrollees and not qualified employees, and would also remove a reference in this section to § 156.260(b) in keeping with the proposed amendments to § 155.725 regarding coverage effective dates that are described below. We continue to believe that a QHP issuer’s notice to an enrollee of the coverage effective date provides important confirmation to the enrollee that his or her enrollment has been processed. This amendment would also establish that issuers must provide this notice to anyone who enrolled in coverage through the SHOP under the proposed amendments to the definitions of qualified employee and enrollee advanced in this rulemaking, if those amendments are finalized as proposed, including dependents (including a new dependent of the employee, when the dependent separately joins the plan), former employees of a qualified employer, and certain business owners. We note that the notices required under this proposal could be incorporated into existing notifications that QHPs provide to their new customers, for example in a welcome document. We also propose a conforming amendment to § 156.285(c) to ensure that QHP issuers participating in the Federally-facilitated SHOP would provide notice to a new enrollee of the enrollee’s effective date of coverage.

e. Enrollment Periods Under SHOP (§ 155.725 and § 156.285)

We propose to amend paragraphs (a), (g), (h), and (j)(5) of § 155.725 and

§ 156.285(b)(1) and (b)(4) to provide clarity regarding the effective dates for coverage that all SHOP Exchanges must establish. We are continuing to evaluate whether other provisions of our regulations would require conforming amendments to reflect these proposals, and welcome comment on this topic as well as on these proposals generally. First, we propose to remove the reference at current § 155.725(a)(1) to the start of the initial open enrollment period for 2014 coverage, and the reference in current § 155.725(a)(2) to § 156.260. The start of the initial open enrollment period for 2014 coverage occurred in the past and thus the reference to it is no longer relevant. We propose to remove the reference to effective dates under § 156.260 because we are proposing to specify effective dates in § 155.725 or to more directly cross-reference the appropriate effective date.

Second, we propose to amend § 155.725(h) so that SHOPs would need only to establish effective dates for employees enrolling in coverage during the initial group enrollment and the employee annual open enrollment period, rather than for special enrollment periods, because SHOPs must ensure that effective dates for employees enrolling during special enrollment periods are consistent with the effective dates specified in § 155.420(b). We propose to provide this flexibility during the initial and annual open enrollment periods in order to provide SHOPs with the ability to encourage issuers to accommodate coverage effective dates for a group as soon as possible under local market conditions. However, we propose to continue to keep effective dates for special enrollment periods standardized to ensure a minimum standard for special enrollment periods and because there are existing mechanisms within § 155.420(b) for a SHOP to achieve earlier effective dates for special enrollment periods. At proposed paragraph (h)(2), we would also codify the effective dates for coverage in the Federally-facilitated SHOP for enrollments during initial and annual open enrollment periods. Specifically, we are proposing to include language in the SHOP regulations specifying the same effective dates that were previously adopted for the Federally-facilitated SHOP under our interpretation of the cross reference in § 156.285(b)(4) to § 156.260, which in turn cross-references § 155.410(c). Former § 155.720(b)(7) conflicted with these cross references, such that while § 155.720(b)(7) could have been

interpreted to permit each SHOP to establish its own rules for effective dates for coverage, these cross references appeared to require the use of effective dates determined based on § 155.410(c). The effective dates proposed for the Federally-facilitated SHOP in this rulemaking are the effective dates HHS interpreted as applicable to the Federally-facilitated SHOP under the former rule. However, we note that the dates set forth in § 155.725(h)(2) would apply only to the Federally-facilitated SHOP and State-based SHOPs would be free to establish their own effective dates for initial and annual open enrollment.

Third, we propose several amendments to paragraph § 155.725(g) regarding enrollment for newly qualified employees. A newly qualified employee is an employee who becomes eligible to participate in the employer's group health plan outside of a qualified employer's initial or annual enrollment period; for example, because he or she was hired outside of those periods. We are moving current paragraph (g) to proposed paragraph (g)(1), and are proposing amendments to the existing language to make explicit our interpretation of current paragraph (g), which is that a newly qualified employee becomes eligible for an enrollment period that begins on the first day of becoming a newly qualified employee regardless of whether the employee is subject to a waiting period. The current rule text could also be read to mean that a newly qualified employee's coverage would begin on the first day of becoming a qualified employee, and this proposal will make it clear that this is not our interpretation of the provision. Thus, in the case of a newly hired employee offered coverage by an employer, the employee's enrollment period would begin on the date of his or her hiring. Additionally, we propose that the duration of a newly qualified employee's enrollment period be at least 30 days. We propose a minimum of 30 days because we believe that a shorter period would not provide an employee sufficient time to compare QHPs where employee choice is offered. Where the employee is subject to a waiting period in excess of 45 days, we propose that the duration of the employee's enrollment period extend until 15 days before what would be the conclusion of the waiting period if the employee selected a plan on the first day of becoming eligible. We propose this to permit an employee in an extended waiting period more time to select a plan. We note that if an employee waits to choose a plan until

the end of such an extended enrollment period, this could have the effect of further delaying the effective date of coverage, consistent with § 147.116(a).

We also propose to add a new paragraph (g)(2) in § 155.725 to provide that the effective date for a newly hired employee would be determined using the same rule for initial and open enrollments that would be established by the SHOP under proposed § 155.725(h). Thus, in the Federally-facilitated SHOP, coverage effective dates for newly qualified employees would be established according to § 155.725(h)(2): plan selections made between the first and the fifteenth day of any month would be effective the first day of the following month, and plan selections made between the 16th and the last day of any month would be effective the first day of the second following month. A newly qualified employee may also be subject to a waiting period under § 147.116, however, and in such cases the effective date may be on the first day of a month that is later than the month in which coverage would take effect under the usual rules established by the SHOP under § 155.725(h). However, in no case could the effective date fail to comply with the limitations on waiting period durations at § 147.116 of this subchapter. For example, in the case of an employee who was hired and offered coverage on March 1, where the employer has a waiting period of 60 days, the earliest coverage effective date under proposed § 155.725(g)(2) would be May 1. If the newly qualified employee selects a plan on March 5, the coverage would be effective May 1.

We seek comment on all aspects of this proposal, including on the interactions between a waiting period and the effective date, adverse selection concerns, and ease of administration.

Fourth, we propose to amend paragraph § 155.725(j)(5) to make it more clear that the effective dates for special enrollment periods in the SHOP should be determined according to § 155.420(b).

Fifth, we propose to harmonize § 156.285(b)(1) and (4) with the proposed amendments to effective dates described above, to specify that QHP issuers must abide by the effective dates established under § 155.725 and must enroll qualified employees in accordance with the qualified employer's initial and annual enrollment periods in § 155.725.

We also propose to amend § 155.725(b) to harmonize rolling enrollment in the SHOP with the regulations applicable to guaranteed availability in States with merged

individual and small group markets. Section 147.104(b)(2) requires that all individual or small group health insurance coverage sold in a State with merged individual and small group risk pools be offered on a calendar year basis, meaning that it must end on December 31 of the year in which the policy was issued. Section 155.725(b), in contrast, requires that SHOPs permit qualified employers to purchase coverage for a small group at any point throughout the calendar year, and that SHOPs ensure that a participating group's plan year lasts for 12 months beginning with the first effective date of coverage. Section 155.725(b) was intended to ensure that qualified employers can offer health insurance through the SHOP at any point during the year while receiving a guaranteed rate 12 months following the purchase of coverage, consistent with the current practice in the small group market. We now propose to harmonize these two provisions, by proposing that SHOP plans in a State with merged risk pools would terminate on December 31st of the year in which they were issued, even if certain qualified employers' plan years would thus be shorter than 12 months. This proposal would not affect a small employer's ability to enroll in coverage at any point in the year. Instead, it would standardize the renewal date of such a plan in a State with merged risk pools at the beginning of each calendar year.

We also propose to modify paragraph (i) to permit a SHOP to elect to renew a qualified employer's offer of coverage where the employer has taken no action during its annual election period to modify or withdraw the prior year's offer of coverage. The qualified employer's offer would not be automatically renewed under this proposal if the employer is no longer eligible to participate in the SHOP—for example, because it no longer operates a business within the State served by the SHOP or no longer has at least one employee. Renewal would also not be automatic if the employer is offering a single QHP and that QHP will no longer be available through the SHOP. We are proposing this modification at the request of State-based SHOPs that desire to conform to existing small group market practice regarding automatic annual renewal of coverage for an employer group. A SHOP would not be required to implement this rule.

Finally, we also propose to add paragraph (k) to make clear that SHOP coverage may not be effectuated if the policy may not be issued to the employer because the group fails to

meet an applicable minimum participation rate.

f. Termination of Coverage (§ 155.735 and § 156.285)

In § 155.735, we propose to amend paragraph (c)(2)(ii) to specify that in the Federally-facilitated SHOP, a termination of coverage due to non-payment of premiums would be effective on the last day of the month for which the Federally-facilitated SHOP received full payment. Prior to this proposal, the effective date of such a termination was not specified in the rule.

In paragraph (c)(2)(iii), we propose to specify that, in the Federally-facilitated SHOP, a qualified employer whose coverage was terminated for non-payment of premiums could be reinstated in its prior coverage only once per calendar year. We propose that the number of reinstatements for a given qualified employer be counted on a calendar year basis, rather than on a plan year basis, for ease of administration. The purpose of this proposal is to discourage employers in the Federally-facilitated SHOP from repeatedly failing to make timely payments for health insurance coverage. We note that any employer whose group's coverage is terminated under this proposal could reapply to the Federally-facilitated SHOP by submitting a new application. However, the enrollment based on the new application would be a new plan, not a reinstatement into the plan that was terminated based on non-payment, and therefore amounts paid toward the deductible and annual limitations on cost-sharing would not be carried over from the previous plan, and information submitted on the original application, including basic information about the employer group and the employee roster, would not carry over to the new application.

In paragraphs (d)(1)(iii) and (g) of § 155.735 and in § 156.285(d)(1)(ii), we propose to amend certain existing notice requirements by transferring them from QHP issuers to the SHOP. Under current § 156.285(d)(1)(ii), a QHP issuer must notify an enrollee and a qualified employer if the enrollee or employer is terminated due to a loss of eligibility, due to a qualified employer's non-payment of premiums, due to a rescission of coverage for fraud or misrepresentation of material fact in accordance with § 147.128, or because the QHP issuer elects not to seek recertification with the Exchange for its QHP. We propose to transfer two of these notice requirements to the SHOP. At § 155.735(g)(1), we propose that the

SHOP be required to provide notice to the enrollee if an enrollee is terminated due to non-payment of premium or a loss of eligibility for participation in the SHOP, including when an enrollee loses eligibility due to a qualified employer's loss of eligibility. We also propose at § 155.735(g)(2) that the SHOP be required to provide notice to qualified employers for termination due to nonpayment of premiums or where applicable, due to loss of the employer's eligibility. This provision would generally apply to terminations for loss of an employer's eligibility when the employer lost eligibility for a reason other than the employer reporting information to the SHOP that resulted in the loss of eligibility. For example, this provision would apply where the SHOP learned through an employee appeals process that the employer refused to provide coverage to all full-time employees, which is a condition of the qualified employer's eligibility under § 155.710(b)(2). Typically, we expect employers to lose eligibility voluntarily because they have informed the SHOP that they no longer intend to offer coverage to all full-time employees or because they no longer have a business location in the SHOP's service area. Where the employer is actively informing the SHOP that it no longer meets the SHOP eligibility requirements, we believe providing notification to the employer of the loss of eligibility would be unnecessary.

HHS is proposing to shift these notice requirements to the SHOP because HHS believes the SHOP would be in a better position to provide notices to enrollees and qualified employers with respect to terminations for loss of eligibility and nonpayment of premiums. The SHOP will have better information regarding the timing of non-payment and why an enrollee or employer lost his or her eligibility than a QHP issuer.

Through the proposed amendments to the definition of "enrollee" discussed above, we also propose to expand the class of people who would receive notices under the proposed amendments to § 155.735 and § 155.285(d)(1)(ii). Thus, for example, notice would be given by the SHOP under these amendments to a dependent of a qualified employee who is enrolled in coverage through the SHOP when the dependent loses coverage.

Through proposed amendments to § 156.285(d)(1)(ii) and § 155.735(d)(1)(iii), we also propose that QHP issuers in the SHOP would continue to be required to provide notice to qualified employers and enrollees when an enrollee's coverage is terminated due to a rescission in

accordance with § 147.128, and when an enrollee's coverage is terminated due to an election by a QHP issuer not to seek recertification with the Exchange for its QHP. We are proposing to amend § 155.735(d)(1)(iii), which currently refers to terminations of SHOP coverage due to a QHP's termination or decertification, by adding a reference to terminations of SHOP coverage due to the non-renewal of a QHP's certification. By proposing to include a cross-reference to § 155.735(d)(1)(iii) in § 156.285(d)(1)(ii), we also propose to expand the notice a QHP issuer must provide regarding the discontinuation of a product in which a qualified employee is enrolled to include circumstances where the QHP is terminated or is decertified as described in § 155.1080. In HHS's view, QHP issuers are best positioned to provide meaningful notice when coverage is terminated due to a rescission in accordance with § 147.128 or when the QHP is terminated, decertified, or its certification is not renewed.

We also propose that each notice required under § 155.735 (g) and the proposed amendments to § 156.285(d)(1)(ii) would have to be provided by the SHOP or QHP issuer promptly and without undue delay. We propose this timeframe because we believe it provides flexibility to SHOPS and issuers when such notices may be sent either electronically or by mail. We would consider an electronic notice that was sent no more than 24 hours after the SHOP or QHP issuer determined coverage was to be terminated to have been provided "promptly and without undue delay." In the case of paper notices, we would consider notices that were mailed no later than 48 hours after the SHOP determined coverage was to be terminated to have been provided "promptly and without undue delay."

7. Exchange Functions: Certification of Qualified Health Plans

a. Certification Standards for QHPs (§ 155.1000)

In § 155.1000, we propose to add paragraph (d) to harmonize QHP certification with rolling enrollment in the SHOP. Under § 155.725(b), an employer may start participating in the SHOP at the beginning of any month in the calendar year. Such coverage lasts for 12 months, unless earlier terminated.³⁶ This means that groups

enrolled in the SHOP might have coverage that does not begin and end on a calendar year basis. A QHP that is certified on a calendar year basis is not, however certified to cover an employer group after the calendar year of its certification ends, even if the group's plan year extends into the next calendar year. Therefore, we propose that if a SHOP certifies QHPs on a calendar year basis, the certification must be in effect for the duration of any employer's plan year that began in the calendar year for which the plan was certified. Under this approach, the certification could be in effect beyond the end of the calendar year of the QHP's certification if the plan year of an employer group enrolled in the QHP ended later than the end of that calendar year. In no case in which a SHOP certified QHPs on a calendar year basis would the certification be in effect after December of the year following the calendar year for which the plan was certified.

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

1. General Provisions

a. Definitions (§ 156.20)

For the reasons described in section III.A.1 of this preamble, we propose to amend § 156.20 to add a definition of "plan," which would have the meaning given the term in § 144.103 as proposed to be amended in this rulemaking.

b. FFE User Fee for the 2016 Benefit Year (§ 156.50)

Section 1311(d)(5)(A) of the Affordable Care Act contemplates an Exchange charging assessments or user fees to participating health insurance issuers, or otherwise generating funding to support its operations. In addition, 31 U.S.C. 9701 permits a Federal agency to establish a charge for a service provided by the agency. 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. 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 years 2014 and 2015, issuers seeking to participate in an FFE in benefit year 2016 will receive two special benefits not available to the general public: (1) The certification of their plans as QHPs; and (2) the ability to sell health insurance coverage through an FFE to individuals determined eligible for enrollment in a QHP. 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.
- Enrollment processes.
- Certification processes for QHPs (including ongoing compliance verification, recertification and decertification).
- Administration of a SHOP Exchange.

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 2016 user fee rate for all participating FFE issuers at 3.5 percent. The user fee rate assessed on FFE issuers is the same as the 2015 user fee rate. In addition, we intend to seek an exception to OMB Circular No. A-25R, which requires that the user fee charge be sufficient to recover the full cost to the Federal government of providing the special benefit. We seek this exception to ensure that the FFE can support many of the goals of the Affordable Care Act, including improving the health of the population, reducing health care costs, and providing access to health coverage as advanced by § 156.50(d). We seek comments on this proposal.

2. Essential Health Benefits Package

a. State Selection of Benchmark (§ 156.100)

We propose to amend paragraph (c) of § 156.100 to delete the language regarding the default base-benchmark plan in the U.S. territories of Guam, the U.S. Virgin Islands, American Samoa,

³⁶ As discussed in section III.G.7.d of this proposed rule, under amendments proposed in this rulemaking, SHOP plans in States that have merged their individual and small group markets would terminate on December 31st of the year in which they were issued, even if the plan year would thus be shorter than 12 months.

and the Northern Mariana Islands. The change reflects HHS's determination, described in more detail in section III.A.1.b of this proposed rule, that certain provisions of the PHS Act enacted in title I of the Affordable Care Act that apply to health insurance issuers are appropriately governed by the definition of "State" set forth in that title. Therefore, the rules regarding EHB (section 2707 of the PHS Act) do not apply to health insurance issuers in the U.S. territories. We are also proposing to make a technical change to this section by replacing "defined in § 156.100 of this section" with "described in this section." We note that this has no effect on Medicaid and CHIP programs and that Alternative Benefit Plans will still have to comply with the essential health benefit requirements. We seek comments on these proposals.

b. Provision of EHB (§ 156.115)

Section 1302(b)(1) of the Affordable Care Act provides that the Secretary is to define the essential health benefits (EHB) that must be covered under section 1302(a)(1) by issuers under non-grandfathered small employer and individual market insurance plans. The Secretary's definition must include 10 enumerated benefit categories, and result in a benefit package with a "scope" that is equal to that under a "typical" employer plan "as determined by the Secretary." In our initial regulations defining EHB, we adopted a benchmark plan approach, codified at § 156.100 and § 156.110, under which each State can elect to base the EHB that must be covered in that State on one of several specified "benchmark" plans (for example the largest health plan by enrollment in any of the three largest small group insurance products).

The benchmark plan selected by the State may be modified in certain ways permitted under the regulations, and must be modified to comply with requirements specified in the regulations. For example, we require under § 156.115(a)(3) that the benefit design of the plan must comply with the mental health parity requirements under the Mental Health Parity and Addiction Equity Act, even where those requirements would not otherwise apply. In this proposed rule, we are proposing certain new EHB requirements that would have to be met in order for an issuer to be considered to be offering EHB.

One of the 10 categories of benefits that must, under section 1302(b)(1)(G) of the Act, be included under the Secretary's definition of EHB is "[r]ehabilitative and habilitative services and devices." If a benchmark

plan does not include habilitative services, § 156.110(c)(6) of the current EHB regulations requires the issuer to cover habilitative services as specified by the State under § 156.110(f) or, if the State does not specify, then the issuer must cover habilitative services in the manner specified in § 156.115(a)(5). Section 156.115(a)(5) states that a health plan may provide habilitative coverage by covering habilitative services benefits that are similar in scope, amount, and duration to benefits covered for rehabilitative services or otherwise determine which services are covered and report the determination to HHS. In some instances, those options have not resulted in comprehensive coverage for habilitative services. Therefore, we propose amending § 156.115(a)(5) to establish a uniform definition of habilitative services that may be used by States and issuers. In addition, we propose to remove § 156.110(c)(6) because that provision gives issuers the option to determine the scope of habilitative services.

We believe that adopting a uniform definition of habilitative services would minimize the variability in benefits and lack of coverage for habilitative services versus rehabilitative services. Defining habilitation services clarifies the difference between habilitative and rehabilitation services. Habilitative services, including devices, are provided for a person to attain, maintain or prevent deterioration of a skill or function never learned or acquired due to a disabling condition. Rehabilitation services, including devices, on the other hand, are provided to help a person regain, maintain or prevent deterioration of a skill or function that has been acquired but then lost or impaired due to illness, injury, or disabling condition.

We seek comment on whether we should maintain the current policy, define habilitative services as described below or permit the use of one or more other specified definitions.

The proposed definition comes from the Glossary of Health Coverage and Medical Terms:³⁷ "health care services that help a person keep, learn, or improve skills and functioning for daily living. Examples include therapy for a child who is not walking or talking at the expected age. These services may include physical and occupational therapy, speech-language pathology and other services for people with disabilities in a variety of inpatient and/or outpatient settings."

³⁷ <http://www.cms.gov/CCIIO/Resources/Files/Downloads/uniform-glossary-final.pdf>.

We considered and invite comment on whether we should require certain specified services to be included as habilitative services.

We are not proposing any changes to § 156.110(f). Several States have made such a determination following benchmark selection for the 2014 plan year, and we wish to continue to defer to States on this matter as long as the State definition complies with EHB policies including non-discrimination. Therefore, under the proposed amendments, if the base-benchmark plan does not include coverage of habilitative services, the State may determine which services are included in that category, as stated in § 156.110(f). If the State does not supplement missing habilitative services or does not supplement in an EHB-compliant manner, issuers should cover habilitative services as defined in § 156.115(a)(5)(i).

We also propose to revise current § 156.115(a)(5)(ii) to provide that plans required to provide EHB cannot impose limits on coverage of habilitative services that are less favorable than any such limits imposed on coverage of rehabilitative services. Since the statutory category includes both rehabilitative and habilitative services and devices, we interpret the statute to require coverage of each. Therefore, issuers that previously excluded habilitative services, but subsequently added them, would be required under our proposal to impose separate limits on each service rather than retaining the rehabilitative services visit limit and having habilitative services count toward the same visit limit. Because we are proposing to establish a uniform definition of habilitative services in new § 156.115(a)(5)(i), we are also proposing to delete § 156.110(c)(6), which would remove the option for issuers to determine the scope of the habilitative services. In § 156.110 we make a technical change to amend the list structure of paragraph (c) by replacing the "and" in (c)(5) with a period and adding an "and" at the end of (c)(4).

In the preamble of the EHB Rule, we stated that pediatric services should be provided until at least age 19 (78 FR 12843). States, issuers, and stakeholders have requested clarification on this standard. To provide this clarification, we propose amending § 156.115(a) to add paragraph (a)(6), specifying that EHB coverage for pediatric services should continue until the end of the plan year in which the enrollee turns 19 years of age. This is proposed as a minimum requirement.

This age limit is consistent with section 1201 of the Affordable Care

Act,³⁸ which phased in the prohibition on preexisting conditions exclusions by first prohibiting them for children under age 19, as well as the age limit for eligibility to enroll in CHIP. In addition, as noted in the EHB Rule, this proposed policy aligns with Medicaid (78 FR 12843), which requires States to cover children up to age 19 with family incomes up to 100 percent of the Federal Poverty Level (FPL) as a mandatory eligibility category. We propose the end of the plan year in which one attains age 19 is best for continuity of care. We seek comment on this proposed standard.

c. Collection of Data To Define Essential Health Benefits (§ 156.120)

In the Essential Health Benefits Bulletin,³⁹ we first stated our intent to define EHB based on a benchmark plan. We outlined ten possible options, including four different plan benchmark types, from which a State could select its benchmark plan. We finalized this benchmark approach in the EHB Rule at §§ 156.100 and 156.110 of our regulations.

In the Patient Protection and Affordable Care Act; Data Collection to Support Standards Related to Essential Health Benefits; Recognition of Entities for the Accreditation of Qualified Health Plans final rule (EHB Data Collection Rule),⁴⁰ we required issuers in each State that offered the three largest health insurance products by enrollment as of March 31, 2012 to submit certain data to HHS by September 4, 2012. These data, gathered from 2012 plans, were used to determine, for each State, the benefits and limitations of the three largest small group products by enrollment, which were potential benchmark plans.

The EHB Rule unintentionally deleted § 156.120, which included the data submission requirement. We are proposing to allow each State to select a new base-benchmark plan for the 2017 plan year. We would allow States to choose a 2014 plan that meets the requirements of § 156.110 as the new

base-benchmark plan, so that issuers can design substantially equal EHB-compliant products for the 2017 plan year. We believe that this would ultimately create efficiencies for issuers in designing plans. Specifically, the use of updated base-benchmark plans should minimize confusion because most 2014 plans are compliant with § 156.110 and the various market reform requirements that became applicable for plan and policy years beginning in 2014. Those 2014 market reform requirements include removal of annual and lifetime dollar limits on EHBs and compliance with the Mental Health Parity and Addiction Equity Act of 2008.

If a category of base-benchmark plans under § 156.100(a)(1)–(4) does not include a plan that that meets the requirements of § 156.110, we are considering permitting the State to select a base-benchmark plan that does not meet the requirements of § 156.110 in that category. However, States would still need to supplement their base-benchmark plan to ensure that all 10 categories of benefits are covered in a benchmark plan. We seek comment on this issue, including alternate ways of addressing situations in which a State has few potential base-benchmark plans that meet the requirements of § 156.110 from which to choose.

We now propose to re-codify part of § 156.120, in a manner similar to that which appeared in our regulations prior to the effective date of the EHB Rule. We propose to require a State that chooses a new benchmark plan in the State or, if a State does not choose a new benchmark plan, the issuer of the default benchmark plan must provide benchmark plan data as of a date specified by HHS. We anticipate collection of new benchmark plan data for the 2017 plan year and the data discussed in § 156.120(b), including administrative data and descriptive information pertaining to all health benefits in the plan, treatment limitations, drug coverage, and exclusions. We believe that this information is already included in the issuer's form filing that the issuer submitted to the State regulator. The definitions previously adopted for the terms health benefits, health insurance product, health plan, small group market, State and treatment limitations are still applicable. We seek comment on this proposal.

d. Prescription Drug Benefits (§ 156.122)

Another category of benefits that must be covered under the Secretary's definition of EHB is "prescription drugs" under section 1302(b)(1)(F).

While we generally implemented this part of the definition by deferring to the scope of coverage under a benchmark plan, we imposed specific additional requirements under § 156.122. For example, under current § 156.122(a)(2), we require that an issuer's drug list be submitted to the Exchange, the State, or United States Office of Personnel Management (OPM) as appropriate. Under this section, we are proposing several revisions to the EHB prescription drug benefit requirements.

First, we are proposing to retain § 156.122(a)(2) with one modification to change "drug list" to "formulary drug list" for uniformity purposes for this section. We are also proposing to renumber this paragraph from § 156.122(a)(2) to § 156.122(a)(1).

Under our current regulations at § 156.122(a)(1) that we are proposing to replace, EHB plans are required to cover the greater of one drug per United States Pharmacopeia (USP) category or class or the same number of drugs in each USP category and class as the State's EHB benchmark plan. To implement this requirement, we worked with issuers, States, the NAIC, and other stakeholders to facilitate the use of the USP classification system based on USP Model Guidelines Version 5.0. We also provided a tool for States and issuers to count clinically distinct drugs and categorize them into the USP system.

The intention of § 156.122(a)(1) was to require comprehensive coverage and establish a common organizational tool for plans to report drug coverage. However, we have found that issuers have often had difficulty developing formularies that conform to the USP drug category and class system. Because the USP system was developed for the Medicare population, some drugs that are likely to be prescribed for the larger EHB population were not reflected. There were also many operational challenges associated with the drug count standard: Newly approved drugs were not counted; some drugs were counted in multiple USP classes; discontinued drugs had to be manually removed from the counting tool; and issuers had to submit justifications to explain their inability to meet the benchmark count due to system issues. We also found that the drug count review did not encourage the inclusion of newly-approved drugs and did not provide an incentive for issuers to cover innovative products or other products that would not be counted using this counting standard. For these reasons, we are proposing an alternative to the above drug count standard, which we discuss below. We are also seeking comment on a second alternative that

³⁸ Section 1201 of the Affordable Care Act added section 2704 of the PHS Act, which prohibited preexisting condition exclusions. Section 1255 of the Affordable Care Act states that the provisions of section 2704 of the PHS Act, as they apply to enrollees who are under 19 years of age, shall become effective for plan years beginning on after September 23, 2010.

³⁹ Essential Health Benefits Bulletin (December 16, 2011), available at: http://www.cms.gov/CCIIO/Resources/Files/Downloads/essential_health_benefits_bulletin.pdf.

⁴⁰ Patient Protection and Affordable Care Act; Data Collection to Support Standards Related to Essential Health Benefits; Recognition of Entities for the Accreditation of Qualified Health Plans, 77 FR 42658 (July 20, 2013) (codified at 45 CFR part 156).

could be adopted in lieu or in combination with our proposal below.

We are proposing to replace the drug count standard with a requirement in § 156.122(a)(2) that plans adopt a pharmacy and therapeutics (P&T) committee and use that committee to ensure that the plan's formulary drug list covers a sufficient number and type of prescription drugs. We are proposing P&T committee standards that must be met for the prescription drug coverage to be considered EHB. We believe that the use of a P&T committee in conjunction with the other standards that we are proposing would help ensure that an issuer's formulary drug list covers a broad array of prescription drugs. The Medicare Part D Prescription Drug Program (Medicare Part D), the NAIC and other stakeholders have defined standards by which a P&T committee should function.⁴¹ We are interested in comments regarding these standards and whether we should adopt them in lieu of or in addition to the standards we are proposing. If this proposal is finalized, plans that are required to cover EHB would cover drugs based on a qualitative rather than merely quantitative perspective, which we believe will provide enrollees with a more robust formulary drug list.

We propose to specify P&T committee standards on membership, meetings, and establishment and development of a formulary drug list. For P&T committee membership, we propose requiring the P&T committee to include members from a sufficient number of clinical specialties to adequately represent the needs of enrollees. For instance, we would expect that the P&T committee members include experts in chronic diseases and in the care of individuals with disabilities. We propose that the majority of members be practicing physicians, practicing pharmacists and other practicing health care professionals. We also solicit comments on whether the types of other practicing health care professionals should be more narrowly defined to only include other practicing health care professionals who can prescribe drugs. Additionally, we propose to require that members of the P&T committee that have a conflict of interest with respect to the issuer or a pharmaceutical manufacturer would be permitted to sit on the P&T committee

but would be prohibited from voting on matters for which the conflict exists. In addition to these requirements, we would also propose that at least 20 percent of the P&T committee's membership must have no conflict of interest with respect to either the issuer or to any pharmaceutical manufacturer. Under these standards, a member who holds more than one health care license, for example, as a nurse practitioner and a pharmacist, would only count as one person. We also solicit comments on the percentage of committee members that should have no conflict of interest, and the proposed requirement that the members of the P&T committee with conflicts of interest should be permitted to sit on the P&T committee but would be prohibited from voting on matters for which the conflict exists. We considered requiring a set number of participants to be independent and have no conflicts of interest, but we were concerned that absent a limitation on the total number committee members, requiring a specific number of committee members to be independent and not have a conflict of interest would have a variable impact, depending on the size of the P&T committee. We are also proposing that the P&T committee would be responsible for defining a reasonable definition of conflict of interest and for managing the conflicts of interest of its committee members. As part of this standard, the P&T committee would require its P&T committee members to sign a conflict of interest statement revealing economic or other relationships with entities, including the issuer and any pharmaceutical manufacturers, affected by drug coverage decisions that could influence committee decisions. We solicit comments on this proposed standard, including the implementation of this conflict of interest standard, whether there are additional conflict of interest standards that should apply and what would constitute a conflict of interest. In particular, we seek comments on what could be considered a permissible relationship with respect to the issuer or a pharmaceutical manufacturer. If this provision is finalized, we would consider providing further guidance regarding conflict of interest.

We also propose that the P&T committee must meet at least quarterly, and maintain written documentation of all decisions regarding formulary drug list's development and revision. With respect to formulary drug list establishment and management, we are proposing that the P&T committee must develop and document procedures to ensure appropriate drug review and

inclusion on the formulary drug list, as well as make clinical decisions based on scientific evidence, such as peer-reviewed medical literature, and standards of practice, such as well-established clinical practice guidelines. The P&T committee must consider the therapeutic advantages of prescription drugs in terms of safety and efficacy when selecting formulary drugs and making recommendations with respect to their formulary tier. The P&T committee must review both newly FDA-approved drugs and new uses for existing drugs. We also propose that a P&T committee must ensure that an issuer's formulary drug list covers a range of drugs across a broad distribution of therapeutic categories and classes and recommended drug treatment regimens that treat all disease states and does not substantially discourage enrollment by any group of enrollees.

Lastly, we propose to require that issuers' formularies provide appropriate access to drugs that are included in broadly accepted treatment guidelines and which are indicative of and consistent with general best practice formularies in widespread use. Broadly accepted treatment guidelines and general best practices could be based on industry standards or other appropriate guidelines that are issued by expert organizations that are current at the time. For instance, broadly accepted treatment guidelines could include guidelines provided in the National Guideline Clearinghouse (NGC), which is a publicly available database of evidence-based clinical practice guidelines and related documents.⁴² As a result of this proposed policy, we would expect that a health plan's formulary drug list would ensure that appropriate access is being afforded to drugs in widely accepted national treatment guidelines and which are indicative of general best practices at the time. Given our proposal to use broadly accepted treatment guidelines and best practices, we would also expect that plans' formulary drug lists be similar to those formulary drug lists then currently in widespread use. We also note that States have primary responsibility for enforcing EHB requirements and if finalized, States would be responsible for the oversight and enforcement of the P&T committee standards. Currently, for QHPs, we have provided States with tools to review formulary drug lists and if these provisions are finalized, we could consider developing additional tools

⁴¹ Medicare Part D plans are required to maintain P&T committees by the Social Security Act § 1860D-4(b)(3)(G) codified at 42 CFR § 423.120(b), 42 CFR § 423.272(b)(2). NAIC has a Model Act entitled Health Carriers Prescription Drug Benefit Management Model Act (July 2003) that includes P&T Committee provisions at: <http://www.naic.org/store/free/MDL-22.pdf>.

⁴² <http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/index.html>.

and resources to assist States in reviewing formulary drug lists. We seek comment on these proposed revisions to § 156.122(a), including the oversight and enforcement of these standards, and whether other standards are needed for P&T committees.

As an alternative to, or in combination with, the above-proposed P&T committee requirements, we are also considering whether to replace the USP standard with a standard based on the American Hospital Formulary Service (AHFS). AHFS is a widely used formulary reference system in the private insurance market and is often used for developing formularies for the population being covered by EHB. The AHFS system is a 4-tier hierarchical drug classification system that is updated and published annually by the American Society of Health-System Pharmacists. These tiers are grouped based on similar pharmacologic, therapeutic, and chemical characteristics. Compared to the USP system, the AHFS system is more gradual and has more classifications than the USP system. We believe that using the AHFS system that incorporates these additional classifications would better ensure that a broader distribution of drugs would be required to be covered to meet the drug count standard than in the current USP system where there are fewer categories and classes. Because we believe that many issuers are already familiar with the AHFS system, we would expect that the impact from switching from the USP system would be minimal, and we have received comments from stakeholders recommending that we consider using AHFS as an alternative to USP.

We seek comment on the proposed P&T committee standard and whether we should consider adopting AHFS or another drug classification system, as well as on any other standards that may be appropriate for this purpose. We are particularly interested in comments on how to use AHFS to develop a minimum standard for issuers to meet. For instance, for the AHFS system, we could switch the current minimum standard that requires coverage of at least the greater of one drug in every USP category and class or the same number of drugs in each USP category and class as the State's EHB-benchmark plan to require at least the greater of one drug in each AHFS class and subclass or the same number of drugs in each AHFS class and subclass as the State's EHB-benchmark plan.

If we were to finalize a P&T committee process in combination with a drug count standard based on either

the AHFS system or the USP system, we would expect the health plan would establish and maintain its formulary drug list in compliance with the P&T committee standards, and in addition, the resulting health plan's formulary drug list would also need to comply with the drug count standard. However, we seek comment on how the drug count system could be used in combination with a P&T committee approach, such as specifying that the formulary drug list is generally being designed by the P&T committee, but that it must also include at least one drug in each AHFS class and subclass or USP category and class.

We could also continue to use the existing USP drug count standard, and update the USP drug count system to use a more current version. States and issuers are now familiar with the USP drug count standard, having used it to develop formularies for the 2014 and 2015 plan years. One of the advantages of the USP system is that it is publicly available, in comparison to the AHFS, which must be licensed.

We also recognize that a requirement to transition to a P&T committee standard or another drug count standard will require lead time for States, issuers and pharmacy benefit managers to implement. Therefore, we are proposing to implement § 156.122(a)(2) starting with the 2017 plan year. We seek comments on this proposed timing of implementation.

Section 156.122(c) currently requires issuers of EHB plans to have procedures in place that allow an enrollee to request and gain access to clinically appropriate drugs not covered by the plan. We believe this requirement is necessary to ensure that an issuer provides the level of drug coverage to cover the EHB category of prescription drugs. This requirement, commonly referred to as the "exceptions process," applies to drugs that are not included on the plan's formulary drug list, as opposed to the appeals process codified at § 147.136, which applies if an enrollee receives an adverse benefit determination for a drug that is included on the plan's formulary drug list. Under current § 156.122(c)(1) (effective in 2015), such procedures must include a process that allows an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber) to request an expedited review based on exigent circumstances. Exigent circumstances exist when an enrollee is suffering from a serious health condition that may seriously jeopardize the enrollee's life, health, or ability to regain maximum function or when an enrollee is undergoing a

current course of treatment using a non-formulary drug. A health plan must make its coverage determination on an expedited review request based on exigent circumstances, and notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage determination no later than 24 hours after it receives the request. A health plan that grants an exception based on exigent circumstances must provide coverage of the non-formulary drug for the duration of the exigency.

We recognize the importance of the procedures under § 156.122(c) for enrollees, especially for those with unique and complex health conditions. The intention of the exceptions process is to better ensure enrollee access to clinically appropriate, non-formulary drugs prescribed for them. However, we believe that enrollees who are trying to gain access to a drug through the exceptions process laid out in current § 156.122(c) would benefit if we set clearer and more uniform standards for issuers that receive an exception request. We believe that these additional parameters are also needed to better ensure that enrollees can obtain drugs that we believe should be covered as prescription drugs under the definition of EHB. Specifically, we are proposing to build on the expedited exception process that we established for 2015 by proposing to also adopt similar requirements for the standard exception process. We are also proposing to adopt standards for a secondary external review process if the first exception request is denied by the plan (regardless of whether the exception is requested using the standard process or the expedited process).

Under proposed § 156.122(c), a health plan providing EHB must have certain exception processes in place that allow an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber) to request and gain access to clinically appropriate drugs not otherwise covered by the health plan, and when an exception requested under one of these processes is granted, the plan must treat the excepted drug as EHB for all purposes, including accrual to the annual limitation on cost-sharing. Proposed § 156.122(c)(1) sets forth the standard exception process. Under this process, we are proposing that a health plan have a process for an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber) to request a standard review of a decision for a drug is not covered by the plan. We propose that the health plan must make its coverage determination on a standard exception

request and notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage determination no later than 72 hours after it receives the request. We are proposing to require a health plan that grants an exception based on the standard review process to provide coverage of the non-formulary drug for the duration of the prescription, including refills and are clarifying that in such a case the excepted drug would be considered EHB for all purposes, including for purposes of counting towards the annual limitation on cost sharing. As stated in the EHB Rule (78 FR 12845), plans are permitted to go beyond the number of drugs offered by the benchmark without exceeding EHB. Therefore, if the plan is covering drugs beyond the number of drugs covered by the benchmark, all of these drugs are EHB and must count towards the annual limitation on cost sharing.

The expedited exception process currently appears in our regulations at § 156.122(c)(1), and we are proposing to move that section to a new § 156.122(c)(2) and to replace "Such procedures must include" with "A health plan must have" in current paragraph (c)(1) (proposed as a new paragraph (c)(2)(i)).

In § 156.122(c)(3) we propose that if the health plan denies an exception request for a non-formulary drug, the issuer must have process for an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber, as appropriate) to request that an independent review organization review the exception request and the denial of that request by the plan. For this external exception review, we propose to apply the same timing that applied to the initial review. Thus, if the enrollee requested the drug under the proposed standard process and the request was denied, then the independent review organization would have to make its determination and the health plan would have to notify the enrollee or enrollee's designee and the prescribing physician (or other prescriber, as appropriate) no later than 72 hours after the time it receives the external exception review request. Likewise, if the initial exception request is for an expedited review and that request is denied by the plan, then the independent review organization must make its coverage determination and provide appropriate notification no later than 24 hours after the time it receives the external exception review request. We also propose that the independent review organization would have to be accredited by a nationally recognized

private accrediting organization and the issuer could use the same independent review organization for the external review for the drug exception process that the plan may contract with under the final external review decision under § 147.136. We seek comment on this proposal, including whether permitting issuers to use the same independent review organization that it may use to conduct external reviews under § 147.136 would ensure consumers access to an independent review while minimizing the burden on States, plans, and issuers.

As discussed in the 2015 Market Standards Rule, we received comments from stakeholders supporting these types of requirements for the exception process under § 156.122(c) and these parameters reflect our previous guidance on § 156.122(c) under Appendix C of the 2014 Letter to Issuers on Federally-facilitated and State Partnership Exchanges (2014 Letter to Issuers).⁴³ We solicit comments on all of the proposed requirements, and whether any additional standards are needed for the exception process. Lastly, we are also proposing to apply the revised § 156.122(c) to the 2016 plan year, and solicit comments on this proposed timing.

Under § 156.122(d), we propose adding a requirement to the EHB prescription drug benefit that a health plan must publish an up-to-date, accurate, and complete list of all covered drugs on its formulary drug list, including any tiering structure that it has adopted and any restrictions on the manner in which a drug can be obtained, in a manner that is easily accessible to plan enrollees, prospective enrollees, the State, the Exchange, HHS, OPM, and the general public. We also solicit comment on whether the formulary tiering information should include cost sharing information, such as the enrollee's applicable pharmacy deductible (for example, \$100), copayment (for example, \$20), or cost sharing percentage for the enrollee (for example, 20 percent).

We are proposing that a formulary drug list is easily accessible when the general public is able to view the formulary drug list on the plan's public Web site through a clearly identifiable link or tab and without creating or accessing an account or entering a policy number. The general public should be able to easily discern which formulary drug list applies to which

plan if the issuer maintains multiple formularies, and the plan associated with each formulary drug list should be clearly identified on the plan's Web site. We are proposing this requirement to better ensure transparency of the EHB prescription drug benefit and to help consumers make more informed choices about their health care coverage.

As a result of this proposed requirement, we would expect the issuers' formulary drug list URL link to be up-to-date and we interpret up-to-date to mean that the formulary drug list URL must accurately list all of the health plan's covered drugs at that time. We solicit comments on this timing. Also, the formulary drug list URL link under this section should be the same direct formulary drug list URL link for obtaining information on prescription drug coverage in the Summary of Benefits and Coverage, in accordance with § 147.200(a)(2)(i)(K). We propose that this requirement would be effective beginning with the 2016 plan year. We solicit comments on these proposed requirements, including whether we should require that additional types of information be included in the formulary drug list.

As part of this proposed requirement that issuers' formulary drug list must be made available to the general public, we are also considering requiring issuers to make this information publicly available on their Web sites in a machine-readable file and format specified by HHS. The purpose of establishing machine-readable files with the formulary drug list data would be to provide the opportunity for third parties to create resources that aggregate information on different plans. We believe this option would increase transparency by allowing software developers to access this information and create innovative and informative tools to help enrollees better understand plans' formulary drug lists. As an alternative, we are also considering whether the formulary drug list information could be submitted to HHS through an HHS-designed standardized template, but we recognize that there may be challenges with keeping this type of template information updated. Thus, we specifically solicit comments on these options, including the technical requirements for developing a machine-readable file and format for a formulary drug list, as well as other technical considerations, such as processes and considerations that should be taken into account for the updating of this information under either of the options being considered.

Currently, issuers are permitted to elect the method for providing covered

⁴³ 2014 Letter to Issuers on Federally-facilitated and State Partnership Exchanges. http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2014_letter_to_issuers_04052013.pdf.

drugs to enrollees, and may use a mail order pharmacy to do so. While this generally is more cost-effective and more convenient for enrollees than requiring the enrollee to visit a retail pharmacy to obtain prescription drugs, there are circumstances under which obtaining drugs via mail order may not be viable. For example, obtaining prescription drugs through mail order may not be a viable option when an individual does not have a stable living environment and does not have a permanent address. In those cases, individuals may not always have the ability to keep a mail order pharmacy delivery confidential. There are also cases in which a drug needs to be provided immediately (for example, antibiotics or pain relievers). In such cases, we do not believe that making drugs available only by mail order constitutes fulfilling the obligation under 1302(b)(1)(F) of the Affordable Care Act to provide prescription drug coverage as part of EHB. We also believe that making drugs available only by mail order would discourage enrollment by, and thus discriminate against, transient individuals and certain individuals who have conditions that they wish to keep confidential.

Accordingly, under § 156.122(e), we are proposing to add new requirements to the EHB prescription drug definition to require that enrollees be provided with the option to access their prescription drug benefit through retail (brick-and-mortar or non-mail order) pharmacies. If finalized, this requirement would mean that a health plan that is required to cover the EHB package cannot have a mail order only prescription drug benefit. This proposed requirement would still allow a health plan to charge a higher cost-sharing amount when obtaining the drug at an in-network retail pharmacy than he or she would pay for obtaining the same covered drug at a mail-order pharmacy. However, as a part of these requirements, we propose to clarify that this additional cost sharing for the covered drug would count towards the plan's annual limitation on cost sharing under § 156.130 and would need to be taken into account when calculating the actuarial value of the health plan under § 156.135. Additionally, issuers will still retain the flexibility under this proposed policy to charge a lower cost sharing amount when obtaining the drug at an in-network retail pharmacy too. While this proposal requires coverage of a drug at an in-network retail pharmacy, for plans that do not have a network, the enrollee should be able to go to any pharmacy to access

their prescription drug benefit and those plans would, therefore, comply with this proposed standard.

We also recognize as part of this proposed requirement that certain drugs have limited access requirements and cannot always be accessed through in-network retail pharmacies. For this reason, we are proposing that the health plan may restrict access to a particular drug when: (1) The FDA has restricted distribution of the drug to certain facilities or practitioners (including physicians); or (2) appropriate dispensing of the drug requires extraordinary special handling, provider coordination, or patient education that cannot be met by a retail pharmacy. For instance, certain drugs have a Risk Evaluation and Mitigation Strategies (REMS) that include Elements to Assure Safe Use that may require that pharmacies, practitioners or healthcare settings that dispense the drug to be specially certified and can limit access to the drugs to certain health care settings.⁴⁴ We propose that additional education or counseling alone would not qualify a drug to be restricted to limited distribution to a non-retail pharmacy within the overall pharmacy network. If the health plan finds it necessary to restrict access to a drug for either of the two reasons listed above, it must indicate this restricted access on the formulary drug list that we are proposing plans must make publicly available under § 156.122(d).

We are soliciting comments on these proposed requirements, including whether additional standards should be adopted to ensure enrollee access to the EHB prescription drug benefit, or whether additional exemptions to accessing drugs at in-network retail pharmacies should be permitted. We are proposing these requirements as market-wide standards to ensure the uniformity of the EHB prescription drug benefit and proposing to implement these requirements beginning with the 2017 plan year. However, we are soliciting comments on this timing and whether it should be implemented in 2016.

In addition to the proposed provisions above, we are also aware that new enrollees in plans that are required to cover EHB may be unfamiliar with what is covered on their new plan's formulary drug list, and how to use the plan's prescription drug exceptions process. Also, some enrollees whose drugs are

covered by the plan's formulary may need to obtain prior authorization or go through step therapy in order to have coverage for the drug. Since new enrollees may need more immediate coverage for drugs that they have been prescribed and are currently taking, we urge issuers to temporarily cover non-formulary drugs (including drugs that are on an issuer's formulary but require prior authorization or step therapy) as if they were on formulary (or without imposing prior authorization or step therapy requirements) during the first 30 days of coverage. We encourage plans to adopt this policy to accommodate the immediate needs of enrollees, while allowing the enrollee sufficient time to go through the prior authorization or drug exception processes. We are considering whether requirements may be needed in this area.

e. Prohibition on Discrimination (§ 156.125)

Section 1302(b)(4) of the Affordable Care Act directs the Secretary to address certain standards in defining EHB, including elements related to balance, discrimination, the needs of diverse sections of the population, and denial of benefits. We have interpreted this provision as a prohibition on discrimination by issuers providing EHB. Within § 156.125, which implements these provisions, we finalized in the EHB Rule that an issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions.

Since we finalized § 156.125, we have become aware of benefit designs that we believe would discourage enrollment by individuals based on age or based on health conditions, in effect making those plan designs discriminatory, thus violating this prohibition. Some issuers have maintained limits and exclusions that were included in the State EHB-benchmark plan. As we have previously stated in guidance, EHB-benchmark plans may not reflect all requirements effective for plan years starting on or after January 1, 2014. Therefore, when designing plans that are substantially equal to the EHB-benchmark plan, issuers should design plan benefits, including coverage and limitations, to comply with requirements and

⁴⁴ FDA requires a Risk Evaluation and Mitigation Strategies (REMS) for certain drugs to ensure that the benefits of a drug or biological product outweigh its risks. The following is FDA's list of currently approved REMS at: <http://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm111350.htm>.

limitations that apply to plans beginning in 2014.⁴⁵

We caution both issuers and States that age limits are discriminatory when applied to services that have been found clinically effective at all ages. For example, it would be arbitrary to limit a hearing aid to enrollees who are 6 years of age and younger since there may be some older enrollees for whom a hearing aid is medically necessary. Although we do not enumerate which benefits fall into each statutory EHB category, issuers should not attempt to circumvent coverage of medically necessary benefits by labeling the benefit as a “pediatric service”, thereby excluding adults.

We also caution issuers to avoid discouraging enrollment of individuals with chronic health needs. For example, if an issuer refuses to cover a single-tablet drug regimen or extended-release product that is customarily prescribed and is just as effective as a multi-tablet regimen, we believe that, absent an appropriate reason for such refusal, such a plan design effectively discriminates against, or discourages enrollment by, individuals who would benefit from such innovative therapeutic options. As another example, if an issuer places most or all drugs that treat a specific condition on the highest cost tiers, we believe that such plan designs effectively discriminate against, or discourage enrollment by, individuals who have those chronic conditions.

As we indicated in the 2014 Letter to Issuers, we will notify an issuer when we see an indication of a reduction in the generosity of a benefit in some manner for subsets of individuals that is not based on clinically indicated, reasonable medical management practices.⁴⁶ We conduct this examination whenever an EHB plan reduces benefits for a particular group. Issuers are expected to impose limitations and exclusions based on clinical guidelines and medical evidence, and are expected to use reasonable medical management. Issuers may be asked to submit justification with supporting document to HHS or the State explaining how the plan design is not discriminatory.

Other nondiscrimination and civil rights laws may apply, including the Americans with Disabilities Act, section 1557 of the Affordable Care Act, Title VI

of the Civil Rights Act of 1964, the Age Discrimination Act of 1975, section 504 of the Rehabilitation Act of 1973 and State law. Compliance with § 156.125 is not determinative of compliance with any other applicable requirements and § 156.125 does not apply to the Medicaid and CHIP programs, including EPSDT, and Alternative Benefit Plans.

We also note that all non-grandfathered health insurance plans in the individual and small group market that are subject to the EHB requirements are also subject to the guaranteed renewability requirements under § 147.106, which allow issuers to make uniform modifications to a product only at the time of coverage renewal. For example, an EHB plan may not change cost sharing for a particular benefit mid-year.

f. Cost-Sharing Requirements (§ 156.130)

We propose to amend § 156.130 to clarify how the annual limitation on cost sharing applies to plans that operate on a non-calendar year, and to make a technical correction to the special rule for network plans. First, we propose to add a new § 156.130(b), which would provide that non-calendar year plans that are subject to the annual limitation on cost sharing in section 1302(c)(1) must adhere to the annual limitation that is specific to the calendar year in which the plan begins. That annual limitation amount would serve as the maximum for the entire plan year. We propose this requirement to clarify that non-calendar plans subject to § 156.130 are not permitted to reset the plan’s annual limitation on cost sharing at the end of the calendar year when the end of the calendar year is not the end of the plan year. The purpose of this proposed change is to ensure that the enrollee should only be required to accumulate cost sharing that applies to one annual limit per plan year. We believe that this requirement ensures an important consumer protection and we solicit comments on this proposal.

Under section 1302(c)(3) of the Affordable Care Act, the term “cost-sharing” includes deductibles, coinsurance, copayments, or similar charges, and any other expenditure required of an individual that is a qualified medical expense (within the meaning of section 223(d)(2) of the Internal Revenue Code of 1986) for EHB covered under the plan. Expenditures that meet this definition of cost sharing must, under section 1302(c) of the Affordable Care Act, count toward the annual limitation on cost sharing incurred under a health plan that is required to cover EHB. The term “cost-sharing” does not include premiums,

balance billing amounts for non-network providers, or spending for non-covered services. This definition was codified in § 155.20.

In this proposed rule, we propose to make a technical correction to the text of § 156.130(c) on the special rule for network plans to replace “shall not” with “is not required to.” This correction is in accordance with the Affordable Care Act Implementation FAQs (Set 18) that was prepared jointly by the Departments of Labor, Health and Human Services (HHS), and the Treasury.⁴⁷ This proposed amendment is to clarify that issuers have the option to count the cost sharing for out-of-network services towards the annual limitation on cost sharing, but are not required to do so. This out-of-network cost sharing would not count toward the calculation of actuarial value under § 156.135(b)(4) or meeting a given level of coverage under § 156.140.

In addition to the above proposed changes to § 156.130, we also propose clarifying that the annual limitation on cost sharing for self-only coverage applies to all individuals regardless of whether the individual is covered by a self-only plan or is covered by a plan that is other than self-only. In both of these cases, an individual’s cost sharing for the EHB may never exceed the self-only annual limitation on cost sharing. For example, under the proposed 2016 annual limitation on cost sharing, if an other than self-only plan has an annual limitation on cost sharing of \$10,000 and one individual in the family plan incurs \$20,000 in expenses from a hospital stay, that particular individual would only be responsible for paying the cost sharing related to the costs of the hospital stay covered as EHB up to the annual limit on cost sharing for self-only coverage that is proposed to be \$6,850 for 2016. However, for a plan with other than self-only coverage, as long as the plan applies an annual limitation on cost sharing that is at or below the annual limitation for self-only coverage (proposed to be \$6,850 for 2016) for each individual in the plan and at or below the annual limitation for other than self-only coverage (which is proposed to be \$13,700 for 2016), the issuer has flexibility on how to apply the plan’s annual limitation on cost sharing between the individuals in the plan.

We seek comments on these requirements and clarifications. We also seek comments on whether other requirements and clarifications are

⁴⁵ Guide to Reviewing EHB Benchmark Plans—<http://www.cms.gov/CCIIO/Resources/Data-Resources/ehb.html#review> benchmarks.

⁴⁶ Letter to Issuers on Federally-facilitated and State Partnership Exchanges, April 5, 2013, page 15 and 2015 Letter to Issuers in the Federally-facilitated Marketplaces, March 14, 2014, page 29.

⁴⁷ http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs18.html. (January 8, 2014).

needed regarding the annual limitation on cost sharing and its application.

g. Minimum Value (§ 156.145)

Section 1401(a) of the Affordable Care Act added a new section 36B to the Code, providing a premium tax credit for certain individuals with household incomes between 100 percent and 400 percent of the Federal poverty level who enroll in, or who have one or more family members enroll in an individual market QHP through an Exchange, and who are not otherwise eligible for MEC. An employer-sponsored plan is MEC, but for purposes of the premium tax credit under Code section 36B(c)(2)(C)(ii) an employee is generally treated as not eligible for MEC under an employer-sponsored plan unless the plan is affordable and provides minimum value (MV). An employer-sponsored plan provides MV only if the plan's share of the total allowed costs of benefits provided under the plan is greater than or equal to 60 percent of the costs. An employee who is eligible for coverage under an employer-sponsored plan that is both affordable and provides MV to the employee may not receive a premium tax credit under Code section 36B for coverage in a qualified health plan. If the employer coverage does not provide MV, the employee may be entitled to a premium tax credit even if the coverage is affordable.

Section 1513 of the Affordable Care Act added a new section 4980H to the Code providing for shared responsibility for employers regarding health coverage. An applicable large employer that does not offer coverage that is affordable and provides MV may be liable for an employer shared responsibility payment under section 4980H of the Code if one or more of its full-time employees receives a premium tax credit.

The MV standard of 60 percent of the total allowed costs of benefits provided under the plan is equivalent to the plan's share of total allowed costs required for a bronze level qualified health plan offered on an Exchange. Section 1302(d)(2)(C) of the Affordable Care Act provides that regulations promulgated by the Secretary of HHS under section 1302(d)(2), addressing actuarial value, apply "in determining under *this title*, the Public Health Service Act, and the *Internal Revenue Code* . . . the *percentage of the total allowed costs of benefits provided* under a group health plan or health insurance coverage that are provided by such plan or coverage." (Emphasis added.) Accordingly, HHS regulations under section 1302(d) implementing actuarial value requirements, which an insurer offering essential health benefits (EHB)

must meet in order for a non-grandfathered individual market or small group health insurance plan to be considered a bronze plan under section 1302(d)(1)(3) of the Affordable Care Act, also form the basis for determining the percentage of the total allowed costs of benefits provided for purposes of whether the value of coverage meets the MV standard under Code section 36B(c)(2)(C)(ii).

HHS published final regulations under section 1302(d)(2) on February 25, 2013 (78 FR 12834). The regulations at § 156.20 define the percentage of the total allowed costs of benefits as (1) the anticipated covered medical spending for EHB coverage paid by a health plan for a standard population, (2) computed in accordance with the plan's cost sharing, and (3) divided by the total anticipated allowed charges for EHB coverage provided to the standard population. HHS regulations at § 156.145(b)(2) apply this definition in the context of MV by taking into account benefits a plan provides that are included in any one of the state EHB benchmarks.

The IRS and Treasury Department published proposed regulations on May 3, 2013 (78 FR 25909), applying the HHS regulations in defining MV for employer-sponsored plans. The proposed regulations provide that the MV percentage is determined by dividing a plan's anticipated medical spending (based on the plan's cost-sharing) for plan benefits that are EHB covered under a particular EHB benchmark plan for the MV standard population by the total allowed charges for EHB coverage for the standard population and converting the result to a percentage. Proposed 26 CFR 1.36B-6(c). Taxpayers may apply the proposed regulations for taxable years ending before January 1, 2015.

The final HHS regulations and proposed Treasury regulations allow plans to determine the MV percentage by using the MV Calculator published by HHS. It has come to our attention that certain group health plan designs that provide no coverage of inpatient hospital services are being promoted, and that representations are being made, based on the MV Calculator, that these plan designs cover 60 percent of the total allowed costs of benefits provided under the plans and thus provide MV. We understand that these designs have been promoted as a way of both minimizing the cost of the plan to the employer (a consequence not only of excluding inpatient hospitalization benefits but also of making an offer of coverage that a substantial percentage of employees will not accept) and avoiding

potential liability for employer shared responsibility payments. Employers adopting these plan designs seek, by offering coverage that is affordable to the employee and that purports to provide MV, to deny their employees the ability to obtain a premium tax credit that could result in the employer becoming subject to a section 4980H employer shared responsibility payment.

In Notice 2014-69 (2014-48 IRB, November 24, 2014), released on November 4, 2014, HHS and Treasury advised that regulations would be proposed providing that plans that fail to provide substantial coverage of inpatient hospital or physician services do not provide MV. Allowing these designs to be treated as providing MV not only would allow an employer to avoid the shared responsibility payment that the statute imposes when an employer does not offer its full-time employees adequate health coverage, but would adversely affect employees (particularly those with significant health risks) who understandably find this coverage unacceptable, by denying them access to a premium tax credit for individual coverage purchased through an Exchange. Plans that omit critical benefits used disproportionately by individuals in poor health will enroll far fewer of these individuals, effectively driving down employer costs at the expense of those who because of their individual health status are discouraged from enrolling.

That the MV standard may be interpreted to require that employer-sponsored plans cover critical benefits is evident in the structure of the Affordable Care Act, the context in which the grant of the authority to the Secretary to prescribe regulations under section 1302 was enacted, and the policy underlying the legislation. Section 1302(b) authorizes the Secretary of HHS to define the EHB to be offered by individual market and small group health insurance plans, provided that this definition "include at least" 10 specified categories of benefits, and that the benefits be "equal to the scope of benefits provided under a typical employer plan." To "inform this determination" as to the scope of a typical employer plan, section 1302(b)(2)(A) provides that "the Secretary of Labor shall conduct a survey of employer sponsored coverage to determine *the benefits typically covered by employers*, including multiemployer plans, and provide a report on such survey to the Secretary

[of HHS].”⁴⁸ (Emphasis added.) These provisions suggest that, while detailed requirements for EHB in the individual and small group health insurance markets were deemed necessary, the benefits covered by typical employer plans providing primary coverage at the time the Affordable Care Act was enacted were seen as sufficient to satisfy the Act’s objectives with respect to the breadth of benefits needed for health plan coverage and, in fact, to serve as the basis for determining EHB. They also suggest that any meaningful standard of minimum coverage may require providing certain critical benefits.

Employer-sponsored plans in the large group market and self-insured employers continue to have flexibility in designing their plans. They are not required to cover all EHB. Providing flexibility, however, does not mean that these plans should not be subject to minimum requirements. A plan that excludes substantial coverage for inpatient hospital and physician services is not a health plan in any meaningful sense and is contrary to the purpose of the MV requirement to ensure that an employer-sponsored plan, while not required to cover all EHB, nonetheless must offer coverage with minimum value at least roughly comparable to that of a bronze plan offered on an Exchange.

For these reasons, the Secretary has concluded that the provisions of section 1302(d)(2) of the Affordable Care Act—requiring that the regulations for determining the percentage of the total allowed costs of benefits that apply to plans that must cover all EHB also be applied as a basis for determining minimum value—reflect a statutory design to provide basic minimum standards for health benefits coverage through the MV requirement, without requiring large group market plans and self-insured plans to meet all EHB standards. Given the scope of benefits covered by typical employer plans, the MV requirement is properly viewed as a means of ensuring that employer-sponsored plans satisfy basic minimum standards while also accommodating flexibility in the design of those plans.

Employers have been able to claim that plans without coverage of inpatient hospital services provide MV under the current quantitative MV test by designing a benefit package that, based on standardized actuarial assumptions used in the MV calculator, offsets the

absence of actuarial value derived from spending on inpatient hospital coverage with increased spending on other benefits. Accordingly, some plan designs may pass the current quantitative test without offering a critical benefit universally understood to be included in any minimally acceptable employer health plan coverage, and which the Department of Labor study determined was included in *all* employer plans it surveyed.

As noted previously, we have concluded that the quantitative test for MV is not exclusive. Accordingly, we propose to amend § 156.145 to require that, in order to provide minimum value, an employer-sponsored plan not only must meet the quantitative standard of the actuarial value of benefits, but also must provide a benefit package that meets a minimum standard of benefits. Specifically, we propose to revise § 156.145 to provide that, in order to satisfy MV, an employer plan must provide substantial coverage of both inpatient hospital services and physician services.

We seek comment on ways to determine whether a plan has offered “substantial” benefits for the purposes of this proposal.

We are not proposing to require that large employer or self-insured employer group health plans provide all EHB as defined under section 1302 of the Affordable Care Act. Rather, we are proposing only to require that, in order to provide MV, employer-sponsored plans provide substantial coverage of the two types of benefits that we believe were envisioned for health plan coverage meeting the MV standard. We have concluded that plans that omit these types of coverage fail to meet universally accepted minimum standards of value expected from, and inherent in the nature of, any arrangement that can reasonably be called a health plan intended to provide the primary health coverage for employees.

Consistent with Notice 2014–69, we propose that these changes to our regulations on MV will apply to employer-sponsored plans, including plans that are in the middle of a plan year, immediately on the effective date of the final regulations. However, because some employers adopted plans prior to publication of Notice 2014–69, we propose that the final regulations not apply before the end of the plan year (as in effect under the terms of the plan on November 3, 2014) to plans that before November 4, 2014, entered into a binding written commitment to adopt, or began enrolling employees into, the plan, so long as that plan year begins no

later than March 1, 2015. For these purposes, a binding written commitment exists when an employer is contractually required to pay for an arrangement, and a plan begins enrolling employees when it begins accepting employee elections to participate in the plan. The Department of the Treasury and the IRS are expected to publish proposed regulations making clear that this delayed applicability date applies solely for purposes of Code section 4980H. At no time will any employee be required to treat a plan that fails to provide substantial coverage of inpatient hospital services or physician services as providing MV for purposes of eligibility for premium tax credit under Code section 36B. We seek comment on this proposed applicability date.

3. Qualified Health Plan Minimum Certification Standards

a. QHP Issuer Participation Standards (§ 156.200)

We propose to revise § 156.200(b)(7), to require that a QHP issuer comply with the standards under 45 CFR part 153 and not just the standards related to the risk adjustment program. This proposed revision would clarify that a QHP issuer maintains responsibility for its compliance and, under § 156.340, the compliance of any of its delegated or downstream entities with the standards set forth in 45 CFR part 153, not just those specifically pertaining to risk adjustment. We seek comment on this proposal.

b. Transparency in Coverage (§ 156.220)

The transparency in coverage standards established under section 1311(e)(3) of the Affordable Care Act, as implemented at § 155.1040(a) and § 156.220, require health insurance issuers that offer a QHP in accordance with a certification from an Exchange to provide specified information to HHS, the Exchange, and the State insurance commissioner and to make this information available to the public in “plain language.” In a frequently asked question dated April 29, 2013,⁴⁹ HHS clarified that, to comply with section 1311(e)(3), issuers offering QHPs certified by an Exchange would be required to begin submitting this information only after QHPs have been certified for one benefit year.⁵⁰ Because

⁴⁹ Affordable Care Act Implementation Set 15, available at: http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs15.html.

⁵⁰ The FAQ also states that because section 2715A of the PHS Act simply extends the transparency provisions set forth in section 1311(e)(3) of the

⁴⁸ See Department of Labor, Special Report: Selected Medical Benefits: A Report from the Department of Labor to the Department of Health and Human Services. <http://www.bls.gov/ncs/ebs/sp/selmedbensreport.pdf>.

a full year of claims data will be available, we anticipate the collection and public display of the required information listed in § 156.220 from QHP issuers offering coverage through Exchanges beginning in 2016. We seek comment on the form and manner of data collection that will be most useful to consumers selecting a QHP in an Exchange. Specifically, we seek comment on how HHS should further specify, in guidance, the data elements to be collected, the format that should be used, and the timeframe or schedule for submission. We also seek comment on mechanisms that issuers could use to submit the information to HHS and how to minimize duplication with information that issuers must already submit to HHS, States or other entities (for example, accreditation organizations). We seek comment on the manner in which HHS, the Exchanges and QHPs should publicly display the collected information. We also request comment related to whether State-based Exchanges should display the same information and in the same format and manner as in an FFE.

c. Network Adequacy Standards (§ 156.230)

In § 156.230, we established the minimum network adequacy criteria that health and dental plans must meet to be certified as QHPs, under the Secretary's authority in section 1311(c)(1)(B) of the Affordable Care Act. We propose modifying § 156.230(a) to specify that this section only applies to QHPs that use a provider network and that a provider network includes only providers that are contracted as in-network. This means that the general availability of out-of-network providers will not be counted for purposes of meeting network adequacy requirements.

We believe that networks that provide sufficient access to benefits are a priority for issuers and consumers. HHS continues to take great interest in ensuring strong network access, particularly for QHPs that must meet the standards in § 156.230. HHS is aware that the NAIC has formed a workgroup

that is drafting a model act relative to network adequacy and will await the results of this workgroup before proposing significant changes to network adequacy policy. For 2016, HHS expects to continue the reasonable access standard adopted in the 2015 Letter to Issuers in the Federally-facilitated Marketplaces (2015 Letter to Issuers)⁵¹ and assess the provider networks information submitted as part of the QHP certification process. We urge State-based Exchanges to employ the same standard when examining network adequacy.

In addition to the proposed provisions above, we are also cognizant that new enrollees in QHPs may need a transition period to switch to a provider that is in-network in their new plan. We encourage QHP issuers that use a network of providers to offer new enrollees transitional care for an ongoing course of treatment. We suggest that this begin with the effective date of coverage of a new enrollee and last for at least 29 days thereafter (for a minimum of 30 days). These benefits would extend to health care services furnished by any provider to the new enrollee, regardless of whether the provider is in the plan's network, as long as the enrollee received health services from that provider under an ongoing course of treatment in the 90 days prior to the effective date of coverage. Because different plans may have different provider networks, when an individual enrolls in a new health plan, he or she may be undergoing a course of treatment with a provider that is not in the new issuer's provider network. In such a case, it may take time for the new enrollee to select a new in-network provider and to meet with the new provider to ensure that there is no disruption in treatment. We encourage issuers to adopt this policy to accommodate the immediate needs of enrollees, while allowing the enrollee sufficient time to go through the process of selecting an in-network provider in their new plan. We are considering whether requirements may be needed in this area.

Under § 156.230(b), we propose changing the current text to read as (b)(1) and adding (b)(2) in order to strengthen the provider directory requirement. Specifically, we propose that a QHP issuer must publish an up-to-date, accurate, and complete provider directory, including information on which providers are accepting new

patients, the provider's location, contact information, specialty, medical group, and any institutional affiliations, in a manner that is easily accessible to plan enrollees, prospective enrollees, the State, the Exchange, HHS and OPM. As part of this requirement, we propose that a QHP issuer must update the directory information at least once a month, and that a provider directory will be considered easily accessible when the general public is able to view all of the current providers for a plan on the plan's public Web site through a clearly identifiable link or tab without having to create or access an account or enter a policy number. The general public should be able to easily discern which providers participate in which plan(s) and provider network(s) if the health plan issuer maintains multiple provider networks and the plan(s) and provider network(s) associated with each provider should be clearly identified on the Web site. We seek comment on this proposal, including with respect to how often updating should occur.

We also are considering requiring issuers to make this information publicly available on their Web sites in a machine-readable file and format specified by HHS. The purpose of establishing machine-readable files with this data would be to provide the opportunity for third parties to create resources that aggregate information on different plans. We believe this would increase transparency by allowing software developers to access this information and create innovative and informative tools to help enrollees better understand the availability of providers in a specific plan. As an alternative, we could also require that this information be submitted to HHS through an HHS-designed standardized template, but we recognize that there may be challenges with keeping this type of template information updated. Thus, we specifically solicit comments on these options, including the technical requirements for developing a machine-readable file and format for a provider directory, as well as other technical considerations, such as processes and considerations that should be taken into account for the updating of this information under either of the options being considered.

We are proposing these requirements to enhance transparency of QHP provider directories and to help consumers make more informed decisions about their health care coverage. We solicit comments on these proposed requirements, as well as with respect to how frequently provider data should be updated, and whether

Affordable Care Act to group health plans and health insurance issuers offering group and individual health insurance coverage, the Departments clarified that the reporting requirements under section 2715A of the PHS Act will become applicable to group health plans and health insurance issuers offering group and individual health insurance coverage no sooner than when the reporting requirements under section 1311(e)(3) of the Affordable Care Act become applicable. Nothing in these proposed regulations would apply any transparency reporting requirements related to section 2715A of the PHS Act, incorporated into section 715(a)(1) of ERISA and section 9815(a)(1) of the Code.

⁵¹ 2015 Letter to Issuers in the Federally-facilitated Marketplaces, March 14, 2014, available at: <http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2015-final-issuer-letter-3-14-2014.pdf>.

additional types of information should be required to be included in the provider directory.

We also seek comment on the feasibility and merits of incorporating information on physical accessibility for individuals with disabilities, including accessibility information regarding facilities and equipment, or other information that would be important to enrollees and potential enrollees, as a part of network adequacy standards in the future.

d. Essential Community Providers (§ 156.235)

At § 156.235, we propose to strengthen the essential community provider (ECP) standard in accordance with section 1311(c)(1)(C) of the Affordable Care Act, which requires that a QHP's network include ECPs, where available, that serve predominantly low-income and medically-underserved populations. As established in section 1311(c)(1)(C) of the Affordable Care Act, ECPs include entities defined in section 340B(a)(4) of the PHS Act and providers described in section 1927(c)(1)(D)(i)(IV) of the Social Security Act as set forth by section 211 of Pub. L. 111–8. Additionally, we propose that ECPs may include not-for-profit or State-owned providers that would be entities described in section 340B of the PHS Act but do not receive Federal funding under the relevant section of law, as these providers satisfy the same 340B requirements and therefore meet the definition of ECPs by virtue of the following description in section 1311(c)(1)(C) of the Affordable Care Act—“such as health care providers

defined in section 340B(a)(4) of the PHS Act and providers in section 1927(c)(1)(D)(i)(IV) of the Act.” For the same reasons described above, we propose that such providers also include not-for-profit or governmental family planning service sites that do not receive a grant under Title X of the PHS Act. Other providers that provide health care to populations residing in low-income zip codes or Health Professional Shortage Areas could also be considered ECPs. We propose that the above proposals apply to plan years 2016 and thereafter.

While commercial health insurance issuers may have a limited history in working with ECPs, ECPs provide important access points in low-income and medically underserved communities. Based on our experience with QHP certification for 2014 and 2015, we have determined that specifying a quantitative standard will assist issuers in ensuring that, in future QHP certification years, they are providing sufficient consumer access to ECPs to satisfy the requirement in section 1311(c)(1)(C) of the Affordable Care Act. Therefore, we propose in new paragraph (a)(2)(i) of this section that, for QHP certification cycles beginning with the 2016 benefit year, a health plan seeking certification to be offered through an FFE must satisfy the general ECP standard described in paragraph (a)(1) of this section by demonstrating in its applications for QHP certification a sufficient percentage, as determined annually by HHS and specified in HHS guidance, of available ECPs in the plan's service area have a contractual agreement to participate in the plan's

provider network. For purposes of this general ECP standard, multiple providers at a single location will count as a single ECP toward the issuer's satisfaction of the proposed ECP participation standard to ensure a sufficient number and geographic distribution of ECPs as required under § 156.235(a). Any update to the general ECP inclusion standards would be based on HHS's post-certification assessments of the adequacy of ECP participation and geographic distribution of such providers and evidence of contractual negotiation efforts provided by issuers in the ECP supplemental response forms.

In addition, we propose in paragraph (a)(2)(ii) of this section that, to satisfy the general ECP standard, the issuer of the plan seeking certification as a QHP in an FFE would be required to offer contracts for participation in the plan for which a certification application is being submitted to the following: (1) All available Indian health providers in the service area, applying the special terms and conditions necessitated by Federal law and regulations as referenced in the recommended model QHP addendum for Indian health providers developed by HHS; and (2) at least one ECP in each ECP category (see Table 10) in each county in the service area, where an ECP in that category is available and provides medical or dental services that are covered by the issuer plan type. We expect that issuers will offer contracts in good faith. A good faith contract should offer the same rates and contract provisions as other contracts accepted by or offered to similarly situated providers that are not ECPs.

TABLE 10—ECP CATEGORIES AND TYPES IN FFES

Major ECP category	ECP provider types
Federally Qualified Health Centers (FQHC).	FQHC and FQHC “Look-Alike” Clinics, ⁵² Outpatient health programs/facilities operated by tribes, tribal organizations, programs operated by Urban Indian Organizations.
Ryan White Providers	Ryan White HIV/AIDS Providers.
Family Planning Providers	Title X Family Planning Clinics and Title X “Look-Alike” Family Planning Clinics. ⁵³
Indian Health Providers	Tribes, Tribal Organization and Urban Indian Organization Providers, Indian Health Service Facilities.
Hospitals	Disproportionate Share Hospital (DSH) and DSH-eligible Hospitals, Children's Hospitals, Rural Referral Centers, Sole Community Hospitals, Free-standing Cancer Centers, Critical Access Hospitals.
Other ECP Providers	STD Clinics, TB Clinics, Hemophilia Treatment Centers, Black Lung Clinics, Community Mental Health Centers, Rural Health Clinics and other entities that serve predominantly low-income, medically underserved individuals.

We propose to add paragraph (a)(3) to this section to specify that if an issuer's

⁵² For more information on FQHC “Look-Alike” Clinics, see <http://bphc.hrsa.gov/about/lookalike/index.html> and section 1861(a)(4) and section 1905(l)(2)(B) of the Social Security Act.

⁵³ For more information on Title X “Look-Alike” Clinics, see section 1927(c)(1)(D)(i)(IV) of the Social Security Act.

QHP certification application to the FFE does not satisfy the ECP standard described in paragraph (a)(2) of this section, the issuer must include as part of its application a narrative justification describing how the provider network(s) of the plans for which certification applications have been submitted provides an adequate

level of service for individuals residing in low-income zip codes or Health Professional Shortage Areas within the plan's service area and how the plan's provider network will be strengthened toward satisfaction of the ECP standard prior to the start of the benefit year. The narrative justification should include the following: The number of contracts

offered to ECPs for the benefit year; the number of additional contracts the issuer expects to offer for the benefit year and the timeframe of planned negotiations; the names of the ECP hospitals FQHCs, Ryan White providers, family planning providers, Indian health providers, and other ECPs to which the issuer has offered contracts, but with whom an agreement has not yet been reached; and contingency plans for how the issuer's provider network(s), as currently designed, will provide adequate care to enrollees who might otherwise be cared for by relevant ECPs. Through HHS's post-certification assessments, HHS may examine an issuer's progress toward satisfying the applicable ECP standard to ensure that the issuer continues to qualify for offering its plan on the Exchange, while OPM would retain this responsibility for issuers of multi-State plans, acting in coordination with HHS as may be appropriate.

We propose to redesignate current paragraph (a)(3) as paragraph (a)(4), in which we clarify that nothing in the requirements under paragraphs (a)(1) through (a)(3) of this section requires any QHP to provide coverage for any specific medical procedure provided by the ECP. We also propose to redesignate current paragraph (a)(2) as paragraph (a)(5).

We propose in paragraph (b)(1) that the alternate ECP standard described in § 156.235(a)(5) will apply to issuers that offer QHPs in any Exchange. Additionally, for plans seeking QHP certification in FFEs, we propose that a QHP issuer described in paragraph (a)(5) of this section be determined to have a sufficient number and geographic distribution of employed or contracted providers by demonstrating in its QHP application that the number of its providers in the following locations meets a percentage specified in HHS guidance, of the number of available ECPs in the service area: (i) Located within a Health Professional Shortage Areas; or (ii) located within five-digit zip codes in which 30 percent or more of the population falls below 200 percent of the FPL. For purposes of this alternate ECP standard, multiple providers at a single location will count as one ECP toward the available ECPs in the plan's service area and toward the issuer's satisfaction of the proposed ECP participation standard to ensure a sufficient number and geographic distribution of ECPs as required under § 156.235(a). Any modification to the alternate ECP inclusion standard would be based on HHS's post-certification assessments of the adequacy of ECP participation and geographic

distribution of such providers to ensure reasonable and timely access to such ECPs for low-income, medically underserved individuals.

Furthermore, we propose in new paragraph (b)(3) of this section that if a QHP certification application of a plan for the FFE does not satisfy the alternate ECP standard described in paragraph (b)(2) of this section, the issuer must include as part of its QHP application a narrative justification describing how the issuer's provider network(s) provides an adequate level of service for low-income and medically underserved enrollees. When assessing whether an issuer has provided a satisfactory narrative justification under either the general or alternate ECP standard, as applicable, HHS will take into account factors and circumstances identified in the ECP Supplemental Response Form,⁵⁴ along with an explanation of how the issuer will provide access for individuals residing in low-income zip codes or Health Professional Shortage Areas within the plan's service area and how the plan's provider network will be strengthened toward satisfaction of the ECP standard prior to the start of the benefit year. Additionally, justifications that include verification of contracts offered in good faith, that include terms that a willing, similarly-situated, non-ECP provider would accept or has accepted, would be considered toward satisfaction of the ECP standard.

We propose in paragraph (c) of this section to remove the language defining ECPs as meeting the criteria on the initial date of the regulation's publication. We propose this change in recognition of the fact that the universe of ECPs, as well as the databases we use to delineate this universe, may vary over time for many reasons, including demographic and provider characteristics. We request comment on this proposed change.

We seek comment on these proposals.

e. Health Plan Applications and Notices (§ 156.250)

Existing § 156.250 establishes basic standards for the format of applications and notices provided by QHP issuers to enrollees. Specifically, QHP issuers must adhere to the readability and accessibility standards established for Exchange applications, forms, and notices in § 155.230(b). The referenced standard, in turn, requires QHP issuers to conform to the standards outlined in § 155.205(c), which provide that

information must be provided in plain language and in a manner that is accessible and timely to individuals living with disabilities and individuals who are limited English proficient, and that individuals must be informed of the availability of such accessibility services. To improve the readability of this referenced standard, we propose to amend § 156.250 to replace the cross-reference to the Exchange application and notices provision at § 155.230(b) with a cross-reference to § 155.205(c). We also propose to change the title of the provision to "Meaningful access to qualified health plan information" for improved clarity. As discussed above, amendments to § 155.205(c) with respect to oral interpretation services are also being proposed.

As participants in one or more Exchanges, QHP issuers interact with qualified individuals, qualified employers, qualified employees, and applicants, in addition to enrollees. QHP issuers provide these individuals with a wide range of information that assists these individuals with accessing and understanding health coverage. We propose to extend the requirements of § 156.250 so that not only applications and notices to enrollees, but all information that is critical for obtaining health insurance coverage or access to health care services through the QHP to qualified individuals, applicants, qualified employers, qualified employees, and enrollees, is provided in a manner consistent with § 155.205(c). In addition, we propose that information would be deemed to be critical for obtaining health insurance coverage or access to health care services if the issuer is required by State or Federal law to provide the document to a qualified individual, applicant, qualified employer, qualified employee, or enrollee. For example, because the summary of benefits and coverage (SBC) disclosure is required to be provided by law under section 2715 of the Public Health Service Act and its implementing regulations at § 147.200, a QHP issuer would be required to provide the SBC in a manner consistent with § 155.205(c). In addition, based on our proposed standard, we would consider information that is critical for obtaining health coverage or access to health care services to include: Applications; consent, grievance, appeal, and complaint forms; notices pertaining to the denial, reduction, modification, or termination of services, benefits, non-payment, or coverage; a plan's explanation of benefits or similar claim processing information; QHP ratings information; rebate notices;

⁵⁴ More information on the supplemental response can be found on the CCIIO Web site at: <http://www.cms.gov/ccio/programs-and-initiatives/health-insurance-marketplaces/ghp.html>.

correspondence containing information about eligibility and participation criteria; notices advising individuals of the availability of free language assistance; and letters or notices that require a signature or response from the qualified individual, applicant, qualified employer, qualified employee, or enrollee. We would not consider marketing materials that are available for advertising purposes only and not otherwise required by law to be critical for obtaining health insurance coverage or access to health care services through the QHP, and therefore an issuer would not be required to make such materials accessible to individuals with disabilities or limited English proficiency. We seek comment on all aspects of this proposal, with a particular interest in whether the parameters set forth above are reasonable, whether there is other information that should be considered to be “critical” and thus subject to the requirements of § 155.205(c), and whether the term “critical” should be further defined in regulation text. Finally, we solicit comment on whether this proposal would present implementation challenges for QHP issuers if it becomes effective before the beginning of the open enrollment period in the individual market for the 2016 benefit year.

f. Enrollment Process for Qualified Individuals (§ 156.265)

Sections 155.240 and 155.400 explicitly authorize Exchanges to establish certain requirements related to premium payment for enrollment in QHPs through the Exchange. Section 156.265 currently only cross-references § 155.240. To clarify that both sets of requirements apply to QHPs, we propose that a QHP issuer must follow the premium payment process established by the Exchange in accordance with § 155.240 and the payment rules established in § 155.400(e).

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

Section 1303 of the Affordable Care Act and § 156.280 specify accounting and other standards for issuers of QHPs through the Exchange in the individual market that cover abortion services for which public funding is prohibited (also referred to as non-expected abortion services). The statute and regulations establish that unless otherwise prohibited by State law, a QHP issuer may elect to cover such services. If an issuer elects to cover such services under a QHP sold through the individual market Exchange, the issuer

must take certain steps to ensure that no premium tax credit or cost-sharing reduction funds are used to pay claims for abortion services for which public funding may not be used.

We are providing guidance on an individual market Exchange issuer's responsibilities with respect to requirements related to QHP coverage of abortion services for which public funding is prohibited. HHS works with stakeholders, including States and issuers, to help them fully understand and follow the statutes and regulations governing the provision of health insurance coverage under a QHP through the Exchange. As is the case with many provisions in the Affordable Care Act, States and State insurance commissioners are the entities primarily responsible for implementing and enforcing the provisions in section 1303 of the Affordable Care Act related to individual market QHP coverage of non-expected abortion services. OPM may issue guidance related to these provisions for multi-State plan issuers.

Under section 1303(b)(2)(B) of the Affordable Care Act, as implemented in § 156.280(e)(2)(i), individual market Exchange issuers must collect a separate payment from each enrollee, for an amount equal to the AV of the coverage for abortions for which public funding is prohibited. However, section 1303 of the Affordable Care Act and § 156.280 do not specify the method an issuer must use to comply with the separate payment requirement. This provision may be satisfied in a number of ways. Several such ways include, but are not limited to: sending the enrollee a single monthly invoice or bill that separately itemizes the premium amount for non-expected abortion services; sending a separate monthly bill for these services; or sending the enrollee a notice at or soon after the time of enrollment that the monthly invoice or bill will include a separate charge for such services and specify the charge. Section 1303 of the Affordable Care Act permits, but does not require a QHP issuer to separately identify the premium for non-expected abortion services on the monthly premium bill in order to comply with the separate payment requirement. A consumer may pay the premium for non-expected abortion services and for all other services in a single transaction, with the issuer depositing the funds into the issuer's separate allocation accounts as required by section 1301(b)(2)(C) of the Affordable Care Act, as implemented in § 156.280(e)(2)(ii) and 156.280(e)(3).

Section 1303(b)(2)(D) of the Affordable Care Act, as implemented in § 156.280(e)(4), establishes requirements

for individual market Exchange issuers with respect to how much they must charge each QHP enrollee for coverage of abortions for which public funding is prohibited. A QHP issuer must estimate the basic per enrollee, per month cost, determined on an average actuarial basis, for including coverage of non-expected abortion services. In making this estimate, a QHP issuer may not estimate the basic cost of coverage for non-expected abortion services to be less than one dollar per enrollee, per month. This means that an issuer must charge each QHP enrollee a minimum premium of one dollar per month for coverage of non-expected abortion services.

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

a. Premium Adjustment Percentage (§ 156.130)

Section 1302(c)(4) of the Affordable Care Act directs the Secretary to determine an annual premium adjustment percentage, which is used to set the rate of increase for three parameters detailed in the Affordable Care Act: the maximum annual limitation on cost sharing (defined at § 156.130(a)), the required contribution percentage by individuals for minimum essential health coverage the Secretary may use to determine eligibility for hardship exemptions under section 5000A of the Code, and the assessable payment amounts under section 4980H(a) and (b) of the Code (finalized at 26 CFR 54.4980H in the “Shared Responsibility for Employers Regarding Health Coverage,” published in the February 12, 2014 **Federal Register** (79 FR 8544)). Section 156.130(e) provides that the premium adjustment percentage is the percentage (if any) by which the average per capita premium for health insurance coverage for the preceding calendar year exceeds such average per capita premium for health insurance for 2013, and that this percentage will be published annually in the HHS notice of benefit and payment parameters.

We established a methodology for estimating average per capita premium for purposes of calculating the premium adjustment percentage in the 2015 Payment Notice.

Under that methodology, the premium adjustment percentage is calculated based on the projections of average per enrollee employer-sponsored insurance (ESI) premiums from the NHEA, which is calculated by the CMS Office of the Actuary.

Accordingly, using the ESI data, the premium adjustment percentage for 2016 is the percentage (if any) by which the most recent NHEA projection of per enrollee ESI premiums for 2015 (\$5,744) exceeds the most recent NHEA projection of per enrollee ESI premiums for 2013 (\$5,303).⁵⁵ Therefore, the proposed premium adjustment percentage for 2016 is 8.316047520 percent. We note that the 2013 premium used for this calculation has been updated to reflect the latest NHEA data. We are also proposing the following cost-sharing parameters for calendar year 2016, based on our proposed premium adjustment percentage for 2016.

Maximum Annual Limitation on Cost Sharing for Calendar Year 2016. Under § 156.130(a)(2), for the 2016 calendar year, cost sharing for self-only coverage may not exceed the dollar limit for calendar year 2014 increased by an amount equal to the product of that amount and the premium adjustment percentage for 2016, and for other than self-only coverage, the limit is twice the dollar limit for self-only coverage. Under § 156.130(d), these amounts must be rounded down to the next lowest multiple of 50. Using the premium adjustment percentage of 8.316047520 for 2016 we established above, and the 2014 maximum annual limitation on cost sharing of \$6,350 for self-only coverage, which was published by the IRS on May 2, 2013,⁵⁶ we propose that the 2016 maximum annual limitation on cost sharing be \$6,850 for self-only coverage and \$13,700 for other than self-only coverage.

b. Reduced Maximum Annual Limitation on Cost Sharing (§ 156.130)

Sections 1402(a) through (c) of the Affordable Care Act direct issuers to reduce cost sharing for EHBs for eligible individuals enrolled in a silver level QHP. In the 2014 Payment Notice, we established standards related to the provision of these cost-sharing reductions. Specifically, in 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 Affordable Care Act states that the Secretary may adjust the cost-sharing limits to ensure that the resulting limits do not cause the AVs of the health plans to exceed the levels specified in 1402(c)(1)(B)(i) (that is, 73 percent, 87 percent or 94 percent, depending on the income of the enrollee(s)). Accordingly, we propose to use a method we established in the 2014 Payment Notice for determining the appropriate reductions in the maximum annual limitation on cost sharing for cost-sharing plan variations. As we proposed above, the 2016 maximum annual limitation on cost sharing would be \$6,850 for self-only coverage and \$13,700 for other than self-only coverage. We analyzed the effect on AV of the reductions in the maximum annual limitation on cost sharing described in the statute to determine whether to adjust the reductions so that the AV of a silver plan variation will not exceed the AV specified in the statute. Below, we describe our analysis for the 2016 benefit year and our proposed results.

Reduced Maximum Annual Limitation on Cost Sharing for Benefit Year 2016. Consistent with our analysis in the 2014 and 2015 Payment Notices, we developed three model silver level QHPs, and analyzed the impact on AV of the reductions described in the Affordable Care Act to the estimated 2016 maximum annual limitation on cost sharing for self-only coverage (\$6,850). The model plan designs are based on data collected for 2015 plan year QHP certification to ensure that they represent a range of plan designs that we expect issuers to offer at the silver level of coverage through the Exchange. For 2016, the model silver level QHPs included a PPO with typical cost-sharing structure (\$6,850 annual limitation on cost sharing, \$2,000 deductible, and 20 percent in-network coinsurance rate), a PPO with a lower annual limitation on cost sharing (\$4,600 annual limitation on cost

sharing, \$2,550 deductible, and 20 percent in-network coinsurance rate), and an HMO (\$6,850 annual limitation on cost sharing, \$2,700 deductible, 20 percent in-network coinsurance rate, and the following services with copays that are not subject to the deductible or coinsurance: \$500 inpatient stay per day, \$350 emergency department visit, \$25 primary care office visit, and \$50 specialist office visit). All three model QHPs meet the AV requirements for silver level health plans.

We then entered these model plans into the proposed 2016 AV calculator developed by HHS and observed how the reductions in the maximum annual limitation on cost sharing specified in the Affordable Care Act affected the AVs of the plans. We found that the reduction in the maximum annual limitation on cost sharing specified in the Affordable Care Act for enrollees with a household income between 100 and 150 percent of the Federal poverty line (FPL) ($\frac{2}{3}$ reduction in the maximum annual limitation on cost sharing), and 150 and 200 percent of the FPL ($\frac{2}{3}$ 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 ($\frac{1}{2}$ 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 2016 benefit year with a household income between 200 and 250 percent of FPL be reduced by approximately $\frac{1}{5}$, rather than $\frac{1}{2}$. 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 approximately $\frac{2}{3}$, as specified in the statute, and as shown in Table 11. These proposed reductions in the maximum annual limitation on cost sharing should adequately account for unique plan designs that may not be captured by our three model QHPs. We also note that selecting a reduction for the maximum annual limitation on cost sharing that is less than the reduction specified in the statute 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

⁵⁵ 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.

⁵⁶ See <http://www.irs.gov/pub/irs-drop/rp-13-25.pdf>.

level. We welcome comment on this analysis and the proposed reductions in the maximum annual limitation on cost sharing for 2016.

We note that for 2016, as described in § 156.135(d), States are permitted to submit for approval by HHS State-specific data sets for use as the standard

population to calculate AV. No State submitted a data set by the September 1 deadline.

TABLE 11—REDUCTIONS IN MAXIMUM ANNUAL LIMITATION ON COST SHARING FOR 2016

Eligibility category	Reduced maximum annual limitation on cost sharing for self-only coverage for 2016	Reduced maximum annual limitation on cost sharing for other than self-only coverage for 2016
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(i) (that is, 100–150 percent of FPL)	\$2,250	\$4,500
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(ii) (that is, 150–200 percent of FPL)	2,250	4,500
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(iii) (that is, 200–250 percent of FPL)	5,450	10,900

c. Plan Variations (§ 156.420)

Sections 1402 and 1412 of the Affordable Care Act provide for reductions in cost sharing on essential health benefits for qualified low- and moderate-income enrollees in silver level health plans offered in the individual market through the Exchanges. Section 1402(d) of the Affordable Care Act also provides for Indians with household income below 300 percent FPL to be enrolled in QHPs with zero cost sharing at any metal level. Implementing regulations, § 156.400 *et seq.*, set forth health insurance issuer responsibilities with respect to the administration of reductions in cost sharing for eligible individuals. In addition, section 2715 of the PHS Act and its implementing regulation, § 147.200, require group health plans and health insurance issuers offering group or individual health insurance coverage to provide a written summary of benefits and coverage (SBC) for each benefit package to all covered entities and individuals, including individuals in the individual market, applying for coverage.

While individual health insurance issuers (including QHP issuers) must provide an SBC for each benefit package, current regulations do not specifically address an issuer's responsibilities to provide an SBC reflecting a QHP with cost-sharing reductions applied, known as a plan variation of the QHP. Consequently, a consumer who is eligible for cost-sharing reductions may receive an SBC that does not accurately represent the cost sharing he or she will be responsible for when receiving essential health benefits. Under the authority stated above, we propose to amend § 156.420 to add § 156.420(h) and require QHP issuers to provide SBCs that accurately represent plan variations

in a manner consistent with the requirements set forth at § 147.200 to ensure that consumers have access to SBCs that accurately represent cost-sharing responsibilities for all coverage options, including plan variations, and are provided adequate notice of the plan variations.

We propose that QHP issuers would be required to provide SBCs for plan variations no later than the first day of the next Exchange open enrollment period for the individual market for the 2016 benefit year, in accordance with § 155.410(e). We seek comments on whether the proposed applicability date would present implementation challenges for QHP issuers as well as on other aspects of this proposal. As discussed above, we note that QHP issuers would be required to provide the SBC in a manner that is consistent with the meaningful access requirements under § 155.205(c).

d. Changes in Eligibility for Cost-Sharing Reductions (§ 156.425)

Under the authority in sections 1402 and 1412 of the Affordable Care Act, which provide for reductions in cost sharing on essential health benefits for qualified low- and moderate-income enrollees in silver level health plans offered in the individual market on Exchanges, we propose to amend § 156.425 to clarify when a QHP issuer would be required to provide an SBC if an individual's assignment to a standard plan or plan variation of the QHP changes in accordance with § 156.425(a). We propose that a QHP issuer must provide an SBC that accurately represents a new plan variation (or the standard plan variation) as soon as practicable after receiving notice from the Exchange of the individual's change in eligibility, but in no case later than 7 business days

following receipt of notice. We propose that QHP issuers would be required to provide SBCs in accordance with this proposed paragraph beginning on the first day of the benefit year that begins on January 1, 2016. We seek comments on this proposal.

e. Cost-Sharing Reductions Reconciliation (§ 156.430)

Sections 1402(a)–(c) of the Affordable Care Act provide for cost-sharing reductions for essential health benefits (EHB) provided by a qualified health plan. Cost-sharing reductions are advanced to issuers throughout the benefit year, and reconciled by HHS following the benefit year against actual cost-sharing amounts provided by issuers to enrollees.

The reconciliation process requires QHP issuers to submit to HHS the total allowed costs for EHB charged for each plan variation policy, the amounts paid by the issuer, and the amounts paid by or on behalf of the enrollee (other than by the Federal government under section 1402 of the Affordable Care Act), as well as the amounts that would have been paid by the enrollee under the standard plan. Under the standard methodology described at § 156.430(c)(2), costs paid by the issuer under the standard plan are calculated by applying actual cost-sharing requirements for the standard plan to the allowed costs for EHB under the enrollee's policy for the benefit year. The difference is the amount of cost-sharing reductions provided.

As stated above, HHS will not reimburse issuers for reductions in out-of-pocket spending for benefits other than EHB. However, we understand that because of technology challenges in these early years of the cost-sharing reduction program, some issuers are presently unable to differentiate on a

policy level between EHB claims and non-EHB claims, as required by HHS when applying the standard cost-sharing reduction reconciliation methodology. The difficulty occurs in plan designs that allow enrollee out-of-pocket spending for EHB and non-EHB claims alike to accumulate toward deductibles and the reduced annual limit on cost sharing. Such plan designs benefit enrollees by allowing them to reach their spending limits sooner. As a result, for the purpose of cost-sharing reduction reconciliation, we propose to allow QHP issuers to submit percentage estimates of the portion of claims attributable to non-EHB for the 2014 benefit year, and to reduce the total claims amount by that percentage, to arrive at an estimated total EHB amount. The percentage estimate would be the estimate of expected non-EHB claims costs previously submitted for each plan variation on the Uniform Rate Review Template (URRT)⁵⁷ and which HHS used to calculate 2014 advance CSR payments. An issuer using this procedure would be required to do so for all plan variations for which the criteria below are met.

As described in proposed § 156.430(c)(2)(i), this exception to permit QHP issuers to use plan-specific URRT estimates of non-EHB claims would be limited to plan designs in which out-of-pocket expenses for non-EHB benefits accumulate toward the deductible and reduced annual limitation on cost sharing, but for which copayments and coinsurance rates for non-EHB are not reduced. This limitation helps assure that the estimated percentage, which is calculated based on the proportion of claims attributable to EHB, does not overstate the proportion of reduced out-of-pocket spending associated with EHB. In addition, the exception would apply only when non-EHB estimated percentages account for less than 2 percent of total claims, helping assure that any inaccuracies in the estimate are unlikely to result in significant inaccuracies in total cost-sharing reduction reimbursement.

5. Minimum Essential Coverage

a. Other Coverage That Qualifies as Minimum Essential Coverage (§ 156.602)

Section 5000A of the Code, as added by section 1501(b) of the Affordable Care Act, requires all non-exempt applicable individuals to maintain minimum essential coverage or make the individual shared responsibility payment. Section 5000A(f) of the Code defines minimum essential coverage as any of the following: (1) Coverage under a specified government sponsored program; (2) coverage under an eligible employer-sponsored plan; (3) coverage under a health plan offered in the individual market within a State; and (4) coverage under a grandfathered health plan. In addition, section 5000A(f)(1)(E) of the Code authorizes the Secretary of HHS, in coordination with the Secretary of the Treasury, to designate other health benefits coverage as minimum essential coverage. The Department of the Treasury and the IRS published final regulations under Code section 5000A on August 30, 2013 (78 FR 53646), codified at 26 CFR 1.5000A-1 through -5.⁵⁸

On July 1, 2013, HHS published final regulations implementing certain functions of an Exchange for determining eligibility for and granting certain exemptions from the individual shared responsibility payment (78 FR 39494).⁵⁹ The HHS final regulations also designate certain types of coverage as minimum essential coverage and outline substantive and procedural requirements for other types of coverage to apply for recognition as minimum essential coverage. In § 156.602 HHS designated the following types of health benefits coverage as minimum essential coverage: (1) Self-funded student health plans for plan or policy years beginning on or before December 31, 2014; (2) Refugee Medical Assistance supported by the Administration for Children and Families (45 CFR part 400 subpart G); (3) Medicare advantage plans; and (4) State high risk pools (as defined in section 2744 of the PHS Act) for plan or policy years beginning on or before December 31, 2014. In addition, § 156.604 outlines the substantive and procedural requirements for other types of health benefit coverage, not statutorily specified in section 5000A of the Code and not designated as

minimum essential coverage in § 156.602, to apply to HHS for recognition as minimum essential coverage. On October 31, 2013, CMS published guidance explaining the administrative process by which such plans may apply for recognition as minimum essential coverage.⁶⁰

In § 156.602(d), HHS applied a one-year transitional period in 2014 to State high risk pool coverage in anticipation of States phasing-out State high risk pools. Some States, however, will still have high risk pools in 2015 because they did not enact legislation to terminate the program. Some of these State high risk pools will be closed to new enrollment. At least one high risk pool that will still be in existence in 2015 primarily provides supplemental coverage to Medicare beneficiaries under age 65.

We understand the difficulty of transitioning individuals from State high risk pool coverage into QHPs through the Exchanges or into another form of minimum essential coverage. High risk pools provide coverage to vulnerable populations of consumers. Accordingly, we propose to revise § 156.602(d) by eliminating the one-year transition period for State high risk pool coverage and designating as minimum essential coverage any qualified high risk pool established in any State as defined by section 2744(c)(2) of the PHS Act that is currently in existence. We propose that this recognition will not be applied to State high risk pools that are formed after the publication date of this proposed rule. This should provide State legislators the opportunity to continue to evaluate the number of high risk pool enrollees, benefits and cost sharing associated with each State high risk pool. State legislatures may decide to eliminate high risk pool coverage once high risk pool enrollees no longer rely on State high risk pool coverage and have transitioned into QHPs through the Exchanges or into other forms of minimum essential coverage. We seek comments on this proposal. Specifically, we seek comments on whether State high risk pools should be permanently designated as minimum essential coverage or whether the designation should be time-limited (for example, for 2015 only). We also seek comments on the cut-off date for formation of State high risk pools that will qualify for recognition under this proposed rule.

⁵⁷ *Percentage of the total allowed costs of benefits* as defined at 45.CFR 156.20 means the anticipated covered medical spending for EHB coverage (as defined in § 156.110(a) of this subchapter) paid by a health plan for a standard population, computed in accordance with the plan's cost-sharing, divided by the total anticipated allowed charges for EHB coverage provided to a standard population, and expressed as a percentage.

⁵⁸ Shared Responsibility Payment for Not Maintaining Minimum Essential Coverage, 78 FR 53646 (August 30, 2013).

⁵⁹ Patient Protection and Affordable Care Act; Exchange Functions: Eligibility for Exemptions; Miscellaneous Minimum Essential Coverage Provisions, 78 FR 39494 (July 1, 2013).

⁶⁰ See CCIIO Sub-Regulatory Guidance: Process for Obtaining Recognition as Minimum Essential Coverage (October 31, 2013). Available at: <http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/mec-guidance-10-31-2013.pdf>.

6. Enforcement Remedies in Federally-Facilitated Exchanges

a. Available Remedies; Scope (§ 156.800)

In the first Program Integrity Rule, HHS finalized § 156.800(c), which established a good faith compliance policy for QHP issuers offering coverage through an FFE for the 2014 calendar year. Specifically, the first Program Integrity Rule provides that HHS will not impose sanctions under subpart I of 45 CFR part 156 against a QHP issuer in an FFE if the QHP issuer has made good faith efforts to comply with applicable Exchange requirements. HHS adopted the good faith compliance policy to help QHP issuers become familiar with the standards unique to the FFEs during the initial stage of operations.

We recognize that during 2014, CMS issued revised guidance on some Exchange processes and also implemented some new processes. To help QHP issuers adjust to these processes, HHS provided guidance and technical assistance through various forums. We are aware that despite HHS's support and the QHP issuers' good faith efforts, some QHP issuers offering coverage through an FFE nonetheless experienced difficulties adapting to these processes. However, we found that most QHP issuers were proactive in contacting their assigned HHS account managers to request technical assistance or clarifications to existing policies, standards and processes to ensure their own compliance with FFE standards. When potential issues were identified, the vast majority of QHP issuers demonstrated a willingness to cooperate with HHS to resolve these issues.

HHS is committed to ensuring that QHP issuers have the opportunity to learn from their experiences in 2014 without undue concern about being subject to formal enforcement actions when the QHP issuer has made reasonable efforts to comply with applicable standards. While immediate formal enforcement actions may be appropriate in some cases, we continue to prefer resolving most compliance issues by providing technical assistance. Accordingly, we propose extending the good faith compliance standard under § 156.800(c) through the end of calendar year 2015. We believe this one-year extension will encourage QHP issuers to continue to self-report any potential compliance issues or other problems that may affect their ability to comply with applicable FFE standards in 2015 and future years, and to continue making improvements to their processes and systems, including training their

staff about FFE operations and applicable standards. Further, if HHS determines that an issuer is not acting in good faith, that issuer may be subject to enforcement remedies including civil monetary penalties and decertification, if applicable.

Finally, we note that irrespective of the good faith compliance standard, QHP issuers are required to comply with all applicable FFE standards (and any applicable Federal or State laws including privacy, security and fraud) at the time of certification and on an ongoing basis. It should also be noted that QHP issuers have an independent obligation to comply with Federal civil rights laws and regulations to the extent they receive Federal financial assistance, and this proposed modification would not limit or otherwise restrict these laws and regulations. We expect our ongoing coordination with States and other regulatory entities to help streamline communications regarding potential compliance issues and avoid unnecessary duplication of oversight efforts. For issuers of multi-State plans, HHS will coordinate as appropriate with OPM to address compliance issues. We seek comment on this proposal.

b. Plan Suppression (§ 156.815)

In the Exchange Establishment Rule, HHS finalized § 155.205(b), which sets forth the required content and information to be included on an Exchange Web site. Among other things, this rule implemented the Secretary's obligations under section 1311(c)(5) of the Affordable Care Act to continue to operate, maintain, and update the Internet portal developed under section 1103 of the Affordable Care Act to provide information to consumers and small businesses on affordable health insurance coverage options. Under the rule, an Exchange Web site must provide information to consumers on each available QHP's premiums, cost-sharing arrangements, summaries of benefits and coverage, coverage ("metal") level, results of the enrollee satisfaction survey, quality ratings, medical loss ratio information, transparency in coverage information, and provider directory. The FFE Web site is located at www.HealthCare.gov and provides enrollees, consumers, and other stakeholders with access to QHP data to facilitate an informed plan selection when shopping for or enrolling in QHPs on an Exchange. The information provided on the FFE Web site is also presented to consumers enrolling through a HealthCare.gov call center representative, by direct enrollment through a QHP issuer's Web

site, or through the Web site of an agent or broker under § 155.220(c)(3).

During the 2014 plan year, we identified situations that made it necessary for purposes of protecting consumers' interests to suppress certain QHPs from each of the avenues of enrollment: enrollment through the HealthCare.gov Web site, enrollment by a HealthCare.gov call center representative, direct enrollment through a QHP issuer Web site, and enrollment through a Web site of an agent or broker. When a QHP is suppressed, the QHP temporarily will not be available for enrollment through the FFE. When all conditions that are grounds for suppression are resolved, the QHP will be unsuppressed.

In § 156.815(a), we propose a definition of suppression which would mean that a suppressed QHP temporarily would not be available for enrollment through the FFE.

In § 156.815(b), we list each of the proposed bases for suppression of a QHP in the FFE. Our first proposed basis for suppression, § 156.815(b)(1), is the issuer's notifying HHS of its withdrawal of the QHP from the FFE when one of the exceptions to guaranteed renewability of coverage related to discontinuing a particular product or discontinuing all coverage under § 147.106(c) or (d) applies. The purpose of this proposed basis for suppression is to clarify the method that we will use to prevent consumers from enrolling in a plan through the FFE after the issuer has notified HHS of its intent to legally withdraw the QHP from the FFE. We note that, per § 156.290(a)(2), issuers withdrawing QHPs from a FFE will be expected to fulfill their obligations to cover benefits for enrollees through the end of the enrollees' plan or benefit year and to comply with other applicable regulations.

In § 156.815(b)(2), we propose to suppress a QHP when we determine that the FFE has incorrect data about the QHP. This basis for suppression is intended for situations where incorrect or incomplete QHP data have been submitted to the FFE by the QHP issuer but the issuer intends to continue offering the QHP on the FFE after the data issue is resolved. We believe that suppression of a QHP with incorrect or incomplete data until the correct or complete information is available is in the best interest of the consumers. The decision to suppress based on incorrect data will be based on the severity of the issue. For example, a QHP with incorrectly submitted rates generally would be suppressed until the rating data are corrected.

In § 156.815(b)(3), we propose to suppress a QHP that is in the process of decertification under § 156.810 or the appeal of a decertification under subpart J of part 156. We believe it is necessary to suspend further enrollment in plans on the FFE where it is likely that consumers will be substantially harmed if the QHP is decertified in the near future. When a QHP is decertified, a consumer enrolled in that QHP will no longer be eligible for advance payments of the premium tax credit under § 155.305(f)(3) or cost-sharing reductions under § 155.305(g)(1) if they choose to remain enrolled in that plan after decertification. If a consumer enrolls in a new plan that is decertified shortly thereafter, the consumer will need to enroll in another QHP to retain access to advance payments of the premium tax credit and cost-sharing reductions. We believe the best way to bolster consumer confidence in the offerings on the FFE and to assist consumers in retaining their subsidies is to prevent further enrollment in a plan at risk of decertification until a determination on decertification is made. HHS will attempt to resolve decertification and appeal proceedings in as timely a manner as possible to minimize any adverse effect of suppression on QHP issuers.

In § 156.815(b)(4), we propose to suppress a QHP when the QHP is the subject of a pending, ongoing, or final State regulatory or enforcement action that could affect the issuer's ability to enroll consumers or otherwise relates to the issuer's ability to offer QHPs in the FFE and would necessitate the removal of a QHP from the FFE until the condition triggering the State action has been resolved. This basis for suppression is intended to protect consumers from enrollment in plans that State insurance regulators have identified as possibly or actually in violation of applicable State or Federal laws and regulations. We recognize that, in the case of pending State regulatory or enforcement action, QHP issuers may ultimately be cleared of alleged wrongdoing. To mitigate the harmful effect of such a scenario, we will base our suppress decision in this instance on the specific details of the pending regulatory or enforcement action, such as, the scope and severity of the alleged violation and the recommendation of State insurance regulators. We are committed to working with State insurance regulators to inform decisions about QHP suppression under this proposal.

In § 156.815(b)(5), we propose allowing suppression of a QHP when either the special rule for network plans

under § 147.104(c) or the application of financial capacity limits provision under § 147.104(d) apply. For example, if an issuer demonstrates to its State department of insurance (DOI) that it does not have the financial reserves necessary to offer additional coverage and the DOI places an enrollment restriction on a QHP to prevent it from enrolling new consumers, commonly referred to as an enrollment cap, we may suppress the QHP until the State DOI has lifted the restriction. We intend to coordinate with States to the greatest extent possible in determining whether suppression under this section is appropriate.

In § 156.815(c), we propose to suppress a QHP that is a multi-State plan upon notification by OPM. Under 45 CFR 800.103, OPM may contract with health insurance issuers to provide at least two multi-State plans on Exchanges and SHOPS in each State. When OPM determines that a compliance violation under subpart E of 45 CFR part 800 or one of the grounds for suppression in § 156.815(b) exists, the Exchange may suppress the multi-State plan upon notification by OPM of the violation or other grounds for suppression. We will continue to coordinate efforts with OPM when multi-State plan compliance violations are found.

We invite comments on these proposed regulations, including whether the proposed bases for suppression are appropriate and whether an appeals process should be available following suppression decisions.

7. Quality Standards

a. Quality Improvement Strategy (§ 156.1130)

Section 1311(c)(1)(E) of the Affordable Care Act specifies that to be certified as a QHP for participation on an Exchange, each health plan must implement a quality improvement strategy (QIS), which is described in section 1311(g)(1) of the Affordable Care Act. Section 1311(g)(1) of the Affordable Care Act describes this strategy as a payment structure that provides increased reimbursement or other incentives to improve the health outcomes of plan enrollees, prevent hospital readmissions, improve patient safety and reduce medical errors, implement wellness and health promotion activities, and reduce health and health care disparities. Section 1311(g)(2) of the Affordable Care Act requires the Secretary to develop guidelines associated with the QIS in consultation with health care quality experts and

stakeholders, including periodic reporting of the activities that the plan has conducted to implement the QIS, to the applicable Exchange, as described in section 1311(g)(3) of the Affordable Care Act. We have already issued regulations in § 155.200(d) to direct Exchanges to evaluate quality improvement strategies, and at § 156.200(b), which directs QHP issuers to implement and report on a quality improvement strategy or strategies consistent with standards set forth in section 1311(g) of the Affordable Care Act as a QHP certification criteria for participation in an Exchange. This rule proposes standards and the associated timeframe for QHP issuers to submit the necessary information to implement QIS standards for QHPs offered through an Exchange under section 1311(g) of the Affordable Care Act beginning in calendar year 2016.

Many provisions in the Affordable Care Act build on related value-based purchasing concepts. HHS has already implemented several programs (for example, the Medicare Shared Savings Program, the Hospital Value-Based Purchasing Program, and the Physician Value-Based Payment Modifier) that focus on rewarding provider-level organizations that use innovative payment and service delivery models to lower costs and improve quality of health care for Medicare beneficiaries. Although these programs are provider-focused and relate to the Medicare program, their elements are closely aligned to the statutory requirements of a QIS for QHPs offered in an Exchange, including, rewarding quality and value through market-based incentives for improving health outcomes through care coordination activities, preventing hospital readmissions, and improving patient safety. We believe it is important to align with public and private payment and service delivery programs, as appropriate, to support the goals of better health outcomes and lower health care costs. The Center for Medicare and Medicaid Innovation has also recognized the importance of multi-payer engagement in quality improvement, releasing models such as Pioneer Accountable Care Organizations and the Comprehensive Primary Care Initiative that require participating providers to work with both public and private payers on care redesign and efficiency. We encourage QHP issuers to consider diverse approaches to value-based payment and enrollee incentives to reward quality and value in health care.

The HHS National Strategy for Quality Improvement in Health Care (National Quality Strategy) defines

priorities that guide efforts to improve health and health care quality for individuals and communities. It also identifies policy levers, such as payment rewards or incentives for providers, and consumer incentives and benefit designs, which represent a business function, resource or action that stakeholders can use to align with the National Quality Strategy and drive quality improvement for better, more affordable health care.⁶¹ The CMS Quality Strategy is built on the foundation of the National Quality Strategy and operationalizes the priorities of the National Quality Strategy to improve health outcomes for all consumers, including those who seek coverage through the Exchange. We propose to establish QIS standards that use market-based incentives for QHPs offered through the Exchanges, and that align with the National Quality Strategy, the CMS Quality Strategy, and other Federal, State and private sector initiatives, as applicable. We acknowledge that there are numerous existing public and private industry standard initiatives that focus on health plan quality improvement strategies and activities. We believe that aligning QHP issuer standards for quality improvement strategies in Exchanges with existing initiatives would reinforce national health care quality priorities while reducing the burden on health plans and stakeholders to implement different and multiple program requirements. This approach is also consistent with the alignment of the quality rating system for QHPs offered through an Exchange under section 1311(c)(3) of the Affordable Care Act to the National Quality Strategy.⁶²

We believe that it is important that the proposed QIS standards leverage existing initiatives and quality improvement strategy tools for QHP issuers to help strengthen health care system-wide efforts to improve health outcomes and lower costs. We reviewed several existing initiatives in the public and private sectors⁶³ such as Federal

health plan quality improvement evaluation programs, private accreditation programs, and other private sector programs to guide the development of the framework for the QIS for QHPs offered through the Exchanges and establish the proposed standards outlined in this rule.

Based on our research, feedback from a QIS Technical Expert Panel (TEP), and discussions with stakeholders, we developed the following principles to guide the development, implementation, and evolution of the QIS standards: (1) The QHP issuer's QIS will focus on one or more of the following topics outlined in section 1311(g)(1) of the Affordable Care Act: Improving health outcomes, implementation of activities to prevent hospital readmissions, implementation of activities to improve patient safety and reduce medical errors, implementation of wellness and health promotion activities, and implementation of activities to reduce health and health care disparities; (2) HHS will seek to minimize administrative burdens through alignment of the QIS data collection and submission standards, where possible, with public and private quality improvement and public reporting programs; (3) The QIS standards will be flexible enough to encourage QHP issuer innovation and promote a culture of continuous quality improvement providing the QHP issuer's strategy is relevant to the characteristics and needs of its enrollees and the Exchange; (4) The QIS standards will allow for flexibility for State Exchanges while still establishing minimum requirements, upon which States, if desired, can build additional reporting requirements in accordance with their needs; (5) The QIS standards will be developed in a public and transparent manner that will seek stakeholder feedback throughout its development and implementation. We believe that these guiding principles and general framework for the QIS standards will promote efficiency, flexibility, and transparency to best engage QHP issuers and serve consumers to improve health and health care quality in the Exchanges.

In § 156.1130(a), we propose that a QHP issuer participating in an Exchange for at least 2 years must implement and report information regarding a quality improvement strategy which includes a payment structure to provide increased reimbursement or other market-based incentives in accordance with the health care topic areas in section 1311(g)(1) of

the Affordable Care Act, for each QHP offered in an Exchange consistent with the guidelines developed by HHS under section 1311(g) of the Affordable Care Act. We note that the statutory QIS requirements, similar to the other Exchange quality standards, extend to all Exchange types, including a State Exchange and the FFE. For the QIS, we propose to provide State Exchanges flexibility to establish the timeline, format, validation, and other requirements related to the annual submission of QIS data by QHP issuers that participate in their respective Exchanges. Under this proposal, the establishment and implementation of such standards and other requirements by State Exchanges would support compliance with § 155.200(d), which requires the Exchange to evaluate and oversee implementation of the QIS (among other QHP issuer quality initiatives on coverage offered through Exchanges). We envision the standards that will be used for the FFE will provide the starting point for State Exchanges to build upon.

We propose to phase in QIS implementation standards and reporting requirements to provide QHP issuers the necessary time to understand the populations enrolling in a QHP offered through the Exchange and to build quality performance data on its QHP enrollees. We believe that implementation of a QIS should be a continuous improvement process for which the QHP issuers are required to define the health outcome needs of their enrollees, set goals for improvement, and use increased reimbursement to their providers or other market-based incentives to stimulate achievement of those goals. We believe this proposed approach is consistent with other QHP issuer quality standards for coverage offered through an Exchange including implementation and reporting for the patient safety standards, Quality Rating System (QRS), and Enrollee Satisfaction Survey (ESS), outlined in subpart L of part 156. We further note that, consistent with existing regulations at § 156.200(h), we anticipate that QHP issuers participating in Exchanges would be required to attest to compliance with QIS standards, along with the other QHP issuer quality initiatives for coverage offered through Exchanges established under subpart L of part 156, as part of the QHP application process.

In paragraph (b), we propose to direct a QHP issuer to submit validated data in a form, manner and reporting frequency specified by the Exchange to support evaluation of quality improvement strategies in accordance with

⁶¹ The National Strategy for Quality Improvement in Health Care available at <http://www.ahrq.gov/workingforquality/nqs/nqs2011annrpt.htm>.

⁶² Patient Protection and Affordable Care Act; Exchanges and Qualified Health Plans, Quality Rating System (QRS) Framework, Measures and Methodology; Notice with Comment, 78 FR 69418 (Nov. 19, 2013).

⁶³ Initiatives include, the Medicaid External Quality Review (EQR) program, the Medicare Advantage Quality Improvement Project and Chronic Care Improvement Program (QIP/CCIP) Program, the Accreditation Association for Ambulatory Health Care (AAAHC), National Committee for Quality Assurance (NCQA), URAC, Integrated Health Association (IHA) Value Based Pay for Performance (P4P) Program, National

§ 155.200(d) and § 156.200(b)(5). We anticipate using the data collected as part of information used to evaluate and oversee compliance of QHP issuers in FFEs with the Exchange QIS standards and encourage State Exchanges to adopt a similar approach. We propose that beginning in 2016, a QHP issuer participating in the FFE for at least 2 years would submit a QIS implementation plan to HHS and the applicable Exchange for each QHP offered in the Exchange, followed by annual progress updates. We anticipate that the implementation plan for a QHP issuer's proposed QIS will reflect a payment structure that provides increased reimbursement or other market-based incentives for addressing at least one of the topics specified in section 1311(g)(1) of the Affordable Care Act.

The QIS design should include elements such as: A rationale that describes its relevance to the QHP's enrollee population; proposed performance measures and targets; description of activities to reduce health and health care disparities, as well as other chosen topics, goals, timeline, and information about barriers and mitigation planning. For example, we are considering requesting information from QHP issuers regarding the percentage of payments to providers that is adjusted based on quality and cost of health care services. We believe that QHP issuers measuring and reporting such information related to payment models that link quality and value of health care services is an important part of an issuer's QIS. We also believe that information regarding provider payment models and market-based incentives that link quality and value would promote transparency of such health plan quality data to Exchanges to help make better informed QHP certification decisions. We propose that one year after submitting the QIS implementation plan, the QHP issuer would submit information including, an annual update including a description of progress of QIS implementation activities, analysis of progress using proposed measures and targets, and any modifications to the QIS. Currently, we do not intend to require specific performance measures to be included in a QIS; however, we anticipate that health plan quality measures required for the QRS could be incorporated in a QHP issuer's QIS. We believe that the proposed implementation and reporting for the QIS over time would provide meaningful QIS data from QHP issuers by minimizing administrative effort while also allowing for flexibility and

innovation. We anticipate issuing technical guidance in the future that will provide operational details including data validation, other data submission processes, timeframes and potential minimum enrollment size threshold for coverage offered through the FFE. This guidance would be updated on an annual basis (or more frequently as may be necessary). We propose to allow State Exchanges to establish the data validation and submission requirements for QIS data from QHP issuers that participate in their respective Exchanges.

In paragraph (c), we propose to direct a QHP issuer to submit data annually for activities that are conducted related to implementation of its QIS, in a manner and timeframe specified by the Exchange. For example, an issuer that participates in the FFE for two consecutive years for coverage beginning in January 2014 and January 2015 would submit a QIS implementation plan to the FFE during the fall 2016 post-certification period, and in a format specified by HHS. A progress update on the QHP issuer's QIS activities would be required the following year. Similarly, an issuer participating in the FFE for the first time during the 2015 open enrollment period for the 2016 coverage year would submit an implementation plan in the 2018 post-certification period to align with our proposed approach of phasing in the QIS over time and allowing a QHP issuer 2 years to collect data and develop quality improvement strategies for its QHPs offered through an Exchange, before the submission of an implementation plan is required. A progress update on the QHP issuer's QIS activities would be required the following year. We propose to allow State Exchanges to establish the specific timeline and format requirements for the annual submission of QIS data by QHP issuers that participate in their respective Exchanges.

We seek comment on the proposed general requirement in paragraph (a) that describes the QIS and the applicability to QHP issuers that have been participating for at least 2 years in an Exchange. We seek comment on whether the proposed QIS standards should be applicable to all types of QHPs offered through the Exchange (for example, stand-alone dental plans, QHPs providing child-only coverage, and health savings accounts) or if different standards should be developed for the different types of QHPs offered through the Exchange. We also seek comment regarding whether certain types of QHPs offered through the

Exchange should be excluded from the QIS certification requirement.

We seek comment on the proposed data requirement in paragraph (b) and the proposed timeline in paragraph (c). We seek comment on the proposed approach of directing QHP issuers to provide information regarding an implementation plan followed by annual progress updates. We seek comment on whether there should be a minimum QHP enrollment size threshold to trigger the applicability of QIS standards proposed in § 155.1130. We also seek comment on what information is important to include for HHS and an Exchange to effectively monitor and evaluate a QIS. We seek comment on requiring information relating to provider payment models, such as an issuer's minimum target or goal set with regards to the percentage of provider payments adjusted for quality and cost, to be submitted for compliance with QIS standards proposed in § 155.1130. We also seek comment on whether QIS data submitted and evaluated under section 1311(g) should be collected in a uniform or standardized format or publically displayed to encourage transparency, support comparison of QHP issuer QIS activities, and align with other quality standards for QHP issuers.

We note that multi-State plans, as defined in § 155.1000(a), are subject to reporting QIS data for evaluation, as described in paragraph (b). This rulemaking proposes to codify this general requirement at § 156.1130(d). We anticipate that OPM will provide guidance on QIS reporting to issuers with whom it holds multi-State plan contracts.

8. Qualified Health Plan Issuer Responsibilities

a. Administrative Appeals (§ 156.1220(c))

In the 2015 Payment Notice, we established an administrative appeals process designed to address unresolved discrepancies regarding advance payments of the premium tax credit, advance payments of cost-sharing reductions, FFE user fee payments, payments and charges for the premium stabilization programs, cost-sharing reduction reconciliation payments and charges, and assessments of default risk adjustment charges. We established a three-tier appeals process: a request for reconsideration under § 156.1220(a); a request for an informal hearing before a CMS hearing officer under § 156.1220(b); and a request for review by the Administrator of CMS under § 156.1220(c).

Under § 156.1220(a), we provided that an issuer may file a request for reconsideration of a processing error by HHS, HHS's incorrect application of the relevant methodology, or HHS's mathematical error only for advance payments of the premium tax credit, advance payments of cost-sharing reductions, FFE user fee payments, payments and charges for the premium stabilization programs, cost-sharing reduction reconciliation payments and charges, and assessments of default risk adjustment charges for a benefit year. In § 156.1220(a)(6), we stated that a reconsideration decision would be final and binding for decisions regarding the advance payments of the premium tax credit, advance payments of cost-sharing reductions, and FFE user fees. A reconsideration decision with respect to other matters would be subject to the outcome of a request for informal hearing filed in accordance with § 156.1220(b).

Under § 156.1220(b), an issuer that elects to challenge the reconsideration decision may request an informal hearing before a CMS hearing officer. The CMS hearing officer's decision would be final and binding, but subject to any Administrator's review initiated in accordance with § 156.1220(c).

We stated in § 156.1220(c)(1) that if the CMS hearing officer upholds the reconsideration decision, the issuer is permitted to request a review by the Administrator of CMS within 15 calendar days of the date of the CMS hearing officer's decision. We are proposing to modify this process to also permit CMS the opportunity to request review of the CMS hearing officer's decision, and to permit the Administrator of CMS to decline to review the CMS hearing officer's decision. Specifically, we propose to amend § 156.1220(c)(1) to permit either the issuer or CMS to request review by the Administrator of the CMS hearing officer's decision. We propose to provide that any request for review of the hearing officer's decision must be submitted to the Administrator of CMS within 15 calendar days of the date of the hearing officer's decision, and must specify the findings or issues that the issuer or CMS challenges. We propose that the issuer or CMS be permitted to submit for review by the Administrator a statement supporting the decision of the CMS hearing officer.

We also propose to amend § 156.1220(c)(2) to provide the Administrator of CMS with the discretion to review or not review the decision of the CMS hearing officer after receiving a request for review under § 156.1220(c)(1). We believe such

discretion will permit the Administrator to focus resources on the priority matters, including disputes with implications for other issuers. In keeping with our current process set forth in § 156.1220(c), we propose that if the Administrator elects to review the CMS hearing officer's decision, the Administrator will review the statements of the issuer and CMS, and any other information included in the record of the CMS hearing officer's decision, and will determine whether to uphold, reverse, or modify the CMS hearing officer's decision. We propose that the issuer or CMS be required to prove its case by clear and convincing evidence with respect to issues of fact, and that the Administrator will send the decision and the reasons for the decision to the issuer. As established in § 156.1220(c)(3), the Administrator's decision is final and binding.

We note that this process is consistent with the Medicare Advantage risk adjustment data validation audit dispute and appeal processes set forth in 42 CFR 422.311 and believe that this proposal will strengthen the administrative appeal process by providing CMS the opportunity to appeal inconsistencies from prior decisions and focus resources on disputes affecting many issuers. We seek comment on this proposal.

I. Part 158—Issuer Use of Premium Revenue: Reporting and Rebate Requirements

1. Treatment of Cost-Sharing Reductions in MLR Calculation

The Premium Stabilization rule (77 FR 17220) aligned the definition of "allowable costs" under the risk corridors program at § 153.500 with the definition of incurred claims under the MLR program at § 158.410 and expenditures for health care quality and health information technology under § 158.150–§ 158.151. In the 2014 Payment Notice, we additionally specified that allowable costs under risk corridors must be reduced by the amount of cost-sharing reduction payments received from HHS. While the MLR regulation describes a number of adjustments to an issuer's incurred claims in the MLR calculation, it currently does not describe how incurred claims should be adjusted to reflect cost-sharing reduction receipts by the issuer. To align the calculations between the two programs, we propose to specify that cost-sharing reduction payments should be deducted from incurred claims under the MLR program just as they are deducted from allowable costs under the risk corridors program. As we previously stated in the 2014

Payment Notice, it is our understanding that in most fee-for-service arrangements, cost-sharing reductions will be passed through to the fee-for-service provider, and therefore no adjustment to incurred claims for cost-sharing reduction payments is required to account for any retained payments. In contrast, in capitated arrangements, cost-sharing reduction payments should be accounted for as a reduction to incurred claims because capitation payments (which are reflected directly in an issuer's incurred claims) will be raised to account for the reductions in providers' cost-sharing income, and the issuer will retain the cost-sharing reduction payments. For these reasons, we propose to amend § 158.140(b)(1) to clarify that cost-sharing reduction payments received by the issuer, to the extent not reimbursed to the provider furnishing the item or service, must be deducted from incurred claims.

2. Reporting of Federal and State Taxes

The MLR December 1, 2010 interim final rule (75 FR 74864) directs issuers to report Federal and State taxes and assessments that are excluded from premium in the MLR and rebate calculations separately from Federal and State taxes and assessments not excluded from premium in MLR and rebate calculations. Specifically, the interim final rule notes that Federal taxes excluded from premium in the MLR include all Federal taxes and assessments allocated to health insurance coverage reported under section 2718 of the PHS Act. The Federal taxes not excluded from premium in the MLR under the interim final rule include Federal income taxes on investment income and capital gains. The State taxes excluded from premium in the MLR under the interim final rule include State income, excise, premium, and certain other taxes, and for certain issuers, community benefit expenditures. The State taxes not excluded from premium in the MLR under the interim final rule include State sales taxes and ceded premium taxes. While our technical guidance and the instructions for the MLR report required by section 2718 of the PHS Act provide some additional details regarding certain types of taxes that may or may not be excluded from premium, we believe that the current reference to all taxes and assessments allocated to health insurance coverage reported under section 2718 of the PHS Act would benefit from further clarification for future MLR reporting years. Specifically, employment taxes such as the employer and employee shares of the Federal Insurance Contributions Act

(FICA) and the Railroad Retirement Tax Act (RRTA) taxes, the Federal Unemployment Act (FUTA) and State unemployment taxes, and other similar taxes represent an administrative cost that is more directly related to an issuer's overhead rather than to the characteristics of its health insurance business in a particular State and market. Therefore, in this rulemaking, we propose to amend the provisions for the reporting of Federal and State taxes in § 158.162(a)(2) and (b)(2) to provide that Federal and State employment taxes should not be excluded from premium in the MLR and rebate calculations.

3. Distribution of Rebates to Group Enrollees in Non-Federal Governmental Plans

The December 7, 2011 MLR Rebate Requirements for Non-Federal Governmental Plans interim final rule (76 FR 76596) directs issuers to distribute rebates to the group policyholders of non-Federal governmental plans. Under CMS's direct enforcement authority over non-Federal governmental plans, the interim final rule further directs the group policyholders of such plans to use the portion of the rebate attributable to the amount of premium paid by subscribers of such plans for the benefit of subscribers in one of three prescribed ways. These provisions were put in place to ensure that rebates are used for the benefit of enrollees of non-Federal governmental plans, who do not receive the protections of Employee Retirement Income Security Act of 1974 (ERISA), as amended. Under ERISA and implementing regulations, most plan participants are assured that the rebate (when the rebate is determined to be a plan asset) is applied for their benefit within 3 months of receipt by the policyholder. Currently, no similar protection is afforded to subscribers of non-Federal governmental plans.

In this proposed rule, we propose to amend the provisions for distribution of rebates in § 158.242(b) to require group policyholders of non-Federal governmental plans to use the subscribers' portion of the rebate for the subscribers' benefit within 3 months of receipt of the rebate by the group policyholder. Under this proposal, plans will continue to be able to use the rebate to reduce the subscribers' portion of premium for the subsequent policy year (including by spreading it over the 12 months of the policy year) as long as the subsequent policy year commences within 3 months of receipt of the rebate by the group policyholder. If the subsequent policy year commences

outside this 3-month window, the group policyholder of a non-Federal governmental plan must distribute the subscribers' portion of the rebate within 3 months in the form of a cash refund or by applying a mid-policy year premium credit to the subscriber's portion of premium. We note that, because under § 158.242(b)(3) group health plans that are not governmental plans and are not subject to ERISA (such as church plans) must follow the same rebate distribution rules in order to receive the rebate directly, the same distribution deadline will apply to such plans. Policyholders that are non-Federal governmental or other group health plans not subject to ERISA that do not apply or distribute rebates within 3 months of receipt will be required to pay interest on the rebates, much the same as issuers are required to do if they do not disburse the rebate to the policyholder by the due date. This proposed policy will ensure that consumers enrolled in group health plans not subject to ERISA do not experience unnecessary delays in receiving the benefit of the rebates.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. This 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 13. 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 a 35 percent increase for fringe benefits

and overhead) for estimating the burden associated with the ICRs.

A. ICRs Regarding Standards for Notification of Change of Ownership (§ 146.152(i), § 147.106(g), § 148.122(j))

When an issuer that offers a QHP, a plan otherwise subject to risk corridors, a risk adjustment covered plan, or a reinsurance eligible plan experiences a change in ownership, the issuer would be required to notify HHS of a change of ownership in a manner to be specified by HHS and provide the legal name, Health Insurance Oversight System (HIOS) plan identifier, and tax identification number of the original and post-transaction issuers and the effective date of the change of ownership. The information would have to be submitted by the latest of (1) the date the transaction is entered into; or (2) the 30th day prior to the effective date of the transaction. The burden associated with this proposed requirement would be the time and effort for the issuer to notify HHS of a change of ownership. We estimate that it would take an insurance operations analyst 30 minutes (at an hourly wage rate of \$56.63) to prepare the data related to the change of ownership, and 10 minutes for a senior manager (at an hourly wage rate of \$103.95) to review the data and transmit it electronically to HHS. We estimate that it would cost an issuer \$45.65 to comply with this reporting requirement. Although at this time we cannot precisely estimate the number of issuers that would be reporting changes of ownership, we expect that no more than 20 issuers would be subject to this reporting requirement annually, for a total burden of \$913.

B. ICRs Regarding Effective Rate Review Programs (§ 154.301)

In § 154.301(b)(2), we propose that if a State intends to make the information contained in Parts I, II, and III of the Rate Filing Justification regarding proposed rate increases subject to review available to the public prior to the date specified in guidance by the Secretary, or if it intends to make the information contained in Parts I, II, and III of the Rate Filing Justification regarding final rate increases available to the public prior to the first day of the annual open enrollment period for the applicable calendar year, the State must notify CMS in writing of its intent to publish this information at least 30 days before it makes the information public and the date it intends to make the information public. We intend to seek OMB approval and solicit public comment on this information collection

requirement, in accordance with the Paperwork Reduction Act of 1995, at a future date.

C. ICRs Regarding Standards for HHS-Approved Vendors of Federally-Facilitated Exchange Training for Agents and Brokers (§ 155.222)

In § 155.222, we describe the information collection and disclosure requirements that pertain to the approval of vendors' FFE agent and broker training programs, including information verification and administration of identity proofing. The burden estimate associated with these disclosure requirements includes the time and effort required for vendors to develop, compile, and submit the application information and any documentation or agreement necessary to support oversight in the form and manner required by HHS. We estimate that HHS would receive applications from nine or fewer vendors, and that it will take each vendor approximately 10 hours to complete an application and the agreement, at a cost of \$24.10 per hour. Therefore, we estimate a total burden of approximately 90 hours and a cost of \$2,169 as a result of this proposed requirement. HHS anticipates developing a model vendor application that will include data elements necessary for HHS review and approval. If the proposal is finalized, HHS would solicit public comment on the model application, estimate the burden on vendors for complying with this provision of the regulation, and submit the application for OMB approval in the future. We request comment on the burden for the application and review process for these entities. In addition, HHS will consider current training costs for State licensed agents and brokers for comparable training offered by the vendor to comparable audiences when reviewing vendor applications.

In § 155.222(d), we propose a process through which HHS would monitor approved vendors for ongoing compliance. HHS may require additional information from approved vendors to be periodically submitted in order to ensure continued compliance related to the obligations described in this section. We estimate that HHS would receive applications from nine or fewer vendors. We estimate that it will take no longer than 10 hours (at a cost of \$24.10 per hour) for each vendor to comply with any additional monitoring by HHS. Therefore, we estimate a total annual burden of 90 hours for all vendors for a total cost burden estimate of \$2,169. In § 155.222(e) of this proposed rule, we propose to establish a process by which a vendor whose

application is not approved or whose approval is revoked by HHS can appeal HHS's determination. We discuss the costs associated with the proposed appeals process in the Regulatory Impact Analysis (RIA) section of this proposed rule.

D. ICRs Regarding Collection of Data To Define Essential Health Benefits (§ 156.120)

In § 156.120, we propose to give States an opportunity to select a new base-benchmark plan to serve as a reference plan to define EHB in that State for the 2017 plan year. The information collection associated with State selection and submission of a benchmark plan and associated benefits is currently approved under OMB Control Number 0938-1174. We expect to collect less information for the 2017 plan year than we previously collected for this purpose, and therefore expect to revise our current burden estimate to reflect the reduced burden on issuers. We intend to seek OMB approval and solicit public comment on this information collection requirement, in accordance with the Paperwork Reduction Act of 1995, at a future date.

E. ICRs Regarding Prescription Drug Benefits (§ 156.122)

In § 156.122, we propose to require health plans that are required to comply with EHB to establish a P&T Committee according to the process and standards proposed in this rule. We expect that health plans have already established P&T Committees that meet these standards and follow these processes. We propose recordkeeping requirements for the P&T committee in this proposed rule. However, because we believe that issuers are already required to maintain such documentation, such as for accreditation purposes, and issuers tend to use the same formulary drug list for multiple plans, we believe that our propose recordkeeping requirement will only impose minimal additional burden on issuers. We, therefore, estimate that it will take a compliance officer approximately 8 hours (at an hourly wage rate of \$43.34) to prepare for and attend meetings on a quarterly basis, and maintain the required documentation. Therefore, for approximately 2,400 plans in the individual and small group market that would be subject to this requirement, we estimate an aggregate annual burden of 76,800 hours (\$3,328,512) associated with this proposed requirement.

F. ICRs Regarding Termination Notices for SHOP (§ 156.285(d)(1)(ii)) and § 155.735(d)(1)(iii) and (g)

We are proposing in § 156.285(d)(1)(ii) and § 155.735(d)(1)(iii) and (g) to require QHP issuers participating in the SHOP to provide notices to qualified employers and enrollees related to terminations due to rescission in accordance with § 147.128 and due to the QHP's termination, decertification, or non-renewal of certification, while shifting the burden of notifying qualified employers and enrollees of terminations due to loss of eligibility or nonpayment of premiums to the SHOP. We note that, while our current rules require issuers to provide notice of terminations when coverage is rescinded in accordance with § 147.128, or when the issuer elects not to seek recertification for a QHP offered through the SHOP, this proposal would expand QHP issuers' notice requirements to circumstances in which the QHP terminates or is decertified in accordance with § 155.1080. The proposed notices must inform the enrollee and qualified employer, promptly and without undue delay, of the termination effective date and the reason for the termination. The burden estimate associated with this requirement includes the time and effort needed to develop the notice and to distribute it through an automated process to qualified employer and the enrollee, as appropriate. We estimate that approximately 445 QHP issuers (including dental issuers) will participate on the SHOP. We estimate that it will take approximately 35 hours annually to develop and transmit this notice, including 4 hours for a health policy analyst (at an hourly wage rate of \$58.05), 3 hours for an operations analyst (at an hourly wage rate of \$56.63), 25 hours for a computer programmer (at an hourly wage rate of \$48.61), 2 hours for a fulfillment manager (at an hourly wage rate of \$27.00), and 1 hour for a senior manager (at an hourly wage rate of \$103.95). Therefore, we estimate an aggregate burden of 15,575 hours across and \$790,004 for QHP issuers participating in the SHOP as a result of this proposed requirement.

Based on the above per-notice development rates and hours, we believe that each State-based SHOP would spend roughly 70 hours annually to prepare the 2 termination notices (35 hours per notice), for a total cost of \$3,550 to design and implement the notices proposed under § 155.725(g). We estimate that there will be

approximately 18 State-based SHOPS, and that all State-based SHOPS would be subject to this requirement.

Therefore, we estimate an aggregate burden of 1,260 hours and \$63,900 for State-based SHOPS as a result of this proposed requirement.

G. ICRs Regarding Plan Variation Notices and Changes in Eligibility for Cost-Sharing Reductions (§ 156.420 and § 156.425)

In § 156.420(h), we propose that an issuer must provide a summary of benefits and coverage (SBC) for each plan variation of a QHP it offers in accordance with the rules set forth under § 156.420 (referred to in this section as a “plan variation SBC”), in a manner that is consistent with the standards set forth in § 147.200. In § 156.425(c), we propose that if an individual’s assignment to a plan variation or standard plan without cost-sharing reductions changes in the course of a benefit year (in accordance with § 156.425(a)), an issuer must provide an SBC in a manner consistent with the standards set forth in § 147.200, as soon as practicable after receiving notice from the Exchange of the individual’s change in eligibility and no later than 7 business days following receipt of notice. The burden associated with this proposed requirement would be the time and effort necessary for an issuer to create and provide plan variation SBCs to affected individuals under § 156.420.

Nearly all issuers that would be affected by this proposal already incurred one-time start-up costs related to implementing the SBC requirements established under § 147.200, and are already providing SBCs that reflect the standard QHPs they offer.⁶⁴ We estimate that QHP issuers would leverage existing processes to generate and distribute plan variation SBCs under proposed § 156.420(h). We estimate that issuers would incur additional burden to produce and distribute plan variation SBCs under the proposed §§ 156.420(h) and 156.425(c). The additional burden would be associated with three tasks: (1) Producing plan variation SBCs; (2) distributing plan variation SBCs; and (3) distributing a plan variation SBC (or standard QHP without cost-sharing reductions) after a change in eligibility in the course of a benefit year. We intend to revise the information

collection approved under OMB Control Number 0938–1187 to reflect this additional burden.

1. Producing Plan Variation SBCs

Because stand-alone dental plans (SADPs) are not required to complete SBCs, we exclude these plans from the number of QHPs that we estimate would be required to comply with the proposed requirement. We estimate that approximately 575 issuers participate in the Exchange, and that each issuer offers one QHP per metal level, with four zero cost-sharing plan variations and four limited cost-sharing plan variations (two per metal level per QHP) and three silver plan variations.⁶⁵ Therefore, we estimate that each issuer offers 11 plan variations, and would produce 11 SBCs to reflect each plan variation, for a total of 6,325 plan variation SBCs annually. We estimate that it will take up to one hour to produce each plan variation SBC, for an annual time burden of 11 hours for each issuer. We estimate that it would take an information technology (IT) professional 5 hours (at an hourly wage rate of \$54.39), a benefits/sales professional 5.5 hours (an hourly wage rate of \$44.90) per hour, and an attorney 30 minutes (at an hourly wage rate of \$84.96) to comply with the proposed requirements. Therefore, we estimate a total annual cost burden of \$561.44 per issuer, and \$322,828 (6,325 hours) for all issuers affected by this proposed requirement.

2. Distributing Plan Variation SBCs

We are unable to estimate the number of CSR-eligible enrollees at this time and the related burden on issuers to provide for these disclosures. We expect that the vast majority (approximately 95 percent) of the total number of plan variation SBCs provided in accordance

with proposed § 156.420(h) would be sent prior to enrollment and electronically at minimal cost, under the timing and form requirements set forth in § 147.200(a)(1)(iv) and (a)(4)(iii). Of the remaining number of plan variation SBCs that would be provided, we estimate that approximately 4 percent of these disclosures would be sent in other instances, in accordance with the other timing requirements that may apply, including, requests for a plan variation SBC made by a consumer in the course of the benefit year. We expect that the vast majority of these disclosures would be provided electronically at minimal cost. We assume that there are costs for paper disclosures, but no costs for electronic disclosures.⁶⁶ We expect that up to one percent of plan variation SBCs would be provided in paper form. We estimate that the labor costs associated with distributing each SBC would be \$1.63 (3 minutes for an administrative assistant at an hourly wage rate of \$32.59), and that printing, mailing, and supply costs would be \$0.69 per SBC (\$0.05 to print each page and \$0.49 for first class postage), for a total costs of \$2.32 per SBC. We estimate an annual burden of \$331 for each QHP issuer and an aggregate burden of \$190,240 for all issuers that would be subject to the proposed requirement.

3. Notice After Changes in Eligibility for Cost-Sharing Reductions

In § 156.425(c), we propose to require an issuer to provide adequate notice to the individual about the availability of the SBC that accurately reflects the applicable plan variation of the QHP (or the standard QHP without CSRs) if an enrollee’s eligibility for CSRs changes in the course of a benefit year. Similarly, if an enrollee changes QHPs as the result of a special enrollment period in accordance with § 155.420(d)(6), the issuer of the new QHP would be required to provide the individual with an SBC that accurately reflects the new QHP. We are unable to estimate the number of CSR-eligible enrollees who would experience a change in eligibility for CSRs at this time and the related burden on issuers to provide for these disclosures. We expect that the vast majority (approximately 99 percent) of the total number of SBCs provided in accordance with proposed § 156.425(c) would be sent electronically at minimal cost. We estimate that the labor costs associated with producing each SBC would be approximately \$1.63 (3 minutes for an administrative assistant at an hourly wage rate of \$32.59), and that printing, and mailing costs would

⁶⁴ Summary of Benefits and Coverage and Uniform Glossary Final Rule (“SBC Final Rule”), 77 FR 8690 (Feb. 14, 2012). We have already received OMB approval under OMB control number 0938–1146 for the collection of information requirements related to the SBC provisions as finalized under current rules.

⁶⁵ Under § 156.420(a), for each of its silver health plans that an issuer offers, the issuer must offer three variations of the standard silver plan that reflect, in addition to the applicable annual limitation on cost-sharing, the following: (1) A silver plan variation with cost-sharing reductions such that the actuarial value (AV) of the variation is 94 percent plus or minus the de minimis variation for a silver plan variation; (2) a silver plan variation with cost-sharing reductions such that the AV of the variation is 87 percent plus or minus the de minimis variation for a silver plan variation; and (3) a silver plan variation with cost-sharing reductions such that the AV of the variation is 73 percent plus or minus the de minimis variation for a silver plan variation. Under § 156.420(b), for each QHP at any metal level that an issuer offers, the issuer must offer two variations to American Indians/Alaska Natives that reflect the following: (1) A variation of the QHP with all cost sharing eliminated; and (2) a variation of the QHP with no cost-sharing on any item or service that is an essential health benefit furnished directly by the Indian Health Service, an Indian Tribe, Tribal Organization, or Urban Indian Organization, or through referral under contract health services.

⁶⁶ SBC Final Rule, 77 FR 8691 (Feb. 14, 2012).

be \$0.69 (\$0.05 to print each page and \$0.49 for first class postage), for a total cost of \$2.32 per SBC. We estimate a total annual cost of \$165 for each QHP issuer and \$95,120 for all QHP issuers that would be subject to this proposed requirement.

H. ICRs Regarding the Collection and Reporting of Quality Improvement Strategies (§ 156.1130)

In § 156.1130, we propose requirements for QHP issuers related to data collection and submission of information regarding a quality improvement strategy (QIS). QIS standards will establish the minimum requirements for the FFE, States with plan management functions and that State Exchanges must follow. State Exchanges can, if desired, build additional reporting requirements in accordance with their needs. Based on

current agency estimates of the number of major medical QHPs and stand-alone dental plans (SADPs) being offered through the Exchange, we estimate that 677 QHP issuers would collect and report QIS data annually. This estimate assumes 677 QHP issuers (all QHP issuers in all Marketplace types, including SADPs) and covers the annual costs for a QHP issuer over a 3-year period (2016–2018). The burden associated with submitting initial attestations as part of the QHP certification process is currently accounted for under OMB Control Number 0938–1187. We estimate that it would take each QHP issuer 48 hours (at a cost of \$3,372) to collect this QIS data and to submit this information to the Exchange. Therefore, we estimate an aggregate burden of 32,496 hours and \$2,282,844 as the total annual burden for the anticipated 677 QHP issuers

associated with these proposed requirements.

If SADPs are not included, the estimate assumes 575 QHP issuers (all issuers in all Marketplaces excluding SADPs) and covers the annual costs for a QHP issuer over a 3-year period (2016–2018). The burden associated with submitting initial attestations as part of the QHP certification process is currently accounted for under OMB Control Number 0938–1187. We estimate that it would take each QHP issuer 48 hours (at a cost of \$3,372) to collect this QIS data and to submit this information to the Exchange. Therefore, we would estimate an aggregate burden of 27,600 hours and \$1,938,900 as the total annual burden for the anticipated 575 QHP issuers associated with these proposed requirements, if SADPs are not included.

TABLE 12—ANNUAL REPORTING, RECORDKEEPING AND DISCLOSURE BURDEN

Regulation section(s)	Number of respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting (\$)	Total labor cost of reporting (\$)	Total capital/maintenance costs (\$)	Total cost (\$)
§ 155.222(a)	9	9	10.00	90	24.10	2,169	0	2,169
§ 155.222(d)	9	9	10.00	90	24.10	2,169	0	2,169
§ 155.725(g)	18	36	35.00	1,260	50.71	63,900	0	63,900
§ 156.122	2,400	2,400	32.00	76,800	43.34	3,328,512	0	3,328,512
§ 156.285(d)	445	445	35.00	15,575	50.72	790,004	0	790,004
§ 156.420	575	6,325	1.00	6,325	51.04	322,828	0	322,828
§ 156.420	575	81,000	0.05	4,050	32.59	131,990	58,250	190,240
§ 156.425	575	41,000	0.05	2,025	32.59	65,995	29,125	95,120
§ 156.1130	677	677	48	32,496	70.25	2,282,844	0	2,282,844
Total	2,400	138,711	6,990,411	87,375	7,007,786

Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule’s information collection requirements. These requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS’ Web site at <http://www.cms.hhs.gov/PaperworkReductionActof1995>; email your request, including your address, phone number, OMB control number, and CMS document identifier, to Paperwork@cms.hhs.gov; or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you comment on these information collection and recordkeeping requirements, please submit your comments electronically as specified in the ADDRESSES section of this proposed rule. Please include

“CMS–9944–P,” the ICR’s OMB control number, and the CMS document ID number in your comment.

PRA-specific comments must be received by January 26, 2015.

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 proposed rule, 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) for the

2016 benefit year, as well as certain modifications for the 2015 benefit year, that will protect issuers from the potential effects of adverse selection and protect consumers from increases in premiums due to issuer uncertainty. The Premium Stabilization Rule and the 2014 and 2015 Payment Notices provided detail on the implementation of these programs, including the specific parameters for the 2014 and 2015 benefit years applicable to these programs. This rule also proposes additional standards related to essential health benefits, meaningful access in the Exchange, consumer assistance tools and programs of an Exchange, non-Navigator assistance personnel, cost-sharing parameters and cost-sharing reduction notices, quality improvement strategy standards for issuers of qualified health plans participating in Exchanges, guaranteed availability and guaranteed renewability, minimum essential coverage, the medical loss ratio

program, the Small Business Health Options Program, and FFE user fees.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects (\$100 million or more in any 1 year).

OMB has determined that this 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 an 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, market standards, and Exchange-related provisions and policies in the Affordable Care Act is to make affordable health insurance available to individuals who do not have access to affordable employer-sponsored coverage. The provisions within this proposed rule are integral to the goal of expanding coverage. For example, the premium stabilization programs help prevent risk selection and decrease the risk of financial loss that health

insurance issuers might otherwise expect in 2016 and the advance payments of the premium tax credit and cost-sharing reduction programs assist low- and moderate-income consumers and American Indians/Alaska Natives in purchasing health insurance. The combined impacts of these provisions affect the private sector, issuers, and consumers, through increased access to health care services including preventive services, decreased uncompensated care, lower premiums, establishment of quality improvement strategy standards, and increased plan transparency. Through the reduction in financial uncertainty for issuers and increased affordability for consumers, these provisions are expected to increase access to affordable health coverage.

HHS anticipates that the provisions of this proposed rule will help further the Department’s goal of ensuring that all consumers have access to quality and affordable health care and are able to make informed choices, that Exchanges operate smoothly, that premium stabilization programs work as intended, that SHOPS are provided flexibility, and that employers and consumers are protected from fraudulent and criminal activities. Affected entities such as QHP issuers would incur costs to comply with the proposed provisions, including administrative costs related to notices, quality improvement strategy requirements, training and recertification requirements, and establishing a larger provider network. In accordance with Executive Order 12866, HHS believes that the benefits of this regulatory action justify the costs.

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

In accordance with OMB Circular A-4, Table 13 below depicts an accounting statement summarizing HHS’s assessment of the benefits, costs, and transfers associated with this regulatory action.

This 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 improved health outcomes and longevity due to continuous quality improvement and increased insurance enrollment—and certain costs—such as the cost of providing additional medical services to newly-enrolled individuals. The effects in Table 13 reflect qualitative impacts and estimated direct monetary costs and transfers resulting from the provisions of this proposed rule for reinsurance contributing entities and health insurance issuers. The annualized monetized costs described in Table 13 reflect direct administrative costs to these entities as a result of the proposed provisions, and include administrative costs related to notices, quality improvement strategy requirements, and training and recertification requirements that are estimated in the Collection of Information section of this proposed rule. The annual monetized transfers described in Table 13 include costs associated with the reinsurance contribution fee and the risk adjustment user fee paid to HHS by issuers, and additional MLR rebate payments from issuers to consumers. We note estimated transfers in Table 13 do not reflect any FFE user fees paid by insurance issuers because we cannot estimate those fee totals. We also note that, while we are proposing a 2016 reinsurance contribution rate that is lower than the 2014 and 2015 reinsurance contribution rates, total reinsurance administrative expenses, included in the reinsurance contribution rate, will slightly increase from 2015 to 2016. In addition, as a result of HHS’s increased contract costs related to risk adjustment operations and risk adjustment data validation, we are proposing to collect a total of \$50 million in risk adjustment user fees or \$1.75 per enrollee per year from risk adjustment issuers, which is greater than the \$0.96 per-enrollee-per-year risk adjustment user fee amount established for benefit year 2015. This increase is due in large part to risk adjustment data validation costs that will occur in 2016. We are also including costs associated with administrative appeals under § 156.1220 in the RIA of this proposed rule.

TABLE 13—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.

TABLE 13—ACCOUNTING TABLE—Continued

* Encourage continuous quality improvement among QHP issuers to improve health outcomes at lower costs.
 * Allow Exchanges to make informed QHP certification decisions.
 * Increasing coverage options for small businesses and part-time employees while mitigating the effect of adverse selection.
 * Ensure that consumers in group health plans not subject to ERISA receive the benefit of MLR rebates in a timely manner.

Costs:	Estimate	Year dollar	Discount rate	Period covered
Annualized Monetized (\$/year)	7.00 million	2014	7%	2015–2018
	7.00 million	2014	3%	2015–2018

Quantitative:

* 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	Year dollar	Discount rate	Period covered
Annualized Monetized (\$/year)	63.61 million	2014	7%	2015–2018
	63.52 million	2014	3%	2015–2018

* Transfers reflect incremental cost increases from 2015–2016 for reinsurance administrative expenses and the risk adjustment user fee, which are transfers from contributing entities and health insurance issuers to the Federal government. Transfers also reflect annual transfer from shareholders or nonprofit stakeholders to enrollees of rebates paid by issuers for coverage in the individual and group markets, resulting from clarification regarding MLR methodology to account for Federal and State employment taxes.
 * Unquantified: Lower premium rates in the individual market due to the improved risk profile of the insured, competition, and pooling.

This RIA expands upon the impact analyses of previous rules and utilizes the Congressional Budget Office’s (CBO) analysis of the Affordable Care Act’s impact on Federal spending, revenue collection, and insurance enrollment. Table 14 summarizes the effects of the risk adjustment and reinsurance programs on the Federal budget from fiscal years 2015 through 2018, with the additional, societal effects of this proposed rule discussed in this RIA. We do not expect the provisions of this proposed rule to significantly alter CBO’s estimates of the budget impact of the risk adjustment, reinsurance and risk corridors programs that are described in Table 14. For this RIA, we

are shifting the estimates for the risk adjustment and reinsurance programs to reflect the 4-year period from fiscal years 2015 through 2018, because 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 the 2015 calendar year for the 2014 benefit year. The CBO assumed that aggregate collections for the risk corridors program 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 13).

In addition to utilizing CBO projections, HHS conducted an internal analysis of the effects of its regulations on enrollment and premiums. Based on these internal analyses, we anticipate that the quantitative effects of the provisions proposed in this rule are consistent with our previous estimates in the 2015 Payment Notice for the impacts associated with the cost-sharing reduction program, the advance payments of the premium tax credit program, the premium stabilization programs, and FFE user fee requirements.

TABLE 14—ESTIMATED FEDERAL GOVERNMENT OUTLAYS AND RECEIPTS FOR THE RISK ADJUSTMENT, REINSURANCE, AND RISK CORRIDORS PROGRAMS FROM FY 2014–2018, IN BILLIONS OF DOLLARS

Year	2014	2015	2016	2017	2018	2014–2018
Risk Adjustment, Reinsurance, and Risk Corridors Program Payments	0	18	19	22	15	74
Risk Adjustment, Reinsurance, and Risk Corridors Program Collections*	0	19	18	22	15	74

* Risk adjustment program payments and receipts lag by one quarter. Receipt will fully offset payments over time. Source: Congressional Budget Office. Updated Estimates of the Insurance Coverage Provisions of the Affordable Care Act.

1. Rate Review

The proposed rule would trigger review of rate increases that meet or exceed the applicable review threshold when such increases happen at the “plan” level rather than at the “product” level. This would protect consumers against unreasonable rate increases for their plans, since, under current regulations, it is possible for a

plan to experience a rate increase higher than the threshold and still avoid review because the average rate increase for the product does not meet or exceed the threshold. Issuers already submit this level of information under an existing information collection and are not likely to experience significant increase in costs related to their submissions. States may have to review

more submissions and experience an increase in related costs. The proposal to establish a uniform timeframe by which issuers in every State must submit a completed Rate Filing Justification to CMS and the applicable State for all rate increases, including both QHPs and non-QHPs, would provide timely information to consumers and other stakeholders and

ensure that State and Federal regulators have adequate time for review prior to implementation of a rate increase. This approach would also reduce the potential for anti-competitive behavior and promote fair market competition between issuers in the Exchange and non-Exchange markets. The proposed amendment to specify the timing for States to make proposed and final rate increase information available to the public would ensure that consumers have timely access to this information.

2. Change of Ownership Notification Requirement

We propose in § 147.106(g) that when an issuer of a QHP, a plan otherwise subject to risk corridors, a risk adjustment covered plan, or a reinsurance-eligible plan, experiences a change in ownership as recognized by the State in which the plan is offered, the issuer must notify HHS in a manner specified by HHS, by the later of (1) the date the transaction is entered into; or (2) the 30th day prior to the effective date of the transaction. We expect that upon notification, issuers may need to work with HHS to clarify operational processes related to the HHS-administered programs, and will follow forthcoming guidance related to such operational processes. We estimate the administrative costs associated with the proposed notification requirement in the Collection of Information section of this proposed rule.

3. Appeals Process for HHS-Approved Vendors for FFE Training of Agents and Brokers

In § 155.222, we propose information collection and disclosure requirements that pertain to the approval of vendors to have their FFE agent and broker training and information verification programs recognized for agents and brokers assisting with or facilitating enrollment in individual market or SHOP coverage through the FFE. We also establish a monitoring and appeals process for such HHS-approved vendors. We estimate that five vendors that apply may not have their application approved, and one vendor may have their approval revoked, and all of those vendors will appeal HHS's determination and submit additional documentation to HHS. We estimate that filing an appeal with HHS will take no longer than one hour. Therefore, at an hourly wage rate of \$24.10, we estimate a total cost of \$144.60 as a result of this proposed appeals process.

4. Risk Adjustment

The risk adjustment program is a permanent program created by the

Affordable Care Act that transfers funds from lower risk, non-grandfathered plans to higher risk, non-grandfathered plans in the individual and small group markets, inside and outside the Exchanges. We established standards for the administration of the risk adjustment program, in subparts D and G of part 45 of the CFR.

A State approved or conditionally approved by the Secretary to operate an Exchange may establish a risk adjustment program, or have HHS do so on its behalf. As described in the 2014 and 2015 Payment Notices, if HHS operates risk adjustment on behalf of a State, it will fund its risk adjustment program operations by assessing a risk adjustment user fee on issuers of risk adjustment covered plans. For the 2016 benefit year, we estimate that the total cost for HHS to operate the risk adjustment program on behalf of States for 2016 will be approximately \$50 million, and that the risk adjustment user fee would be approximately \$1.75 per enrollee per year. The increased risk adjustment user fee for 2016 is the result of the increased contract costs to support the risk adjustment data validation process.

5. Reinsurance

The Affordable Care Act directs that a transitional reinsurance program be established in each State to help stabilize premiums for coverage in the individual market by helping to pay the cost of treating high-cost enrollees. In the 2014 and 2015 Payment Notices, we expanded upon the standards set forth in subparts C and E of the Premium Stabilization Rule and established the 2014 and 2015 uniform reinsurance payment parameters and national contribution rate. In this proposed rule, we set forth the 2016 uniform reinsurance payment parameters and contribution rate and also propose a modification to the 2015 benefit year attachment point.

Section 153.220(c) provides that HHS will publish the uniform per capita reinsurance contribution rate for the upcoming benefit year in the annual HHS notice of benefit and payment parameters. Section 1341(b)(3)(B)(iii) of the Affordable Care Act specifies that \$10 billion for reinsurance contributions is to be collected from contributing entities 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 2014, 2015 and 2016 benefit years of the reinsurance program under the uniform per capita contribution rate.

In the 2015 Payment Notice, we estimated that the Federal administrative expenses of operating the reinsurance program would be \$25.4 million, based on our estimated contract and operational costs. We propose to use the same methodology to estimate the administrative expenses for the 2016 benefit year. We estimate this amount to be approximately \$32 million for the 2016 benefit year. This estimate increased for the 2016 benefit year due to increased audit and data validation contract costs. We believe that this figure reflects the Federal government's significant economies of scale, which helps to decrease the costs associated with operating the reinsurance program. Based on our estimate of covered lives for which reinsurance contributions are to be made for 2016, we are proposing a uniform reinsurance contribution rate of \$0.17 annually per capita for HHS administrative expenses. If a State establishes its own reinsurance program, HHS would transfer \$0.085 of the per capita administrative fee to the State for purposes of administrative expenses incurred in making reinsurance payments, and retain the remaining \$0.085 to offset the costs of collecting contributions. We note that the administrative expenses for reinsurance payments will be distributed to those States that operate their own reinsurance program in proportion to the State-by-State total requests for reinsurance payments made under the uniform reinsurance payment parameters.

6. Risk Corridors

The Affordable Care Act creates a temporary risk corridors program for the years 2014, 2015, and 2016 that applies to QHPs, as defined in § 153.500. Section 1342 of the Affordable Care Act directs the Secretary to establish a temporary risk corridors program that protects issuers against inaccurate rate setting from 2014 through 2016. The Affordable Care Act establishes the risk corridors program as a Federal program; consequently, HHS will operate the risk corridors program under Federal rules with no State variation.

In this proposed rule, we are proposing a clarification to the risk corridors transitional adjustment for

benefit year 2014. We are proposing to clarify that we intend to implement the risk corridors transitional adjustment for transitional plans only, as stated in the 2015 Payment Notice. This proposed clarification does not affect the impact of the risk corridors transitional adjustment.

For benefit year 2016, we are also proposing the treatment of excess risk corridors collections that may remain after the 3-year duration of the program. We are proposing to adjust the allowable administrative cost ceiling and profit floor so that any excess risk corridors collections that remain in benefit year 2016 are paid out to eligible QHP issuers. We anticipate that collections will fully offset payments over the 3-year duration of the program. Consequently, we do not believe that this proposal will have a monetary impact on QHP issuers or the Federal government.

7. SHOP

The SHOP facilitates the enrollment of eligible employees of small businesses 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.⁶⁷

Please see the Collection of Information section of this proposed rule for the costs expected to be incurred by State-based SHOPS and QHP issuers participating in the SHOP related to the proposed notification requirements related to terminations of coverage. We believe this cost is justified because SHOPS are best positioned to provide meaningful notice regarding terminations due to loss of eligibility and nonpayment of premiums in a timely manner, while issuers are best positioned to provide meaningful notice when coverage is terminated due to a rescission in accordance with § 147.128 or when the QHP is terminated, decertified, or its certification is not renewed. In this proposed rule, we also seek comment on whether to permit the Federally-facilitated SHOP to accept premium payment using a credit card and the impact of this potential policy, including how many FF-SHOP employers expect to use credit cards for payment.

8. User Fees

To support the operation of FFEs, we require in § 156.50(c) that a participating issuer offering a plan

⁶⁷ Available at: <http://ccio.cms.gov/resources/files/Files2/03162012/hie3r-ria-032012.pdf>.

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 2016 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 fees at this time because we do not yet have a count of the number of States in which HHS will run an FFE or Federally-facilitated SHOP in 2016. For the user fee charge assessed on issuers in the FFE, we intend to seek an exception to OMB Circular No. A-25R, which requires that the user fee charge be sufficient to recover the full cost to the Federal government of providing the special benefit. We seek this exception to ensure that the FFE can support many of the goals of the Affordable Care Act, including improving the health of the population, reducing health care costs, and providing access to health coverage as advanced by § 156.50(d).

9. Essential Health Benefits, Cost Sharing, and Actuarial Value

Issuers may incur minor administrative costs associated with altering benefits, cost-sharing and/or AV parameters of their plan designs to ensure compliance with the EHB requirements under this proposed rule. For example, issuers that do not currently meet the standards for EHB prescription drug coverage will incur contracting and one-time administrative costs to bring their prescription drug benefits into compliance. HHS expects that the process for compliance with the proposed EHB requirements will not significantly add to existing compliance costs because issuers have extensive experience in offering products with various benefits and levels of cost sharing and these modifications are expected to be relatively minor for most issuers.

In addition, we are proposing standards for a health plan's formulary exception process that includes an external review. We believe that issuers that provide EHB already have formulary exceptions processes and procedures in place that allow an enrollee to request and gain access to clinically appropriate drugs not covered by the plan. We do not expect the proposed requirements to significantly increase the volume of reviews conducted under issuers' contracts with Independent Review Organizations. Therefore, we do anticipate that this

proposed requirement would result in any significant new cost for issuers.

10. Network Adequacy

Issuers may incur minor administrative costs associated with updating their provider directory to ensure compliance with the requirements under this proposed rule. Since issuers already maintain a directory and the expected modification is to re-locate that directory to a more user-friendly location on the issuer Web site, HHS expects that compliance will not demand any additional resources.

11. Downstream Entities

We propose to revise § 156.200(b)(7), to require that a QHP issuer comply with the standards under 45 CFR part 153 and not just the standards related to the risk adjustment program. Under § 156.340, notwithstanding any relationship(s) that a QHP issuer may have with delegated and downstream entities, a QHP issuer maintains responsibility for its compliance and the compliance of any of its delegated or downstream entities, as applicable, with all applicable standards, including the standards of subpart C of part 156 for each of its QHPs on an ongoing basis. Because we believe that QHP issuers have existing agreements with downstream entities that define responsibilities, we do not believe that this requirement will impose an additional burden on QHP issuers.

12. Provisions Related to Cost Sharing

The Affordable Care Act provides for the reduction or elimination of cost sharing for certain eligible individuals enrolled in QHPs offered through the Exchanges. This assistance will help many low- and moderate-income individuals and families obtain health insurance—for many people, cost sharing is a barrier to obtaining needed health care.⁶⁸

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. Consistent with our analysis in the 2014 and 2015 Payment Notices, we developed three model silver level QHPs and analyzed the impact on their AVs of the reductions described in the Affordable Care Act to the estimated

⁶⁸ 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>.

2016 maximum annual limitation on cost sharing for self-only coverage (\$6,850). We do not believe these changes will result in a significant economic impact. 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 2015 Payment Notice.

We also proposed the premium adjustment percentage for the 2016 benefit year. Section 156.130(e) provides that the premium adjustment percentage is the percentage (if any) by which the average per capita premium for health insurance coverage for the preceding calendar year exceeds such average per capita premium for health insurance for 2013. The annual premium adjustment percentage sets the rate of increase for three parameters detailed in the Affordable Care Act: The annual limitation on cost sharing (defined at § 156.130(a)), the required contribution percentage by individuals for minimum essential health coverage the Secretary may use to determine eligibility for hardship exemptions under Section 5000A of the Code, and the section 4980H(a) and section 4980H(b) assessable payment amounts (finalized at 26 CFR 54.4980H in the “Shared Responsibility for Employers Regarding Health Coverage,” published in the *Federal Register* on February 12, 2014 (79 FR 8544)). We believe that the proposed 2016 premium adjustment percentage of 8.316047520 percent is well within the parameters used in the modeling of the Affordable Care Act, and we do not expect that these proposed provisions will alter CBO’s April 2014 baseline estimates of the budget impact.

The proposed rule would also replace the one-year period with ongoing recognition of State high risk pools as minimum essential coverage, which would facilitate transition of enrollees into QHPs through the Exchange or into other forms of minimum essential coverage, while ensuring continued access to coverage.

13. Minimum Essential Coverage

The proposed rule would replace the one-year temporary designation with ongoing recognition of State high risk pools as minimum essential coverage. This would facilitate the transition of State high risk pool enrollees into QHPs through the Exchange or into other forms of minimum essential coverage, while ensuring continued access to coverage. It would also help ensure that this vulnerable population will not be subject to the shared responsibility payment during this transition, and

thereby avoid an increase in out-of-pocket costs.

14. Quality Improvement Strategy

The proposed standards requiring QHP issuers participating in Exchanges to establish and submit information regarding a quality improvement strategy would encourage continuous quality improvement among QHP issuers to help strengthen system-wide efforts to improve health outcomes at lower costs, promote provider payment models that link quality and value of services, allow for flexibility and innovation of diverse market-based incentive approaches, encourage meaningful improvements as well as provide regulators and stakeholders with information to use for monitoring and evaluation purposes. We discuss the administrative costs associated with submitting this information in the Collection of Information section of this proposed rule.

15. Administrative Appeals

In § 156.1220, we establish an administrative appeals process to address unresolved discrepancies for advance 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). We estimated the burden associated with the administrative appeals process in the 2015 Payment Notice, and in the Supporting Statement approved under OMB Control Number 0938–1155. We will revise the information collection currently approved OMB Control Number 0938–1155 with an October 31, 2015 expiration date. We do not believe that the provisions in this proposed rule will alter the economic impact of this requirement that was estimated in the 2015 Payment Notice.

16. Medical Loss Ratio

This proposed rule would clarify the treatment of cost-sharing reductions in the MLR calculations. This proposed rule would also ensure timely distribution of rebates for the benefit of subscribers of group health plans not subject to ERISA. Specifically, the proposed amendments to the MLR provisions governing the distribution of rebates to group enrollees in non-Federal governmental and other group health plans not subject to ERISA would ensure that group policyholders of such plans do not withhold the benefit of rebates from the enrollees for longer than 3 months. We do not anticipate that this proposed provision in this

proposed rule will have any significant effect on MLR program estimates. This proposed rule would also amend the MLR regulations to provide that premium in MLR and rebate calculations should not be reduced by the amount of Federal and State employment taxes. Assuming that all issuers previously interpreted the MLR December 1, 2010 interim final rule to reduce premium by the amount of Federal and State employment taxes, based on MLR data for the 2013 MLR reporting year, the proposed clarification regarding the treatment of such taxes in the MLR and rebate calculations would result in additional rebate payments from issuers to consumers of approximately \$35 million.

D. Regulatory Alternatives Considered

In the preamble discussion of the 2016 reinsurance payment parameters, we also considered, when setting forth the proposed 2016 reinsurance payment parameters, a set of uniform reinsurance payment parameters that would have substantially lowered the reinsurance cap, but believe those uniform reinsurance payment parameters would have raised the complexity of estimating the effects of reinsurance for issuers.

We also considered expanding the risk corridors transitional adjustment to apply to early renewal plans. This approach would have increased the impact of the risk corridors adjustment and altered the impact analysis related to the risk corridors transitional adjustment that was published in the 2015 Payment Notice. However, we decided not to propose this alternate policy.

We considered ending the good faith compliance policy for QHP issuers. However we determined that subjecting QHP issuers to increased punitive actions in the early years of the Exchange would be less effective than working with issuers to address compliance issues.

We considered not suppressing QHPs on the FFE, but this approach would have resulted in less flexibility for the FFE to address situations that could affect consumers’ interests. For example, this alternative would increase the burden for consumers who may have to select a new QHP mid-year if their QHP was decertified.

We also considered not recognizing vendors for training and registration of agents and brokers in the FFE. However, we believe that recognizing vendors will make it easier for agents and brokers to identify appropriate vendors who meet HHS standards for training and registration.

Additionally, we considered not requiring QIS reporting for QHP issuers. However, we decided to propose the policy in this proposed rule because we believe that QIS reporting will result in higher quality QHPs being offered in the Exchange and make it easier for consumers to select a high quality QHP.

E. Regulatory Flexibility Act

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

In this proposed rule, we propose standards for the risk adjustment, reinsurance, and risk corridors programs, which are intended to stabilize premiums as insurance market reforms are implemented and Exchanges facilitate increased enrollment. Because we believe that insurance firms offering comprehensive health insurance policies generally exceed the size thresholds for “small entities” established by the SBA, we do not believe that an initial regulatory flexibility analysis is required for such firms.

For purposes of the RFA, we expect the following types of entities to be affected by this 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 \$32.5 million or less.

In this proposed rule, we proposed standards for 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 businesses offering employer sponsored insurance. We believe the processes that we have established constitute the minimum amount of requirements necessary to implement the SHOP program and accomplish our policy goals, and that no appropriate regulatory alternatives could be developed to further lessen the compliance burden.

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.

Based on data from MLR annual report submissions for the 2013 MLR reporting year, approximately 141 out of 500 issuers of health insurance coverage nationwide had total premium revenue of \$38.5 million or less. This estimate may overstate the actual number of small health insurance companies that would be affected, since 77 percent of these small companies belong to larger holding groups, and many if not all of these small companies are likely to have non-health lines of business that would result in their revenues exceeding \$38.5 million. Only 16 of these small entities owed a rebate for the 2013 reporting year, and none of these small entities are estimated to experience a rebate increase of more than 0.1 percent of total premium revenue under the proposed provisions. None of the small entities that did not previously owe rebates are expected to owe rebates as a result of the proposed provisions. Based on data from MLR annual report submissions for the 2013 MLR reporting year, approximately 286,750 out of 1.6 million small group policyholders and 13,500 out of 228,000 large group policyholders nationwide were owed rebates for the 2013 reporting year. It is uncertain how many of the group policyholders obtaining coverage from health insurance issuers subject to MLR are both (a) small entities that fall below the size thresholds set by the SBA for

various industries, and (b) enrolled in group health plans not subject to ERISA, and would therefore be subject to the proposed provisions related to MLR. However, the proposed provisions only establish a deadline for the use of MLR rebates by certain policyholders similar to the deadline that is already followed by most group policyholders, and do not otherwise alter the requirements for rebate use by such policyholders. In addition, the proposed clarification regarding how health insurance issuers must treat cost-sharing reductions in their MLR calculations simply aligns the MLR regulatory language with the risk corridors program.

F. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a 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 2014, 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 would not impose substantial direct

requirement costs on State and local governments, this regulation has Federalism implications due to direct effects on the distribution of power and responsibilities among the State and Federal governments relating to determining standards relating to health insurance that is offered in the individual and small group markets. Each State electing to establish an Exchange must adopt the Federal standards contained in the Affordable Care Act and in this 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, and Reporting and recordkeeping requirements.

45 CFR Part 146

Health care, Health insurance, and Reporting and recordkeeping requirements.

45 CFR Part 147

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

45 CFR Part 148

Administrative practice and procedure, Health care, Health insurance, Penalties, and Reporting and recordkeeping requirements.

45 CFR Part 153

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

45 CFR Part 154

Administrative practice and procedure, Claims, Health care, Health insurance, Health plans, Penalties, Reporting and recordkeeping requirements.

45 CFR Part 155

Administrative practice and procedure, Health care access, Health insurance, Reporting and recordkeeping requirements, State and local governments, Required Contribution Percentage, Cost-sharing reductions, Advance payments of the premium tax credit, Administration and calculation of advance payments of the premium tax credit, Plan variations, Actuarial value.

45 CFR Part 156

Administrative appeals, Administrative practice and procedure, Administration and calculation of advance payments of the premium tax credit, Advertising, Advisory Committees, Brokers, Conflict of interest, Consumer protection, Cost-sharing reductions, Grant programs-health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, American

Indian/Alaska Natives, Individuals with disabilities, Loan programs-health, Organization and functions (Government agencies), Medicaid, Payment and collections reports, Public assistance programs, Reporting and recordkeeping requirements, State and local governments, Sunshine Act, Technical assistance, Women, and Youth.

45 CFR Part 158

Administrative practice and procedure, Claims, Health care, Health insurance, Health plans, penalties, Reporting and recordkeeping requirements, Premium revenues, Medical loss ratio, Rebating.

For the reasons set forth in the preamble, the Department of Health and Human Services proposes to amend 45 CFR parts 144, 146, 147, 148, 153, 154, 155, 156, and 158 as set forth below.

PART 144—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

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

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

■ 2. Section 144.103 is amended by revising the definitions of “Plan” and “State” to read as follows:

§ 144.103 Definitions.

* * * * *

Plan means, with respect to an issuer and a product, the pairing of the health insurance coverage benefits under the product with a particular cost-sharing structure, provider network, and service area. The product comprises all plans offered with those characteristics and the combination of the service areas for all plans offered within a product constitutes the total service area of the product.

* * * * *

State means each of the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands; except that for purposes of part 147, the term does not include Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

* * * * *

PART 146—REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET

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

Authority: Secs. 2702 through 2705, 2711 through 2723, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg-1 through 300gg-5, 300gg-11 through 300gg-23, 300gg-91, and 300gg-92).

■ 4. Section 146.152 is amended by revising paragraph (c)(2) to read as follows:

§ 146.152 Guaranteed renewability of coverage for employers in the group market.

* * * * *

(c) * * *

(2) The issuer offers to each plan sponsor provided that particular product the option, on a guaranteed issue basis, to purchase all (or, in the case of the large group market, any) other health insurance coverage currently being offered by the issuer to a group health plan in that market. An issuer that automatically enrolls a plan sponsor into a product of another health insurance issuer does not satisfy the requirement of this paragraph (c)(2); and

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

■ 5. 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.

■ 6. Section 147.104 is amended by—

- A. Revising paragraphs (b)(1)(i)(C), (b)(2), and (b)(4).
- B. Redesignating paragraphs (f) through (h) as paragraphs (g) through (i).
- C. Adding new paragraph (f).

The revisions and addition read as follows:

§ 147.104 Guaranteed availability of coverage.

* * * * *

(b) * * *
(1) * * *
(i) * * *

(C) With respect to coverage in the small group market, and in the large group market if such coverage is offered through a Small Business Health Options Program (SHOP) in a State, coverage must become effective consistent with the dates described in § 155.725 of this subchapter, except as provided in paragraph (b)(1)(iii) of this section.

* * * * *

(2) *Limited open enrollment periods.* A health insurance issuer in the individual market must provide a limited open enrollment period for the

events described in § 155.420(d) of this subchapter, excluding § 155.420(d)(3) (concerning citizenship status), § 155.420(d)(8) (concerning Indians), and § 155.420(d)(9) (concerning exceptional circumstances).

* * * * *

(4) *Length of enrollment periods.* (i) In the group market, enrollees must be provided 30 calendar days after the date of the qualifying event described in paragraph (b)(3) of this section to elect coverage.

(ii) In the individual market, enrollees must be provided 60 calendar days after the date of an event described in paragraph (b)(2) and (b)(3) of this section to elect coverage, as well as 60 calendar days before certain triggering events as provided for in § 155.420(c)(2) of this subchapter.

* * * * *

(f) *Calendar year plans.* An issuer that offers coverage in the individual market, or in a merged market in a State that has elected to merge the individual market and small group market risk pools in accordance with section 1312(c)(3) of the Affordable Care Act, must ensure that such coverage is offered on a calendar year basis with a policy year ending on December 31 of each calendar year.

* * * * *

■ 7. Section 147.106 is amended by—

- A. Revising paragraph (c)(2).
- B. Redesignating paragraphs (g) through (j) as paragraphs (h) through (k).
- C. Adding new paragraph (g).

The revision and addition read as follows:

§ 147.106 Guaranteed renewability of coverage.

* * * * *

(c) * * *

(2) The issuer offers to each plan sponsor or individual, as applicable, provided that particular product the option, on a guaranteed availability basis, to purchase all (or, in the case of the large group market, any) other health insurance coverage currently being offered by the issuer to a group health plan or individual health insurance coverage in that market. An issuer that automatically enrolls a plan sponsor or individual, as applicable, into a product of another health insurance issuer does not satisfy the requirement of this paragraph (c)(2).

* * * * *

(g) *Notification of change of ownership.* If an issuer of a QHP, a plan otherwise subject to risk corridors, a risk adjustment covered plan, or a reinsurance-eligible plan experiences a change of ownership, as recognized by

the State in which the plan is offered, the issuer must notify HHS in a manner specified by HHS, by the later of—

(1) The date the transaction is entered into; or

(2) The 30th day prior to the effective date of the transaction.

* * * * *

PART 148—REQUIREMENTS FOR THE INDIVIDUAL HEALTH INSURANCE MARKET

■ 8. The authority citation for part 148 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.

■ 9. Section 148.122 is amended by revising paragraph (d)(2) to read as follows:

§ 148.122 Guaranteed renewability of individual health insurance coverage.

* * * * *

(d) * * *

(2) Offers to each covered individual, on a guaranteed issue basis, the option to purchase any other individual health insurance coverage currently being offered by the issuer for individuals in that market. An issuer that automatically enrolls an individual into a product of another health insurance issuer does not satisfy the requirement of this paragraph (d)(2).

* * * * *

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

■ 10. The authority citation for part 153 continues to read as follows:

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

■ 11. Section 153.100 is amended by revising paragraph (c) to read as follows:

§ 153.100 State notice of benefit and payment parameters.

* * * * *

(c) *State notice deadlines.* If a State is required to publish an annual State notice of benefit and payment parameters for a particular benefit year, it must do so by the later of March 1 of the calendar year prior to the applicable benefit year, or by the 30th day following the publication of the final HHS notice of benefit and payment parameters for that benefit year.

* * * * *

■ 12. Section 153.400 is amended by revising paragraph (a)(1)(iii) and adding paragraph (c) to read as follows:

§ 153.400 Reinsurance contribution funds.

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

(iii) Such plan or coverage is expatriate health coverage, as defined by the Secretary, or for the 2015 and 2016 benefit years only, is a self-insured group health plan with respect to which enrollment is limited to participants who reside outside of their home country for at least 6 months of the plan year, and any covered dependents; or

(c) Determination of a debt. Any amount owed to the Federal government by a self-insured group health plan (including a group health plan that is partially self-insured and partially insured, where the health insurance coverage does not constitute major medical coverage) and its affiliates for reinsurance is a determination of a debt.

- 13. Section 153.405 is amended by—
■ A. Revising paragraphs (b), (c)(1), (d) introductory text, (g)(4)(i) introductory text, and (g)(4)(ii) introductory text.
■ B. Removing paragraph (c)(2).
■ C. Redesignating paragraph (c)(3) as paragraph (c)(2).
■ D. Revising newly designated paragraph (c)(2).

The revisions read as follows:

§ 153.405 Calculation of reinsurance contributions.

* * * * *

(b) Annual enrollment count. No later than November 15 of benefit year 2014, 2015, or 2016, as applicable, or, if such date is not a business day, the next business day, a contributing entity must submit an annual enrollment count of the number of covered lives of reinsurance contribution enrollees for the applicable benefit year to HHS. The count must be determined as specified in paragraphs (d) through (g) of this section, as applicable.

(c) * * *
(1) Following submission of the annual enrollment count described in paragraph (b) of this section, HHS will notify the contributing entity of the reinsurance contribution amount allocated to reinsurance payments, administrative expenses and the U.S. Treasury to be paid for the applicable benefit year.

(2) A contributing entity must remit reinsurance contributions to HHS no later than January 15, 2015, 2016, or 2017, as applicable, or, if such date is not a business day, the next business day, if making a combined contribution or the first payment of the bifurcated contribution, and no later than November 15, 2015, 2016, or 2017, as applicable, or, if such date is not a business day, the next business day, if

making the second payment of the bifurcated contribution.

(d) Procedures for counting covered lives for health insurance issuers. A health insurance issuer must use the same method in a benefit year for all of its health insurance plans in the State (including both the individual and group markets) for which reinsurance contributions are required. To determine the number of covered lives of reinsurance contribution enrollees under all health insurance plans in a State for a benefit year, a health insurance issuer must use one of the following methods:

* * * * *
(g) * * *
(4) * * *

(i) Multiple group health plans including an insured plan. If at least one of the multiple plans is an insured plan, the average number of covered lives of reinsurance contribution enrollees must be calculated using one of the methods specified in either paragraph (d)(1) or paragraph (d)(2) of this section, applied across the multiple plans as a whole. The following information must be determined by the plan sponsor:

(ii) Multiple group health plans not including an insured plan. If each of the multiple plans is a self-insured group health plan, the average number of covered lives of reinsurance contribution enrollees must be calculated using one of the methods specified either in paragraph (e)(1) or paragraph (e)(2) of this section, applied across the multiple plans as a whole. The following information must be determined by the plan sponsor:

- 14. Section 153.500 is amended by revising the definition of “Adjustment percentage” to read as follows:

§ 153.500 Definitions.

* * * * *

Adjustment percentage means, with respect to a QHP:

- (1) For benefit year 2014—
(i) For a QHP offered by a health insurance issuer with allowable costs of at least 80 percent of after-tax premium in a transitional State, the percentage specified by HHS for such QHPs in the transitional State; and otherwise
(ii) Zero percent.
(2) For benefit year 2015, for a QHP offered by a health insurance issuer in any State, 2 percent.
(3) For benefit year 2016—
(i) For a QHP offered by a health insurance issuer with allowable costs of at least 80 percent of after-tax premium, the percentage specified by HHS; and otherwise.

(ii) Zero percent.

* * * * *

- 15. Section 153.740 is amended by revising paragraph (a) and adding paragraph (c) to read as follows:

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

(a) Enforcement actions. If an issuer of a risk adjustment covered plan or reinsurance-eligible plan fails to establish a dedicated distributed data environment in a manner and timeframe specified by HHS; fails to provide HHS with access to the required data in such environment in accordance with § 153.700(a) or otherwise fails to comply with the requirements of §§ 153.700 through 153.730; fails to adhere to the reinsurance data submission requirements set forth in § 153.420; or fails to adhere to the risk adjustment data submission and data storage requirements set forth in §§ 153.610 through 153.630, HHS may impose civil money penalties in accordance with the procedures set forth in § 156.805 of this subchapter. Civil monetary penalties will not be imposed for non-compliance with these requirements during the 2014 or 2015 calendar year under this paragraph if the issuer has made good faith efforts to comply with these requirements.

* * * * *

(c) Information sharing. HHS may consult and share information about issuers of risk adjustment covered plans and reinsurance-eligible plans with other Federal and State regulatory and enforcement entities to the extent the consultation and information is necessary for purposes of State or Federal oversight and enforcement activities.

PART 154—HEALTH INSURANCE ISSUER RATE INCREASES: DISCLOSURE AND REVIEW REQUIREMENTS

- 16. The authority citation for part 154 continues to read as follows:

Authority: Section 2794 of the Public Health Service Act (42 U.S.C. 300gg–94).

- 17. Section 154.102 is amended by—

- A. Revising the definitions of “Individual market,” “Rate increase,” “Small group market,” and “State.”
■ B. Adding a definition of “Plan” in alphabetical order.

The revisions and addition read as follows:

§ 154.102 Definitions.

* * * * *

Individual market has the meaning given the term in § 144.103 of this subchapter.

* * * * *

Plan has the meaning given the term in § 144.103 of this subchapter.

* * * * *

Rate increase means any increase of the rates for a specific product or plan within a product offered in the individual or small group market.

* * * * *

Small group market has the meaning given the term in § 144.103 of this subchapter.

State means each of the 50 States and the District of Columbia.

* * * * *

■ 18. Section 154.200 is amended by revising paragraphs (a) and (c) to read as follows:

§ 154.200 Rate increases subject to review.

(a) A rate increase filed for coverage effective on or after January 1, 2016 is subject to review if:

(1) The rate increase is 10 percent or more for any plan within the product applicable to a 12-month period that begins on January 1, as calculated under paragraph (c) of this section; or

(2) The rate increase for any plan within the product meets or exceeds a State-specific threshold applicable to a 12-month period that begins on January 1, as calculated under paragraph (c) of this section, determined by the Secretary. A State-specific threshold shall be based on factors impacting rate increases in a State to the extent that the data relating to such State-specific factors is available by August 1. States interested in proposing a State-specific threshold for approval are required to submit a proposal to the Secretary by August 1.

* * * * *

(c) A rate increase meets or exceeds the applicable threshold set forth in paragraph (a) of this section if an increase in the plan-adjusted index rate (as described in § 156.80 of this subchapter) for any plan within the product meets or exceeds the applicable threshold.

* * * * *

■ 19. Section 154.215 is amended by revising paragraph (a) to read as follows:

§ 154.215 Submission of rate filing justification.

(a) If any plan within a product is subject to a rate increase, a health insurance issuer must submit a Rate Filing Justification for all products in the single risk pool, including new or

discontinuing products, on a form and in a manner prescribed by the Secretary.

* * * * *

■ 20. Section 154.220 is revised to read as follows:

§ 154.220 Timing of providing the rate filing justification.

A health insurance issuer must submit to CMS and the applicable State a Rate Filing Justification for all rate increases that are filed for coverage effective on or after January 1, 2016, by the earlier of the following:

(a) The date by which the State requires that a proposed rate increase be filed with the State; or

(b) The date specified in guidance by the Secretary.

■ 21. Section 154.301 is amended by revising paragraph (b) to read as follows:

§ 154.301 CMS's determinations of Effective Rate Review Programs.

* * * * *

(b) *Public disclosure and input.* (1) In addition to satisfying the provisions in paragraph (a) of this section, a State with an Effective Rate Review Program must provide:

(i) For proposed rate increases subject to review, access from its Web site to at least the information contained in Parts I, II, and III of the Rate Filing Justification that CMS makes available on its Web site (or provide CMS's Web address for such information), and have a mechanism for receiving public comments on those proposed rate increases, no later than the date specified in guidance by the Secretary.

(ii) For all final rate increases (including those not subject to review), access from its Web site to at least the information contained in Parts I, II, and III of the Rate Filing Justification that CMS makes available on its Web site (or provide CMS's Web address for such information), no later than the first day of the annual open enrollment period for the applicable calendar year.

(2) If a State intends to make the information in paragraph (b)(1)(i) of this section available to the public prior to the date specified by the Secretary, or if it intends to make the information in paragraph (b)(1)(ii) of this section available to the public prior to the first day of the annual open enrollment period for the applicable calendar year, the State must notify CMS in writing, no later than 30 days prior to the date it intends to make the information public, of its intent to do so and the date it intends to make the information public.

(3) A State with an Effective Rate Review Program must ensure the information in paragraphs (b)(1)(i) and (ii) of this section is made available to

the public at a uniform time for all proposed and final rate increases, as applicable, in the relevant market segment and without regard to whether coverage is offered through or outside an Exchange.

* * * * *

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

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

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

■ 23. Section 155.20 is amended by—

■ A. Revising paragraph (2) of the definition of “Applicant.”

■ B. Revising the definitions of “Enrollee” and “Qualified employee”.

The revisions read as follows:

§ 155.20 Definitions.

* * * * *

Applicant * * *

(2) An employer, employee, or former employee seeking eligibility for enrollment in a QHP through the SHOP for himself or herself, and, if the qualified employer offers dependent coverage through the SHOP, seeking eligibility to enroll his or her dependents in a QHP through the SHOP.

* * * * *

Enrollee means a qualified individual or qualified employee enrolled in a QHP. Enrollee also means the dependent of a qualified employee enrolled in a QHP through the SHOP. Provided that at least one employee enrolls in a QHP through the SHOP, enrollee also means a business owner enrolled in a QHP through the SHOP, or the dependent of a business owner enrolled in a QHP through the SHOP.

* * * * *

Qualified employee means any employee or former employee of a qualified employer who has been offered health insurance coverage by such qualified employer through the SHOP for himself or herself and, if the qualified employer offers dependent coverage through the SHOP, for his or her dependents.

* * * * *

■ 24. Section 155.205 is amended by revising paragraph (c)(2)(i) to read as follows:

§ 155.205 Consumer assistance tools and programs of an Exchange.

* * * * *

(c) * * *

(2) * * *

(i) Oral interpretation. For Exchanges, QHP issuers, and agents or brokers subject to § 155.220(c)(3)(i) only, this standard includes telephonic interpreter services in at least 150 languages;

* * * * *

■ 25. Section 155.215 is amended by revising paragraph (h) to read as follows:

§ 155.215 Standards applicable to Navigators and Non-Navigator Assistance Personnel carrying out consumer assistance functions under §§ 155.205(d) and (e) and 155.210 in a Federally-facilitated Exchange and to Non-Navigator Assistance Personnel funded through an Exchange Establishment Grant.

* * * * *

(h) *Physical presence.* All non-Navigator entities carrying out consumer assistance functions under § 155.205(d) and (e) in an Exchange operated by HHS during the exercise of its authority under § 155.105(f) and all non-Navigator entities funded through an Exchange Establishment Grant under section 1311(a) of the Affordable Care Act must maintain a physical presence in the Exchange service area, so that face-to-face assistance can be provided to applicants and enrollees. In a Federally-facilitated Exchange, no individual or entity shall be ineligible to operate as a non-Navigator entity or as non-Navigator assistance personnel solely because its principal place of business is outside of the Exchange service area.

* * * * *

■ 26. Section 155.222 is added to read as follows:

§ 155.222 Standards for HHS-approved vendors of Federally-facilitated exchange training for agents and brokers.

(a) *Application for approval.* A vendor must be approved by HHS, in a form and manner to be determined by HHS, in order to have its training and information verification program recognized for agents and brokers assisting with or facilitating enrollment in individual market or SHOP coverage through the Exchange consistent with § 155.220. As part of the training program, the vendor must require agents and brokers to complete identity proofing, provide identifying information, and successfully complete the required curriculum. HHS will approve vendors on an annual basis for a given plan year, and each vendor must submit an application for each year that approval is sought.

(b) *Standards.* To be approved by HHS and maintain its status as an approved vendor for plan year 2016 and future plan years, a vendor must meet each of the following standards:

(1) Submit a complete and accurate application by the deadline established by HHS, which includes demonstration of prior experience with successfully conducting online training and identity proofing, as well as providing technical support to a large customer base.

(2) Adhere to HHS specifications for content, format, and delivery of training and information verification.

(3) Collect, store, and share with HHS all data from agent and broker users of the vendor's training and information verification in a manner specified by HHS, and protect the data in accordance with applicable privacy and security laws and regulations.

(4) Execute an agreement with HHS, in a form and manner to be determined by HHS, which requires the vendor to comply with HHS guidelines for interfacing with HHS data systems, the implementation of the training and information verification processes, and the use of all data collected.

(5) Permit any individual who holds a valid State license or equivalent State authority to sell health insurance products to access the vendor's training and information verification.

(c) *Approved list.* A list of approved vendors will be published on an HHS Web site.

(d) *Monitoring.* HHS may periodically monitor and audit vendors approved under this subpart, and their records related to the training and information verification functions described in this section, to ensure ongoing compliance with the standards in paragraph (b) of this section. If HHS determines that an HHS-approved vendor is not in compliance with the standards required in paragraph (b) of this section, the vendor may be removed from the approved list described in paragraph (c) of this section and may be required by HHS to cease performing the training and information verification functions described under this subpart.

(e) *Appeals.* A vendor that is not approved by HHS after submitting the application described in paragraph (a) of this section, or an approved vendor whose agreement is revoked under paragraph (d) of this section, may appeal HHS's decision by notifying HHS in writing within 15 days from receipt of the notification of not being approved and submitting additional documentation demonstrating how the vendor meets the standards in paragraph (b) of this section and (if applicable) the terms of their agreement

with HHS. HHS will review the submitted documentation and make a final approval determination within 30 days from receipt of the additional documentation.

■ 27. Section 155.400 is amended by revising paragraph (e) to read as follows:

§ 155.400 Enrollment of qualified individuals into QHPs.

* * * * *

(e) *Premium payment.* Exchanges may, and the Federally-facilitated Exchange will, require payment of the first month's premium to effectuate an enrollment. An Exchange may establish a standard policy for setting premium payment deadlines.

* * * * *

■ 28. Section 155.410 is amended by revising paragraphs (e) and (f) to read as follows:

§ 155.410 Initial and annual open enrollment periods.

* * * * *

(e) *Annual open enrollment period.*

(1) For the benefit year beginning on January 1, 2015, the annual open enrollment period begins on November 15, 2014, and extends through February 15, 2015.

(2) For benefit years beginning on or after January 1, 2016, the annual open enrollment period begins on October 1 and extends through December 15 of the calendar year preceding the benefit year.

(f) *Effective date.* (1) For the benefit year beginning on January 1, 2015, the Exchange must ensure coverage is effective—

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

(ii) February 1, 2015, for QHP selections received by the Exchange from December 16, 2014 through January 15, 2015.

(iii) March 1, 2015, for QHP selections received by the Exchange from January 16, 2015 through February 15, 2015.

(2) For enrollments made under any annual open enrollment periods for benefit years beginning on or after January 1, 2016, the Exchange must ensure that coverage is effective as of January 1 of the year following the open enrollment period.

* * * * *

■ 29. Section 155.420 is amended by—

■ A. Revising paragraphs (b)(2)(i), (b)(2)(iv), (c)(2), (d)(1)(ii), (d)(2), and (d)(4).

■ B. Adding paragraphs (b)(2)(v), (b)(2)(vi), and (d)(6)(iv).

■ C. Removing paragraph (d)(10).

The revisions and additions read as follows:

§ 155.420 Special enrollment periods.

* * * * *

- (b) * * *
- (2) * * *

(i) In the case of birth, adoption, placement for adoption, or placement in foster care as described in paragraph (d)(2)(i) of this section, the Exchange must ensure that coverage is effective for a qualified individual or enrollee on the date of birth, adoption, placement for adoption, or placement in foster care, or it may permit the qualified individual or enrollee to elect a coverage effective date in accordance with paragraph (b)(1) of this section. If the Exchange permits the qualified individual or enrollee to elect a coverage effective date in accordance with paragraph (b)(1) of this section, the Exchange must ensure coverage is effective on the date duly selected by the qualified individual or enrollee.

* * * * *

(iv) If a consumer loses coverage as described in paragraph (d)(1), (d)(6)(iii), or gains access to a new QHP as described in paragraph (d)(7) of this section, if the plan selection is made before or on the day of the triggering event, the Exchange must ensure that the coverage effective date is on the first day of the month following the loss of coverage. If the plan selection is made after the triggering event, the Exchange must ensure that coverage is effective in accordance with paragraph (b)(1) of this section or on the first day of the following month, at the option of the Exchange.

(v) In the case of a court order as described in paragraph (d)(2)(i) of this section, the Exchange must ensure that coverage is effective for a qualified individual or enrollee on the date the court order is effective, or it may permit the qualified individual or enrollee to elect a coverage effective date in accordance with paragraph (b)(1) of this section. If the Exchange permits the qualified individual or enrollee to elect a coverage effective date in accordance with paragraph (b)(1) of this section, the Exchange must ensure coverage is effective on the date duly elected by the qualified individual or enrollee.

(vi) If an enrollee or his or her dependent dies as described in paragraph (d)(2)(iv) of this section, the Exchange must ensure that coverage is effective on the first day of the month following the death, or it may permit the enrollee or his or her dependent to elect a coverage effective date in accordance with paragraph (b)(1) of this section. If the Exchange permits the enrollee or his or her dependent to elect a coverage effective date in accordance with

paragraph (b)(1) of this section, the Exchange must ensure coverage is effective on the date duly elected by the enrollee or his or her dependent.

* * * * *

- (c) * * *

(2) *Advanced availability.* A qualified individual or his or her dependent who is described in paragraph (d)(1), (d)(6)(iii) or, effective January 1, 2016, (d)(7), of this section, has 60 days before and after the triggering event to select a QHP. Prior to January 1, 2016, a qualified individual or his or her dependent who is described in paragraph (d)(7) of this section may select a QHP in accordance with paragraph (c)(1) of this section.

* * * * *

- (d) * * *

- (1) * * *

(ii) Is enrolled in any non-calendar year group health plan or individual health insurance coverage, even if the qualified individual or his or her dependent has the option to renew such coverage. The date of the loss of coverage is the last day of the plan or policy year;

* * * * *

(2)(i) The qualified individual gains a dependent or becomes a dependent through marriage, birth, adoption, placement for adoption, or placement in foster care, or through a child support order or other court order.

(ii) The enrollee loses a dependent or is no longer considered a dependent through divorce or legal separation as defined by State law in the State in which the divorce or legal separation occurs, or if the enrollee, or his or her dependent, dies.

* * * * *

(4) The qualified individual's or his or her dependent's, enrollment or non-enrollment in a QHP is unintentional, inadvertent, or erroneous and is the result of the error, misrepresentation, misconduct, or inaction of an officer, employee, or agent of the Exchange or HHS, its instrumentalities, or a non-Exchange entity providing enrollment assistance or conducting enrollment activities. For purposes of this provision, misconduct includes the failure to comply with applicable standards under this part, part 156 of this subchapter, or other applicable Federal or State laws as determined by the Exchange.

* * * * *

- (6) * * *

(iv) A qualified individual in a non-Medicare expansion State who was previously ineligible for advance payments of the premium tax credit solely because of a household income

below 100 percent FPL, who was ineligible for Medicaid during that same timeframe, who has experienced a change in household income that makes the qualified individual newly eligible for advance payments of the premium tax credit.

* * * * *

■ 30. Section 155.430 is amended by revising paragraphs (b)(1)(i) and (d)(6), and adding paragraphs (b)(1)(iii), (d)(2)(v), and (d)(8) to read as follows:

§ 155.430 Termination of coverage.

* * * * *

- (b) * * *

- (1) * * *

(i) The Exchange must permit an enrollee to terminate his or her coverage in a QHP, including as a result of the enrollee obtaining other minimum essential coverage. To the extent the enrollee has the right to cancel the coverage under applicable State laws, including "free look" cancellation laws, the enrollee may do so, in accordance with such laws.

* * * * *

(iii) The Exchange must establish process to permit individuals, including enrollees' authorized representatives, to report the death of an enrollee for purposes of initiating termination of the enrollee's Exchange enrollment. The Exchange may require the reporting party to submit documentation of the death. Any applicable premium refund, or premium due, must be processed by the deceased enrollee's qualified health plan in accordance with State law.

* * * * *

- (d) * * *

- (2) * * *

(v) The retroactive termination date requested by the enrollee, if specified by applicable State laws.

* * * * *

(6) In the case of a termination in accordance with paragraph (b)(2)(v) of this section, the last day of coverage in an enrollee's prior QHP is the day before the effective date of coverage in his or her new QHP, including any retroactive enrollments effectuated under § 155.420(b)(2)(iii).

* * * * *

(8) In cases of retroactive terminations dates, the Exchange will ensure that appropriate actions are taken to make necessary adjustments to advance payments of the premium tax credit, cost-sharing reductions, premiums, claims, and user fees.

* * * * *

■ 31. Section 155.605 is amended by revising paragraphs (g)(3) and (g)(6)(i) and adding paragraph (g)(6)(iii) to read as follows:

§ 155.605 Eligibility standards for exemptions.

* * * * *

(g) * * *

(3) Filing threshold. The IRS may allow an applicant to claim an exemption without obtaining an exemption certificate number from an Exchange for a taxable year if, for such year, the applicant could not be claimed as a dependent by another taxpayer and the applicant's gross income was less than the applicant's applicable return filing threshold described in section 5000A(e)(2) of the Code;

* * * * *

(6) * * *

(i) The Exchange must determine an applicant eligible for an exemption for any month if he or she is an Indian eligible for services through an Indian health care provider, as defined in 42 CFR 447.51 and not otherwise eligible for an exemption under paragraph (f) of this section, or an individual eligible for services through the Indian Health Service in accordance with 25 U.S.C. 1680c(a), (b), or (d)(3).

* * * * *

(iii) The IRS may allow an applicant to claim the exemption specified in paragraph (g)(6) of this section without obtaining an exemption certificate number from an Exchange.

■ 32. Section 155.700(b) is amended by removing the definition of "Group participation rule" and by adding the definition of "Group participation rate" to read as follows:

§ 155.700 Standards for the establishment of a SHOP.

* * * * *

(b) * * *

Group participation rate means the minimum percentage of all eligible individuals or employees of an employer that must be enrolled.

* * * * *

■ 33. Section 155.705 is amended by—

- A. Revising paragraph (b)(4)(i)(B).
■ B. Redesignating paragraphs (b)(4)(ii)(A) and (b)(4)(ii)(B) as paragraphs (b)(4)(ii)(B) and (b)(4)(ii)(C), respectively.
■ C. Adding new paragraph (b)(4)(ii)(A).
■ D. Revising paragraphs (b)(7), (b)(10) introductory text, and (b)(10)(i).

The additions and revisions read as follows:

§ 155.705 Functions of a SHOP.

* * * * *

(b) * * *

(4) * * *

(i) * * *

(B) Collect from each employer the total amount due and make payments to QHP issuers in the SHOP for all

enrollees except as provided for in paragraph (b)(4)(ii)(A) of this section; and

* * * * *

(ii) * * *

(A) The SHOP may, upon an election by a qualified employer, enter into an agreement with a qualified employer to facilitate the administration of continuation coverage by collecting premiums for continuation coverage enrolled in through the SHOP directly from a qualified employee and remitting premium payments for this coverage to QHP issuers. A Federally-facilitated SHOP may elect to limit this service to the collection of premiums related to Federally mandated continuation coverage.

* * * * *

(7) QHP availability in merged markets. If a State merges the individual market and the small group market risk pools in accordance with section 1312(c)(3) of the Affordable Care Act, the SHOP may permit a qualified employee to enroll in any QHP meeting level of coverage requirements described in section 1302(d) of the Affordable Care Act.

* * * * *

(10) Participation rules. Subject to § 147.104 of this subchapter, the SHOP may authorize a uniform group participation rate for the offering of health insurance coverage in the SHOP, which must be a single, uniform rate that applies to all groups and issuers in the SHOP. If the SHOP authorizes a minimum participation rate, such rate must be based on the rate of employee participation in the SHOP and in coverage through another group health plan, governmental coverage (such as Medicare, Medicaid, or TRICARE), coverage sold through the individual market, or in other minimum essential coverage, not on the rate of employee participation in any particular QHP or QHPs of any particular issuer.

(i) Subject to § 147.104 of this subchapter, a Federally-facilitated SHOP must use a minimum participation rate of 70 percent, calculated as the number of full-time employees accepting coverage offered by a qualified employer plus the number of full-time employees who, at the time the employer submits the SHOP group enrollment, are enrolled in coverage through another group health plan, governmental coverage (such as Medicare, Medicaid, or TRICARE), coverage sold through the individual market, or in other minimum essential coverage, divided by the number of full-time employees offered coverage.

* * * * *

■ 34. Section 155.710 is amended by revising paragraph (e) to read as follows:

§ 155.710 Eligibility standards for SHOP.

* * * * *

(e) Employee eligibility requirements.

An employee is a qualified employee eligible to enroll in coverage through a SHOP if such employee receives an offer of coverage from a qualified employer. A qualified employee is eligible to enroll his or her dependents in coverage through a SHOP if the offer from the qualified employer includes an offer of dependent coverage.

■ 35. Section 155.720 is amended by:

- A. Removing ";" from paragraph (b)(5) and adding "; and" it its place.
■ B. Removing "; and" from paragraph (b)(6) and adding a period in its place.
■ C. Removing paragraph (b)(7).
■ D. Revising paragraph (e).

The revisions read as follows:

§ 155.720 Enrollment of employees into QHPs under SHOP.

* * * * *

(e) Notification of effective date. The SHOP must ensure that a QHP issuer notifies an enrollee enrolled in a QHP through the SHOP of the effective date of his or her coverage.

* * * * *

■ 36. Section 155.725 is amended by revising paragraphs (a), (b), (g), (h), (i), and (j)(5) and by adding paragraph (k) to read as follows:

§ 155.725 Enrollment periods under SHOP.

(a) General requirements. The SHOP must ensure that enrollment transactions are sent to QHP issuers and that such issuers adhere to coverage effective dates in accordance with this section.

(b) Rolling enrollment in the SHOP. The SHOP must permit a qualified employer to purchase coverage for its small group at any point during the year. The employer's plan year must consist of the 12-month period beginning with the qualified employer's effective date of coverage, unless the plan is issued in a State that has elected to merge its individual and small group risk pools under section 1312(c)(3) of the Affordable Care Act, in which case the plan year will end on December 31 of the calendar year in which coverage first became effective.

* * * * *

(g) Newly qualified employees. (1) The SHOP must provide an employee who becomes a qualified employee outside of the initial or annual open enrollment period an enrollment period beginning on the first day of becoming a qualified employee. A newly qualified employee must have at least 30 days from the

beginning of his or her enrollment period to select a QHP. The enrollment period must end no sooner than 15 days prior to the date that any applicable employee waiting period longer than 45 days would end if the employee made a plan selection on the first day of becoming eligible.

(2) The effective date of coverage for a QHP selection received by the SHOP from a newly qualified employee must always be the first day of a month, and must generally be determined in accordance with § 155.725(h), unless the employee is subject to a waiting period consistent with § 147.116 of this subchapter, in which case the effective date may be on the first day of a later month, but in no case may the effective date fail to comply with § 147.116 of this subchapter.

(h) *Initial and annual open enrollment effective dates.* (1) The SHOP must establish effective dates of coverage for qualified employees enrolling in coverage for the first time, and for qualified employees enrolling during the annual open enrollment period described in paragraph (e) of this section.

(2) For a QHP selection received by the Federally-facilitated SHOP from a qualified employee in his or her initial or annual open enrollment period:

(i) Between the first and fifteenth day of any month, the Federally-facilitated SHOP must ensure a coverage effective date of the first day of the following month

(ii) Between the 16th and last day of any month, the Federally-facilitated SHOP must ensure a coverage effective date of the first day of the second following month.

(i) *Renewal of coverage.* (1) If a qualified employee enrolled in a QHP through the SHOP remains eligible for coverage, such employee will remain in the QHP selected the previous year unless—

(i) The qualified employee terminates coverage from such QHP in accordance with standards identified in § 155.430;

(ii) The qualified employee enrolls in another QHP if such option exists; or

(iii) The QHP is no longer available to the qualified employee.

(2) The SHOP may treat a qualified employer offering coverage through the SHOP as offering the same coverage under § 155.705(b)(3) at the same level of contribution under § 155.705(b)(11) unless:

(i) The qualified employer is no longer eligible to offer such coverage through the SHOP;

(ii) The qualified employer elects to offer different coverage or a different contribution through the SHOP;

(iii) The qualified employer withdraws from the SHOP; or

(iv) In the case of a qualified employer offering a single QHP, the single QHP is no longer available through the SHOP.

(j) * * *

(5) The effective dates of coverage for special enrollment periods are determined using the provisions of § 155.420(b).

* * * * *

(k) *Limitation.* Qualified employees will not be able to enroll unless the employer group meets any applicable minimum participation rate implemented under § 155.705(b)(10).

■ 37. Section 155.735 is amended by revising paragraphs (c)(2)(ii), (c)(2)(iii), and (d)(1)(iii) and adding paragraph (g) to read as follows:

§ 155.735 Termination of coverage.

* * * * *

(c) * * *

(2) * * *

(ii) If premium payment is not received 31 days from the first of the coverage month, the Federally-facilitated SHOP may terminate the qualified employer for lack of payment. The termination would take effect on the last day of the month for which the Federally-facilitated SHOP received full payment.

(iii) If a qualified employer is terminated due to lack of premium payment, but within 30 days following its termination the qualified employer requests reinstatement, pays all premiums owed including any prior premiums owed for coverage during the grace period, and pays the premium for the next month's coverage, the Federally-facilitated SHOP must reinstate the qualified employer in its previous coverage. A qualified employer may be reinstated in the Federally-facilitated SHOP only once per calendar year.

(d) * * *

(1) * * *

(iii) The QHP in which the enrollee is enrolled, terminates, is decertified as described in § 155.1080, or its certification as a QHP is not renewed;

* * * * *

(g) *Notice of termination.* (1) If any enrollee's coverage through the SHOP is terminated due to non-payment of premiums or due to a loss of the enrollee's eligibility to participate in the SHOP, including where an enrollee loses his or her eligibility because a qualified employer has lost its eligibility, the SHOP must, promptly and without undue delay, provide the enrollee with a notice of termination of coverage that includes the termination

effective date and reason for termination.

(2) If an employer group's coverage through the SHOP is terminated due to non-payment of premiums or, where applicable, due to a loss of the qualified employer's eligibility to offer coverage through the SHOP, the SHOP must, promptly and without undue delay, provide the employer with a notice of termination of coverage that includes the termination effective date and the reason for termination.

■ 38. Section 155.1000 amended by adding paragraph (d) to read as follows:

§ 155.1000 Certification standards for QHPs.

* * * * *

(d) *Special rule for SHOP.* In a SHOP that certifies QHPs on a calendar-year basis, the certification shall remain in effect for the duration of any plan year beginning in the calendar year for which the QHP was certified, even if the plan year ends after the calendar year for which the QHP was certified.

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

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

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

■ 40. Section 156.20 is amended by adding a definition of “Plan” in alphabetical order to read as follows:

§ 156.20 Definitions.

* * * * *

Plan has the meaning given the term in § 144.103 of this subchapter.

* * * * *

■ 41. Section 156.100 is amended by revising paragraph (c) to read as follows:

§ 156.100 State selection of benchmark.

* * * * *

(c) *Default base-benchmark plan.* If a State does not make a selection using the process described in this section, the default base-benchmark plan will be the largest plan by enrollment in the largest product by enrollment in the State's small group market.

■ 42. Section 156.110 is amended by revising paragraphs (c)(4) and (c)(5) and removing paragraph (c)(6) to read as follows.

§ 156.110 EHB-benchmark plan standards.

* * * * *

(c) * * *

(4) The plan described in paragraph (b)(2)(i) of the section with respect to pediatric oral care benefits; and

(5) The plan described in paragraph (b)(3)(i) of this section with respect to pediatric vision care benefits.

* * * * *

■ 43. Section 156.115 is amended by revising paragraph (a)(5) and adding paragraph (a)(6) to read as follows:

§ 156.115 Provision of EHB.

(a) * * *

(5) If the EHB-benchmark plan does not include coverage for habilitative services as described in § 156.110(f), the plan must:

(i) Cover health care services that help a person keep, learn, or improve skills and functioning for daily living; and

(ii) Provide coverage of habilitative services in a manner no less favorable than coverage of rehabilitative services.

(6) For pediatric services that are required under § 156.110(a)(10), provide coverage for enrollees until at least the end of the plan year in which the enrollee turns 19 years of age.

* * * * *

■ 44. Section 156.120 is added to read as follows:

§ 156.120 Collection of data to define essential health benefits.

(a) *Definitions.* The following definitions apply to this section, unless the context indicates otherwise:

Health benefits means benefits for medical care, as defined at § 144.103 of this subchapter, which may be delivered through the purchase of insurance or otherwise.

Health insurance product has the meaning given to the term in § 159.110 of this subchapter.

Health plan has the meaning given to the term, "Portal Plan" in § 159.110 of this subchapter.

Small group market has the meaning given to the term in § 155.20 of this subchapter.

State has the meaning given to the term in § 155.20 of this subchapter.

Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of coverage, or other similar limits on the scope or duration of treatment. Treatment limitations include only quantitative treatment limitations. A permanent exclusion of all benefits for a particular condition or disorder is not a treatment limitation.

(b) *Reporting requirement.* A State that selects a base-benchmark plan or an issuer that offers a default base-

benchmark plan in accordance with § 156.100 must submit to HHS the following information in a form and manner, and by a date, determined by HHS:

(1) Administrative data necessary to identify the health plan;

(2) Data and descriptive information for each plan on the following items:

(i) All health benefits in the plan;

(ii) Treatment limitations;

(iii) Drug coverage; and

(iv) Exclusions.

■ 45. Section 156.122 is amended by—

■ A. Revising paragraphs (a)(1), (a)(2), and (c).

■ B. Adding paragraphs (d) and (e).

The revisions and additions read as follows:

§ 156.122 Prescription drug benefits.

(a) * * *

(1) Submits its formulary drug list to the Exchange, the State or OPM.

(2) Uses a pharmacy and therapeutic (P&T) committee that meets the following standards

(i) *Membership standards.* The P&T committee must:

(A) Have members that represent a sufficient number of clinical specialties to adequately meet the needs of enrollees.

(B) Consist of a majority of individuals who are practicing physicians, practicing pharmacists and other practicing health care professionals.

(C) Prohibit any member with a conflict of interest with respect to the issuer or a pharmaceutical manufacturer from voting on any matters for which the conflict exists.

(D) Require at least 20 percent of its membership have no conflict of interest with respect to the issuer and any pharmaceutical manufacturer.

(ii) *Meeting standards.* The P&T committee must:

(A) Meet at least quarterly.

(B) Maintain written documentation of the rationale for all decisions regarding formulary drug list development or revision.

(iii) *Formulary drug list establishment and management.* The P&T committee must:

(A) Develop and document procedures to ensure appropriate drug review and inclusion.

(B) Make clinical decisions based on scientific evidence such as peer reviewed medical literature, standards of practice such as well-established clinical practice guidelines and other sources of appropriate information.

(C) Consider the therapeutic advantages of drugs in terms of safety and efficacy when selecting formulary

drugs and making recommendations on placing them on formulary tiers.

(D) Review new FDA-approved drugs and new uses for existing drugs.

(E) Ensure the issuer's formulary drug list:

(1) Covers a range of drugs across a broad distribution of therapeutic categories and classes and recommended drug treatment regimens that treat all disease states and does not substantially discourage enrollment by any group of enrollees; and

(2) Provides appropriate access to drugs that are included in broadly accepted treatment guidelines and which are indicative of, and consistent with, general best practice formularies currently in widespread use.

* * * * *

(c) A health plan providing essential health benefits must have the following processes in place that allow an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber, as appropriate) to request and gain access to clinically appropriate drugs not otherwise covered by the health plan (a request for exception). In the event that an exception request is granted, the plan must treat the excepted drug(s) as an essential health benefit, including by counting any cost-sharing towards the plan's annual limitation on cost-sharing under § 156.130 and when calculating the plan's actuarial value under § 156.135.

(1) *Standard exception request.* (i) A health plan must have a process for an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber) to request a standard review of a decision that a drug is not covered by the plan.

(ii) A health plan must make its determination on a standard exception and notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage determination no later than 72 hours following receipt of the request.

(iii) A health plan that grants a standard exception request must provide coverage of the non-formulary drug for the duration of the prescription, including refills.

(2) *Expedited exception request.* (i) A health plan must have a process for an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber) to request an expedited review based on exigent circumstances.

(ii) Exigent circumstances exist when an enrollee is suffering from a health condition that may seriously jeopardize the enrollee's life, health, or ability to

regain maximum function or when an enrollee is undergoing a current course of treatment using a non-formulary drug.

(iii) A health plan must make its coverage determination on an expedited review request based on exigent circumstances and notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage determination no later than 24 hours following receipt of the request.

(iv) A health plan that grants an exception based on exigent circumstances must provide coverage of the non-formulary drug for the duration of the exigency.

(3) *External exception request review.* (i) If the health plan denies a request for a standard exception paragraph (c)(1) of this section or for an expedited exception under paragraph (c)(2) of this section, the health plan must have a process for the enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber) to request an external exception review by an independent review organization to review the original exception request and subsequent denial of such request.

(ii) A health plan must make its determination on the external exception request and notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage determination no later than 72 hours following its receipt of the request, if the original request was a standard exception request under paragraph (c)(1) of this section, and no later than 24 hours following its receipt of the request, if the original request was an expedited exception request under paragraph (c)(2) of this section.

(d)(1) A health plan must publish an up-to-date, accurate, and complete list of all covered drugs on its formulary drug list, including any tiering structure that it has adopted and any restrictions on the manner in which a drug can be obtained, in a manner that is easily accessible to plan enrollees, prospective enrollees, the State, the Exchange, HHS, the U.S. Office of Personnel Management, and the general public. A formulary drug list is easily accessible when:

(i) It can be viewed on the plan's public Web site through a clearly identifiable link or tab without requiring an individual to create or access an account or enter a policy number; and

(ii) If an issuer offers more than one plan, when an individual can easily discern which formulary drug list applies to which plan.

(2) [Reserved]

(e) A health plan must have the following access procedures:

(1) A health plan must allow enrollees to access prescription drug benefits at in-network retail pharmacies, unless:

(i) The drug is subject to restricted distribution by the U.S. Food and Drug Administration; or

(ii) The drug requires special handling, provider coordination, or patient education that cannot be provided by a retail pharmacy.

(2) If a health plan charges enrollees a higher cost-sharing amount for obtaining a covered drug at a retail pharmacy, the higher cost-sharing will count towards the plan's annual limitation on cost-sharing under § 156.130 and must be accounted for in the plan's actuarial value calculated under § 156.135.

■ 46. Section 156.130 is amended by adding paragraph (b) and revising paragraph (c) to read as follows:

§ 156.130 Cost sharing requirements

* * * * *

(b) *Non-calendar year plans.* Non-calendar year plans subject to paragraph (a) of this section must adhere to the annual limitation on cost sharing beginning on the date the plan begins and ending one year later.

(c) *Special rule for network plans.* In the case of a plan using a network of providers, cost sharing paid by, or on behalf of, an enrollee for benefits provided outside of such network is not required to count toward the annual limitation on cost sharing (as defined in paragraph (a) of this section).

* * * * *

■ 47. Section 156.145 is amended by revising paragraph (a) introductory text to read as follows:

§ 156.145 Determination of minimum value.

(a) *Acceptable methods for determining MV.* An employer-sponsored plan provides minimum value (MV) only if the percentage of the total allowed costs of benefits provided under the plan is greater than or equal to 60 percent, and the benefits under the plan include substantial coverage of inpatient hospital services and physician services. An employer-sponsored plan may use one of the following methods to determine whether the percentage of the total allowed costs of benefits provided under the plan is not less than 60 percent.

* * * * *

■ 48. Section 156.200 is amended by revising paragraph (b)(7) to read as follows:

§ 156.200 QHP issuer participation standards.

* * * * *

(b) * * *

(7) Comply with the standards under 45 CFR part 153.

* * * * *

■ 49. Section 156.230 is amended by revising paragraph (a) introductory text and (b) to read as follows:

§ 156.230 Network adequacy standards.

(a) *General requirement.* Each QHP issuer that uses a provider network must ensure that the provider network consisting of in-network providers, as available to all enrollees, meets the following standards—

* * * * *

(b) *Access to provider directory.* (1) A QHP issuer must make its provider directory for a QHP available to the Exchange for publication online in accordance with guidance from HHS and to potential enrollees in hard copy upon request. In the provider directory, a QHP issuer must identify providers that are not accepting new patients.

(2) A QHP issuer must publish an up-to-date, accurate, and complete provider directory, including information on which providers are accepting new patients, the provider's location, contact information, specialty, medical group, and any institutional affiliations, in a manner that is easily accessible to plan enrollees, prospective enrollees, the State, the Exchange, HHS and OPM. A provider directory is easily accessible when—

(i) The general public is able to view all of the current providers for a plan in the provider directory on the issuer's public Web site through a clearly identifiable link or tab and without creating or accessing an account or entering a policy number; and

(ii) If a health plan issuer maintains multiple provider networks, the general public is able to easily discern which providers participate in which plans and which provider networks.

■ 50. Section 156.235 is revised to read as follows:

§ 156.235 Essential community providers.

(a) *General ECP standard.* (1) A QHP issuer that uses a provider network must include in its provider network a sufficient number and geographic distribution of essential community providers (ECPs), where available, to ensure reasonable and timely access to a broad range of such providers for low-income individuals or individuals residing in Health Professional Shortage Areas within the QHP's service area, in accordance with the Exchange's network adequacy standards.

(2) A plan applying for QHP certification to be offered through an FFE has a sufficient number and geographic distribution of ECPs if it demonstrates in its QHP application that—

(i) The network includes as participating providers at least a minimum percentage, as specified by HHS, of available ECPs in each plan's service area with multiple providers at a single location counting as a single ECP toward both the available ECPs in the plan's service area and the issuer's satisfaction of the ECP participation standard; and

(ii) The issuer of the plan offers contracts to—

(A) All available Indian health providers in the service area, applying the special terms and conditions necessitated by federal law and regulations as referenced in the recommended model QHP addendum for Indian health providers developed by HHS; and

(B) At least one ECP in each of the five ECP categories (Federally Qualified Health Centers, Ryan White Providers, Family Planning Providers, Indian Health Providers, Hospitals and other ECP providers) in each county in the service area, where an ECP in that category is available and provides medical or dental services that are covered by the issuer plan type.

(3) If a plan applying for QHP certification to be offered through an FFE does not satisfy the ECP standard described in paragraph (a)(2) of this section, the issuer must include as part of its QHP application a narrative justification describing how the plan's provider network provides an adequate level of service for low-income enrollees or individuals residing in Health Professional Shortage Areas within the plan's service area and how the plan's provider network will be strengthened toward satisfaction of the ECP standard prior to the start of the benefit year.

(4) Nothing in paragraphs (a)(1) through (a)(3) of this section requires any QHP to provide coverage for any specific medical procedure provided by an ECP.

(5) A plan that provides a majority of covered professional services through physicians employed by the issuer or through a single contracted medical group may instead comply with the alternate standard described in paragraph (b) of this section.

(b) *Alternate ECP standard.* (1) A plan described in paragraph (a)(5) of this section must have a sufficient number and geographic distribution of employed providers and hospital facilities, or providers of its contracted

medical group and hospital facilities, to ensure reasonable and timely access for low-income individuals or individuals residing in Health Professional Shortage Areas within the plan's service area, in accordance with the Exchange's network adequacy standards.

(2) A plan described in paragraph (a)(5) of this section applying for QHP certification to be offered through an FFE has a sufficient number and geographic distribution of employed or contracted providers if it demonstrates in its QHP application that the number of its providers in the following locations satisfies a minimum percentage, specified by HHS, of available ECPs in the plan's service area. Multiple providers at a single location count as a single ECP, if—

(i) Located within Health Professional Shortage Areas; or

(ii) Located within five-digit zip codes in which 30 percent or more of the population falls below 200 percent of the Federal Poverty Level.

(3) If a plan does not satisfy the alternate ECP standard described in paragraph (b)(2) of this section, the issuer must include as part of its QHP application a narrative justification describing how the plan's provider networks provides an adequate level of service for low-income enrollees or individuals residing in Health Professional Shortage Areas within the plan's service area and how the plan's provider network will be strengthened toward satisfaction of the ECP standard prior to the start of the benefit year.

(c) *Definition.* An essential community provider is a provider that serves predominantly low-income, medically underserved individuals, including a health care provider defined in section 340B(a)(4) of the PHS Act; or described in section 1927(c)(1)(D)(i)(IV) of the Act as set forth by section 221 of Public Law 111-8, unless the provider has lost its status under either of these sections, 340(B) of the PHS Act or 1927 of the Act as a result of violating Federal law.

(d) *Payment rates.* Nothing in paragraph (a) of this section must be construed to require a QHP issuer to contract with an ECP if such provider refuses to accept the generally applicable payment rates of such issuer.

(e) *Payment of Federally qualified health centers.* If an item or service covered by a QHP is provided by a Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Act) to an enrollee of a QHP, the QHP issuer must pay the Federally qualified health center for the item or service an amount that is not less than the amount of payment that would have been paid

to the center under section 1902(bb) of the Act for such item or service. Nothing in this paragraph (e) precludes a QHP issuer and Federally-qualified health center from agreeing upon payment rates other than those that would have been paid to the center under section 1902(bb) of the Act, as long as that rate is at least equal to the generally applicable payment rate of the issuer described in paragraph (d) of this section.

■ 51. Section 156.250 is revised to read as follows:

§ 156.250 Meaningful access to qualified health plan information.

A QHP issuer must provide all information that is critical for obtaining health insurance coverage or access to health care services through the QHP, including applications, forms, and notices, to qualified individuals, applicants, qualified employers, qualified employees, and enrollees in accordance with the standards described in § 155.205(c) of this subchapter. Information is deemed to be critical for obtaining health insurance coverage or access to health care services if the issuer is required by law or regulation to provide the document to a qualified individual, applicant, qualified employer, qualified employee, or enrollee.

■ 52. Section 156.265 is amended by revising paragraph (d) to read as follows:

§ 156.265 Enrollment process for qualified individuals.

* * * * *

(d) *Premium payment.* A QHP issuer must follow the premium payment process established by the Exchange in accordance with § 155.240 of this subchapter and the payment rules established in § 155.400(e) of this subchapter.

* * * * *

■ 53. Section 156.285 is amended by—

■ A. Revising paragraphs (b)(1), (b)(4) and (d)(1)(ii);

■ B. Redesignating paragraph (c)(3), (c)(4), (c)(5), (c)(6), and (c)(7) as (c)(4), (c)(5), (c)(6), (c)(7), and (c)(8) respectively; and

■ C. Adding new paragraph (c)(3).

The revisions and addition read as follows:

§ 156.285 Additional standards specific to SHOP.

* * * * *

(b) * * *

(1) Enroll a qualified employee in accordance with the qualified employer's initial and annual employee

open enrollment periods described in § 155.725 of this subchapter;

(4) Adhere to effective dates of coverage established in accordance with § 155.725 of this subchapter.

(c) * * *

(3) Provide new enrollees with notice of their effective date of coverage consistent with § 155.720(e) of this subchapter.

(d) * * *

(1) * * *

(ii) If a QHP issuer terminates an enrollee's coverage in accordance with § 155.735(d)(1)(iii) or (v) of this subchapter, the QHP issuer must, promptly and without undue delay, provide the qualified employer and the enrollee with a notice of termination of coverage that includes the termination effective date and reason for termination.

■ 54. Section 156.410 is amended by removing the second paragraph designated as paragraph (d)(4)(ii) and adding paragraph (d)(4)(iii) to read as follows:

§ 156.410 Cost-sharing reductions for enrollees.

(d) * * *

(4) * * *

(iii) If the excess cost sharing was not paid by the provider, then, if the enrollee requests a refund, the refund must be provided to the enrollee within 45 calendar days of the date of the request.

■ 55. Section 156.420 is amended by adding paragraph (h) to read as follows:

§ 156.420 Plan variations.

(h) *Notice.* No later than the first day of the Exchange open enrollment period for the 2016 benefit year, for each plan variation that an issuer offers in accordance with the rules of this section, an issuer must provide a summary of benefits and coverage that accurately represents each plan variation consistent with the requirements set forth in § 147.200 of this subchapter.

■ 56. Section 156.425 is amended by adding paragraph (c) to read as follows:

§ 156.425 Changes in eligibility for cost-sharing reductions.

(c) *Notice upon assignment.* Beginning on January 1, 2016, if an individual's assignment to a standard plan or plan variation of the QHP

changes in accordance with paragraph (a) of this section, the issuer must provide to that individual a summary of benefits and coverage that accurately reflects the new plan variation (or standard plan variation without cost-sharing reductions) in a manner consistent with § 147.200 of this subchapter as soon as practicable following receipt of notice from the Exchange, but not later than 7 business days following receipt of notice.

■ 57. Section 156.430 is amended by adding paragraph (c)(2)(i) and by reserving paragraph (c)(2)(ii) to read as follows:

§ 156.430 Payment for cost-sharing reductions.

(c) * * *

(2) * * *

(i) For reconciliation of cost-sharing reduction amounts advanced for the 2014 benefit year, an issuer of a QHP may calculate claims amounts attributable to EHB, including cost sharing amounts attributable to EHB, by reducing total claims amounts by the plan-specific percentage estimate of non-essential health benefit claims submitted on the 2014 Uniform Rate Review Template, if the following conditions are met:

(A) The non-essential health benefits percentage estimate is less than 2 percent; and

(B) Out-of-pocket expenses for non-EHB benefits are included in the calculation of amounts subject to a deductible or annual limitation on cost sharing, but copayments and coinsurance rates on non-EHB benefits are not reduced under the plan variation.

(ii) [Reserved]

■ 58. Section 156.602 is amended by revising paragraph (d) to read as follows:

§ 156.602 Other coverage that qualifies as minimum essential coverage.

(d) *State high risk pool coverage.* A qualified high risk pool established on or before November 26, 2014 in any State as defined by section 2744(c)(2) of the Public Health Service Act.

■ 59. Section 156.800 is amended by revising paragraph (c) to read as follows:

§ 156.800 Available remedies; Scope.

(c) *Compliance standard.* For calendar years 2014 and 2015, sanctions under this subpart will not be imposed if the

QHP issuer has made good faith efforts to comply with applicable requirements.

■ 60. Section 156.815 is added to subpart I to read as follows:

§ 156.815 Plan suppression.

(a) *Suppression* means temporarily making a QHP certified to be offered through the FFE unavailable for enrollment through the FFE.

(b) *Grounds for suppression.* A QHP may be suppressed as described in paragraph (a) of this section on one or more of the following grounds:

(1) The QHP issuer notifies HHS of its intent to withdraw the QHP from an FFE when one of the exceptions to guaranteed renewability of coverage related to discontinuing a particular product or discontinuing all coverage under § 147.106(c) or (d) of this subchapter applies;

(2) Data submitted for the QHP is incomplete or inaccurate;

(3) The QHP is in the process of being decertified as described in § 156.810(c) or § 156.810(d) or the QHP issuer is appealing a completed decertification as described in subpart J of this part;

(4) The QHP issuer offering the QHP is the subject of a pending, ongoing, or final State regulatory or enforcement action or determination that could affect the issuer's ability to enroll consumers or otherwise relates to the issuer offering QHPs in the FFE; or

(5) One of the exceptions to guaranteed availability of coverage related to special rules for network plans or financial capacity limits under § 147.104(c) or (d) of this subchapter applies.

(c) A multi-State plan may be suppressed as described in paragraph (a) of this section if OPM notifies the Exchange that:

(1) OPM has found a compliance violation within the multi-State plan, or

(2) One of the grounds for suppression in paragraph (b) exists for the multi-State plan.

■ 61. Section 156.1130 is added to subpart L to read as follows:

§ 156.1130 Quality improvement strategy.

(a) *General requirement.* A QHP issuer participating in an Exchange for 2 or more consecutive years must implement and report on a quality improvement strategy including a payment structure that provides increased reimbursement or other market-based incentives in accordance with the health care topic areas in section 1311(g)(1) of the Affordable Care Act, for each QHP offered in an Exchange, consistent with the guidelines developed by HHS under section 1311(g) of the Affordable Care Act.

(b) *Data requirement.* A QHP issuer must submit data, that has been validated in a manner and timeframe specified by the Exchange to support the evaluation of quality improvement strategies in accordance with § 155.200(d) of this subchapter.

(c) *Timeline.* A QHP issuer must submit data annually to evaluate compliance with the standards for a quality improvement strategy in accordance with paragraph (a) of this section, in a manner and timeframe specified by the Exchange.

(d) *Multi-State plans.* Issuers of multi-State plans, as defined in § 155.1000(a) of this subchapter, must provide the data described in paragraph (b) of this section to the U.S. Office of Personnel Management, in the manner and timeframe specified by the U.S. Office of Personnel Management.

■ 62. Section 156.1220 is amended by revising paragraph (c) to read as follows:

§ 156.1220 Administrative appeals.

* * * * *

(c) *Review by the Administrator.* (1) Either the issuer or CMS may request review by the Administrator of CMS of the CMS hearing officer's decision. A request for review of the CMS hearing officer's decision must be submitted to the Administrator of CMS within 15 calendar days of the date of the CMS hearing officer's decision, and must specify the findings or issues that the issuer or CMS challenges. The issuer or CMS may submit for review by the Administrator a statement supporting the decision of the CMS hearing officer.

(2) After receiving a request for review, the CMS Administrator has the discretion to elect to review the CMS hearing officer's decision or to decline to review the CMS hearing officer's decision. If the Administrator elects to

review the CMS hearing officer's decision, the Administrator will also review the statements of the issuer and CMS, and any other information included in the record of the CMS hearing officer's decision, and will determine whether to uphold, reverse, or modify the CMS hearing officer's decision. The issuer or CMS must prove its case by clear and convincing evidence with respect to issues of fact. The Administrator will send the decision and the reasons for the decision to the issuer.

(3) The Administrator's determination is final and binding.

PART 158—ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS

■ 63. The authority citation for part 158 continues to read as follows:

Authority: Section 2718 of the Public Health Service Act (42 U.S.C. 300gg-18), as amended.

■ 64. Section 158.140 is amended by adding paragraph (b)(1)(iii) to read as follows:

§ 158.140 Reimbursement for clinical services provided to enrollees.

* * * * *

(b) * * *

(1) * * *

(iii) Cost-sharing reduction payments received by the issuer to the extent not reimbursed to the provider furnishing the item or service.

* * * * *

■ 65. Section 158.162 is amended by revising paragraph (a)(2) and adding paragraph (b)(2)(iv) to read as follows:

§ 158.162 Reporting of Federal and State taxes.

(a) * * *

(2) Federal taxes not excluded from premium under subpart B which include Federal income taxes on investment income and capital gains, as well as Federal employment taxes, as other non-claims costs.

(b) * * *

(2) * * *

(iv) State employment and similar taxes and assessments.

* * * * *

■ 66. Section 158.242 is amended by adding paragraph (b)(1)(v) to read as follows:

§ 158.242 Recipients of rebates.

* * * * *

(b) * * *

(1) * * *

(v) All rebate distributions made under paragraphs (b)(1)(i), (ii), or (iii) of this section must be made within 3 months of the policyholder's receipt of the rebate. Rebate distributions made after 3 months must include late payment interest at the current Federal Reserve Board lending rate or 10 percent annually, whichever is higher, on the total amount of the rebate, accruing from the date payment was due under this section.

* * * * *

Dated: November 14, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Dated: November 19, 2014.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

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