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Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

[CMS–9937–F]

RIN 0938–AS57

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017

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

ACTION: Final rule.

SUMMARY: This final rule sets forth payment parameters and provisions related to the risk adjustment, reinsurance, and risk corridors programs; cost-sharing parameters and cost-sharing reductions; and user fees for Federally-facilitated Exchanges. It also provides additional amendments regarding the annual open enrollment period for the individual market for the 2017 and 2018 benefit years; essential health benefits; cost sharing; qualified health plans; Exchange consumer assistance programs; network adequacy; patient safety; the Small Business Health Options Program; stand-alone dental plans; third-party payments to qualified health plans; the definitions of large employer and small employer; fair health insurance premiums; student health insurance coverage; the rate review program; the medical loss ratio program; eligibility and enrollment; exemptions and appeals; and other related topics.

DATES: These regulations are effective on May 9, 2016.

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SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary
II. Background
A. Legislative and Regulatory Overview
B. Stakeholder Consultation and Input
C. Structure of Final Rule
III. Provisions of the Final Regulations and Analyses and Responses to Public Comments
A. Part 144—Requirements Relating to Health Insurance Coverage
B. Part 146—Requirements for the Group Health Insurance Market
C. Part 147—Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets
D. Part 153—Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment under the Affordable Care Act
E. Part 154—Health Insurance Issuer Rate Increases: Disclosure and Review Requirements
F. Part 155—Exchange Establishment Standards and Other Related Standards Under the Affordable Care Act
G. Part 156—Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges
H. Part 158—Issuer Use of Premium Revenue: Reporting and Rebate Requirements
IV. Collection of Information Requirements
A. ICRs Regarding Student Health Insurance Coverage
B. ICRs Regarding Submission of Risk Corridors Data
C. ICRs Regarding Submission of Rate Filing Justification
D. ICRs Regarding Election to Operate an Exchange after 2014
E. ICRs Regarding Standards for Certified Application Counselors
F. ICRs Regarding Network Adequacy Standards
G. ICR Regarding Monthly SHOP Enrollment Reconciliation Files Submitted by Issuers
H. ICR Regarding Patient Safety Standards
I. ICRs Regarding Other Notices
V. Regulatory Impact Analysis
A. Statement of Need
B. Overall Impact
C. Impact Estimates of the Payment Notice Provisions and Accounting Table
D. Regulatory Alternatives Considered
E. Regulatory Flexibility Act
F. Unfunded Mandates
G. Federalism
H. Congressional Review Act

Acronyms and Abbreviations

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
AHRQ Agency for Healthcare Research and Quality
APTC Advance payments of the premium tax credit
AV Actuarial value
BBEDCA Balanced Budget and Emergency Deficit Control Act of 1985
CCN CMS Certification Number
CFR Code of Federal Regulations
CHIP Children's Health Insurance Program
CMP Civil money penalty
CMS Centers for Medicare & Medicaid Services
CSR Cost-sharing reduction
ECN Exemption certificate number
ECP Essential community provider
EHB Essential health benefits
FFE Federally-facilitated Exchange
FF–SHOP Federally-facilitated Small Business Health Options Program

FPL Federal poverty level
FR Federal Register
FTE Full-time equivalent
GDP Gross domestic product
HCC Hierarchical condition category
HEN Hospital engagement network
HHS United States Department of Health and Human Services
HICS Health Insurance Casework System
HIOS Health Insurance Oversight System
HIPAA Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191)
HRSA Health Resources and Services Administration
HSA Health Savings Account
IRS Internal Revenue Service
MAGI Modified adjusted gross income
MAT Medication assisted treatment
MLR Medical loss ratio
MV Minimum value
NAIC National Association of Insurance Commissioners
NHEA National Health Expenditure Accounts
OMB Office of Management and Budget
OPM United States Office of Personnel Management
PBM Prescription benefit manager
PHS Act Public Health Service Act
PII Personally identifiable information
PMPM Per member per month
PRA Paperwork Reduction Act of 1995
PSO Patient safety organization
PSQIA Patient Safety and Quality Improvement Act (Pub. L. 109–41)
QHP Qualified health plan
QIO Quality improvement organizations
RADV Risk adjustment data validation
SADP Stand-alone dental plan
SBC Summary of benefits and coverage
SBE State-based Exchange
SBE–FP State-based Exchange on the Federal platform
SHOP Small Business Health Options Program
The Code Internal Revenue Code of 1986 (26 U.S.C. 1, *et seq.*)

I. Executive Summary

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 (the Affordable Care Act) enacted a set of reforms that are making high-quality health insurance coverage and care more affordable and accessible to millions of Americans. These reforms include the creation of competitive marketplaces called Affordable Insurance Exchanges, or ''Exchanges'' (in this final rule, we also call an Exchange a Health Insurance Marketplace℠,[1] or Marketplace℠) through which qualified individuals and qualified employers can purchase health insurance coverage. In addition, many individuals who enroll in qualified health plans (QHPs) through individual market Exchanges are eligible to receive a 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. These Affordable Care Act reforms also include the premium stabilization programs (risk adjustment, reinsurance and risk corridors) and rules that mitigate the potential impact of adverse selection and stabilize the price of health insurance in the individual and small group markets. In previous rulemaking, we have outlined the major provisions and parameters related to many Affordable Care Act programs.

In this rule, we seek to improve States' ability to operate efficient Exchanges by leveraging the economies of scale available through the Federal eligibility and enrollment platform and information technology infrastructure. We are finalizing a codification of a new Exchange model—the State-based Exchange using the Federal platform (SBE–FP). This Exchange model will enable State-based Exchanges (SBEs) to execute certain processes using the Federal eligibility enrollment infrastructure. The SBE–FP will be required to enter into a Federal platform agreement with HHS that will define a set of mutual obligations, including the set of Federal services upon which the SBE–FP agrees to rely. Under this Exchange model, certain requirements that were previously only applicable to QHPs offered on a Federally-facilitated Exchange (FFE) and their downstream and delegated entities will apply to QHPs offered on an SBE–FP and their downstream and delegated entities. For 2017, we are finalizing a mechanism through which SBE–FPs will offset some of the Federal costs of providing this infrastructure. In addition, we are finalizing rules requiring agents and brokers facilitating enrollments through SBE–FPs to comply with the FFE registration and training requirements.

We are also finalizing a number of amendments that will improve the stability of the Exchanges and support consumers' ability to make informed choices when purchasing health insurance. These include the introduction of ''standardized options'' in the individual market FFEs. Additional amendments will increase the accessibility of high-quality health insurance and improve competition, transparency, and affordability.

Our intent in offering standardized options is to simplify the consumer shopping experience and to allow consumers to more easily compare plans across issuers in the individual market FFEs. We are finalizing a standardized option with a specified cost-sharing structure at each of the bronze, silver (with cost-sharing reduction (CSR) plan variations), and gold metal levels. This policy does not restrict issuers' ability to offer non-standardized options. We anticipate differentially displaying these standardized options to allow consumers to compare plans based on differences in price and quality rather than cost-sharing structures.

We are also finalizing policies relating to network adequacy for QHPs on the FFEs. We proposed, but are not finalizing, a minimum quantitative network adequacy threshold for each State. As States continue their work to implement the National Association of Insurance Commissioners' (NAIC's) Health Benefit Plan Network Access and Adequacy Model Act (NAIC Network Adequacy Model Act), we will continue to use the same quantitative time-distance standards in our review of plans for QHP certification on the FFEs, which we will detail in the annual Letter to Issuers, which we are issuing in final form concurrently with this final rule. We are finalizing our proposed policy regarding standardized categorization of network breadth for QHPs on the FFEs on HealthCare.gov. We are also finalizing two provisions to address provider transitions in the FFE and a standard for all QHPs governing cost sharing that would apply in certain circumstances when an enrollee receives essential health benefit (EHB) provided by an out-of-network ancillary provider at an in-network setting.

We discuss the authority for FFEs to continue to select QHPs based on meeting the interests of qualified individuals and qualified employers. We will use this authority to strengthen oversight as needed in the short term.

We also seek to improve consumers' ability to make choices regarding health insurance coverage by ensuring they receive high-quality assistance in their interactions with the Exchange. For example, this final rule amends program requirements for Navigators, certain non-Navigator assistance personnel, and certified application counselors. These amendments will require FFE Navigators to assist consumers with certain post-enrollment and other issues beginning in 2018, require all Navigators to provide targeted assistance to underserved or vulnerable populations, and require Navigators and non-Navigator assistance personnel to complete training prior to conducting outreach and education activities. We are also amending our rules regarding the giving of gifts by Navigators, certain non-Navigator assistance personnel, and certified application counselors. In

[1] Health Insurance Marketplace℠ and Marketplace℠ are service marks of the U.S. Department of Health & Human Services.

addition, we are finalizing our proposal that certified application counselor designated organizations will be required to submit data and information related to the organization's certified application counselors, upon the request of the Exchanges in which they operate.

In addition, this final rule takes several steps to increase transparency. This rule finalizes provisions to enhance the transparency of rates in all States and the effectiveness of the rate review program.

This rule also establishes dates for the individual market annual open enrollment period for future benefit years. For 2017 and 2018, we will maintain the same open enrollment period we adopted for 2016—that is, November 1 of the year preceding the benefit year through January 31 of the benefit year, and for 2019 and later benefit years, we are establishing an open enrollment period of November 1 through December 15 of the year preceding the benefit year. The rule also finalizes two narrow changes to the Exchange re-enrollment hierarchy, prioritizing re-enrollment into silver plans, and providing Exchanges with the flexibility to re-enroll consumers into plans of other Exchange issuers if the consumer is enrolled in a plan from an issuer that does not have another plan available for re-enrollment through the Exchange.

We summarize input we have received on whether special enrollment periods are being appropriately provided, and discuss our plans to conduct an assessment of special enrollment periods granted to consumers through the FFEs. We are also codifying a number of Exchange policies relating to exemptions in order to provide certainty and transparency around these policies for all stakeholders.

We are finalizing our proposals for the risk adjustment program—in particular, we are finalizing our introduction of preventive services into the methodology, and our calculation of model coefficients based on the 2012, 2013, and 2014 MarketScan claims data. This final rule also amends the risk corridors provisions related to the reporting of allowable costs.

In addition to provisions aimed at stabilizing premiums, we are finalizing several provisions related to cost sharing. First, we are finalizing the premium adjustment percentage for 2017, 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 2017. We are also finalizing the maximum annual limitations on cost sharing for the 2017 benefit year for cost-sharing reduction plan variations. We also finalize standards for stand-alone dental plans (SADPs) related to the annual limitation on cost sharing, and standards related to third party payments for premiums and cost sharing made on behalf of enrollees by Federal, State, and local governments; Ryan White HIV/AIDS programs; and Indian tribes, tribal organizations, or urban Indian organizations.

We finalize several improvements that seek to ensure consumers have access to affordable, high-quality health care coverage. We are amending requirements for QHPs, including essential community providers (ECPs) and meaningful difference requirements. This rule also contains technical amendments to QHP issuer oversight provisions. This rule includes amendments to further strengthen the patient safety requirements for QHP issuers offering coverage through Exchanges.

For consumers purchasing coverage through the Small Business Health Options Program (SHOP), we finalize a new ''vertical choice'' model for Federally-facilitated SHOPs for plan years beginning on or after January 1, 2017, under which employers would be able to offer qualified employees a choice of all plans across all available actuarial value levels of coverage from a single issuer. States with a Federally-facilitated Small Business Health Options Program (FF–SHOP) will have the opportunity to recommend that vertical choice not be implemented in their State, and SBEs relying on the FF–SHOP eligibility and enrollment platform will be able to choose not to have vertical choice implemented in their State.

We also finalize adjustments to our programs and rules, as we do each year, so that our rules and policies reflect the latest market developments. We finalize the following changes and clarifications to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and Affordable Care Act health insurance reform requirements. We revise the definitions of small employer and large employer to bring them into conformance with the Protecting Affordable Coverage for Employees Act (Pub. L. 114–60). We also finalize provisions to ensure that a network plan in the small group market with a limited service area can be appropriately rated for sale based on geography. Lastly, we finalize some of the proposed provisions regarding the application of the actuarial value (AV) and single risk pool provisions to student health insurance coverage.

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 final rule, we refer to the two statutes collectively as the Affordable Care Act.

Subtitles A and C of title I of the Affordable Care Act reorganized, amended, and added to the provisions of 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, age, and tobacco use.

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.[2]

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 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

[2] Before enactment of the Affordable Care Act, the Health Insurance Portability and Accountability Act of 1996 amended the PHS Act (formerly section 2711) to generally require guaranteed availability of coverage for employers in the small group market.

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 medical loss ratio (MLR) report to HHS, and provide rebates to enrollees if the issuers 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.[3] 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) of the PHS Act further directs the Secretary, in conjunction with the States, to monitor premium increases of health insurance coverage offered through an Exchange and outside of an Exchange beginning with plan years starting in 2014.

Section 1252 of the Affordable Care Act provides that any standard or requirement adopted by a State under title I of the Affordable Care Act, or any amendment made by title I of the Affordable Care Act, is to be applied uniformly to all health plans in each insurance market to which the standard and requirement apply.

Section 1302 of the Affordable Care Act provides for the establishment of an EHB package that includes coverage of EHB (as defined by the Secretary), cost-sharing limits, and actuarial value 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.

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.

Section 1302(d) of the Affordable Care Act describes the various levels of coverage based on actuarial value. Consistent with section 1302(d)(2)(A) of the Affordable Care Act, actuarial value 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 Small Business Health Options Program assist qualified small employers in facilitating the enrollment of their employees in qualified health plans 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 allow issuers to offer QHPs in the large group market through an Exchange.[4]

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)(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.

Sections 1311(d)(4)(K) and 1311(i) of the Affordable Care Act direct all Exchanges to establish a Navigator program.

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

Section 1312(a)(2) of the Affordable Care Act provides that in a SHOP, a qualified employer may select any level of coverage under section 1302(d) of the Affordable Care Act to be made available to employees through the SHOP, and that employees may then, in turn, choose plans within the level selected by the qualified employer.

Section 1321(a) of the Affordable Care Act provides broad authority for the Secretary to establish standards and regulations to implement the statutory requirements related to Exchanges, QHPs and other components of title I of the Affordable Care Act. Section 1321(a)(1) directs the Secretary to issue regulations that set standards for meeting the requirements of title I of the Affordable Care Act with respect to, among other things, the establishment and operation of Exchanges.

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.

When operating an FFE under section 1321(c)(1) of the Affordable Care Act, HHS has the authority under sections

[3] 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).

[4] 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) under section 2701(a)(5) of the PHS Act.

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 reduces the impact of inaccurate rate setting from 2014 through 2016. Section 1343 of the Affordable Care Act establishes a permanent risk adjustment program to provide 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, among other things, reductions in cost sharing for EHB for qualified low- and moderate-income enrollees in silver level health plans offered through the individual market Exchanges.

Section 5000A of the Internal Revenue Code of 1986 (the Code), as added by section 1501(b) of the Affordable Care Act, requires all non-exempt individuals to maintain minimum essential coverage for each month 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.

The Protecting Affordable Coverage for Employees Act amended section 1304(b) of the Patient Protection and Affordable Care Act and section 2791(e) of the PHS Act to amend the definition of small employer in these statutes to mean, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 1 but not more than 50 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year. It also amended these statutes to make conforming changes to the definition of large employer, and to provide that a State may treat as a small employer, with respect to a calendar year and a plan year, an employer who employed an average of at least 1 but not more than 100 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year.

1. Premium Stabilization Programs

In the July 15, 2011 **Federal Register** (76 FR 41929), we published a proposed rule outlining the framework for the premium stabilization programs. We implemented the premium stabilization programs in a final rule, published in the March 23, 2012 **Federal Register** (77 FR 17219) (Premium Stabilization Rule). In the December 7, 2012 **Federal Register** (77 FR 73117), 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 15409).

In the December 2, 2013 **Federal Register** (78 FR 72321), 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 13743).

In the November 26, 2014 **Federal Register** (79 FR 70673), we published a proposed rule outlining the benefit and payment parameters for the 2016 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 2016 Payment Notice). We published the 2016 Payment Notice final rule in the February 27, 2015 **Federal Register** (80 FR 10749).

2. Program Integrity

In the June 19, 2013 **Federal Register** (78 FR 37031), 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 54069) and the ''second Program Integrity Rule'' published in the October 30, 2013 **Federal Register** (78 FR 65045).

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 41865) to implement components of the Exchanges, and a rule in the August 17, 2011 **Federal Register** (76 FR 51201) 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 18309) (Exchange Establishment Rule).

We established standards for SHOP in the 2014 Payment Notice. We also set forth standards related to Exchange user fees in the 2014 Payment Notice. We 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 39869) (Preventive Services Rule).

In a final rule published in the July 17, 2013 **Federal Register** (78 FR 42823), we established standards for Navigators and non-Navigator assistance personnel in FFEs and for non-Navigator assistance personnel funded through an Exchange establishment grant. This final rule also established a certified application counselor program for Exchanges and set standards for that program.

4. Essential Health Benefits and Actuarial Value

On December 16, 2011, HHS released a bulletin [5] (the EHB Bulletin) that outlined an intended regulatory approach for defining EHB, including a benchmark-based framework. HHS also published a bulletin that outlined its intended regulatory approach to calculations of AV on February 24, 2012.[6] A proposed rule relating to EHBs and AVs was published in the November 26, 2012 **Federal Register** (77 FR 70643). 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 12833) (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 health insurance 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 30239) (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 81003). A final rule with comment period implementing the rate review program was published in the May 23, 2011 **Federal Register** (76 FR 29963) (Rate Review Rule). The provisions of the Rate Review Rule were amended in final rules published in the September 6, 2011 **Federal Register** (76 FR 54969), the February 27, 2013 **Federal Register** (78 FR 13405), the May 27, 2014 **Federal Register** (79 FR 30339), and the February 27, 2015 **Federal Register** (80 FR 10749).

7. Medical Loss Ratio

We published a request for comment on section 2718 of the PHS Act 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 74863). A final rule with a 30-day comment period was published in the December 7, 2011 **Federal Register** (76 FR 76573). An interim final rule with a 60-day comment period was published in the December 7, 2011 **Federal Register** (76 FR 76595). A final rule was published in the **Federal Register** on May 16, 2012 (77 FR 28790).

B. Stakeholder Consultation and Input

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

C. Structure of Final Rule

The regulations outlined in this final rule will be codified in 45 CFR parts 144, 147, 153, 154, 155, 156 and 158.

The regulations in part 144, consistent with recent legislation, revise the definitions of ''large employer'' and ''small employer.''

The regulations in part 147 clarify the definition of principal business address, and establish the appropriate rating area under specific circumstances, for purposes of geographic rating. They also address the treatment of student health insurance coverage with regard to the AV and single risk pool requirements.

The regulations in part 153 codify how HHS will evaluate the risk adjustment and reinsurance data submitted to an issuer's dedicated distributed data environment. This rule also includes the risk adjustment user fee for 2017 and outlines certain modifications to the HHS risk adjustment methodology. This rule clarifies reporting requirements for the risk adjustment, reinsurance, and risk corridors programs.

The regulations in part 154 outline certain modifications to enhance the transparency and effectiveness of the rate review program. We require the submission of a Unified Rate Review Template from all issuers offering single risk pool coverage in the individual and small group market, including coverage with rate decreases or unchanged rates, as well as rates for new plans. We also announce our intention to disclose all proposed rate increases for single risk pool coverage at a uniform time on the CMS Web site, including rates with increases of less than 10 percent. Finally, we reiterate the process for establishing the uniform timeline that proposed rate increases subject to review and all final rate increases (including those not subject to review) for single risk pool coverage must be posted at a uniform time by States with Effective Rate Review Programs.

The regulations in part 155 include clarifications related to the functions of an Exchange, and establish the individual market open enrollment period for the 2017 and 2018 benefit years. Certain proposals in part 155 are related to the eligibility and verification processes related to eligibility for insurance affordability programs. We also amend and clarify rules related to enrollment of qualified individuals into QHPs. We describe changes to the process of submitting certain exemption applications and options for State Exchanges to handle exemptions. The finalized regulations also provide for a Federal platform agreement through which a State Exchange may agree to rely on the FFE for certain functions as an SBE–FP. We also finalize various proposals related to the SHOPs. We amend the standards applicable to the consumer assistance functions performed by Navigators, non-Navigator assistance personnel, and certified application counselors. We also discuss our approach to QHP certification, and modify standards for FFE-registered agents and brokers and requirements for HHS-approved vendors of FFE training. Part 155 also includes clarification to

[5] Essential Health Benefits Bulletin. (Dec. 16, 2011), available at *https://www.cms.gov/CCIIO/Resources/Files/Downloads/essential_health_benefits_bulletin.pdf.*

[6] Actuarial Value and Cost-Sharing Reductions Bulletin. (Feb. 24, 2012), available at *https://www.cms.gov/CCIIO/Resources/Files/Downloads/Av-csr-bulletin.pdf.*

the policy regarding additional State-required benefits.

The regulations in part 156 establish parameters 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 2017. We amend the timeframe to request reconsideration under the administrative appeals process applicable to the premium stabilization programs. Amendments to part 156 also include provisions related to EHB prescription drug rules. We amend network adequacy requirements (including application of out-of-network costs to the annual limitation on cost sharing for EHBs covered under QHPs in the small group and individual markets), and essential community provider requirements. We establish standardized options for cost-sharing structures, indexing for the stand-alone dental plan annual limitation on cost sharing, changes to our process for updating the AV Calculator for QHPs, meaningful difference standards for QHPs, and minor changes to QHP issuer oversight standards. We also amend provisions related to the third-party premium payments from certain entities and the next phase of implementation for patient safety standards for issuers of QHPs offered on Exchanges.

The amendments to the regulations in part 158 finalize revisions related to the definitions of large employer and small employer consistent with recent legislation.

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

In the December 2, 2015 **Federal Register** (80 FR 75487), we published the ''Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017'' proposed rule. We received 524 comments, including 112 substantially similar letters regarding our solicitation for comment on whether the substance use disorder requirement in essential health benefits needs additional clarification regarding medication-assisted treatment for opioid addiction. Comments were received from the National Association of Insurance Commissioners, State departments of insurance, State Exchanges, a member of Congress, health insurance issuers, providers, consumer groups, labor entities, industry groups, patient safety groups, national interest groups, and other stakeholders. The comments ranged from general support of or opposition to the proposed provisions to specific questions or comments regarding proposed changes. We received a number of comments and suggestions that were outside the scope of the proposed rule that will not be addressed in this final rule.

In this final rule, we provide a summary of each proposed provision, a summary of those public comments received that directly related to proposals, our responses to them, and a description of the provisions we are finalizing.

Comment: We received a number of comments stating that the comment period was unreasonably short, making it difficult for stakeholders to provide in-depth analysis and input. Commenters urged HHS to provide a comment period of 60 days from the date of publication in the **Federal Register** for this and future HHS Notices of Benefit and Payment Parameters.

Response: The timeline for publication of this final rule accommodates issuer filing deadlines for the 2017 benefit year. A 60-day comment period would have delayed the publication of this final rule, and created significant challenges for States, Exchanges, issuers, and other entities in meeting deadlines related to implementing these rules.

Comment: We received a number of comments disapproving of the wide array of topics covered in the rule.

Response: Many of the programs covered by this final rule are closely linked. To simplify the regulatory process, facilitate public comment, and provide the information needed to meet statutory deadlines, we have elected to propose and finalize these regulatory provisions in one rule, as we have in years past.

Comment: A number of comments, many focused primarily on proposals related to network adequacy, urged HHS to allow States to continue their oversight of their insurance markets and defer to the NAIC for the development of important industry-wide, State-based standards.

Response: We aim to establish Federal oversight standards that complement State standards while meeting Federal obligations, including for qualified health plans on Federally-facilitated Exchanges. We will continue to coordinate closely with State authorities to address compliance issues, eliminate duplicative requirements or review, and to reduce the burden on stakeholders.

Comment: Several comments emphasized the importance of ensuring coverage is affordable to consumers, or expressed concern that coverage purchased through the Exchanges is not affordable.

Response: We appreciate the importance of ensuring coverage purchased through the Exchanges is affordable to consumers, and believe affordability is critical to the success of the Exchanges.

A. Part 144—Requirements Relating to Health Insurance Coverage

1. Definitions (§ 144.103)

Section 144.103 sets forth definitions of terms that are used throughout parts 146 through 150. In the proposed rule, we discussed the definition of ''plan year'' and proposed revisions to the definitions of small employer and large employer that would be consistent with recent legislation. We also proposed a technical correction in the definition of excepted benefits to cross reference the group market provisions in § 146.145(b) rather than § 146.145(c). We are finalizing these provisions as proposed.

a. Plan Year

In the preamble to the proposed rule (80 FR at 79495), we explained that we interpret the definition of plan year in § 144.103 with respect to both grandfathered and non-grandfathered group health plans to mean a period that is no longer than 12 months.

Comment: One commenter requested clarification that a plan year may be shorter than 12 months under certain circumstances.

Response: A plan year may be shorter than 12 months under certain circumstances, but a plan year may not be longer than 12 months.

b. Large Employer and Small Employer

We proposed to revise the regulatory definitions of large employer and small employer in §§ 144.103 and 155.20 consistent with section 1304(b) of the Affordable Care Act and section 2791(e) of the PHS Act, as amended by the Protecting Affordable Coverage for Employees Act. We also proposed to codify statutory language providing that in the case of an employer that was not in existence throughout the preceding calendar year, the determination of whether the employer is a large employer or a small employer is based on the average number of employees that it is reasonably expected the employer will employ on business days in the current calendar year. We are finalizing these revisions as proposed.

Comment: Several commenters supported our proposed definitions of large employer and small employer, including the codification related to employers that were not in existence throughout the preceding calendar year.

Response: We are finalizing the revisions to the definitions of large

employer and small employer in §§ 144.103 and 155.20 as proposed.[7]

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

1. Guaranteed Availability of Coverage for Employers in the Small Group Market (§ 146.150)

For a discussion of the proposed amendment to § 146.150, please see the preamble to § 147.104.

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

1. Fair Health Insurance Premiums (§ 147.102)

a. Principal Business Address

Under section 2701 of the PHS Act and regulations at § 147.102, the rating area for a small group plan is based on the group policyholder's principal business address. We proposed to amend § 147.102(a)(1)(ii) to provide that if the employer has registered an in-State principal business address with the State, that location is the principal business address. We noted that an in-State address registered solely for purposes of service of process would not be considered the employer's principal business address, unless it is a substantial worksite for the employer's business. If an in-State principal business address is not registered with the State or is only registered for purposes of service of process and is not a substantial worksite, we proposed that the employer would designate as its principal business address the business address within the State where the greatest number of employees work in the applicable State.

When a network plan offered in a State has a limited service area, we noted that this policy could result in an issuer having to make a plan available under the guaranteed availability rules to an employer—because the employer has an employee who lives, works, or resides in the service area—but not be able to apply a geographic rating factor under the current rule—because the issuer might not have established rates applicable to the location of the employer's principal business address outside the plan's service area.

We proposed to amend § 147.102 to provide for an additional principal business address to be identified within a plan's service area in these circumstances so that the plan can be appropriately rated for sale to the employer. In such instances, the additional principal business address would be the business address within the plan's service area where the greatest number of employees work as of the beginning of the plan year, or, if there is no such business address, an address within the service area selected by the employer that reasonably reflects where the greatest number of employees live or reside as of the beginning of the plan year.

As stated in the preamble to the proposed rule, SHOPs, including the FF–SHOPs, may use the address that was used to establish a qualified employer's eligibility for participation in the SHOP to determine the applicable geographic rating area when calculating premiums for participating employers. The intent of these proposals was to establish a uniform set of rules that can be applied as simply as possible, while allowing plans to be properly rated.

We are finalizing the provisions proposed in § 147.102 of the proposed rule without substantive modification. However, we are finalizing the regulatory text in a way that does not refer to a location where employees live or reside as a principal business address, as we believe doing so in the proposed regulatory text was confusing, and we are making additional minor edits for clarity. These are not substantive modifications, as the proposed rule and this final rule apply the same test to determine the policyholder's rating area with respect to a network plan in such a situation.

Comment: Several commenters supported our proposed definition of principal business address, and our approach for allowing an employer to identify an additional principal business address within the service area of a network plan. Two commenters suggested HHS should not modify the standards for geographic rating, suggesting that the proposed rule provides opportunities and incentives for small employers to select an address based upon factors other than the true business location of the employer. These commenters did not provide an alternative approach to allow plans to be rated in this circumstance.

Response: We have revised the proposed rule text such that it no longer refers to an employer selecting a location where employees live or reside as a principal business address. The rule instead provides that if an employer does not have a business location in the issuer's service area, but has employees who live or reside within the service area, the geographic rating area for purposes of the network plan is the rating area where the greatest number of employees within the plan's service area live or reside as of the beginning of the plan year. We believe these standards for identifying an applicable rating area within the issuer's service area will ensure that a network plan can be appropriately rated for sale to the employer consistent with guaranteed availability requirements.

Comment: One commenter suggested we define ''substantial worksite'' to determine when a business address registered solely for purposes of service of process would be considered the employer's principal business address for rating purposes.

Response: The final rule does not provide a specific definition of substantial worksite. We believe the term is sufficiently clear and will not cause confusion. Nevertheless, we will monitor the implementation of this policy in considering whether it is appropriate to clarify what constitutes a substantial worksite in the future.

Comment: One commenter requested that the FF–SHOP verify that an address entered by an employer is the official principal place of business. We also received a comment requesting that we modify the FF–SHOP application process to allow more than one account per State and thus, allow for more than one rating area for an employer.

Response: Under § 155.710(b)(3), one criterion for being a qualified employer eligible to purchase coverage through a SHOP is that the employer has its principal business address in the Exchange service area and offers coverage to all its full-time employees through that SHOP, or offers coverage to each eligible employee through the SHOP serving that employee's primary worksite. If we receive a report that incorrect or inaccurate information has been provided on an FF–SHOP application, we may investigate and take corrective action as needed. Further, as stated in the preamble to the proposed rule, due to operational limitations, the SHOPs, including the FF–SHOPs, may not be able to accommodate multiple principal business addresses within a State for premium calculation purposes. As a result, due to current operational limitations, when a single employer application is completed in a State with an FF–SHOP, plan availability and premium calculations will be based on the principal business address entered on the FF–SHOP employer application.

[7] This final rule has no effect on previously issued guidance by CMS clarifying that offices of the Members of Congress, as qualified employers, are eligible to participate in a SHOP regardless of the size requirements set forth in the definition of ''qualified employer'' in 45 CFR 155.20. See Members of Congress and Staff Accessing Coverage through Health Insurance Exchanges (Marketplaces) (Sept. 30, 2013), available at: *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/members-of-congress-faq-9-30-2013.pdf.*

Comment: One commenter asked for clarification on the interaction between § 155.710(b)(3) (governing eligibility standards for SHOP) and § 147.102(a)(1)(ii) (governing geographic rating).

Response: If SHOPs, including the FF–SHOPs, have operational limitations that do not permit them to fully implement the policy described above, they may use the address that was used to establish a qualified employer's eligibility for participation in the SHOP to determine which plans are available to the employer, as well as the applicable geographic rating area when calculating premiums for participating employers.

b. Other Issues Related to Rating Areas

In the preamble to the proposed rule, we noted that we have observed wide variations in the size of rating areas in the various States. We identified a concern that this variation could lead to smaller rating areas with a high concentration of higher-risk groups, which potentially compromises the risk-spreading objective that the single risk pool requirement is intended to achieve. At the same time, States are the primary regulators of health insurance, and we believe it is important to recognize the unique needs of each State. We also recognize the consumer disruption that could result from changes to rating areas. Therefore, we sought comment on whether we should seek more uniformity in the size of rating areas or establish a minimum size for rating areas, and if so, how that should be achieved, consistent with the principle of flexibility for States.

We also recognized the inconsistency that can occur between an issuer's rating area and the service area of some of its network-based plans. We indicated that it could be beneficial for the rating area and the service area to generally be consistent and sought comment on whether and how to achieve this objective.

Comment: One commenter supported rating areas of a minimum size as a way to spread risk, and two others suggested applying a minimum number of residents per rating area or a minimum number that is no less than a specified percentage of residents in the non-metropolitan statistical areas of a State. Many commenters, however, stated their opposition to any further Federal regulation defining rating areas, stating that the States are best equipped to determine how rating areas are established. One commenter stated that our example that each rating area be a contiguous area would adversely affect service area strategies that identify non-contiguous areas with similar pricing and network dynamics that may warrant placing them in the same service area. One commenter stated that limiting the number of rating areas to the number of metropolitan statistical areas plus one would be arbitrary. One commenter stated that basing rating areas on the relative population of each area would require frequent changes in rating areas due to population shifts.

Many commenters also opposed aligning rating areas with service areas. One stated that such an alignment could cause issuers to leave an entire geographic area rather than attempt to establish contracts with providers in other parts of a rating area, due to additional costs associated with establishing a broader network. One commenter observed that rating areas are based on geographic differences in cost of care, while service areas are constructed to ensure that a network plan has providers that can serve enrollees in specific geographic locations. One commenter observed that aligning rating areas with service areas could result in a significant increase in the number of plans submitted for approval and rate review and Health Insurance Oversight System (HIOS) plan IDs.

Response: We are not making changes to these regulations in this final rule, and will consider these comments as we continue to study these issues.

c. Child Age Rating

Section 147.102(e) provides for a uniform age curve in each State. When a State does not specify an age curve, a Federal default uniform age curve will apply. We stated in the proposed rule that we are investigating the child age rating factor in the Federal uniform age curve, and seek to determine whether the default factor is appropriate, or fails to adequately differentiate the health risk of children of different ages. We sought comment and data on the most appropriate child age curve, and the policy reasons underlying any recommendation.

Comment: One commenter did not support a varying child age curve, believing that in the individual market, children may need more care at certain ages, so a fixed age rating factor that applies to all children should continue to apply. With regard to the current fixed factor, several commenters stated that the current default factor of 0.635 for children under age 21 may be set too low.

Several commenters supported a varying child age curve, and set forth specific age gradations. Two commenters stated that the child age curve should be increased by a set amount for plans with embedded pediatric dental benefits. One commenter stated that we should consider using data consistent with data used to calibrate risk adjustment to determine child age factors, while one commenter stated that the age calibration for children must be adjusted in the uniform age curve.

Response: We recognize that the child age band and factor may need to be updated to better reflect the health risk of children and intend to address child age rating in future rulemaking or guidance.

2. Guaranteed Availability of Coverage (§ 147.104)

a. Product Discontinuance and Market Withdrawal Exceptions to Guaranteed Availability

In the proposed rule, we expressed concern about whether it would be in consumers' or issuers' interest to require guaranteed availability of a product while the issuer is in the process of winding down operations with respect to that product or all its products in a market. Therefore, we proposed to codify an exception to the guaranteed availability requirements under § 147.104 when the exception to guaranteed renewability of coverage related to discontinuing a product or all coverage in the market applies. Specifically, we proposed that an issuer may deny coverage to new individuals or employers during the applicable 90-day or 180-day notice period when the issuer is discontinuing a product or exiting the market. We proposed that an issuer must apply the denial uniformly to all employers or individuals in the large group, small group, or individual market, as applicable, in the State consistent with applicable State law, and without regard to the claims experience or any health-status related factor relating to those individuals or employers and their employees (or their respective dependents). We proposed that this exception not relieve issuers of their obligations to existing policyholders, such as their obligation to enroll dependents under an applicable special enrollment period. We proposed parallel provisions under § 146.150 addressing guaranteed availability of coverage for employers in the small group market under the HIPAA rules.

We are not finalizing the provisions proposed in §§ 147.104 and 146.150 of the proposed rule. As noted in the proposed rule, the product discontinuance exception to the guaranteed renewability requirement in

§ 147.106(c) requires an issuer to provide notice in writing, in the form and manner specified by the Secretary, to each plan sponsor or individual, as applicable, (and to all participants and beneficiaries covered under such coverage) of the discontinuation at least 90 calendar days before the date the coverage will be discontinued. The market withdrawal exception to the guaranteed renewability requirement in § 147.106(d) requires an issuer to provide notice in writing to the applicable State authority and to each plan sponsor or individual, as applicable (and to all participants and beneficiaries covered under the coverage) of the discontinuation at least 180 calendar days prior to the date the coverage will be discontinued. We therefore proposed to interpret the interaction between the guaranteed availability and these guaranteed renewability provisions to permit an issuer to deny enrollments during the applicable product discontinuance or market withdrawal notice period. However, with regard to situations where an issuer decides to discontinue a product, we are concerned that the proposed policy could have an impact on the issuer's risk pool and rating for its other products. While a market withdrawal does not have the same impact since all of the issuer's products in a market are being discontinued, we believe this interpretation of the interaction between the laws to provide for an exception to the guaranteed availability requirements would have to be applied consistently in both a product discontinuance and market withdrawal situation. Therefore, going forward, we will not interpret these statutes to recognize an exception to the guaranteed availability requirement in either scenario, and the issuer must continue to offer coverage to and accept every employer or individual in the State that applies for coverage under a product until such time that the product is discontinued.

Consistent with previous guidance, with regard to individuals who enroll in a product after the specified deadline for providing the applicable product discontinuance or market withdrawal notice and before the particular product or products are discontinued, HHS will consider an issuer to satisfy the requirement to provide notice if the issuer provides prominent and effective notice at the time of application or enrollment that the product will be discontinued, in any form and manner permitted by applicable law and regulations.[8]

b. Minimum Participation and Contribution Rules

In the proposed rule, we expressed concern that the use of minimum group participation and employer contribution rules to deny coverage in the small group market could result in some applicable large employers, as defined in section 4980H of the Code, not reasonably being able to offer coverage to their full-time employees (and their dependents) and therefore potentially being liable for an employer shared responsibility payment under section 4980H of the Code, particularly in States that elect to expand the small group market to include employers with up to 100 employees.

In recognition of this dynamic, we noted that a State electing to expand its small group market to include employers with up to 100 employees may opt, under its own authority, to prohibit an issuer from restricting the availability of small group coverage based on employer contribution or group participation rules. Alternatively, in cases where a State expands the definition of a small employer to include employers with up to 100 employees, we could amend the guaranteed availability regulations, with respect to small employers with 51–100 employees or with respect to all small employers altogether, to achieve this objective. We sought comment on such an approach.

Comment: Several commenters stated that we should retain the ability of issuers to limit, to November 15 to December 15 of each year, when issuers must sell a policy to a small employer that fails to meet the issuer's group participation or contribution rules. Some commenters stated that issuers should retain this ability even with respect to groups of 51–100 employees, as doing otherwise would have an adverse impact on risk pools. One commenter stated that if we eliminate the ability of issuers to apply minimum contribution and participation rules, we should at least exempt issuers from having to offer and renew coverage to employers that selectively offer insured and self-funded coverage simultaneously to separate classes of employees. Such employers, the commenter stated, leave issuers with the highest-risk individuals. One commenter stated that we should amend the guaranteed availability requirements so that any employer, regardless of size, that can document that it is subject to Code section 4980H, must be sold a policy anytime during the year. The commenter stated that we should consider this approach for the entire small group market as well.

Response: This final rule does not make any changes to the guaranteed availability requirements as they apply in connection with minimum participation or contribution rules. We note that States have flexibility to further restrict the use of minimum employer contribution or group participation rules as appropriate.

3. Guaranteed Renewability of Coverage (§ 147.106)

Title XXVII of the PHS Act includes several exceptions to its guaranteed renewability provisions, including when a group health plan sponsor has violated a material plan provision relating to employer contribution or group participation rules, provided applicable State law allows an exception to guaranteed renewability under such circumstances; and for coverage made available in the individual market, or small or large group market only through one or more bona fide associations, if the individual's or employer's membership in the association ceases. Although the Affordable Care Act removed from Title XXVII these exceptions as they applied to guaranteed availability, it did not do so with respect to guaranteed renewability. Therefore, as we pointed out in the preamble to the proposed rule, a large employer whose coverage is non-renewed for one of these reasons, and a small employer whose coverage is non-renewed due to membership ceasing in an association, could be seen to have a right to immediately purchase that same coverage (if available in the market) from that same issuer in accordance with guaranteed availability. In the preamble to the proposed rule, we suggested that this renders effectively meaningless these two exceptions to guaranteed renewability in these contexts, and we proposed to amend § 147.106 to remove these guaranteed renewability exceptions.

For the reasons discussed in greater detail below, the final rule does not remove the guaranteed renewability exceptions related to failure to satisfy minimum employer contribution or group participation rules, or loss of association membership, because we have determined upon further consideration these exceptions can

[8] CMS Insurance Standards Bulletin Series, Form and Manner of Notices when Discontinuing or Renewing a Product in the Group or Individual Market (Sept. 2, 2014), available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Renewal-Notices-9-3-14-FINAL.pdf.*

affect the insurance plan choices available to consumers and employers.

Comment: Two commenters suggested we should not remove the guaranteed renewability exceptions when a small employer's membership in an association ceases. The commenters stated that typically a blanket master policy is issued to the association and it would not be appropriate for small employers who leave the association to continue to receive coverage through the same policy.

Response: Based on the comments received and after further review and consideration of the statutory provisions, we have concluded that the guaranteed availability requirements do not render effectively meaningless the guaranteed renewability exceptions for loss of association membership or failure to meet group participation or contribution rules. For example, an employer with association coverage leaving the association mid-year and losing coverage may be subject to a different premium rate under a new policy based on a quarterly rate update in the small group market or a new experience rate in the large group market. Further, we recognize that association members who cease membership in an association and lose coverage may have their deductible and maximum out of pocket limit reset under a new policy. The same logic applies with respect to employers whose coverage is terminated mid-year for failure to meet an issuer's participation or contribution rules. And, small employers whose coverage is terminated for failure to meet minimum participation or contribution rules might not be able to purchase new coverage until the next annual enrollment period from November 15 to December 15. For these reasons, we believe these exceptions to guaranteed renewability continue to have relevance, and we are not finalizing our proposal to remove them from the regulations.

4. Student Health Insurance Coverage (§ 147.145)

a. Index Rate Setting Methodology for Student Health Insurance Coverage

Under § 147.145, student health insurance coverage is a type of individual health insurance coverage that, subject to certain limited exceptions, must comply with the PHS Act requirements that apply to individual health insurance coverage. However, section 1560(c) of the Affordable Care Act provides that nothing in title I of the Affordable Care Act (or an amendment made by title I) is to be construed to prohibit an institution of higher education from offering a student health insurance plan to the extent that the requirement is otherwise permitted under applicable Federal, State, or local law. HHS has exercised its authority under section 1560(c) of the Affordable Care Act to modify some of its rules as applied to student health insurance coverage, including those related to the guaranteed availability, guaranteed renewability, and single risk pool requirements.

As we stated in the preamble to the proposed rules, our intent in exempting student health insurance coverage from the single risk pool requirement was to provide that student health insurance issuers need not include their student health insurance coverage in their overall individual market (or merged market) risk pool, and also need not have one single risk pool composed of their total statewide book of student health insurance business. Rather, we intended that issuers could establish risk pools for students and their dependents separate from the issuer's individual market or merged market risk pool, including by establishing separate risk pools for different institutions of higher education, or multiple risk pools within a single institution. However, as explained in the preamble to the proposed rule, we have learned that student health insurance issuers may be using certain rating factors that lead to rates that might not be actuarially justified.

As stated in the preamble to the proposed rule, we do not intend to disrupt rate setting for student health insurance, but we do seek to ensure that rates are based on actuarially justified factors. To clarify our intent, we proposed, for policy years beginning on or after January 1, 2017, that student health insurance coverage be subject to the index rate setting methodology of the single risk pool provision in the regulation at § 156.80(d). However, student health insurance issuers still would be permitted to establish separate risk pools from their individual market single risk pool (or merged market risk pool, where applicable) for student health insurance coverage, including by establishing separate risk pools for different institutions of higher education, or multiple risk pools within a single institution, provided they are based on a bona fide school-related classification (for example, graduate students and undergraduate students) and not a health status-related factor as described in § 146.121. Consistent with our single risk pool policy, the index rates for these risk pools would be based upon actuarially justified estimates of claims. We proposed that permissible plan-level adjustments to these index rates would be limited to those permitted under our rules. This approach would continue to allow rates for student health insurance coverage to reflect the unique characteristics of the student population at the particular institution, while more clearly delineating our intent with regard to the treatment of student health insurance coverage. We sought comment on any potential operational challenges associated with this proposal, including potential challenges related to filing rates for student health insurance coverage and how this policy might be adjusted to address those challenges.

We finalize in this rule our proposal that student health insurance issuers may establish one or more risk pools per institution of higher education, provided that the risk pools are based on a bona fide school-related classification and not based on a health factor as described in § 146.121. In response to comments, we are not finalizing our proposal that student health insurance coverage must comply with the single risk pool index rate setting methodology. However, we are requiring that student health insurance rates reflect the claims experience of individuals who comprise the risk pool and any adjustments to rates within a risk pool must be based on actuarially justified factors. We are also removing outdated provisions in § 147.145(b)(2) and (d) providing that student health insurance issuers may impose annual dollar limits for policy years beginning before January 1, 2014. Those provisions, by their own terms, no longer apply, as student health insurance issuers are subject to the provisions in § 147.126 that prohibit annual dollar limits on EHB for policy years beginning on or after January 1, 2014. Accordingly, we are finalizing the AV provision proposed in paragraph (b)(4) at paragraph (b)(2), and deleting outdated paragraphs (d) and (e).

Comment: While one commenter supported the proposal to subject student health insurance issuers to the index rate setting methodology, several commenters were opposed to the proposal, citing concerns about additional administrative and regulatory burdens on both issuers and State regulators, as well as concerns about limiting consumer choice and flexibility and undermining the role of institutions of higher education in arranging for coverage that best meets the needs of their student populations.

Response: After carefully considering these comments, we have determined not to apply the single risk pool index

rate setting methodology to student health insurance coverage. While we continue to have concerns that student health insurance issuers may be setting rates that are not based upon actuarially justified estimates of claims, we are also mindful of the concerns about potential administrative burden. The single risk pool rate setting methodology is one means of ensuring rates are actuarially justified. Therefore, while student issuers will not be required to use that particular methodology to establish rates, the final rule requires that rates for student health insurance coverage reflect the claims experience of individuals who comprise the risk pool and any adjustments to rates within a risk pool must be actuarially justified. We intend to monitor whether factors are being used to develop rates for student health insurance coverage that are not actuarially justified, such as adjusting rates based upon the length of time the coverage has been underwritten by the issuer.

Comment: Several commenters supported our proposal to permit issuers to establish one or more risk pools per institution of higher education, provided the risk pools are based on a bona fide school-related classification and not a health factor as described in § 146.121. Two commenters urged us not to permit multiple risk pools within a single institution of higher education, expressing concern that subgroups could be discriminatory in nature. One commenter requested clarification that issuers may create risk pools comprised of more than one college or university.

Response: The final rule provides that student risk pools must be based on a bona fide school-related classification and not a health factor as defined in § 146.121. The risk pools may include enrollees at one or multiple institutions of higher educations in the State or nationally, or certain subgroups within a single institution of higher education, provided that the risk pools are based on a bona fide classification and not discriminatory based on health status. We believe these standards balance issuer flexibility with appropriate safeguards against potentially discriminatory risk pooling practices. We note that nothing prevents a State from requiring broader risk pooling with respect to student health insurance coverage than provided for in this final rule (for example, requiring each student health insurance issuer to establish one risk pool comprised of its entire student health insurance book of business).

Comment: Some commenters requested clarification that issuers may establish separate risk pools for students and dependents. Other commenters suggested that issuers should be permitted to apply actuarially justified rating factors to distinguish between students and their dependents who are on the same plan or cross-subsidize between students and dependents in order to keep premiums for dependent coverage affordable.

Response: Under this final rule, an issuer may create separate risk pools for students and dependents. Dependent rates may vary from those for students as long as dependents constitute a separate risk pool and are enrolled in separate coverage from students. However, consistent with the rating rules under section 2701 of the PHS Act, if students and dependents are enrolled in the same coverage, then rates may not vary based on student or dependent status, but may vary based on age and family size. Nothing in this final rule prevents an issuer from including students and dependents in the same risk pool.

b. Actuarial Value Requirements for Student Health Insurance Plans

As stated in the preamble to the proposed rule, many colleges and universities have reported to us that they offer student health insurance plans that are rich in benefits (for example, providing an actuarial value of 96 percent) and that they are reluctant to reduce the level of benefits to meet an actuarial value metal level. We stated that because enrollees in student health insurance plans are not typically selecting among such plans, there is less need for standardization of actuarial levels in this part of the individual market. Therefore, we proposed to add an exemption to the requirements for student health insurance coverage in § 147.145, under which, for plan years beginning on or after January 1, 2017, student health insurance coverage would be exempt from the actuarial value ''metal level'' requirements under section 1302(d) of the Affordable Care Act, as implemented in §§ 156.135 and 156.140, but would be required to provide an actuarial value of at least 60 percent. To determine a plan's actuarial value for purposes of the application of the 60 percent actuarial value requirement to student health insurance coverage, we proposed to require student health insurance coverage issuers to obtain certification by an actuary that the plan provides an actuarial value of at least 60 percent. This determination would be required to be made by a member of the American Academy of Actuaries, based on analysis in accordance with generally accepted actuarial principles and methodologies. We sought comment on this proposal, including whether to continue to require student health insurance issuers to determine the actuarial value of their coverages by using the actuarial value calculator, as currently required, instead of through actuarial certification.

We are finalizing our proposal to require student health insurance coverage to meet a minimum 60 percent actuarial value, as opposed to meeting any specific metal level. We are not finalizing our proposal that actuarial value would be determined by certification of an actuary but rather require that it be determined using the actuarial value calculator, as is the case for other individual market and small group market coverage. Requiring the actuarial value of student health insurance coverage to be calculated using the same methodology as those other types of coverage will allow students and their dependents to better compare the generosity of student health insurance with other available coverage options, such as coverage under a parent's plan or coverage through the Exchange. We also specify that this provision will apply for ''policy years'' beginning on or after July 1, 2016 as opposed to plan years beginning on or after January 1, 2017. The reference to ''policy years'' is the more appropriate term with regard to student health insurance coverage, a type of individual market coverage. We recognize that student health plans typically operate on a policy year that is not the calendar year, and therefore we have modified the provision to take effect beginning with coverage for the upcoming academic year as was our intent in the proposed rule.

Comment: Several commenters supported our proposal to require student health insurance plans to meet at least 60 percent actuarial value, instead of meeting any specific metal level. However, several commenters stated that student health insurance plans should be required to meet metal levels, for purposes of transparency and comparability with other plans.

Response: Although we are finalizing the 60 percent actuarial value proposal, we agree that it is important for enrollees and potential enrollees in student health insurance plans to be able to compare such plans with others for which they may be eligible, such as their parents' plan or an individual market non-student plan. In the proposed rule, we had solicited comments on whether to require student health insurance issuers to specify, in their summary of benefits and coverage

(SBC) documents, enrollment materials, marketing materials, or other materials, the actuarial value of the coverage, the next lowest metal level the coverage would otherwise satisfy, based on its actuarial value, or any other data that would give enrollees and prospective enrollees information about the actuarial value of the coverage. Several commenters supported this general approach. One opposed it, arguing that the actuarial value for student health insurance coverage is an unreliable indicator of the true value of the plan. However, we believe that disclosing the actuarial value of the coverage, and the next lowest metal level the coverage would otherwise satisfy, based on its actuarial value, would be a helpful tool. Therefore, we are finalizing a requirement that student health insurance issuers must disclose, in any plan materials summarizing the terms of the coverage, the actuarial value of the coverage and the metal level (or next lowest metal level) the coverage would satisfy. This requirement will not apply to the SBC, unless and until such information is incorporated into the SBC template and instructions.

Comment: One commenter recommended removing the 92 percent actuarial value cap on platinum level student plans instead of eliminating the metal level requirements altogether.

Response: We believe that the same reasons to give platinum plans flexibility with respect to actuarial value also apply to other metal level plans. Therefore, we are providing flexibility in this final rule for student health insurance plans to provide any AV at or above 60 percent.

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

In the proposed rule, we proposed a number of modifications to the risk adjustment, reinsurance, and risk corridors programs.

Comment: One commenter asked that HHS present all regulatory information related to the premium stabilization programs in a clear, transparent, reliable and timely manner. Another commenter asked that the risk adjustment and reinsurance data collection requirements be limited to data currently held by plans in order to not increase the administrative burden on providers.

Response: HHS is committed to providing regulations and guidance in a clear and timely manner, and seeks to minimize the administrative burden of our data collection.

1. Sequestration

In accordance with the OMB Report to Congress on the Joint Committee Reductions for Fiscal Year 2016,[9] both the transitional reinsurance program and permanent risk adjustment program are subject to the fiscal year 2016 sequestration. The Federal government's 2016 fiscal year began on October 1, 2015. The reinsurance program will be sequestered at a rate of 6.8 percent for payments made from fiscal year 2016 resources (that is, funds collected during the 2016 fiscal year). To meet the sequestration requirement for the risk adjustment program for fiscal year 2016, HHS will sequester risk adjustment payments made using fiscal year 2016 resources in all States where HHS operates risk adjustment at a sequestration rate of 7.0 percent. HHS estimates that increasing the sequestration rate for all risk adjustment payments made in fiscal year 2016 to all issuers in the States where HHS operates risk adjustment by 0.2 percent will permit HHS to meet the required national risk adjustment program sequestration percentage of 6.8 percent noted in the OMB Report to Congress.

HHS, in coordination with OMB, has determined that, under section 256(k)(6) of the Balanced Budget and Emergency Deficit Control Act of 1985 (the BBEDCA), as amended, and the underlying authority for these programs, the funds that are sequestered in fiscal year 2016 from the reinsurance and risk adjustment programs will become available for payment to issuers in fiscal year 2017 without further Congressional action. If the Congress does not enact deficit reduction provisions that replace the Joint Committee reductions, these programs will be sequestered in future fiscal years, and any sequestered funding will become available in the fiscal year following the one in which it was sequestered.

Comment: One commenter stated that risk adjustment payments should not be subject to sequestration because the risk adjustment program is budget neutral and the Federal government is simply transferring funds among issuers.

Response: The BBEDCA requires all non-exempt budgetary resources be sequestered in amounts sufficient to achieve the savings targets established in the Budget Control Act of 2011. Risk adjustment payments are subject to sequestration as they are budgetary resources provided for by Federal law, and the risk adjustment program is not specifically exempted under section 255 of the BBEDCA. Therefore, as clarified in the OMB Report to Congress on the Joint Committee Reductions for Fiscal Year 2016, the risk adjustment program is subject to sequestration. Under section 256(k)(6) of the BBEDCA and the underlying authority for these programs, funds that are sequestered in fiscal year 2016 from the reinsurance and risk adjustment programs will become available for payment to issuers in fiscal year 2017 without further Congressional action.

2. Provisions and Parameters for the Permanent Risk Adjustment Program

In subparts D and G of 45 CFR part 153, we established standards for the administration of the risk adjustment program. The risk adjustment program is a permanent program created by section 1343 of the Affordable Care Act that transfers funds from lower risk, non-grandfathered plans to higher risk, non-grandfathered plans in the individual and small group markets, inside and outside the Exchanges. In accordance with § 153.310(a), 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.

On January 8, 2016, we announced that HHS will hold a public conference to discuss potential improvements to the HHS risk adjustment methodology for the 2018 benefit year and beyond. The conference will take place on March 31, 2016, in the Grand Auditorium at the Centers for Medicare and Medicaid Services in Baltimore, Maryland.[10] Prior to the conference, we intend to issue a White Paper that will be open for public comment. The conference and White Paper will focus on what we have learned from the 2014 benefit year of the risk adjustment program, and specific areas of potential refinements to the methodology, including prescription drug model exploration, accounting for partial year enrollment, future recalibrations using risk adjustment data, and discussion of the risk adjustment transfer formula. Registration for the conference opened on January 25, 2016, and is available at *https://www.regtap.info/* until March 23, 2016, for onsite attendance registration, and March 28, 2016, for remote attendance registration. Stakeholders who are unable to attend

[9] Office of Management and Budget, OMB Report to the Congress on the Joint Committee Reductions for Fiscal Year 2016 (Feb. 2, 2015), available at *https://www.whitehouse.gov/sites/default/files/omb/assets/legislative_reports/sequestration/2016_jc_sequestration_report_speaker.pdf.*

[10] HHS-Operated Risk Adjustment Methodology Meeting; March 31, 2016, 81 FR 4633 (Jan. 27, 2016).

the conference in person may live stream the conference and provide feedback via the webinar. Additional information can be found at *https://www.regtap.info/RAonsite.php.*

a. Overview of the HHS Risk Adjustment Model (§ 153.320)

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 of the inputs into the risk adjustment payment transfer formula, which determines the payment or charge that an issuer will receive or be required to pay for that plan. Thus, the HHS risk adjustment model predicts 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.

We received several general comments regarding the HHS risk adjustment methodology.

Comment: Many commenters reiterated their support for the HHS risk adjustment methodology. Some commenters requested a cap on risk adjustment transfers. Some commenters also suggested that, under our methodology, low-cost and low-risk-score issuers subsidize higher cost issuers, and that the model has adverse effects on limited network plans and new, small, and fast-growing plans. Commenters requested exempting new, small, and fast-growing plans from risk adjustment for the first 3 to 5 plan years, in recognition of the difficulty they are having in obtaining complete hierarchical condition categories (HCC) diagnostic classifications for their enrollees. Commenters also suggested gradually phasing in new issuers to risk adjustment or instituting a credibility threshold for participation. One commenter requested that issuers with fewer than 5,000 enrollees or less than 5 percent market share be exempt from risk adjustment. Two commenters requested that HHS set a cap on risk adjustment transfers based on MLR when the amount of the transfer causes the issuer's MLR to hit 90 percent. Specifically, the commenters requested excluding issuers with an MLR of 90 percent or greater, and capping an issuer's risk adjustment payment once it causes the issuer's MLR to rise to 90 percent.

Response: We agree that the risk adjustment program is intended to work with the fair rating rules under the Affordable Care Act to reimburse issuers who take on riskier enrollees, not to prevent issuers, including small and fast-growing issuers, from participating in the individual and small group markets. In this final rule, we are finalizing more accurate model coefficients for 2017 benefit year risk adjustment. We will discuss in the upcoming White Paper potential future improvements to the HHS risk adjustment methodology that we believe will continue to improve the accuracy of the model and benefit all consumers and issuers in these markets by helping ensure fair rating practices across those risk pools because issuers will have the expectation of accurate risk adjustment payments. Any changes we make to the HHS risk adjustment methodology would be implemented through rulemaking as necessary.

Comment: One commenter requested that HHS verify that plans that are subject to risk adjustment data validation (RADV) are correctly implementing the definition of small group, suggesting that eligibility can be verified with an employer's wage and tax statements.

Response: We will consider ways to enhance the RADV audits in operationally feasible ways without infringing on the States' primary regulatory and oversight authority over health insurance issuers.

Comment: One commenter recommended that HHS advance its schedule for publishing the proposed Notice of Benefit and Payment Parameters to early fall, and requested that HHS provide a 60-day comment period to allow for more detailed and substantive comments on major proposed changes to the risk adjustment model.

Response: We are exploring our flexibility in moving the Payment Notice schedule to an earlier timeframe.

b. Proposed Updates to the Risk Adjustment Model (§ 153.320)

In the proposed rule, we proposed to continue to use the same risk adjustment methodology finalized in the 2014 Payment Notice. We proposed to make certain updates to the risk adjustment model to incorporate preventive services into our simulation of plan liability, and to reflect more current data. The proposed data updates are similar to the ones we effectuated for 2016 risk adjustment in the 2016 Payment Notice. We proposed to recalculate the weights assigned to the various hierarchical condition categories and demographic factors in our risk adjustment models using the most recent data available. As we previously described, 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 attributable to 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 proposed to recalibrate the HHS risk adjustment models for 2017 by using more recent claims data to develop updated risk factors. The risk factors published in the proposed 2017 Payment Notice were developed using the Truven Health Analytics 2012 and 2013 MarketScan® Commercial Claims and Encounters database (MarketScan); we proposed to update the risk factors in the HHS risk adjustment model using 2012, 2013, and 2014 MarketScan data in the final 2017 Payment Notice when 2014 MarketScan became available. In using 2012, 2013, and 2014 MarketScan data, we blend, or average, the resulting coefficients from the separately solved models from each dataset. We do not weight one year more heavily than the others.

We stated that we believe we can more accurately account for high-cost conditions with new treatments that are not reflected in our model due to lags in the data available to us for recalibration. We believe that stability across our models is important, but sought comment and data that may inform better methods of accurately compensating for new treatments for high cost conditions. For example, we

sought comment on whether there are ways to model the severity of these conditions in a manner that will more fully capture the highest cost enrollees.

Comment: One commenter requested that HHS incorporate 2014 and 2015 data for the individual and small group populations subject to risk adjustment, giving issuers notice of this incorporation no later than December 2016, so that they can determine and file plan year 2018 rates with each State.

Response: Under our current distributed data collection approach, we do not have access to enrollee-level data, which is necessary for risk adjustment recalibration. However, we intend to discuss incorporating enrollee-level data in future recalibrations in the upcoming White Paper, which will be published for public comment.

Comment: Commenters stated that risk adjustment coefficients are too low for enrollees without HCCs and too high for those with one or more HCCs. One commenter recommended that the adult and child models be calculated regionally or specifically for each State. One commenter encouraged HHS to include socioeconomic status and oral health services in the model, especially the child model.

Response: We have attempted to address the range between enrollees without HCCs and those with HCCs by finalizing the incorporation of preventive services into our simulation of plan liability. While overall this is not a very large effect, it does have a noticeable effect on certain demographic subgroups, resulting in more accurate payments for enrollees without HCCs. As for calculating the adult and child models regionally or by State, we believe that the use of the geographic cost factor (GCF) in the payment transfer formula should reflect prevailing utilization and expenditure patterns in the geographic location of the plan's enrollees. We intend to explore whether accounting for socioeconomic status is feasible in the risk adjustment model in the future.

Comment: All commenters on this section of the proposed rule supported HHS's efforts to make the risk adjustment models more accurate by addressing the lag in available health claims data. Many commenters also supported various approaches in more accurately addressing high-cost conditions, which are particularly susceptible to the lag in health claims costs because of the rapidly rising costs of certain specialty drugs. One commenter opposed the use of 2014 data unless the updated model is provided in time to be used for 2017 rate filings. Conversely, another commenter recommended HHS use 2013, 2014, and 2015 MarketScan data for 2017 risk adjustment, and 2014, 2015, and 2016 MarketScan data for 2018 risk adjustment, stating that HHS should finalize the process and methodology in each year's Payment Notice and release the updated factors later. A commenter acknowledged that the incorporation of new 2014 data in the calibration of the risk weights helps address new high-cost treatments, but that under the current model, the benefits of the modification are limited because the use of 3-year averaging means it will take 3 years for the risk weights to fully reflect changes in treatment patterns. Commenters recommended that HHS consider whether individual market data might show different relative weights for certain high-cost conditions than the population currently used for the risk adjustment calibration. Commenters also recommended that HHS evaluate the increase in costs for chronic conditions (specifically Hepatitis C, for which expensive prescription drug therapies have become recently available) year over year and trend or adjust the aggregated claims data or model to reflect the changes—this would allow HHS to respond to changes in treatment practices without relying on additional external data. One commenter recommended that more weight and credibility should be given to the most recent data to best capture emerging trends in treatments, drug therapies, and costs.

Response: We agree with commenters that there may be more precise ways to trend expenditures to accommodate the data lag and more accurately reflect the introduction of new treatments, including prescription drug therapies, for high cost conditions. Based on commenters' feedback on the need to better model the risk of high-cost conditions and rapidly changing health care costs, we re-examined the underlying trend factor we used to trend medical and prescription drug expenditures in the MarketScan data, because those expenditures account for a large portion of the recent changes in costs to treat high-cost conditions. Because we were using the same trend for both sets of expenditures, we looked at historical MarketScan drug data, subdivided by traditional (including branded and generic) drugs, specialty drugs, and medical and surgical expenditures, and found varying growth rates. In order to address commenters' feedback, we consulted with actuaries and industry reports to derive a specialty drug trend rate and traditional drug trend rate through 2017. We believe that using these more granular trend rates better reflect the growth in specialty drug expenditures and drugs generally as compared to medical and surgical expenditures. Further, we believe that more accurately trending drug expenditures through 2017 will more accurately compensate issuers providing new treatments associated with specific HCCs by providing a more finely tuned estimate of the relative costs of various conditions under the HHS risk adjustment methodology. We have incorporated different trend factors for (i) traditional drugs, (ii) specialty drugs, and (iii) medical and surgical expenditures, and are finalizing this approach for 2017 risk adjustment. This approach is reflected in the finalized coefficients in this final rule.

We proposed to incorporate preventive services into our simulation of plan liability in the recalibration of the risk adjustment models for 2017. We identified preventive services for the 2012, 2013, and 2014 MarketScan samples using procedure and diagnosis codes, prescription drug therapeutic classes, and enrollee age and sex. We relied on lists of preventive services from several major issuers, the preventive services used for the AV Calculator, and Medicare's preventive services benefit to operationalize preventive services definitions for incorporation in the risk adjustment models. We then adjusted plan liability by adding 100 percent of preventive services covered charges to simulate plan liability for all metal levels. We also applied standard benefit cost sharing rules by metal level to covered charges for non-preventive services. Total adjusted simulated plan liability is the sum of preventive services covered charges, and non-preventive services simulated plan liability.

We re-estimated the risk adjustment models by metal level, predicting plan liability adjusted to account for preventive services without cost sharing. We compared the model coefficients predicting original (that is, non-adjusted for preventive services) and adjusted simulated plan liability. Adjusting for preventive services increases age-sex coefficients relative to HCC coefficients, especially in the lower metal tiers (bronze and silver), and in age/sex ranges with high preventive services expenditures (for example, young adult females). The implication of the changes to the model coefficients is that the risk scores of healthy enrollees (whose risk scores are based solely on model age-sex coefficients) will likely rise relative to the risk scores of the less healthy (whose risk scores

include one or more HCC coefficients in addition to an age-sex coefficient), especially in bronze and silver plans. As a result of the risk score changes for individuals, we expect that the incorporation of preventive services will increase the risk scores of bronze and silver plans with healthier enrollees relative to other plans' risk scores when preventive services are taken into account. This incorporation of preventive services will more accurately compensate risk adjustment covered plans with enrollees who use preventive services.

Comment: Most commenters supported the incorporation of preventive services into our simulation of plan liability in the risk adjustment model. Two commenters expressed concern that this change would unintentionally create an incentive for issuers to attract and retain healthier individuals rather than higher risk individuals, while another commenter supported including preventive services, but suggested that the approach proposed by HHS appears to compensate all plans, regardless of whether their members receive preventive services, thereby creating a ''free rider'' problem. One commenter noted that while the incorporation of preventive services does increase demographic factors for catastrophic plans and for females within bronze plans, the impact of this change is relatively small and does not resolve concerns about unbalanced incentives to attract enrollees with HCC diagnoses.

Response: Section 2713 of the PHS Act, as added by the Affordable Care Act requires that individual and small group non-grandfathered plans (among others) provide coverage for a range of preventive services and may not impose cost sharing on patients receiving these services. We believe it is essential that we are consistent with the goals of the Affordable Care Act and provide compensation to issuers who are required to provide these services without cost sharing. As such, we also believe that accurately accounting for services provided by issuers to healthier enrollees is a fair adjustment to real, baseline costs paid by these issuers. As for concerns about a ''free rider'' problem, all risk adjustment covered plans are required to provide zero cost sharing preventive services. Even if different enrollees use preventive services to different extents, by incorporating zero cost sharing preventive services in the calculation of plan liability when calibrating the models' coefficients, we will increase the accuracy of the model overall, accounting for any differential use of preventive services at the plan level. We believe that this increased accuracy for demographic factors coupled with our adjustments to medical and prescription drug expenditures will promote increased accuracy for all enrollees, with and without HCCs. We are finalizing the incorporation of preventive services into our simulation of plan liability as proposed.

Additionally, we are evaluating whether and how we may incorporate prescription drug data in the Federally certified risk adjustment methodology that HHS uses when it operates risk adjustment. Prescription drug data could be used in the risk adjustment methodology to supplement diagnostic data by using the prescription drug data as a severity indicator, or as a proxy for diagnoses in cases where diagnostic data are likely to be incomplete. We are assessing these approaches, with particular sensitivity to reliability and the potential for strategic behavior with respect to prescribing behavior. As we noted in the 2014 Payment Notice, we did not use prescription drug utilization as a predictor of expenditures to avoid creating adverse incentives to modify discretionary prescribing. We are evaluating whether we can improve the models' predictive power through the incorporation of prescription drugs without unduly incentivizing altered prescribing behavior. We sought comment and any data that could inform effective methods of incorporating prescription drug data in future recalibrations.

Comment: Most commenters supported incorporating prescription drugs as predictors in the risk adjustment model either as a proxy for missing diagnoses or an indicator of severity. Some commenters shared HHS's concerns about creating incentives to modify discretionary prescribing to artificially increase the severity of diagnoses and one commenter expressed concern about keeping the model current with pharmaceutical developments that could create an additional operational burden for both health plans and HHS. Some commenters suggested that prescription drugs be included for 2017 risk adjustment. One commenter requested that HHS incorporate prescription drugs as soon as possible. Commenters supported 2018 implementation (rather than 2017) and one commenter suggested that any changes to include prescription drugs should include greater detail and go through the regular notice and comment process. Commenters suggested that HHS include prescription drug data in a limited manner, such as drugs with no off label use or drugs approved for treatment of a single condition. One commenter recommended that all prescription drugs used to treat HCC conditions be included. Commenters stated that including prescription drugs could significantly increase payment accuracy and yield benefits to the payment system far in excess of any additional administrative burden. Commenters further stated that prescription drug claims data have certain advantages in that the data are fairly uniform across plans and do not have many of the issues associated with diagnosis data, such as timeliness and inconsistency of reporting across providers, in addition to already being included in EDGE Server data and readily available to HHS. Commenters also stated that including prescription drugs as a proxy for missing diagnoses could level the playing field for smaller issuers that are less experienced with medical coding. Similarly, commenters supported the inclusion of pharmacy data to address partial year enrollees with chronic conditions that have prescription drug claims, but may not have a provider encounter with a documented diagnosis. One commenter requested that HHS work with stakeholders to refine the prescription drug data that would be utilized if this proposal is finalized and requested that HHS consider how to gather and incorporate data on prescription drug utilization collected by electronic health records. Commenters cautioned HHS to be mindful that different characteristics of prescription drug utilization will be more or less predictive depending on the condition. Commenters also warned that gaming concerns need to be balanced with the desire to enhance the risk adjustment methodology's predictive power. A commenter also cautioned that the proposed use of prescription drug data should have definitions and guardrails that delineate its use. Lastly, commenters stated that using prescription drug data is important because without an accurate risk adjustment methodology that accounts for the extra costs that plans incur by enrolling high-risk patients, plans have an incentive to design benefits in a manner that discourages enrollment by these patients.

Response: We will explore the incorporation of prescription drugs in the risk adjustment model in the White Paper and at the conference in March 2016. We agree with commenters that prescription drugs have the potential to increase the predictive power of the risk adjustment models. We agree that different prescription drugs will likely

be more or less predictive depending on the condition. We also remain cautious about creating incentives to modify discretionary prescribing to artificially increase the severity of diagnoses. However, we look forward to continuing to explore this potential improvement to the models with stakeholders and to share our developments in the White Paper and at the risk adjustment conference on March 31, 2016.

Lastly, we stated in the proposed rule that we would like to explore the effect of partial year enrollment in the HHS risk adjustment methodology. We have received input that issuers are experiencing higher than expected claims costs for partial year enrollees. We have also received input that the methodology does not capture enrollees with chronic conditions who may not have accumulated diagnoses in their partial year enrollment. At the same time, as compared to full year enrollees of the same relative risk, partial year enrollees are less likely to have spending that exceeds the deductible or annual limitation on cost sharing. We sought comment on how the methodology could be made more predictive for partial year enrollees.

Comment: Many commenters supported addressing partial year enrollees in the model. One commenter noted that many medical events for enrollees in the commercial market (for example, maternity, surgeries) represent acute rather than chronic events, so the enrollee can incur most of their annual medical expenses during a short period of time. Commenters suggested that the use of prescription drug claims could help address enrollees with a chronic condition but who do not have a provider encounter with a documented diagnosis. Commenters also suggested that the impact of partial year enrollment could be measured by taking a population that had multiple years of enrollment and comparing risk scores and health care costs when only a partial year is considered. Commenters noted Massachusetts' adjustment for partial-year enrollment, and suggested that HHS consider additional analysis to determine whether that approach is appropriate for the HHS risk adjustment methodology. One commenter suggested a member-level adjustment while another commenter suggested a duration-based adjustment. Another commenter recommended that the adjustment vary by metal level and length of time enrolled, with higher weights for gold and platinum plans and shorter enrollment periods. One commenter suggested that HHS should permit risk scores to travel with an enrollee across issuers. Two commenters opposed an explicit adjustment for partial year enrollees, because they said such an adjustment would accommodate liberal enforcement of special enrollment periods, incentivizing issuers to employ loose eligibility standards to gain members, but ultimately eroding individual market stability. A few commenters recommended that to better address partial year enrollment in risk adjustment, changes should be made to special enrollment period processes and policies to encourage continuous coverage and prevent fraud and abuse. Commenters stated that unverified special enrollment periods have produced selection issues for health plans, as enrollees enter through a special enrollment period, utilize high-cost services, and then switch to a lower metal level plan in the following open enrollment period or drop coverage altogether. One commenter cautioned that any additions to the model to account for partial year enrollment should improve reliability and predictive power, not influence clinical judgment or plan behavior with respect to enrollees' coverage.

Response: We appreciate commenters' substantive feedback on accounting for partial year enrollment in future recalibrations and will continue to analyze this issue and include our findings in the White Paper for discussion at the March 31, 2016 risk adjustment conference.

c. List of Factors To Be Employed in the Model (§ 153.320)

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 factors resulting from the blended factors from the 2012, 2013, and 2014 separately solved models (with the incorporation of preventive services, and with different trend rates for medical and surgical expenditures, for traditional prescription drug expenditures, and for specialty prescription drug expenditures) 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 2 contains the HHS HCCs in the severity illness indicator variable. Table 3 contains the factors for each child model. Table 4 contains the factors for each infant model. We are finalizing these factors, with the adjustment for the differing medical and traditional and specialty prescription drug trend factors incorporated in the 2012, 2013, and 2014 blended coefficients.

TABLE 1—ADULT RISK ADJUSTMENT MODEL FACTORS

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors					
Age 21–24, Male	0.236	0.180	0.119	0.082	0.081
Age 25–29, Male	0.246	0.186	0.122	0.083	0.082
Age 30–34, Male	0.287	0.216	0.138	0.089	0.088
Age 35–39, Male	0.346	0.264	0.172	0.112	0.111
Age 40–44, Male	0.420	0.326	0.221	0.151	0.149
Age 45–49, Male	0.496	0.392	0.273	0.192	0.191
Age 50–54, Male	0.633	0.512	0.372	0.275	0.274
Age 55–59, Male	0.722	0.585	0.429	0.320	0.318
Age 60–64, Male	0.843	0.683	0.502	0.372	0.369
Age 21–24, Female	0.379	0.296	0.200	0.138	0.137
Age 25–29, Female	0.460	0.359	0.247	0.173	0.172

TABLE 1—ADULT RISK ADJUSTMENT MODEL FACTORS—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Age 30–34, Female	0.582	0.466	0.337	0.254	0.252
Age 35–39, Female	0.668	0.542	0.405	0.318	0.316
Age 40–44, Female	0.742	0.604	0.455	0.357	0.355
Age 45–49, Female	0.750	0.608	0.450	0.344	0.342
Age 50–54, Female	0.845	0.691	0.518	0.398	0.395
Age 55–59, Female	0.849	0.690	0.510	0.380	0.378
Age 60–64, Female	0.909	0.734	0.537	0.395	0.392
Diagnosis Factors					
HIV/AIDS	8.942	8.450	8.099	8.142	8.143
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	10.686	10.511	10.405	10.461	10.462
Central Nervous System Infections, Except Viral Meningitis	6.632	6.532	6.468	6.489	6.489
Viral or Unspecified Meningitis	4.657	4.422	4.263	4.222	4.222
Opportunistic Infections	8.503	8.404	8.337	8.319	8.319
Metastatic Cancer	24.314	23.880	23.578	23.637	23.638
Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	12.630	12.296	12.062	12.066	12.066
Non-Hodgkin's Lymphomas and Other Cancers and Tumors	5.845	5.611	5.435	5.388	5.387
Colorectal, Breast (Age < 50), Kidney, and Other Cancers	5.152	4.918	4.738	4.690	4.689
Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors	2.957	2.786	2.650	2.597	2.596
Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors	1.448	1.295	1.160	1.069	1.067
Pancreas Transplant Status/Complications	5.455	5.233	5.091	5.112	5.114
Diabetes with Acute Complications	1.187	1.049	0.925	0.822	0.820
Diabetes with Chronic Complications	1.187	1.049	0.925	0.822	0.820
Diabetes without Complication	1.187	1.049	0.925	0.822	0.820
Protein-Calorie Malnutrition	13.686	13.693	13.702	13.762	13.763
Mucopolysaccharidosis	2.277	2.159	2.061	2.008	2.007
Lipidoses and Glycogenosis	2.277	2.159	2.061	2.008	2.007
Amyloidosis, Porphyria, and Other Metabolic Disorders	2.277	2.159	2.061	2.008	2.007
Adrenal, Pituitary, and Other Significant Endocrine Disorders	2.277	2.159	2.061	2.008	2.007
Liver Transplant Status/Complications	16.042	15.868	15.759	15.771	15.772
End-Stage Liver Disease	7.119	6.877	6.718	6.736	6.737
Cirrhosis of Liver	3.852	3.690	3.569	3.535	3.535
Chronic Hepatitis	3.852	3.690	3.569	3.535	3.535
Acute Liver Failure/Disease, Including Neonatal Hepatitis	4.430	4.269	4.158	4.148	4.148
Intestine Transplant Status/Complications	32.604	32.555	32.516	32.559	32.559
Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	11.820	11.561	11.383	11.413	11.413
Intestinal Obstruction	6.537	6.272	6.101	6.120	6.121
Chronic Pancreatitis	5.455	5.233	5.091	5.112	5.114
Acute Pancreatitis/Other Pancreatic Disorders and Intestinal Malabsorption	2.702	2.515	2.379	2.331	2.331
Inflammatory Bowel Disease	3.657	3.392	3.190	3.098	3.096
Necrotizing Fasciitis	6.576	6.378	6.239	6.254	6.255
Bone/Joint/Muscle Infections/Necrosis	6.576	6.378	6.239	6.254	6.255
Rheumatoid Arthritis and Specified Autoimmune Disorders	4.848	4.587	4.394	4.385	4.385
Systemic Lupus Erythematosus and Other Autoimmune Disorders	1.205	1.070	0.952	0.868	0.867
Osteogenesis Imperfecta and Other Osteodystrophies	3.115	2.917	2.758	2.699	2.697
Congenital/Developmental Skeletal and Connective Tissue Disorders	3.115	2.917	2.758	2.699	2.697
Cleft Lip/Cleft Palate	1.295	1.137	1.010	0.942	0.941
Hemophilia	46.436	46.150	45.931	45.939	45.939
Myelodysplastic Syndromes and Myelofibrosis	12.671	12.534	12.440	12.448	12.449
Aplastic Anemia	12.671	12.534	12.440	12.448	12.449
Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	9.737	9.576	9.454	9.445	9.445
Sickle Cell Anemia (Hb-SS)	9.737	9.576	9.454	9.445	9.445
Thalassemia Major	9.737	9.576	9.454	9.445	9.445
Combined and Other Severe Immunodeficiencies	5.432	5.284	5.182	5.183	5.183
Disorders of the Immune Mechanism	5.432	5.284	5.182	5.183	5.183
Coagulation Defects and Other Specified Hematological Disorders	2.805	2.707	2.628	2.599	2.599
Drug Psychosis	3.830	3.574	3.380	3.286	3.284
Drug Dependence	3.830	3.574	3.380	3.286	3.284

TABLE 1—ADULT RISK ADJUSTMENT MODEL FACTORS—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Schizophrenia	3.189	2.934	2.744	2.680	2.679
Major Depressive and Bipolar Disorders	1.714	1.547	1.404	1.308	1.307
Reactive and Unspecified Psychosis, Delusional Disorders	1.714	1.547	1.404	1.308	1.307
Personality Disorders	1.176	1.043	0.910	0.814	0.812
Anorexia/Bulimia Nervosa	2.693	2.527	2.392	2.334	2.333
Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	2.632	2.504	2.403	2.354	2.353
Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes	1.056	0.951	0.849	0.778	0.776
Autistic Disorder	1.176	1.043	0.910	0.814	0.812
Pervasive Developmental Disorders, Except Autistic Disorder	1.176	1.043	0.910	0.814	0.812
Traumatic Complete Lesion Cervical Spinal Cord	12.005	11.851	11.737	11.735	11.735
Quadriplegia	12.005	11.851	11.737	11.735	11.735
Traumatic Complete Lesion Dorsal Spinal Cord	9.157	9.000	8.886	8.874	8.875
Paraplegia	9.157	9.000	8.886	8.874	8.875
Spinal Cord Disorders/Injuries	5.635	5.424	5.275	5.246	5.246
Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	3.029	2.792	2.625	2.585	2.585
Quadriplegic Cerebral Palsy	1.206	0.997	0.839	0.777	0.776
Cerebral Palsy, Except Quadriplegic	0.124	0.068	0.034	0.011	0.011
Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies	0.071	0.019	0.000	0.000	0.000
Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	5.247	5.099	4.994	4.971	4.971
Muscular Dystrophy	2.147	1.981	1.860	1.785	1.784
Multiple Sclerosis	13.590	13.187	12.905	12.950	12.951
Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders	2.147	1.981	1.860	1.785	1.784
Seizure Disorders and Convulsions	1.495	1.337	1.207	1.137	1.136
Hydrocephalus	6.388	6.266	6.165	6.139	6.138
Non-Traumatic Coma, and Brain Compression/Anoxic Damage	9.207	9.070	8.964	8.958	8.957
Respirator Dependence/Tracheostomy Status	34.719	34.708	34.706	34.772	34.773
Respiratory Arrest	10.554	10.403	10.306	10.370	10.371
Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes	10.554	10.403	10.306	10.370	10.371
Heart Assistive Device/Artificial Heart	35.114	34.869	34.711	34.771	34.772
Heart Transplant	35.114	34.869	34.711	34.771	34.772
Congestive Heart Failure	3.280	3.171	3.095	3.089	3.089
Acute Myocardial Infarction	10.129	9.795	9.580	9.691	9.693
Unstable Angina and Other Acute Ischemic Heart Disease	5.227	4.952	4.779	4.793	4.794
Heart Infection/Inflammation, Except Rheumatic	6.297	6.163	6.063	6.042	6.041
Specified Heart Arrhythmias	2.829	2.681	2.565	2.512	2.511
Intracranial Hemorrhage	9.423	9.144	8.954	8.963	8.964
Ischemic or Unspecified Stroke	3.167	2.982	2.869	2.875	2.876
Cerebral Aneurysm and Arteriovenous Malformation	3.940	3.742	3.600	3.559	3.558
Hemiplegia/Hemiparesis	5.468	5.374	5.317	5.360	5.361
Monoplegia, Other Paralytic Syndromes	3.452	3.319	3.226	3.207	3.207
Atherosclerosis of the Extremities with Ulceration or Gangrene	10.940	10.840	10.784	10.853	10.854
Vascular Disease with Complications	7.727	7.543	7.416	7.417	7.417
Pulmonary Embolism and Deep Vein Thrombosis	3.841	3.675	3.555	3.529	3.529
Lung Transplant Status/Complications	36.419	36.227	36.103	36.180	36.181
Cystic Fibrosis	18.011	17.687	17.444	17.467	17.467
Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	0.942	0.825	0.717	0.641	0.640
Asthma	0.942	0.825	0.717	0.641	0.640
Fibrosis of Lung and Other Lung Disorders	1.889	1.771	1.682	1.641	1.640
Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	7.594	7.520	7.471	7.485	7.485
Kidney Transplant Status	10.183	9.919	9.744	9.735	9.735
End Stage Renal Disease	38.463	38.228	38.078	38.198	38.201
Chronic Kidney Disease, Stage 5	2.088	1.989	1.925	1.920	1.920
Chronic Kidney Disease, Severe (Stage 4)	2.088	1.989	1.925	1.920	1.920
Ectopic and Molar Pregnancy, Except with Renal Failure, Shock, or Embolism	1.340	1.156	0.979	0.795	0.791
Miscarriage with Complications	1.340	1.156	0.979	0.795	0.791
Miscarriage with No or Minor Complications	1.340	1.156	0.979	0.795	0.791
Completed Pregnancy With Major Complications	3.630	3.150	2.862	2.712	2.713
Completed Pregnancy With Complications	3.630	3.150	2.862	2.712	2.713
Completed Pregnancy with No or Minor Complications	3.630	3.150	2.862	2.712	2.713

TABLE 1—ADULT RISK ADJUSTMENT MODEL FACTORS—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Chronic Ulcer of Skin, Except Pressure	2.356	2.233	2.150	2.134	2.134
Hip Fractures and Pathological Vertebral or Humerus Fractures	9.460	9.245	9.100	9.136	9.136
Pathological Fractures, Except of Vertebrae, Hip, or Humerus	2.000	1.871	1.758	1.688	1.687
Stem Cell, Including Bone Marrow, Transplant Status/Complications	31.027	31.022	31.017	31.035	31.036
Artificial Openings for Feeding or Elimination	10.038	9.946	9.886	9.924	9.925
Amputation Status, Lower Limb/Amputation Complications	5.263	5.112	5.015	5.044	5.045
Interaction Factors					
Severe illness x Opportunistic Infections	10.408	10.632	10.799	10.894	10.895
Severe illness x Metastatic Cancer	10.408	10.632	10.799	10.894	10.895
Severe illness x Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	10.408	10.632	10.799	10.894	10.895
Severe illness x Non-Hodgkin's Lymphomas and Other Cancers and Tumors	10.408	10.632	10.799	10.894	10.895
Severe illness x Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	10.408	10.632	10.799	10.894	10.895
Severe illness x Heart Infection/Inflammation, Except Rheumatic	10.408	10.632	10.799	10.894	10.895
Severe illness x Intracranial Hemorrhage	10.408	10.632	10.799	10.894	10.895
Severe illness x HCC group G06 (G06 is HCC Group 6 which includes the following HCCs in the blood disease category: 67, 68)	10.408	10.632	10.799	10.894	10.895
Severe illness x HCC group G08 (G08 is HCC Group 8 which includes the following HCCs in the blood disease category: 73, 74)	10.408	10.632	10.799	10.894	10.895
Severe illness x End-Stage Liver Disease	1.906	2.039	2.141	2.225	2.226
Severe illness x Acute Liver Failure/Disease, Including Neonatal Hepatitis	1.906	2.039	2.141	2.225	2.226
Severe illness x Atherosclerosis of the Extremities with Ulceration or Gangrene	1.906	2.039	2.141	2.225	2.226
Severe illness x Vascular Disease with Complications	1.906	2.039	2.141	2.225	2.226
Severe illness x Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	1.906	2.039	2.141	2.225	2.226
Severe illness x Artificial Openings for Feeding or Elimination	1.906	2.039	2.141	2.225	2.226
Severe illness x HCC group G03 (G03 is HCC Group 3 which includes the following HCCs in the musculoskeletal disease category: 54, 55)	1.906	2.039	2.141	2.225	2.226

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	0.224	0.145	0.067	0.021	0.020
Age 5–9, Male	0.155	0.098	0.038	0.004	0.004
Age 10–14, Male	0.220	0.158	0.089	0.053	0.053
Age 15–20, Male	0.290	0.219	0.142	0.097	0.096
Age 2–4, Female	0.178	0.109	0.044	0.011	0.010
Age 5–9, Female	0.127	0.076	0.027	0.003	0.002
Age 10–14, Female	0.204	0.145	0.085	0.054	0.054

TABLE 3—CHILD RISK ADJUSTMENT MODEL FACTORS—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Age 15–20, Female	0.330	0.248	0.157	0.101	0.100
Diagnosis Factors					
HIV/AIDS	4.875	4.437	4.110	4.033	4.032
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	17.228	17.069	16.969	16.994	16.995
Central Nervous System Infections, Except Viral Meningitis	10.808	10.631	10.506	10.511	10.511
Viral or Unspecified Meningitis	3.128	2.925	2.775	2.687	2.686
Opportunistic Infections	22.943	22.880	22.834	22.825	22.825
Metastatic Cancer	36.648	36.404	36.207	36.207	36.207
Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	12.117	11.833	11.604	11.547	11.546
Non-Hodgkin's Lymphomas and Other Cancers and Tumors	9.328	9.058	8.836	8.754	8.753
Colorectal, Breast (Age <50), Kidney, and Other Cancers	3.508	3.291	3.097	2.989	2.987
Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors	3.016	2.816	2.642	2.538	2.537
Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors	1.723	1.553	1.397	1.294	1.292
Pancreas Transplant Status/Complications	30.468	30.333	30.245	30.256	30.256
Diabetes with Acute Complications	2.521	2.197	1.946	1.703	1.699
Diabetes with Chronic Complications	2.521	2.197	1.946	1.703	1.699
Diabetes without Complication	2.521	2.197	1.946	1.703	1.699
Protein-Calorie Malnutrition	13.570	13.484	13.421	13.450	13.450
Mucopolysaccharidosis	8.509	8.238	8.020	7.987	7.986
Lipidoses and Glycogenosis	8.509	8.238	8.020	7.987	7.986
Congenital Metabolic Disorders, Not Elsewhere Classified	8.509	8.238	8.020	7.987	7.986
Amyloidosis, Porphyria, and Other Metabolic Disorders	8.509	8.238	8.020	7.987	7.986
Adrenal, Pituitary, and Other Significant Endocrine Disorders	8.509	8.238	8.020	7.987	7.986
Liver Transplant Status/Complications	30.468	30.333	30.245	30.256	30.256
End-Stage Liver Disease	13.077	12.927	12.822	12.821	12.821
Cirrhosis of Liver	9.604	9.445	9.326	9.286	9.286
Chronic Hepatitis	2.567	2.418	2.280	2.216	2.215
Acute Liver Failure/Disease, Including Neonatal Hepatitis	12.729	12.576	12.460	12.447	12.447
Intestine Transplant Status/Complications	30.468	30.333	30.245	30.256	30.256
Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	14.795	14.463	14.217	14.238	14.238
Intestinal Obstruction	5.389	5.155	4.965	4.885	4.884
Chronic Pancreatitis	9.713	9.478	9.319	9.319	9.319
Acute Pancreatitis/Other Pancreatic Disorders and Intestinal Malabsorption	2.561	2.426	2.303	2.217	2.216
Inflammatory Bowel Disease	6.321	5.943	5.650	5.553	5.551
Necrotizing Fasciitis	4.467	4.231	4.041	3.989	3.988
Bone/Joint/Muscle Infections/Necrosis	4.467	4.231	4.041	3.989	3.988
Rheumatoid Arthritis and Specified Autoimmune Disorders	3.904	3.662	3.448	3.365	3.364
Systemic Lupus Erythematosus and Other Autoimmune Disorders	1.305	1.154	1.003	0.893	0.891
Osteogenesis Imperfecta and Other Osteodystrophies	1.560	1.429	1.303	1.232	1.231
Congenital/Developmental Skeletal and Connective Tissue Disorders	1.560	1.429	1.303	1.232	1.231
Cleft Lip/Cleft Palate	1.563	1.351	1.172	1.061	1.059
Hemophilia	66.792	66.309	65.939	65.927	65.927
Myelodysplastic Syndromes and Myelofibrosis	15.978	15.807	15.672	15.654	15.654
Aplastic Anemia	15.978	15.807	15.672	15.654	15.654
Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	7.706	7.432	7.214	7.145	7.144
Sickle Cell Anemia (Hb-SS)	7.706	7.432	7.214	7.145	7.144
Thalassemia Major	7.706	7.432	7.214	7.145	7.144
Combined and Other Severe Immunodeficiencies	6.686	6.507	6.364	6.310	6.309
Disorders of the Immune Mechanism	6.686	6.507	6.364	6.310	6.309
Coagulation Defects and Other Specified Hematological Disorders	4.828	4.689	4.560	4.494	4.493
Drug Psychosis	5.390	5.135	4.948	4.887	4.887
Drug Dependence	5.390	5.135	4.948	4.887	4.887
Schizophrenia	5.242	4.853	4.561	4.472	4.471
Major Depressive and Bipolar Disorders	1.913	1.691	1.485	1.334	1.332
Reactive and Unspecified Psychosis, Delusional Disorders	1.913	1.691	1.485	1.334	1.332
Personality Disorders	0.783	0.653	0.504	0.376	0.374
Anorexia/Bulimia Nervosa	2.742	2.539	2.370	2.309	2.308

TABLE 3—CHILD RISK ADJUSTMENT MODEL FACTORS—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	3.362	3.155	3.013	2.980	2.979
Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes	1.787	1.605	1.459	1.378	1.376
Autistic Disorder	1.771	1.577	1.389	1.248	1.246
Pervasive Developmental Disorders, Except Autistic Disorder	0.907	0.766	0.597	0.448	0.445
Traumatic Complete Lesion Cervical Spinal Cord	13.209	13.168	13.154	13.225	13.227
Quadriplegia	13.209	13.168	13.154	13.225	13.227
Traumatic Complete Lesion Dorsal Spinal Cord	11.619	11.410	11.267	11.269	11.270
Paraplegia	11.619	11.410	11.267	11.269	11.270
Spinal Cord Disorders/Injuries	4.847	4.614	4.433	4.359	4.358
Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	8.218	7.979	7.791	7.744	7.744
Quadriplegic Cerebral Palsy	3.387	3.141	2.983	2.995	2.996
Cerebral Palsy, Except Quadriplegic	0.861	0.675	0.530	0.451	0.450
Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies	1.282	1.135	1.010	0.944	0.943
Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	9.635	9.457	9.315	9.279	9.279
Muscular Dystrophy	3.374	3.176	3.021	2.948	2.947
Multiple Sclerosis	8.431	8.101	7.852	7.820	7.820
Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders	3.374	3.176	3.021	2.948	2.947
Seizure Disorders and Convulsions	2.095	1.913	1.735	1.609	1.607
Hydrocephalus	5.122	5.002	4.912	4.903	4.903
Non-Traumatic Coma, and Brain Compression/Anoxic Damage	7.539	7.391	7.276	7.236	7.235
Respirator Dependence/Tracheostomy Status	40.112	40.012	39.969	40.084	40.086
Respiratory Arrest	12.354	12.151	12.015	12.013	12.013
Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes	12.354	12.151	12.015	12.013	12.013
Heart Assistive Device/Artificial Heart	30.468	30.333	30.245	30.256	30.256
Heart Transplant	30.468	30.333	30.245	30.256	30.256
Congestive Heart Failure	6.999	6.888	6.791	6.751	6.751
Acute Myocardial Infarction	9.715	9.553	9.443	9.441	9.442
Unstable Angina and Other Acute Ischemic Heart Disease	6.438	6.331	6.260	6.262	6.262
Heart Infection/Inflammation, Except Rheumatic	16.113	15.984	15.888	15.866	15.866
Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders	6.323	6.111	5.905	5.794	5.792
Major Congenital Heart/Circulatory Disorders	1.778	1.651	1.493	1.391	1.389
Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders	1.202	1.090	0.952	0.872	0.871
Specified Heart Arrhythmias	4.399	4.213	4.049	3.984	3.983
Intracranial Hemorrhage	15.936	15.685	15.510	15.504	15.504
Ischemic or Unspecified Stroke	8.574	8.456	8.381	8.396	8.396
Cerebral Aneurysm and Arteriovenous Malformation	3.865	3.650	3.490	3.433	3.432
Hemiplegia/Hemiparesis	4.815	4.703	4.625	4.610	4.610
Monoplegia, Other Paralytic Syndromes	3.627	3.487	3.391	3.361	3.361
Atherosclerosis of the Extremities with Ulceration or Gangrene	15.571	15.296	15.096	15.012	15.011
Vascular Disease with Complications	18.826	18.672	18.564	18.569	18.569
Pulmonary Embolism and Deep Vein Thrombosis	15.291	15.130	15.023	15.041	15.042
Lung Transplant Status/Complications	30.468	30.333	30.245	30.256	30.256
Cystic Fibrosis	20.415	19.976	19.647	19.686	19.687
Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	0.435	0.348	0.231	0.149	0.147
Asthma	0.435	0.348	0.231	0.149	0.147
Fibrosis of Lung and Other Lung Disorders	4.116	3.973	3.845	3.789	3.788
Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	10.256	10.199	10.157	10.177	10.177
Kidney Transplant Status	16.425	16.083	15.843	15.848	15.848
End Stage Renal Disease	39.805	39.631	39.521	39.592	39.593
Chronic Kidney Disease, Stage 5	7.087	6.923	6.771	6.675	6.673
Chronic Kidney Disease, Severe (Stage 4)	7.087	6.923	6.771	6.675	6.673
Ectopic and Molar Pregnancy, Except with Renal Failure, Shock, or Embolism	1.126	0.939	0.750	0.559	0.555
Miscarriage with Complications	1.126	0.939	0.750	0.559	0.555
Miscarriage with No or Minor Complications	1.126	0.939	0.750	0.559	0.555
Completed Pregnancy With Major Complications	3.159	2.712	2.427	2.240	2.240
Completed Pregnancy With Complications	3.159	2.712	2.427	2.240	2.240

TABLE 3—CHILD RISK ADJUSTMENT MODEL FACTORS—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Completed Pregnancy with No or Minor Complications	3.159	2.712	2.427	2.240	2.240
Chronic Ulcer of Skin, Except Pressure	1.941	1.836	1.731	1.675	1.675
Hip Fractures and Pathological Vertebral or Humerus Fractures	5.725	5.450	5.215	5.124	5.123
Pathological Fractures, Except of Vertebrae, Hip, or Humerus	1.574	1.428	1.264	1.147	1.145
Stem Cell, Including Bone Marrow, Transplant Status/Complications	30.468	30.333	30.245	30.256	30.256
Artificial Openings for Feeding or Elimination	14.575	14.480	14.443	14.551	14.553
Amputation Status, Lower Limb/Amputation Complications	8.195	7.923	7.727	7.631	7.630

TABLE 4—INFANT RISK ADJUSTMENT MODELS FACTORS

Group	Platinum	Gold	Silver	Bronze	Catastrophic
Extremely Immature * Severity Level 5 (Highest)	378.927	377.561	376.491	376.507	376.508
Extremely Immature * Severity Level 4	194.401	193.057	192.003	191.981	191.981
Extremely Immature * Severity Level 3	46.419	45.304	44.390	44.236	44.234
Extremely Immature * Severity Level 2	46.419	45.304	44.390	44.236	44.234
Extremely Immature * Severity Level 1 (Lowest)	46.419	45.304	44.390	44.236	44.234
Immature *Severity Level 5 (Highest)	190.323	189.030	188.013	188.027	188.028
Immature *Severity Level 4	85.852	84.500	83.442	83.437	83.437
Immature *Severity Level 3	46.419	45.304	44.390	44.236	44.234
Immature *Severity Level 2	28.986	27.832	26.907	26.738	26.736
Immature *Severity Level 1 (Lowest)	28.986	27.832	26.907	26.738	26.736
Premature/Multiples * Severity Level 5 (Highest)	156.158	154.846	153.824	153.791	153.791
Premature/Multiples * Severity Level 4	32.573	31.292	30.290	30.173	30.173
Premature/Multiples * Severity Level 3	17.215	16.169	15.315	15.020	15.016
Premature/Multiples * Severity Level 2	8.942	8.081	7.334	6.884	6.876
Premature/Multiples * Severity Level 1 (Lowest)	6.222	5.557	4.867	4.376	4.367
Term *Severity Level 5 (Highest)	130.728	129.499	128.518	128.414	128.413
Term *Severity Level 4	16.874	15.867	15.038	14.685	14.681
Term *Severity Level 3	6.324	5.648	4.969	4.448	4.438
Term *Severity Level 2	3.857	3.319	2.700	2.139	2.128
Term *Severity Level 1 (Lowest)	1.639	1.321	0.772	0.358	0.350
Age1 *Severity Level 5 (Highest)	54.166	53.499	52.963	52.894	52.892
Age1 *Severity Level 4	9.298	8.787	8.351	8.169	8.167
Age1 *Severity Level 3	3.380	3.034	2.676	2.465	2.461
Age1 *Severity Level 2	2.155	1.873	1.549	1.320	1.316
Age1 *Severity Level 1 (Lowest)	0.572	0.441	0.274	0.199	0.197
Age 0 Male	0.685	0.637	0.608	0.554	0.553
Age 1 Male	0.145	0.127	0.106	0.081	0.081

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.

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

Severity Category	HCC
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.
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.

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

Severity Category	HCC
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.

d. Cost-Sharing Reductions Adjustments (§ 153.320)

We proposed to continue including an adjustment for the receipt of cost-sharing reductions in the model to account for increased plan liability due to increased utilization of health care services by enrollees receiving cost-sharing reductions. The proposed cost-sharing reduction adjustment factors for 2017 risk adjustment are unchanged from those finalized in the 2016 Payment Notice and are set forth in Table 7. These adjustments are effective for 2015, 2016, and 2017 risk adjustment, and are multiplied against the sum of the demographic, diagnosis, and interaction factors. We will continue to evaluate this adjustment in future years as more data becomes available.

Comment: One commenter also recommended that HHS consider looking at other elements of adverse selection and induced demand within the individual market that are not currently captured in the risk adjustment model. Another commenter requested that if HHS were to operate risk adjustment in Massachusetts in 2017, HHS should include a cost-sharing reduction adjustment table that will account for the higher AVs of the ''Connector Care'' plans with wrap-around subsidies in Massachusetts.

Response: As we stated in the 2015 Payment Notice, in some States, expansion of Medicaid benefits under section 2001(a) of the Affordable Care Act may take the form of enrolling newly Medicaid-eligible enrollees into individual market plans. These enrollees could be placed into silver plan variations—either the 94 percent silver plan variation or the zero cost sharing plan variation—with a portion of the premiums and cost sharing paid for by Medicaid on their behalf. In Massachusetts, Connector Care plans represent these Medicaid alternative plans in the individual market. To address this induced utilization in the context of cost-sharing reduction plan variations in the HHS risk adjustment methodology, our methodology increases the risk score for individuals in these plan variations by the same factor that we use to adjust for induced utilization for individuals enrolled in cost-sharing plan variations to adjust for induced utilization for individuals enrolled in the corresponding Medicaid alternative plan variations. Here, those factors are both 1.12. We intend to evaluate these adjustments in the future after data from the initial years of risk adjustment is available. We are finalizing the cost-sharing reduction adjustment factors as proposed.

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

e. Model Performance Statistics (§ 153.320)

To evaluate the model's 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.[11] Because we are blending, that is to mean, averaging, the coefficients from separately solved models based on MarketScan 2012, 2013, and 2014 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		
	2012	2013	2014
Platinum Adult	0.3905	0.3790	0.3610
Platinum Child	0.2669	0.2518	0.2341
Platinum Infant	0.2848	0.3223	0.3089
Gold Adult	0.3865	0.3746	0.3558
Gold Child	0.2621	0.2467	0.2288
Gold Infant	0.2826	0.3204	0.3069
Silver Adult	0.3828	0.3707	0.3512
Silver Child	0.2576	0.2422	0.2241
Silver Infant	0.2812	0.3191	0.3054
Bronze Adult	0.3808	0.3686	0.3488
Bronze Child	0.2554	0.2400	0.2218
Bronze Infant	0.2812	0.3190	0.3052
Catastrophic Adult	0.3807	0.3685	0.3488
Catastrophic Child	0.2554	0.2400	0.2218
Catastrophic Infant	0.2812	0.3190	0.3052

f. Overview of the Payment Transfer Formula (§ 153.320)

We did not propose to alter our payment transfer methodology. Plan average risk scores will continue to 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

[11] Winkleman, Ross and Syed Mehmud. ''A Comparative Analysis of Claims-Based Tools for Health Risk Assessment.'' Society of Actuaries (Apr. 2007), available at *https://www.soa.org/research/research-projects/health/hlth-risk-assement.aspx.*

adjustment transfers (payments and charges) will be calculated after issuers have completed 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 will 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.

Comment: Commenters requested that administrative expenses be removed from the calculation of the statewide average premium. A commenter suggested that amending the transfer formula by eliminating administrative costs from the statewide average premium would make it ''benefit cost based.'' A commenter suggested that HHS consider basing the payment transfer on a portion of State average premium—namely, the portion representing the sum of claims, claims adjustment expenses, and taxes that are calculated on premium after risk adjustment transfers, by using a specified percentage of State average premiums. The commenter suggested the specified percentage could be determined based on data submitted by issuers on the Unified Rate Review Template (URRT) for the portion of premium needed for claims and on data from financial reporting statements for claim adjustment expenses and relevant taxes as a percent of premium and could vary by State or market. Some commenters opposed the use of the statewide average premium because it disadvantages issuers with below average premiums. Commenters requested that 2014 and later risk adjustment transfers for all plans with below average premiums in a State be calculated using the plans' own average premium amount or average claims cost, so that efficient plans are not penalized using the Statewide average premium. Commenters requested use of a ''care coordination factor'' in the risk transfer formula, and stated that risk adjustment results are distorted by regional biases, risks, and coding and demographic differences. One commenter recommended that risk scores be compared to other scores in the same geographic region, not to State averages, to avoid regional biases and to permit a fairer and more accurate comparison.

Response: We did not propose changes to the transfer formula, and therefore, are not addressing comments that are outside the scope of this rulemaking. We may be able to evaluate geographic differences in the future if we obtain enrollee-level data for future recalibrations—a topic that we also intend to discuss in the White Paper and at the March 31, 2016 risk adjustment conference.

(1) Overview of the Payment Transfer Formula

Although we did not propose to change the payment transfer formula from what was finalized in the 2014 Payment Notice (78 FR 15430 through 15434), we believe it is useful to republish the formula in its entirety, since, as noted above, we are recalibrating 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:

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

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.

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.

g. State-Submitted Alternate Risk Adjustment Methodology

We are not recertifying the alternate State methodology for use in Massachusetts for 2017 risk adjustment. Massachusetts and HHS will begin the transition that will allow HHS to operate risk adjustment in Massachusetts in 2017. HHS will operate risk adjustment in all States for the 2017 benefit year.

h. Risk Adjustment User Fee (§ 153.610(f))

As noted above, 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 with the meaning of § 153.20 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 2016 Payment Notice, we estimated Federal administrative

expenses of operating the risk adjustment program to be $1.75 per enrollee per year, based on our estimated contract costs for risk adjustment operations. For the 2017 benefit year, we proposed 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 divided 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 estimated that the total cost for HHS to operate the risk adjustment program on behalf of States for 2017 would be approximately $52 million, and that the risk adjustment user fee would be $1.80 per enrollee per year. We stated that the risk adjustment user fee contract costs for 2017 include costs related to 2017 risk adjustment data validation, and are slightly higher than the 2016 contract costs because some contracts were rebid. We do not anticipate that Massachusetts' decision to use the Federal risk adjustment methodology will substantially affect the risk adjustment user fee rate for 2017.

Comment: One commenter strongly supported the assessment of a higher risk adjustment user fee to support the RADV program. Another commenter requested transparency for the user fee rate and that HHS consider less costly alternatives. One commenter expressed concern over the risk adjustment user fee proposal since HHS collected increased user fees accounting for 2014 risk adjustment data validation in 2016 but delayed 2014 risk adjustment data validation. This commenter recommended that HHS use those increased fees to pay for risk adjustment data validation in 2017 and decline to increase user fees for 2017 risk adjustment.

Response: In response to the comment regarding risk adjustment data validation costs, we re-examined all assumptions that went into the calculation of the risk adjustment user fee. First, we determined that our expected contract costs for 2017 risk adjustment are lower than anticipated, currently estimated at approximately $24 million. Then, we looked at the enrollment assumptions we were using to calculate the previous benefit year user fees. Because we now have actual 2014 risk adjustment enrollment, we were able to base expected 2017 enrollment on projected member month enrollment rather than total enrollees. We are revising the risk adjustment user fee to reflect lower contract costs for the 2017 benefit year and more accurate enrollment projections. Therefore, we are finalizing the 2017 risk adjustment user fee at $1.56 per enrollee per year, or $0.13 PMPM.

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. In the 2016 Payment Notice, we established the reinsurance payment parameters and uniform reinsurance contribution rate for the 2016 benefit year and certain clarifying provisions related to the operation of the reinsurance program.

a. Decreasing the Reinsurance Attachment Point for the 2016 Benefit Year

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 non-grandfathered, individual market issuers for high-risk claims that provides for the equitable allocation of funds. In the Premium Stabilization Rule (77 FR 17228), we provided that reinsurance payments to issuers of reinsurance-eligible plans will be made for a portion of an enrollee's claims costs paid by the issuer (the coinsurance rate) that exceeds an attachment point (when reinsurance would begin), subject to a reinsurance cap (when the reinsurance program stops paying claims for a high-cost individual). The coinsurance rate, attachment point, and reinsurance cap together constitute the uniform reinsurance payment parameters.

We provided in the 2015 Payment Notice (79 FR 13777) that HHS will use any excess contributions for reinsurance payments for a benefit year by increasing the coinsurance rate for that benefit year up to 100 percent before rolling over any remaining funds in the next year. In the proposed rule, we proposed that if any contribution amounts remain after calculating reinsurance payments for the 2016 benefit year (and after HHS increases the coinsurance rate to 100 percent for the 2016 benefit year), HHS would decrease the 2016 attachment point of $90,000 to pay out any remaining contribution amounts to issuers of reinsurance-eligible plans in an equitable manner for the 2016 benefit year.

We received numerous comments in support of this proposal and are finalizing this provision as proposed.

Comment: One commenter stated that changing the reinsurance payment parameters at the end of the program—instead of identifying and updating the parameters in earlier benefit years as current information is available—would be disruptive. The commenter stated that this proposal would cause disruption for States that exercised the option to create supplemental reinsurance programs and that need to set uniform reinsurance payment parameters.

Response: The final 2016 reinsurance coinsurance rate and attachment point, which would reflect a potential increase in coinsurance rate from 50 to 100 percent and a potential decrease in the attachment point from $90,000 to an amount that pays out remaining contributions in an equitable manner, will not be set until HHS confirms the total amount of contributions available and reinsurance payment requests for the 2016 benefit year. HHS understands that no State-operated reinsurance program established supplemental reinsurance payment parameters under §§ 153.220(d) and 153.232 and therefore no States will be affected by this provision. We believe that expending all remaining reinsurance contribution funds as payments for the 2016 benefit year will support the reinsurance program's goals of promoting nationwide premium stabilization and market stability in the early years of Exchange operations while providing issuers with incentives to continue to effectively manage enrollee costs.

Comment: One commenter asked that HHS use excess reinsurance contributions to fund the deficit in the risk corridors program.

Response: Section 1341 of the Affordable Care Act establishes the transitional reinsurance program to compensate non-grandfathered individual market plans for high-cost enrollees in the initial years of the Exchange. We believe that our policy to expend any remaining reinsurance contribution funds as reinsurance payments for the 2016 benefit best aligns with that statutory purpose.

b. Audit Authority Extends to Entities That Assist Contributing Entities (§ 153.405(i))

In accordance with § 153.405(i), HHS or its designee has the authority to audit a contributing entity to assess compliance with the reinsurance program requirements. In 2014, HHS implemented a streamlined approach through which a contributing entity, or a third party such as a third party administrator or an administrative services-only contractor acting on behalf of a contributing entity, could register on Pay.gov, calculate the annual enrollment count and schedule reinsurance contribution payments. During the 2014 and 2015 contribution submission process, many third party administrators and administrative services-only contractors assisted contributing entities by calculating the contributing entity's annual enrollment count and maintaining the records necessary to validate that enrollment. In the proposed rule, we proposed to amend § 153.405(i) to specify that the audit authority extends to any third party administrators, administrative services-only contractors, or other third parties that complete any part of the reinsurance contribution submission process on behalf of contributing entities or otherwise assist contributing entities with compliance with the requirements for the transitional reinsurance program. Additionally, we proposed to amend § 153.405(i) to specify that a contributing entity that chooses to use a third party administrator, administrative services-only contractor, or other third party to assist with its obligations under the reinsurance program must ensure that this third party administrator, administrative services-only contractor, or other third party cooperate with any audit under this section.

After reviewing the comments received on this proposal, we will not finalize our amendment to § 153.405(i) that extended the audit authority to third party administrators, administrative services-only contractors or other third parties that assist a contributing entity with compliance with reinsurance program requirements. However, HHS will finalize as proposed the amendment to § 153.405(i) specifying that a contributing entity that chooses to use a third party administrator, administrative services-only contractor, or other third party to assist with its obligations under the reinsurance program must ensure that this third party administrator, administrative services-only contractor, or other third party cooperates with any audit under that section. We note that under § 153.405(i) HHS, or its designee, has the authority to audit contributing entities' compliance with their obligations under the reinsurance program.

Comment: One commenter disagreed with HHS's proposal to extend the audit authority to third party administrators, administrative services-only contractors, or other third parties, arguing that it was unnecessary and would increase the costs of compliance.

Response: We recognize the commenter's concerns about increasing compliance costs, and are not finalizing our proposal to extend the audit authority. However, a contributing entity that uses a third party administrator, administrative services-only contractor, or other third party to assist with its obligations under the reinsurance program must ensure that such organization cooperates with any audit of the contributing entity under this section.

4. Provisions for the Temporary Risk Corridors Program

This section contains proposals related to the temporary risk corridors program, and therefore applies only to issuers of QHPs, as defined at § 153.500, with respect to the benefit years 2014 through 2016.

a. Risk Corridors Payment Methodology (§ 153.510(g))

To ensure the integrity of data used in risk corridors and MLR calculations, in prior guidance we indicated that we would propose in the HHS Notice of Benefit and Payment Parameters for 2017 an adjustment to correct for any inaccuracies in risk corridors payment and charge amounts that could result from issuers reporting a certified estimate of cost-sharing reductions on the 2014 MLR and Risk Corridors Annual Reporting Form.[12] The use of a certified estimate that is lower than the actual cost-sharing reductions provided would affect the MLR calculation and the risk corridors financial transfers by increasing incurred claims and allowable costs, thereby increasing the MLR and potentially increasing the risk corridors payment or lowering the risk corridors charge. We believe that requiring an update of these reported amounts through recalculation of the risk corridors and MLR amounts for the 2014 benefit year will be disruptive to the market and consumers, as well as administratively burdensome and difficult to operationalize for issuers and HHS. Therefore, consistent with our earlier guidance, we proposed to add a new paragraph (g) to the risk corridors payment methodology set forth in § 153.510 stating that if the issuer reported a certified estimate of 2014 cost-sharing reductions on its 2014 MLR and Risk Corridors Annual Reporting Form that is lower than the actual cost-sharing reductions provided (as calculated under § 156.430(c) for the 2014 benefit year, which will take place in the spring of 2016), HHS would make an adjustment to the amount of the issuer's 2015 benefit year risk corridors payment or charge measured by the full difference between the certified estimate reported and the actual cost-sharing reductions provided as calculated under § 156.430(c) in order to address the impact of the inaccurate reporting on the risk corridors and MLR calculations for the 2014 benefit year. We are finalizing this policy and the amendment to § 153.510(g) as proposed.

Comment: Several commenters recommended that, to the extent the certified estimate of cost-sharing reductions reported on the 2014 MLR and Risk Corridors Annual Reporting Form is lower than the actual cost-sharing reductions provided, the difference should be reflected as an adjustment to the cost-sharing reduction amount reported for the 2015 benefit year rather than the risk corridors payment or charge.

Response: We note that we are also amending § 153.710(g) (see III.D.5.d of this preamble) to require that issuers adjust the cost-sharing reduction amount reported for the 2015 benefit year to account for the difference between cost-sharing reduction amounts reported for the 2014 benefit year and actual cost-sharing reduction amounts as determined under § 156.430(c). The separate, direct adjustment to the 2015 risk corridors payment or charge set

[12] Cost-Sharing Reduction Amounts in Risk Corridors and Medical Loss Ratio Reporting (Jun. 19, 2015), available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Advance-CSR-Payment-and-RC-MLR-submission_6192015.pdf.*

forth in § 153.510(g) was intended as a program integrity measure, to help ensure that issuers did not report certified estimates of cost-sharing reduction amounts for the 2014 benefit year that they knew would likely be lower than their advance payment amounts.

b. Risk Corridors Data Requirements (§ 153.530)

In the proposed rule (80 FR 75488), we proposed to amend § 153.530 to require that for the 2015 and later benefit years, issuers must true up their claims liabilities and reserve amounts that were used to determine their allowable costs reported for the risk corridors program for the preceding benefit year to reflect the actual claims payments made through June 30 of the year following the benefit year. We also requested comments on how to handle the true-up of unpaid claims estimates for 2016, suggesting four alternatives: provide for a 2017 payment or charge; provide for a simplified true-up process; require that the 2016 estimate be based on actual 2014 and 2015 amounts; or provide for no true-up in the final year.

Comment: One commenter supported our proposal. Several commenters opposed our proposal, noting that any improvement in the accuracy of risk corridor payments to issuers under the proposal would be outweighed by the administrative burden on issuers, and minimized by the operational mechanics of the risk corridor program and the potential for continued shortfall in the program. However, most of these commenters were primarily concerned with our proposal to require claims valuation at June 30 rather than March 31, and not with the proposal to true-up claims estimates. Other commenters opposed only the true-up of 2016 unpaid claims estimates, and additionally expressed concern that 2014 and 2015 claims experience may not accurately reflect 2016 experience.

Response: We acknowledge commenters' concern regarding the potential lack of practical advantages of requiring claims valuation at June 30 rather than March 31 and requiring a true-up of 2016 unpaid claims estimates. However, we continue to believe that a true-up of 2014 and 2015 unpaid claims estimates is important to preserve the integrity of the risk corridors program. Therefore, we are finalizing the amendment adding § 153.530(b)(2)(iv) as proposed with respect to the true-up of 2014 and 2015 experience in the reporting for the 2015 and 2016 benefit years. We will address the true-up of 2016 experience after we have evaluated the results of the true-up of 2014 experience.

5. Distributed Data Collection for the HHS-Operated Programs

a. Interim Dedicated Distributed Data Environment Reports (§ 153.710(d))

In the proposed rule, we proposed deleting § 153.710(d), which sets forth an interim discrepancy reporting process by which an issuer must notify HHS of any discrepancy it identifies between the data to which the issuer has provided access to HHS through its dedicated distributed data environment (that is, an issuer's EDGE server) and the interim dedicated distributed data environment report (that is, an issuer's interim EDGE report), or confirm to HHS that the information in the interim report accurately reflects the data to which the issuer has provided access to HHS through its dedicated distributed data environment in accordance with § 153.700(a) for the timeframe specified in the report. We proposed that this change would be effective beginning with the 2016 benefit year.[13]

We received numerous comments in support of this proposal, and are finalizing this provision as proposed. We also finalize our proposal to remove any cross-references in §§ 153.710 and 156.1220 to the interim discrepancy reporting process currently codified at § 153.710(d) and conforming amendments to redesignate paragraph (e) as paragraph (d), as well as to revise and redesignate paragraph (f) as (e).

Comment: Some commenters asked that HHS confirm that there will continue to be a robust process to allow issuers to identify and resolve potential discrepancies throughout the data submission process.

Response: HHS is committed to working with issuers prior to the data submission deadline to address any data issues so that reinsurance payment and risk adjustment transfer calculations can be made accurately and timely. Throughout the data collection period, HHS will continue to maintain a help desk, host user group calls and webinars, and make reports available to issuers on their respective EDGE servers to assist issuers with the identification and resolution of data submission errors and to provide technical assistance.

Comment: One commenter asked that HHS allow issuers 30 days to respond to the final dedicated distributed data environment report with any discrepancies, rather than the 15-calendar-day timeframe set forth in § 153.710(e) (now finalized as § 153.710(d)).

Response: HHS will continue to require issuers to respond within 15 calendar days to the final dedicated distributed data environment report. As we explained in the 2015 Payment Notice final rule (79 FR 13790), the 15-calendar day reporting timeframe for the final dedicated distributed data environment report is necessary so that HHS can notify issuers of their risk adjustment payment or charge and total estimated reinsurance payments by June 30 of the year following the applicable benefit year, as required under §§ 153.310(e) and 153.240(b)(1)(ii).

Comment: One commenter asked HHS to release guidance on the 2015 discrepancy reporting process in early January.

Response: HHS intends to issue future guidance on the final discrepancy reporting process set forth in § 153.710(e) (now finalized as § 153.710(d)) prior to the final discrepancy reporting window.

b. Risk Adjustment Interim Reports

We did not propose any provisions related to risk adjustment interim reports in the Payment Notice. However, we received a number of comments related to the schedule of risk adjustment reports and the availability of additional information prior to the final summary report on June 30 of the year following the applicable benefit year.

Comment: Several commenters requested that HHS issue the summary report earlier than June 30. Commenters also requested interim or quarterly reports so that issuers could incorporate improved estimates into rate setting. Commenters suggested HHS provide interim reports with issuers' calculated risk scores, market-wide risk scores, and the other components of the payment transfer formula, including the Statewide average premium. Commenters also recommended that HHS disclose any issues with the completeness of data in the report so that issuers can take this into account when reviewing results. Commenters further suggested that HHS may want to consider publishing additional details such as the issuer's market share, market average distribution by metal plan, market allowable rating factor, and market proportion of claims with HCCs.

[13] For the 2015 benefit year, issuers are not required to confirm that the information in the interim report accurately reflects the reinsurance and risk adjustment data to which the issuer has provided access through its EDGE server; or describe any discrepancy an issuer identifies in the interim report. See FAQ 14247 (Dec. 15, 2015), available at *www.regtap.info.*

Response: We issued an FAQ on January 8, 2016 [14] stating that we will release an interim public summary report in March 2016 for those States and risk pools where the risk adjustment data that has been submitted by February 1, 2016 meets HHS's data sufficiency thresholds. The interim summary report will include the following transfer formula elements by State and risk pool: (1) Average monthly premiums; (2) average plan liability risk score; (3) average allowable rating factor; (4) average actuarial value; (5) billable member months; and (6) geographic cost factors. We will also provide issuers with an interim report that contains their own issuer-specific information and that will not be released publicly. We are providing this information because issuers have indicated that, taken in concert with other data available to them, it may help them formulate more accurate estimates of their risk adjustment transfers. However, we continue to caution that data provided in these interim reports will be preliminary, do not represent any determination by HHS regarding the credibility of the data submitted, and that final risk adjustment results may be substantially different.

c. Evaluation of Quality and Quantity of EDGE Data Submissions (§ 153.710(f))

Under § 153.740(b), if an issuer of a risk adjustment covered plan fails to provide HHS with access to the required data in a dedicated distributed data environment 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. Similarly, under §§ 153.420 and 153.740(a), an issuer of a reinsurance-eligible plan will forfeit reinsurance payments it otherwise might have received if the issuer fails to establish a dedicated distributed data environment or fails to meet the data requirements set forth in §§ 153.420 and 153.700 through 153.730. On April 24, 2015, HHS released guidance entitled ''Evaluation of EDGE Data Submissions'' describing the approach it would use to evaluate whether the quality and quantity of the data that an issuer provided to a dedicated distributed data environment was sufficient for HHS to calculate reinsurance payments and apply the HHS risk adjustment methodology for the 2014 benefit year.[15] In the proposed rule, we proposed to codify this practice for future benefit years to support the integrity of payments and charges under the HHS-operated risk adjustment program and payments under the reinsurance program, both of which depend upon the submission of accurate and complete by issuers.

Consistent with the approach for review of 2014 benefit year data, to determine if an issuer meets *data quantity* standards, we proposed that HHS would compare an issuer's self-reported baseline data of total enrollment and claims counts by market to the data submitted to the issuer's dedicated distributed data environment. An issuer whose total enrollment counts were lower than its baseline data submission by the deadline for submitting data to the dedicated distributed data environment would be subject to a default risk adjustment charge under § 153.740(b). An issuer whose total claims counts were lower than its baseline data submission by the deadline for submitting data to the dedicated distributed data environment would be subject to a default risk adjustment charge only if the default charge was lower than the charge it would have received through the risk adjustment transfer calculation. Additionally, an issuer with either a low enrollment count or a low claims count following the final data submission deadline would forgo reinsurance payments for any claims that it failed to submit. In the proposed rule, HHS stated that it would set forth in guidance, on an annual basis, the appropriate threshold by which HHS will deem data sufficient as to quantity for a given benefit year.[16] We also stated that HHS would also specify in guidance the format and timeline for submission of baseline data to HHS.[17]

To determine if an issuer meets the *data quality* standards required for HHS to calculate reinsurance payments and apply the HHS risk adjustment methodology, HHS proposed to perform an outlier analysis using select metrics that target reinsurance data quality and risk adjustment data quality.[18] As with our data quantity metrics, HHS plans to describe in guidance, on an annual basis, the metrics used for a given benefit year.[19] An issuer may be assessed a risk adjustment default charge if it does not meet data quality standards on any of the risk adjustment metrics, and may forfeit reinsurance payments it might otherwise have received if it does not meet data quality standards for any of the reinsurance metrics.

HHS would conduct these data quantity and quality analyses after the deadline for submission of data specified in § 153.730 (that is, April 30, of the year following the applicable benefit year).[20] We proposed to add a new paragraph (f) to § 153.710 to specify that HHS will assess default risk adjustment charges based on these analyses no later than the date of the notification provided by HHS under § 153.310(e) (that is, June 30 of the year following the applicable benefit year); and to describe the responsibilities of issuers in relation to the quantity and quality analyses. In § 153.710(f)(1), we proposed to codify the requirement for issuers to provide baseline data on their total enrollment and claims counts by market, in a format and on a timeline specified by HHS in guidance. In § 153.710(f)(2), we proposed that if HHS identifies a data outlier that would cause the data that a risk adjustment covered plan or a reinsurance-eligible plan made available through a dedicated distributed data environment to fail HHS's quality thresholds, the issuer may, within 10 calendar days of receiving notification of the outlier,

[14] See FAQ 14572, (Jan. 8, 2016), available at *https://www.regtap.info/.*

[15] EDGE Server Data Bulletin—INFORMATION; Evaluation of EDGE Data Submissions (Apr. 24, 2015), available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/EDGE-guidance-42415-final.pdf.*

[16] For information on the data quantity thresholds that will be used to evaluate issuer's EDGE server data for the 2015 benefit year related to the release of interim reinsurance payments and interim risk adjustment summary reports, see EDGE Server Data Bulletin—INFORMATION; Evaluation of EDGE Data Submissions for 2015 Benefit Year for Interim Reinsurance Payment and Interim Risk Adjustment Summary Report (Jan. 20, 2016), available at *https://www.regtap.info/uploads/library/EDGEServer_DataBulletin_5CR_012016.pdf.* Guidance on the on-going and final quantity evaluation processes will be released in the near future.

[17] *Ibid.*

[18] For the 2014 benefit year, HHS used the following five key metrics: Percentage of all enrollees with at least one HCC; average number of conditions per enrollee with at least one HCC; issuer average risk score; percentage of individual market enrollees with reinsurance payments; and average reinsurance payment per enrollee for which the issuer would receive reinsurance payments.

[19] For information on the data quality thresholds that will be used to evaluate issuer's EDGE server data for the 2015 benefit year related to the release of interim reinsurance payments and interim risk adjustment summary reports, see EDGE Server Data Bulletin—INFORMATION; Evaluation of EDGE Data Submissions for 2015 Benefit Year for Interim Reinsurance Payment and Interim Risk Adjustment Summary Report (Jan. 20, 2016), available at *https://www.regtap.info/uploads/library/EDGEServer_DataBulletin_5CR_012016.pdf.* Guidance on the on-going and final quantity evaluation processes will be released in the near future.

[20] For the 2015 benefit year, the data submission deadline is Monday, May 2, 2016 because April 30, 2016 is a Sunday. See FAQ 14472, (Dec. 21, 2015), available at *https://www.regtap.info.*

submit a justification of the outlier for HHS to consider in determining whether the issuer met the reinsurance and risk adjustment data requirements.

We indicated that HHS expects to perform informal data quantity and quality analyses throughout the data submission process, providing issuers with time to address any outlier before the data submission deadline. Issuers may provide justifications of data outliers, updates to their respective EDGE server data, and corrected baseline enrollment or claims counts at any time during the data submission process, and are encouraged to do so as early as possible. The timeframe we proposed in § 153.710(f)(2) would apply to the final data quantity and quality analyses only, which are performed following the deadline for submission of data specified in § 153.730 (that is, April 30, of the year following the applicable benefit year).

We are finalizing these provisions as proposed, with two modifications. In § 153.710(f), we are removing the proposed language that set forth a time limitation for HHS to assess a default risk adjustment charge based on the data quantity and quality analyses because the administrative appeals process set forth in § 156.1220 could result in imposition of a default risk adjustment charge. For example, if we determine during the administrative appeals process that a data submission error was of such magnitude that the issuer did not meet the data quantity and quality thresholds set forth for that benefit year, then we may assess a default risk adjustment charge if that charge is lower than the charge the issuer is being assessed for that benefit year. We also changed the heading for § 153.710(f) from ''Data Sufficiency'' to ''Evaluation of Dedicated Distributed Data.''

Comment: Numerous commenters asked that HHS extend the 10-day deadline to submit an explanation of the outlier to HHS. Several commenters asked that HHS provide issuers 15 days or 30 days to respond. One commenter agreed with the 10-day deadline.

Response: The 10-day deadline only applies when HHS conducts the final quality and quantity analyses of the data submitted to an issuer's dedicated distributed data environment, which are performed following the deadline for submission of data specified in § 153.730 (that is, April 30 of the year following the applicable benefit year). As noted above, HHS will continuously analyze the quantity and quality of an issuer's data, providing reports and notices to issuers and allowing time to correct any outliers during the data submission window. The 10-day deadline is necessary because HHS must review an issuer's outlier justification to calculate reinsurance payments and apply the HHS risk adjustment methodology by the June 30 notification.

Comment: Some commenters asked that the data quantity and quality analysis prior to the data submission deadline for an applicable benefit year be robust and that HHS quickly respond to issuers to allow them to identify and resolve issues during the data submission process.

Response: HHS will perform informal data quantity and quality analyses throughout the data submission process, providing issuers with reports and notices to allow time to address any outliers before the data submission deadline. HHS encourages issuers to work with HHS any time an issue or problem is encountered. Issuers may provide justifications, update their EDGE server data, and correct baseline enrollment or claims counts at any time during the data submission process, and are encouraged to do so as early as possible.

Comment: One commenter recommended that HHS provide full transparency into the evaluation process, including with respect to how HHS intends to apply its measurements for baseline data and quality. Another commenter asked that HHS publish the timeframes for the data quantity and quality analysis in the annual Letter to Issuers.

Response: HHS strives to be transparent with respect to these processes, and will issue guidance regarding the data quantity and quality process and timeframes. See *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/index.html* or *http://www.regtap.info/.*

Comment: One commenter urged HHS to publish the timeline and format for submission of baseline data as soon as possible prior to the applicable benefit year.

Response: HHS will continue to publish timeframe and guidance materials related to the baseline submission process as soon as practicable. HHS has already released guidance regarding the submission of baseline data for the 2015 benefit year.[21]

Comment: One commenter requested that HHS establish an appeals process for issuers whose data is determined to fail the data quantity and quality standards.

Response: As we stated in the proposed rule in the preamble section to § 156.1220, an issuer may file a request for reconsideration if it believes that HHS made a processing error, incorrectly applied its methodology, or made a mathematical error related to the data quantity and quality standards. For example, an issuer may file a request for reconsideration to challenge the assessment of a default risk adjustment charge if the issuer believes the default charge was assessed because HHS incorrectly applied its methodology regarding data quantity and quality standards. We note that, under § 156.1220(a)(4)(ii), a reconsideration with respect to a processing error by HHS, HHS's incorrect application of the relevant methodology, or HHS's mathematical error may be requested only if, to the extent the issue could have been previously identified by the issuer to HHS under § 153.710(d)(2), it was identified and remains unresolved.

d. Data Requirements (§ 153.710(g))

We proposed revising § 153.710(g)(1)(iii) to require an issuer to report the amount of cost-sharing reductions calculated under § 156.430(c) in its annual MLR and risk corridors report, regardless of whether the issuer had any unresolved discrepancy under § 156.1210, or whether the issuer had submitted a request for reconsideration under § 156.1220(a)(1)(v). Additionally, consistent with the process outlined in § 153.710(g)(2), we proposed to require an issuer to adjust the cost-sharing reduction amount it reports on its 2015 risk corridors and MLR forms by the difference (if any) between the reported cost-sharing reduction amount used to adjust allowable costs and incurred claims on the 2014 MLR Annual Reporting Form and the amount of cost-sharing reductions as calculated under § 156.430(c) for the 2014 benefit year.

Consistent with the approach currently outlined in § 153.710(g)(2), we proposed to amend this paragraph to require an issuer to report any adjustment made or approved by HHS for any risk adjustment payment or charge, reinsurance payment, cost-sharing reduction payment to reflect actual cost-sharing reduction amounts received, or risk corridors payment or charge, where the adjustment has not been accounted for in a prior MLR and Risk Corridors Annual Reporting Form in the next following year. For example, if an issuer's risk adjustment charges or payments are adjusted as a result of the administrative appeals process, the issuer should adjust these reported amounts in the next MLR and risk corridors reporting cycle, after the

[21] 2015 EDGE Server Status and Baseline Reporting (Oct, 20, 2015), available at *https://www.regtap.info/reg_library.php?libfilter_topic=3.*

appeal has been resolved. Similarly, if HHS makes changes to an issuer's risk adjustment charges or payments after the risk corridors and MLR reporting cycle has closed for the applicable reporting year, the issuer should adjust these reported amounts in the next MLR and risk corridors reporting cycle to account for the difference between the reported amounts and the amounts actually received or paid for the previous benefit year. However, if an issuer is notified about the modification during an open MLR and risk corridors submission period, it must report the modified amounts in that open reporting cycle.

We also proposed to clarify in § 153.710(g)(1)(iii) that cost-sharing reduction amounts to be reported under this section must exclude amounts reimbursed to providers of services or items. This clarifying language is consistent with how the instructions for cost-sharing reductions amounts are reported under §§ 153.530(b)(2)(iii) (risk corridors data requirements) and 158.140(b)(iii) (MLR data requirements).

We also proposed to revise paragraph (g)(1)(iv) to require that for medical loss ratio reporting only, issuers should report the risk corridors payment to be made or charge assessed by HHS, as reflected under § 153.510. Lastly, HHS learned in the first year of implementation of the premium stabilization and Exchange financial assistance programs that some flexibility is needed when reporting these program amounts for purposes of risk corridors and MLR reporting. As such, we proposed in § 153.710(g)(3) that HHS have the ability to modify the reporting instructions set forth in § 153.710(g)(1) and (2) through guidance. Our intent in issuing any such guidance would be to avoid having the application of the reporting instructions lead to unfair or misleading financial reporting in exceptional circumstances.

Based on comments received, we are finalizing these provisions as proposed, with one modification. We are modifying § 153.710(g)(2) to specify that an issuer must report any adjustment made or approved by HHS by August 15, or the next applicable business day, of the reporting year for any risk adjustment payment or charge, including an assessment of risk adjustment user fees; any reinsurance payment; any cost-sharing reduction payment or charge; or any risk corridors payment or charge, in the current MLR and risk corridors reporting year, unless the adjustment meets the criteria for a ''de minimis'' change outlined in prior guidance.[22] HHS will also finalize as proposed the conforming amendments to the introductory language at § 153.710(g)(1) to remove the cross-references to the interim discrepancy reporting process currently codified at § 153.710(d). See III.D.5.a of this preamble for a discussion of the conforming amendments related to the removal of interim discrepancy reporting process.

Comment: One commenter agreed with the proposal to require an issuer to report any adjustment made or approved by HHS for any risk adjustment payment or charge, reinsurance payment, cost-sharing reduction payment to reflect actual cost-sharing reduction amounts received, or risk corridors payment or charge, where the adjustment has not been accounted for in a prior MLR and Risk Corridors Annual Reporting Form, in the following year, but further recommended that we establish a cut-off date for notifications of adjustments of June 30, after which adjustments must be reported in the following year's MLR and risk corridors reporting cycle. The commenter suggested that notifications by June 30 would give issuers sufficient time to incorporate data changes into their MLR and risk corridors submissions by the July 31 reporting deadline.

Response: We recognize that, in some cases, the timing of notifications of changes to data such as risk adjustment charges or payments may affect an issuer's MLR and risk corridors submission. Issuers must adhere to the July 31 regulatory deadline for submitting MLR and risk corridors data for the preceding benefit year. In order to accommodate potential adjustments to reinsurance payments, risk adjustment payments or charges, or payments or charges resulting from the cost-sharing reduction reconciliation process, in the period immediately after the issuance of the June 30 report while also maintaining the accuracy of issuers' MLR and risk corridors submissions, we are modifying § 153.710(g)(2) to specify that if HHS notifies an issuer about an adjustment by August 15, the issuer must report the adjustment in the current year reporting cycle, unless the adjustment meets the criteria for a ''de minimis'' change outlined in prior guidance.[23] We note that we expect only a small number of issuers to be required to resubmit data due to such an adjustment, and that all issuers should prepare to disburse rebates by the September 30 deadline. For those issuers who may be notified an adjustment that does not meet the ''de minimis'' criteria by August 15, HHS will work with the issuer to facilitate resubmission of its MLR and risk corridors submissions and to address the impact on MLR rebates, if necessary, in a manner that limits additional operational burden for the issuer.

Comment: One commenter asked that HHS not finalize § 153.710(g)(1)(iii), stating this change would limit the ability of issuers with alternative payment models to receive cost-sharing reduction amounts for capitated payment arrangements.

Response: The language under § 153.710(g)(1)(iii) does not limit the ability of issuers with alternative payment arrangements to receive cost-sharing reduction payments, and is consistent with other cost-sharing reduction reporting requirements, for example, allowable costs under § 153.530(b)(2)(iii) (risk corridors data requirements) must be reduced by the amount of cost-sharing reduction payments received by the issuer, except for, or excluding, any part of those payments used by the issuer to reimburse providers.

e. Good Faith Safe Harbor

In the second Program Integrity Rule, we finalized § 153.740(a), which permits HHS to impose civil money penalties upon issuers of risk adjustment covered plans and reinsurance-eligible plans for failure to adhere to certain standards relating to their dedicated distributed data environments. In the proposed rule, consistent with our previous statements in the 2016 Payment Notice (80 FR 10780), we stated that we would not be extending the good-faith safe harbor to 2016. Starting in the 2016 calendar year and beyond, civil money penalties may be imposed 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, even if the issuer has made good faith efforts to comply with

[22] Risk Corridors and Medical Loss Ratio (MLR) Resubmissions for the 2014 Benefit Year, (Aug. 14, 2015), available at *https://www.regtap.info/uploads/library/RC_MLR_ResubmissionFAQ_5CR_081415.pdf.*

[23] *https://www.regtap.info/uploads/library/RC_MLR_ResubmissionFAQ_5CR_081415.pdf.*

these requirements. This safe harbor provision parallels a similar safe harbor for QHP issuers in FFEs under § 156.800 that also expired at the end of the 2015 calendar year. See III.G.7 of this preamble for the accompanying discussion of the safe harbor provision under § 156.800. However, we are clarifying that HHS will not impose civil money penalties under § 153.740(a) in 2016 or later based on activities that occurred in the 2014 or 2015 calendar year if the issuer acted in good faith at that time.

Comment: Several commenters asked HHS to extend the good faith safe harbor to 2016, while others supported our proposal. Some commenters asked that HHS allow a good faith safe harbor for all new processes, such as policy-based payments and reconciliation of advance payments of cost-sharing reductions.

Response: HHS will not extend the good faith safe harbor to cover conduct in 2016 or later years (including with respect to activities that occur in the 2016 calendar year or later relating to data from earlier benefit years). We believe that the 2 calendar years that we provided under this policy were sufficient to permit issuers to transition into compliance with the applicable risk adjustment, reinsurance and distributed data collection requirements. Of course, in all our enforcement actions, we will continue to take into account all facts and circumstances, including the reasonable good faith action of issuers.

Comment: A few commenters asked that HHS make clear that the good faith safe harbor continues to apply to conduct for benefit years prior to 2016 in perpetuity.

Response: HHS will not impose civil money penalties in 2016 or later based on activities that occurred in the 2014 or 2015 calendar year if the issuer acted in good faith at that time.

f. 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. In the 2016 Payment Notice, we established how a default risk adjustment charge will be allocated among risk adjustment covered plans.

As described in the second final Program Integrity Rule, the total risk adjustment default charge for a risk adjustment covered plan equals a PMPM amount multiplied by the plan's enrollment.

$T_n = C_n * E_n$

Where:

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

C_n = the PMPM amount for plan n; and

E_n = the total enrollment (total billable member months) for plan n.

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

In the 2015 Payment Notice, we determined that we would calculate C_n—the PMPM amount for a plan—equal to the product of the statewide average premium (expressed as a PMPM amount) for a risk pool and the 75th percentile plan risk transfer amount expressed as a percentage of the respective Statewide average PMPM premiums for the risk pool. The nationwide percentile would reflect only plans in States where HHS is operating the risk adjustment program and would be calculated based on the absolute value of plan risk transfer amounts. The PMPM amount determined using the method described here would be multiplied by the non-compliant plan's enrollment, as determined using the sources finalized in the second final Program Integrity Rule, to establish the plan's total default risk adjustment charge.

For the second year of risk adjustment, the 2015 benefit year, we proposed to calculate C_n in the same manner, but increased to the 90th percentile plan risk transfer amount expressed as a percentage of the respective statewide average PMPM premiums for the risk pool. We believe that the 75th percentile was reasonable for the initial year of risk adjustment, as we did not yet know the distribution of risk adjustment transfers and issuers were more likely to experience technical difficulties in establishing a dedicated distributed data environment. In the second year of risk adjustment, now that issuers have set up EDGE servers and participated in the calculation of risk adjustment transfers, we believe that adjusting the default charge upwards to the 90th percentile of plan risk transfer amounts expressed as a percentage of the respective statewide average PMPM premiums for the risk pool will encourage continued compliance with risk adjustment data submission requirements. We are concerned that, absent this change, some issuers may prefer receiving a default charge at the 75th percentile over participating in the risk adjustment program; a default charge at this level might lack sufficient deterrent value. We stated that we believe the proposed 90th percentile default charge will incentivize issuers to participate in the risk adjustment program.

Comment: Commenters generally supported the increased default risk adjustment charge for 2015 benefit year risk adjustment. Two commenters opposed the increase, stating the increase is overly punitive.

Response: We believe that the increased default charge will encourage participation in the second year of implementation of the risk adjustment program. In establishing the amount of the default charge, we must balance setting a fair risk allocation and discouraging strategic behavior from issuers with low-risk enrollees against avoiding unduly penalizing issuers who fail to make proper submissions for operational, and not strategic, reasons. In the second year of risk adjustment, we believe that most issuers will encounter fewer operational difficulties in establishing an EDGE server and meeting data quantity and quality thresholds, and that the opportunity for strategic behavior is greater because risk transfer distributions will be better understood. We believe that raising the default risk adjustment charge from the 75th percentile PMPM transfer amount to the 90th percentile transfer amount is a fair balancing of these goals. We are finalizing this policy as proposed

For the 2016 benefit year, we proposed a separate calculation of C_n for issuers where E_n statewide, in the individual and small group markets combined, is 500 billable member months or fewer. For these issuers, we proposed to calculate C_n, or the PMPM charge for a plan, as 14 percent of premium, which we calculated as the mean charge as a percent of premium of issuers with 500 billable member months or fewer in the 2014 benefit year in the small group market. We based the charge itself on the experience of small group issuers in the 2014 benefit year, as we believe that individual market issuers are more likely to set up an EDGE server because of the availability of reinsurance. Limiting the applicability in the 2016 benefit year of this default charge to issuers with 500 billable member months or fewer is intended to ensure that the only issuers with this option are issuers that are so small that their removal from the overall risk adjustment risk pool would have a minimal impact on transfers nationwide. In 2014, approximately 125 issuers would have had fewer than 500 member months in the individual and small group markets combined. Of those approximately 125 small issuers, 80

were assessed risk adjustment charges greater than the proposed default charge of 14 percent of premium PMPM. Those charges amounted to less than 0.09 percent (that is, less than one tenth of one percent) of total risk adjustment charges assessed nationally. Assuming every one of those issuers elect to accept the proposed 14 percent default risk charge, and none of the small issuers that received risk adjustment payments or with charges below 14 percent of premium PMPM did so (which we believe unlikely, due to the administrative expenses of setting up an EDGE server), the assessment of the proposed 14 percent of premium default charge on those 80 issuers would have resulted in a 0.05 percent reduction in risk adjustment charges collected nationally. Because issuers of this size have a minimal impact on the overall risk adjustment risk pools and have a disproportionately high operational burden to comply with risk adjustment data submission requirements, we believe that a separate default charge for these issuers would promote efficiency and data quality in the risk adjustment program. We proposed to establish this risk adjustment default charge as the mean charge in the small group for these small issuers, or 14 percent of statewide average premium PMPM, to compensate on average for the absence of these immaterial amounts in the affected risk pools. We intend that this policy would apply only to the very smallest issuers, in recognition of the disproportionately high operational burden on these issuers.

Comment: Commenters opposed the separate, lower default charge, stating that compliance with risk adjustment is a cost of doing business under the Affordable Care Act. One commenter stated that the 500-member-months threshold is too small. One commenter recommended a graded approach to the default risk charge that would adjust the percentile factor from 50th to 75th for those issuers with 500 to 2,000 billable members to allow an issuer more flexibility as they transition into participation on the EDGE server. One commenter recommended that the threshold should be 720,000 billable member months.

Response: We agree that, in general, compliance with risk adjustment is a cost of doing business under the new market rules. However, as we explained in the proposed rule, we believe that an exception for the very smallest issuers recognizes that for those issuers the administrative costs of implementing an EDGE server will substantially outweigh the risk adjustment benefits to the risk pool. We are finalizing this policy as proposed.

g. Insolvent Issuers

We are aware that a health insurance issuer may become insolvent or exit a market during a benefit year. In some cases, another entity, such as another issuer or liquidator may take over the issuer's operations, or a State guaranty fund may become responsible for paying claims for the insolvent issuer. In some instances when this occurs, both the insolvent issuer and the entity seeking to acquire business from the insolvent issuer would lack a full year of enrollee data to submit to the EDGE server for the risk adjustment or reinsurance programs.

To address this concern, we proposed to clarify that an entity acquiring or entering into another arrangement with an issuer to serve the current enrollees under a plan, or a State guaranty fund that is responsible for paying claims on behalf of the insolvent issuer, with substantially the same coverage terms may accrue the previous months of claims experience for purposes of risk adjustment and reinsurance to fully reflect the enrollees' risk and claims costs. We proposed the ''substantially the same'' standard because we understood that in many of these situations, an acquiring entity's platform may require some adjustments to the plan arrangements and coverage terms. As part of meeting this standard, an acquiring entity would be required to carry over of accumulators for deductibles and annual limitations on cost sharing. If the substantially the same standard is met, and the insolvent issuer and acquiring entity agree that the acquiring entity will accrue the previous months of claims experience, the acquiring entity must take responsibility for submitting to HHS complete and accurate claims and baseline information for that benefit year (including data from the insolvent issuer) in accordance with HHS's operational guidance to maintain eligibility to receive payments under this program for the given benefit year. Operationally, the acquiring entity may elect to have the insolvent issuer submit the data on behalf of both entities. We will work with issuers and other acquiring entities in these situations to facilitate the submission of the necessary data to EDGE servers for HHS to calculate risk adjustment financial transfers and reinsurance payments.

We also recognized that guaranty funds may not meet all of the requirements to be considered a risk adjustment covered plan or reinsurance eligible plan (for example, they may not meet the definition of ''health insurance issuer''), and so we proposed to permit a guaranty fund to participate in those programs notwithstanding these definitions, to the extent it has taken over liability for a risk adjusted covered plan or reinsurance eligible plan during a benefit year.

We sought comment on these policies, including with respect to permissible ways in which the acquiring entity's arrangements may differ and other ways of ensuring the submission of the data necessary for HHS to calculate the risk adjustment financial transfer amounts and the reinsurance payment amounts when another party will take over operations of the insolvent issuer, or pay claims on behalf of the insolvent issuer, during a benefit year. We also solicited comments on whether additional flexibility is needed with respect to the data submission requirements for the reinsurance and risk adjustment programs, such as with respect to the definition of a ''paid claim'' to account for situations when an issuer is unable to pay claims for covered services, for example, due to insolvency.

We received a number of comments on these policies. Most commenters supported the general intent of the policies but requested additional information or clarification of certain aspects of them. We are finalizing this policy with certain clarifications, as detailed below.

Comment: Two commenters requested that we clarify the term ''substantially the same'' in this context, and one of these commenters questioned whether a guaranty fund that pays only a portion of the original covered benefits would meet this standard.

Response: With respect to the acquisition of business from an insolvent issuer, an acquiring entity must, at a minimum, carry over accumulators for deductibles and annual limitations on cost sharing to meet the substantially the same standard. We note that this standard is unrelated to the standards under § 153.500 for determining whether a health plan offered outside of the Exchange is the same as a QHP for the purposes of the risk corridors program. We will continue to monitor situations involving issuer insolvencies and intend to issue further guidance as necessary.

Comment: Two commenters expressed concern about the opportunity for gaming by acquiring issuers if they have the option, but are not required to accrue and submit claims experience for the insolvent issuer, because they could select the

approach that would be most favorable to their risk adjustment calculation.

Response: We appreciate the concern, but we believe that a single EDGE server submission better reflects the true economic risk of the enrollment in the plans of the insolvent issuer, and note that an acquiring entity taking over the insolvent issuer's business could structure the acquisition to provide for separate submissions. We will work with issuers and acquiring entities in these situations to facilitate the submission of accurate and complete data to EDGE servers that is necessary to calculate risk adjustment financial transfers and reinsurance payments.

Comment: One commenter encouraged us to address situations involving a State guaranty fund or liquidator separately from those involving an acquiring issuer, given their differing roles and responsibilities. This commenter also requested that liquidators, in addition to guaranty funds, be given explicit ability to participate in the reinsurance and risk adjustment programs as they are often responsible for providing pre-liquidation coverage. Another commenter questioned whether a guaranty fund would be able to participate in risk adjustment under State law or operationally. A separate commenter proposed that the policies apply to providers in the same manner as guaranty associations, because the majority of issuers in its State are not subject to the guaranty association to pay claims; however, providers are required to hold consumers harmless if their insurance company becomes insolvent.

Response: We clarify that this policy permits participation of a liquidator or a State guaranty fund in the risk adjustment and reinsurance programs, to the extent it has taken over liability for a risk adjustment covered plan or reinsurance eligible plan during a benefit year, unless otherwise prohibited by State law. We recognize that restrictions under State law, or operational limits, may apply. In the case where a guaranty fund assumes liability for a risk-adjustment covered plan or reinsurance eligible plan, the guaranty fund would submit data acting on behalf of the insolvent issuer; however, the insolvent issuer would retain responsibility for the coordination of the EDGE data submission. While we understand that policyholders in some States are not covered by guaranty funds, it is not clear how providers could coordinate the submission of an EDGE server because the responsibility to submit data to the EDGE server applies to the issuer and the EDGE server does not support the submission of individual claims from providers.

Comment: One commenter recommended that, in the event that an issuer in a market in a State is unable to pay a risk adjustment charge in full, HHS adjust both risk adjustment payments and charges in that market and State, rather than only payments, to ensure that the shortfall is distributed proportionally among issuers in the risk pool.

Response: We appreciate the recommendation and will consider proposing this approach in rulemaking for future benefit years.

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

1. Disclosure and Review Provisions

a. Rate Increases Subject To Review (§ 154.200)

In the proposed rule, we proposed amending paragraph (c)(2) of § 154.200 to re-establish that a rate increase for single risk pool coverage effective on or after January 1, 2017, must be calculated as the premium-weighted average rate increase for all enrollees. The proposed change would reverse a previous amendment [24] that defined a rate increase for single risk pool coverage effective on or after January 1, 2017 as an increase in the plan-adjusted index rate. We note that the previous amendment also established a plan level trigger for a product being subject to review for coverage effective on or after January 1, 2017. The proposed amendment maintained the plan level trigger for the subject-to-review threshold.

We proposed the amendment to the calculation method because an increase in the plan-adjusted index rate does not reflect changes to adjustment factors for rating area, age, or tobacco use. For example, an issuer could change geographic rating area factors such that members in a certain rating area receive a larger increase, but if the plan-adjusted index rate did not meet or exceed the threshold then the rate increase would not be subject to rate review.

We are finalizing this section as proposed, so that a rate increase for single risk pool coverage effective on or after January 1, 2017 is subject to review if the average increase, including premium rating factors described in § 147.102, for all enrollees weighted by premium volume for any plan within the product meets or exceeds the applicable threshold. This amendment strengthens consumer protections against unreasonable rate increases by ensuring that coverage with a significant rate increase due to changes in rating factors is subject to review.

We maintain that the plan level rate increase, as opposed to the product level rate increase, will determine whether the increase is subject to review. The plan level trigger was finalized in the 2016 Payment Notice (80 FR 10781) effective for coverage beginning on or after January 1, 2017.

Comment: Some commenters expressed concern regarding the inclusion of premium rating factors and requested HHS clarify how rate changes should be calculated according to the proposal.

Response: All rating factors, including rating area and tobacco use factors, should be captured in the calculation of plan rate changes. The intent here, in the context of the rate review program, is to measure the premium change based on an issuer's current population compared to that same population if the new rates were implemented. This is not intended to capture demographic changes, such as a member aging up or moving to a new geographic location.

b. Submission of Rate Filing Justification (§ 154.215)

In the proposed rule, we proposed to revise § 154.215(a)(1) to require health insurance issuers to submit the Unified Rate Review Template (also known as Part I of the Rate Filing Justification) for all single risk pool coverage in the individual or small group (or merged) market, regardless of whether any plan within a product is subject to a rate increase. This proposal was made to carry out the Secretary's responsibility, in conjunction with the States, under section 2794(b)(2)(A) of the PHS Act to monitor premium increases of health insurance coverage offered through as well as outside of an Exchange. We also expressed our intent to disclose information that is not a trade secret or confidential commercial or financial information for all proposed rate increases for single risk pool coverage, rather than only proposed rate increases subject to review, as well as all final rate increases.

We proposed to revise paragraph (a) to insert paragraph (a)(1) to establish that health insurance issuers must submit the Unified Rate Review Template (''URRT,'' also known as Part I of the Rate Filing Justification) for all single risk pool products in the individual or small group (or merged) market, regardless of whether any plan within a product is subject to a rate

[24] 80 FR 10749, 10863 (Feb. 27, 2015).

increase. We also proposed to insert paragraph (a)(2) to capture the existing requirement that issuers must submit a URRT and an Actuarial Memorandum (also known as Parts I and III of the Rate Filing Justification) when a single risk pool product has a plan that is subject to a rate increase of any size. Similarly, we proposed to insert paragraph (a)(3) to capture the existing requirement that an issuer must provide that all three parts of the Rate Filing Justification (that is, the Part I URRT, the Part II written description justifying a rate increase, and the Part III Actuarial Memorandum) when a single risk pool product has a plan with a rate increase that is subject to review. Accordingly, we proposed to revise paragraph (b) to provide that a Rate Filing Justification for single risk pool plans must include one or more of the three parts, as appropriate, but not necessarily all three. We also proposed to remove and reserve paragraph (c), as it was unnecessary in light of the proposed amendments to paragraphs (a) and (b). We are finalizing all of the amendments to this regulation as proposed.

Comment: A majority of commenters supported the proposal and several recommended that all proposed rate changes should be made public, rather than just proposed rate increases. Some commenters, however, expressed concern regarding the proposal, citing the statutory obligation to review only unreasonable premium increases, rather than all increases. A few commenters stated that publicizing rate filings before they are finalized eliminates competitive advantages for plans.

Response: We are finalizing the proposal to collect rate filings for all single risk pool products in order to carry out the Secretary's statutory responsibility [25] to monitor premium increases of health insurance coverage. HHS will post information for all proposed rate filings for the individual and small group markets within a state at a uniform time to promote fair market competition between issuers through and outside of the Exchange and further enhance transparency of the rate-setting process. We note that States with an Effective Rate Review Program are required to post proposed rate increases subject to review and have a mechanism for receiving public comments on those proposed rate increases. CMS's decision to post information for all proposed rate filings for single risk pool coverage does not affect or change the State's obligation to post proposed rate increases under § 154.301(b).

Comment: Some commenters requested that HHS should make final rate information publicly available at least 15 days before open enrollment.

Response: Final rate increase information must be posted at a uniform time for all single risk pool coverage (regardless of whether the coverage is sold on the Exchange) by the first day of open enrollment,[26] but States may establish an earlier uniform posting timeframe with appropriate notice to CMS.[27] We believe this timeframe strikes a balance between providing State and Federal regulators sufficient time to complete their reviews, while providing consumers the information needed to make informed purchasing decisions.

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

In the proposed rule, we proposed technical changes to § 154.220 to remove references to rate increases and clarify that the timeframes listed pertain to all single risk pool products with or without rate changes to conform with the proposed amendments to § 154.215. We are finalizing the amendments to this regulation as proposed.

Comment: Some commenters requested that HHS change the filing deadline to a time after the risk adjustment report is released to issuers. Other commenters suggested States establish their own rate filing submission deadlines rather than adhering to HHS filing deadlines.

Response: We acknowledge the comments, and consistent with the approach outlined in guidance being released with this rule,[28] we are providing States with an effective rate review program [29] with additional flexibility with respect to the submission deadline for proposed rate filings for single risk pool products. Issuers in a State effective rate review program must submit proposed rate filings for single risk pool coverage (for both QHPs and non-QHPs) on a date set by the State, so long as the date is not later than July 15, 2016. We encourage States with effective rate review programs that are served by the HealthCare.gov platform to set a date that aligns with the Federally-facilitated Exchange QHP filing deadlines; [30] however, we understand some States may face challenges in doing so. Issuers in States without effective rate review programs [31] must submit proposed rate filings for single risk pool coverage (for both QHPs and non-QHPs) on a date set by the State, so long as the date is not later than May 11, 2016. Further, we note that all States retain flexibility to establish an earlier submission date under § 154.220(b).

d. Submission and Posting of Final Justifications for Unreasonable Rate Increases (§ 154.230)

We proposed to fix a typographical error and change the cross reference in § 154.230(c)(2)(i) to reference § 154.215(h) rather than § 154.215(i). There were no comments submitted regarding this section. We are finalizing the amendment as proposed.

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

In the proposed rule, we restated that making rate information available to the public at a uniform time (rather than a rolling basis) is one of the criteria for determining whether a State has an Effective Rate Review program.[32] We expressed our intent to propose a uniform timeline for release of proposed rate increases subject to review and for all final rate increases for single risk pool coverage. We are maintaining the requirement for releasing rate information at a uniform time rather than on a rolling basis. We released the proposed timeline for the 2016 Filing Year on December 23, 2015.[33] Public comments were accepted until January 22, 2016. We are releasing the final timeline in guidance [34] with this final rule, as discussed above.

Comment: Many commenters expressed support for requiring States to post all rate increases at the same time. Some commenters opposed having a uniform posting timeline, requesting that States be able to establish the timeline for SBEs.

[25] Section 2794(b)(2)(A) of the Public Health Service Act.

[26] § 154.301(b)(1)(ii).

[27] § 154.301(b)(2).

[28] CMS Insurance Standards Bulletin: Timing of Submission and Posting of Rate Filing Justifications for the 2016 Filing Year for Single Risk Pool Coverage, (Feb. 29, 2016).

[29] See 45 CFR 154.301 for a list of criteria that CMS considers when evaluating whether a State has an effective rate review program

[30] Final 2017 Letter to Issuers in the Federally-facilitated Marketplaces (Feb. 29, 2016).

[31] For the 2017 plan year, health insurance issuers in Alabama, Missouri, Oklahoma, Texas, and Wyoming are required to submit rate filings for review by CMS to determine reasonableness.

[32] § 154.301(b).

[33] DRAFT Bulletin: Timing of Submission and Posting of Rate Filing Justifications for the 2016 Filing Year for Single Risk Pool Coverage1 Effective on or after January 1, 2017, (Dec. 23, 2015), available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Timeline-Bulletin-12-23-15-FINAL.pdf.*

[34] CMS Insurance Standards Bulletin: Timing of Submission and Posting of Rate Filing Justifications for the 2016 Filing Year for Single Risk Pool Coverage (Feb. 29, 2016).

Response: The requirement for a State with an Effective Rate Review program to post proposed rate increases that it reviews, and to have a mechanism for receiving public comments on those proposed rate increases, has been in effect for several years. The uniform timeline requires States to ensure that the proposed rate increases subject to review, as well as all final rate increases, are released to the public at the same time. This policy ensures that rate information is available simultaneously for coverage offered through and outside of the Exchange, which enhances transparency and promotes fair market competition. We note that the guidance being released with this final rule provides States with an effective rate review program with flexibility to set a date to post proposed rate filings for single risk pool products with rate increases subject to review, provided the date set by the State is no later than August 1, 2016. Nothing in this rule prevents States from making additional information available to the public, or prevents States from establishing earlier uniform timeframes for public disclosure.

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

1. Definitions (§ 155.20)

In § 155.20, we proposed to amend the definition of ''applicant'' for the small group market so that the term also includes an employer seeking eligibility to purchase coverage through a SHOP, without necessarily enrolling in that coverage themselves. The current definition of an applicant contemplates an employer, employee, or former employee seeking eligibility for enrollment in a QHP through the SHOP for himself or herself. For consistency with our existing regulations governing the SHOP application process at §§ 155.710 and 155.715 and for consistency with how the small group market typically works, we proposed that the term applicant also include an employer who is seeking eligibility to purchase coverage through a SHOP, but who is not seeking to enroll in that coverage for himself or herself. We received no comments on this proposal and are finalizing this amendment as proposed.

We proposed to modify the definitions of ''small employer'' and ''large employer'' at § 155.20 to align with the Protecting Affordable Coverage for Employees Act, which was recently enacted, as further described in the preamble to § 144.103. For a discussion of the provisions of this final rule related to the definitions of small employer and large employer in § 155.20, please see the preamble to § 144.103. We did not propose to change the applicability of the counting methodology under section 4980H(c)(2) of the Code to these definitions in § 155.20, but we proposed amendments to these definitions that eliminate language about the timing of the applicability of the counting methodology under section 4980H(c)(2) of the Code under these definitions, because that language is no longer relevant. We did not receive any comments regarding this aspect of the proposal and are finalizing as proposed the elimination of the language about the timing of applicability of the counting methodology under section 4980H(c)(2) of the Code.

We proposed to amend § 155.20 to add a definition for ''Federal platform agreement'' to apply to this part. We defined a Federal platform agreement to mean an agreement entered into by a State Exchange and HHS, under which the State Exchange agrees to rely on the Federal platform to carry out select Exchange functions. We are finalizing the definition, with a slight modification to reflect the fact that the State election to implement the SBE–FP would occur through the Blueprint process in § 155.106(c) rather than the Federal platform agreement, which will reflect the agreement between the parties and will be entered into at the end of the Blueprint process. The Federal platform agreement, which we will publish later this year, will also contain the parties' mutual obligations with respect to those Exchange functions and related matters.

For a discussion of the provisions of this final rule regarding standardized options, please see the preamble to part 156, regarding standardized options.

2. General Standards Related to the Establishment of an Exchange

a. Election To Operate an Exchange After 2014 (§ 155.106)

We proposed to modify the timeframes for submission and approval of documentation specifying how an Exchange established by a State or a regional Exchange meets the Exchange approval standards (that is, the Exchange Blueprint). Based on our experience over the last two open enrollment periods, we believe the current Exchange Blueprint application deadlines for States intending to operate a State Exchange do not sufficiently balance the need to provide States with time to adequately prepare their Blueprint applications against the need to ensure HHS has sufficient time to accurately assess a State's progress and ability to timely build the necessary Exchange information technology. In our experience, the process for seeking approval to operate a State Exchange involves substantial technical assistance and collaboration between HHS and the State in developing plans to transition from one Exchange operational model and information technology infrastructure to another, including key milestones, deadlines, and contingency measures. Since the completion of some of these key milestones and deadlines would need to occur prior to the submission of the Blueprint application, we proposed that we will make that technical assistance available and initiate the transition process following submission of a declaration letter from the State, as provided for in the Blueprint approval process. The declaration letter would serve as formal notification to HHS of a State's intent to operate a State Exchange, including operating an SBE–FP, and to submit a Blueprint (or Blueprint update) for HHS approval. The declaration letter would initiate coordination between the State and HHS on a transition plan. The declaration letter would also serve as a starting point for HHS to communicate the operational steps that a State must complete in order to become an SBE, as well as a starting point for HHS to assess a State's progress by the time of the State's Blueprint or Blueprint update submission. We would require a declaration letter approximately 21 months prior to the beginning of the SBE's first annual enrollment and approximately 9 months prior to the beginning of an SBE–FP's first annual open enrollment. HHS would assess later submissions on a case-by-case basis, recognizing operational realities and need for adequate notice for stakeholders, including issuers and consumers.

In § 155.106(a)(2), we proposed to require States that are establishing a State Exchange (not including a State Exchange using the Federal platform for certain functions) to submit an Exchange Blueprint at least 15 months prior to the date the Exchange proposes to begin open enrollment as a State Exchange. We also proposed in § 155.106(a)(3) to increase the time that the State must have in effect an approved or conditionally approved Exchange Blueprint from 6.5 months to 14 months prior to the date the Exchange proposes to begin open enrollment as a State Exchange. We recognized that in some situations the open enrollment period may not have

been established when Blueprints are due. Therefore, we proposed in paragraph (a)(5), if the open enrollment period for the year the State intends to begin operating an SBE has not been established, a State should assume open enrollment will begin on the same date as open enrollment is to begin for the year in which they are submitting the Blueprint.

We proposed to revise paragraph (b) to clarify that HHS will operate the Exchange if a State Exchange ceases operations.

We proposed to add a paragraph (c) to establish requirements for a State that elects to operate an SBE–FP. These States must submit an Exchange Blueprint (or submit an update to an existing approved Exchange Blueprint) at least 3 months prior to the date open enrollment is to begin for the State as an SBE–FP; and must have in effect an approved, or conditionally approved, Exchange Blueprint and operational readiness assessment at least 2 months prior to the date on which the Exchange proposes to begin open enrollment as an SBE–FP. If the State Exchange has a conditionally approved Exchange Blueprint application, we proposed that it would not be required to submit a new Blueprint application, but instead must submit any significant changes to that application for HHS approval at least 3 months prior to the date on which the Exchange proposes to begin open enrollment as an SBE–FP. As part of HHS's approval or conditional approval of the Exchange Blueprint or amended Blueprint, these States must execute a Federal platform agreement and be required to coordinate with HHS on a transition plan.

Lastly, we want to be clear that we only proposed changes to the timelines for submission of the Blueprint application. We did not otherwise propose any modifications to the information and documents that States must submit as part of the Exchange Blueprint application.

We are finalizing our proposals as proposed, except that, in order to provide additional time for the transition, we are amending the timing of the Federal platform agreement, so that it must be executed prior to approval or conditional approval of the Exchange Blueprint.

Comment: Several commenters expressed concern that the proposed Blueprint submission and approval timelines for a State transitioning to an SBE–FP do not allow sufficient time for a State and its issuers to make the necessary operational changes to prepare for the State's transition to the SBE–FP model, and for HHS to make an assessment of the State's progress. A commenter indicated that they would also like to see a timeline for when the Federal platform agreement must be fully executed. Finally, comments were received regarding the need for HHS to publish the operational steps involved in the transition to an SBE–FP, including the need for issuer outreach and flexibility in transition plans for individual States.

Response: We are finalizing the regulations as proposed. We believe that the Blueprint timeline provides sufficient time for a State to become or transition to an SBE–FP because that transition will begin with the submission of the declaration letter. Part of the technical assistance provided upon submission of the declaration letter will be the communication of the operational steps that a State must complete in order to become an SBE–FP, including the operational steps States are required to take with their issuers. We plan to publish guidance on these operational steps.

b. Additional Required Benefits (§ 155.170)

Section 1311(d)(3)(B) of the Affordable Care Act permits a State, at its option, to require QHPs to cover benefits in addition to the EHB, but requires a State to make payments, either to the individual enrollee or to the issuer on behalf of the enrollee, to defray the cost of these additional State-required benefits. In the 2016 Payment Notice, we instructed States to select a new EHB base-benchmark plan to take effect beginning for the 2017 plan year. The final EHB base-benchmark plans selected as a result of this process have been made publicly available.[35]

Section 1311(d)(3)(B) of the Affordable Care Act refers to situations in which the State requires QHPs to cover benefits. That section is not specific to State statutes, and we have interpreted that section to apply not only in cases of legislative action but also in cases of State regulation, guidance, or other State action. Therefore, we proposed to reword § 155.170(a)(2) to make clear that a benefit required by the State through action taking place on or before December 31, 2011 is considered an EHB.

In the EHB Rule (78 FR 12837 through 12838), we discussed § 155.170(a)(2), which implements section 1311(d)(3)(B) of the Affordable Care Act. In our discussion of that provision, we provided that State-required benefits enacted on or before December 31, 2011 (even if not effective until a later date) may be considered EHB, which would obviate the requirement for the State to defray costs for these State-required benefits. This policy continues to apply. Therefore, benefits required by a State through action taking place after December 31, 2011 that directly apply to the QHPs are not considered EHB (unless enactment is directly attributable to State compliance with Federal requirements, as discussed below).

Although benefits requirements enacted by States after December 31, 2011 that directly apply to the QHP and that were not enacted for purposes of compliance with Federal requirements are not considered EHB,[36] the base-benchmark plan might cover some of those non-EHB. Nonetheless, issuers must treat those benefits as they would other non-EHB, such as those identified in § 156.115(d),[37] and the State must defray the cost. We proposed to codify this interpretation in § 155.170(a)(2).

At § 155.170(a)(3), we currently require the Exchange to identify which additional State-required benefits, if any, are in excess of EHB. We proposed to amend paragraph (a)(3) to designate the State, rather than the Exchange, as the entity that identifies which State-required benefits are not EHB. We proposed this change because we believe insurance regulators are generally more familiar with State-required benefits. We believe each State should determine the appropriate State entity best suited to identify newly required benefits. Additionally, for consistency of terminology, we proposed to amend paragraph (a)(3) to replace the reference to ''in excess of EHB'' with ''in addition to EHB.''

In current § 155.170(c)(2)(iii), we require QHP issuers to quantify the cost attributable to each additional State-required benefit and report their calculations to the Exchange. We proposed to designate the State as the entity that receives issuer calculations in paragraph (c)(2)(iii). Since the Affordable Care Act requires the State to remit a payment to an enrollee or issuer, we stated that we believe the calculation should be sent directly to the State rather than to the Exchange.

[35] Available at *https://downloads.cms.gov/cciio/FinalListofBMPs_15_10_21.pdf.*

[36] The 2016 Payment Notice provides that States are not expected to defray the cost of State-required benefits enacted on or after January 1, 2012 that were required in order to comply with new Federal requirements. (80 FR 10749, 10813 (Feb. 27, 2015)).

[37] An issuer of a plan offering EHB may not include routine non-pediatric dental services, routine non-pediatric eye exam services, long-term/custodial nursing home care benefits, or non-medically necessary orthodontia as EHB.

The 2016 Payment Notice specified that a State may need to supplement habilitative services if the base-benchmark plan does not cover such services. We noted that if a State supplements the base-benchmark plan, there is no requirement to defray the cost of the benefits added through supplementation, as long as the State must supplement the base-benchmark to comply with the Affordable Care Act or another Federal requirement. Examples of such Federal requirements include: Requirements to provide benefits and services in each of the 10 categories of EHB; requirements to cover preventive services; requirements to comply with the Mental Health Parity and Addiction Equity Act; and the removal of discriminatory age limits from existing benefits.

In some States, the base-benchmark plan may be a large group (non-Medicaid HMO or State employee) plan. We stated that we have received questions regarding State-required benefits that are embedded in those large group base-benchmark plans. As stated earlier in this section, if the State-required benefit in question was required by State action after December 31, 2011, applies directly to the QHP, and was not enacted for purposes of compliance with Federal requirements, the benefit is not considered EHB, even if the benefit is embedded in the base-benchmark plan. However, we stated that a benefit required only in the large group market and reflected in a large group base-benchmark plan is not an EHB for QHPs offered in the individual or small group markets because such a benefit requirement does not apply directly to those plans, and to the extent it is included in the base-benchmark plan, it may be substituted for, in accordance with § 156.115(b). Therefore, the State would not have to defray the cost of individual and small group market QHPs covering State-required benefits that are required in the large group market only. (However, to the extent the State permits large group plans to be sold as QHPs through the State's Exchange, the State would have to defray the cost of the large group QHPs covering the mandated benefit.) We noted that plans subject to the EHB requirements offered in the individual and small group markets in those States would have to be substantially equal to the base-benchmark plan, and therefore may cover the State-required benefit as EHB since it is embedded in the base-benchmark plan. In such a case, we proposed to clarify that the benefit is an EHB because it is covered by the base-benchmark plan, but the cost of coverage by individual and small group QHPs does not have to be defrayed, because the State-required benefit does not apply directly to those QHPs.

We noted that some States have imposed new benefit requirements only on individual and small group plans that are not QHPs such that only individual and small group plans sold outside the Exchange must cover the State-required benefit. We noted that a QHP generally may be sold outside the Exchanges in which case it would be subject to these new benefit requirements. We cautioned States, however, that imposing different benefit mandates depending on a plan's status as a QHP or because it is sold through the Exchange may violate section 1252 of the Affordable Care Act. Under this section, State standards or requirements implementing, or related to, standards or requirements in title I of the Act must be applied uniformly within a given insurance market. Thus, if a State requires that non-QHPs in the individual or small group market provide any benefits, under section 1252, the State must require QHPs sold through the Exchange in that same market to provide those same benefits, and consistent with our earlier stated policy at § 155.170(a)(2), States would generally be required to defray the cost of QHPs providing the required benefits if they were required through State action taking place after December 31, 2011.

We noted that the Protecting Affordable Coverage for Employees Act, enacted in October 2015, amended the definitions of small employer and large employer in section 1304(b) of the Affordable Care Act and section 2791(e) of the PHS Act such that a small employer is generally [38] an employer with 1–50 employees, with the option for States to expand the definition of small employer to 1–100 employees.[39]

We noted that several States have enacted benefit requirements that would apply to small group insurance plans offered to employers with 51–100 employees, but not to employers with 1–50 employees. This may arise because the State-required benefit was designed to apply only in the large group market when the large group market included employers with more than 50 employees, but the State has since then availed itself of the option to define a small employer as an employer with 1–100 employees.

We noted that section 2702 of the PHS Act and § 147.104 generally require an issuer to offer all approved products to any individual or employer in the market for which the product was approved and to accept any individual or employer that applies for any approved product in a given market. If a State elects to expand the definition of small employer so that it covers employers with 1–100 employees, all products approved for sale in the small group market (defined by the State as 1–100 employees) generally must be offered to employers with 1–100 employees. This effectively means that existing State benefits mandates that apply to insurance coverage sold to employers with 51–100 employees would then effectively also apply to all products sold to employers with 1–100 employees. As long as the benefit was required by State action taken on or before December 31, 2011, the expansion of coverage would not trigger the requirement to defray, because the expansion was required to comply with Federal guaranteed availability laws. If a State does not opt to expand the definition of small employer to 1–100 employees, then any State-required benefits applicable in the large group market (including to employers with 51–100 employees) would continue to not apply in the small group market. If a State-required benefit was imposed by State action taking place January 1, 2012 or later, then defrayal generally would be required. We are finalizing our proposals and clarifications as proposed.

Comment: Several commenters agreed that a benefit required by a State through action taking place on or before December 31, 2011 is considered an EHB. Multiple commenters supported the proposal that States and not the Exchange identify what is in addition to EHB.

Response: We agree that a benefit required by action taking place on or before December 31, 2011 is considered EHB; this has been our policy since releasing the EHB Rule. We recognize that States regulators are generally more familiar with State-required benefits than an Exchange. We believe each State should determine the appropriate State entity best suited to identify newly

[38] Prior to enactment of the Protecting Affordable Coverage for Employees Act, small employer was defined to mean, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 1 but not more than 100 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year. In case of plan years beginning before January 1, 2016, a State was able to elect to define small employer by substituting ''50 employees'' for ''100 employees''. For ease of reference with regard to this section, we will refer to employers as having 1–50 or 1–100 employees.

[39] States that elect to extend the small employer definition were requested to notify CMS of their election by October 30, 2015 at *marketreform@cms.hhs.gov.*

required benefits. Therefore, we are finalizing the rule as proposed.

Comment: Numerous commenters questioned how States can supplement an EHB category without assuming the financial burden. Multiple commenters sought guidance on how to determine that a State requirement, particularly a habilitative services requirement, goes beyond EHB, and how to determine the additional cost attributed to each such additional required benefit.

Response: The ten categories of EHB, and the process for supplementing base-benchmark plans to establish EHB-benchmark plans, are outlined in § 156.110. In the 2016 Payment Notice (80 FR 10749, 10813), we stated that benefit requirements enacted by States after December 31, 2011 that directly apply to QHPs, and that were not enacted for purposes of compliance with Federal requirements are not considered EHB. We also stated that if the base-benchmark plan does not include coverage for habilitative services, the State may define that benefit category. There is no requirement to defray the cost of the State-required benefits, as long as the State requirement is consistent with section 1302 of the Affordable Care Act and § 156.110. We also note that § 156.110(f) allows States to determine services included in the habilitative services and devices category if the base-benchmark plan does not include coverage; and that States are not expected to defray the cost of State-required benefits enacted after December 31, 2011 that were required in order to comply with new Federal requirements. We are affirming that the State has the flexibility to define habilitative services; however, the State must use a reasonable interpretation as to what services are habilitative. Further, a State may also modify that definition in future years, as medical evidence and treatments evolve. We note that any State definition must comply with applicable nondiscrimination rules. This final rule requires the State to determine, based on these standards, when State requirements require issuers to provide benefits in addition to EHB.

Section 155.170(c)(1) requires issuers to quantify the cost attributable to each additional State-required benefit. We are finalizing our proposal that QHP issuers must report their calculation to the State. Since the State is required by statute to remit a payment to an enrollee or issuer, we believe the calculation should be sent directly to the State rather than to the Exchange. The actual cost attributed can then be made public by the State, if it so chooses. Section 155.170(c)(2)(i) through (iii) states that QHP issuers' calculations must (1) be based on an analysis performed in accordance with generally accepted actuarial principles and methodologies; (2) conducted by a member of the American Academy of Actuaries; and (3) reported to the State.

Comment: Some commenters disagreed with our interpretation that State-required benefits that apply only to individual and small group plans that are not QHPs may violate section 1252 of the Affordable Care Act.

Response: Section 1252 of the Affordable Care Act provides that State requirements under Title I of the Affordable Care Act must be applied uniformly to all health plans in an insurance market. We reiterate that a requirement that depends upon a plan's status as a QHP or whether it is sold through the Exchange may violate section 1252 of the Affordable Care Act.

Comment: Some commenters expressed concerns about discriminatory benefit design, and sought further guidance regarding what benefit designs could be deemed discriminatory.

Response: Under § 156.125(a), 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. Furthermore, plans may not establish annual dollar limits on individual items or services that are EHB. We will consider providing further guidance regarding discriminatory benefit design in the future.

3. General Functions of an Exchange

a. Functions of an Exchange (§ 155.200)

We proposed a technical correction to § 155.200(a) to include a reference to subpart M, which establishes oversight and program integrity standards for State Exchanges, and subpart O, which establishes quality reporting standards for Exchanges.

We also proposed to amend § 155.200 by adding a paragraph (f) to address SBE–FPs. This arrangement is intended to permit a State Exchange to leverage existing Federal assets and operations by relying on HHS services for performing certain Exchange functions, particularly eligibility and enrollment functions. The SBE–FP would also rely on HHS to perform certain consumer call center functions and casework processes, and maintain related information technology infrastructure. The SBE–FP would retain responsibility for plan management functions, including QHP certification functions, subject to certain rules requiring the SBE–FP to require its QHP issuers to comply with certain FFE standards governing QHPs and issuers (as proposed in § 155.200(f)(2) of this proposed rule), and consumer support functions, subject to FFE rules governing consumer assistance functions.

Under § 155.200(f)(1), we proposed that a State may receive approval or conditional approval to operate an SBE–FP through the Blueprint process under proposed § 155.106(c) and meet its obligations under § 155.200(a) by entering into a Federal platform agreement with HHS. Through the Federal platform agreement, an SBE–FP would agree to rely on HHS for services related to the individual market Exchange, the SHOP Exchange, or both the individual market and SHOP Exchanges. The Federal platform agreement would specify the Federal services on which the State Exchange relies, the user fee (as specified at § 156.50(c)(2)) that HHS will collect from issuers in that SBE–FP for the Federal services, and other mutual obligations relating to the arrangement, including obligations for the transfer of data. The Federal platform agreement would specify expectations between the State and HHS across various operational areas. We indicated our intent to release the Federal platform agreement at a later date. We noted that at this point the Federal services on which SBE–FPs may rely will come as an entire package. That is, HHS will not at this time offer a ''menu'' of Federal services from which an SBE–FP may select some but not other services available on the Federal platform. However, we indicated we would explore the feasibility of doing so in the future.

Although the SBE–FPs would retain primary responsibility for certifying QHPs and overseeing QHPs and issuers, we proposed under § 155.200(f)(2) to require an SBE–FP to establish and oversee certain requirements for its QHPs and QHP issuers that are no less strict than the requirements that apply to QHPs and QHP issuers on an FFE. We proposed these requirements to include the existing and proposed standards under the following sections: § 156.122(d)(2) (the requirement for QHPs to make available published up-to-date, accurate, and complete formulary drug list on its Web site in a format and at times determined by HHS); § 156.230 (network adequacy standards); § 156.235 (essential community providers standards);

§ 156.298 (meaningful difference standards); § 156.330 (changes of ownership of issuers requirement); § 156.340(a)(4) (QHP issuer compliance and compliance of delegated and downstream entities requirements); § 156.705 (maintenance of records standard); § 156.715 (compliance reviews standard); and § 156.1010 (casework standards).

Applying the changes of ownership issuers' requirement to SBE–FPs will help fulfill the Federal platform's need for data and technical consistency. It will ensure that HHS maintains the most accurate and updated information to present a consistent experience to consumers through its branded platform, HealthCare.gov. HHS must be able to monitor and provide regulatory oversight over change in control situations with regards to the operation of the Federal platform. Change in control has a significant operational impact on the Federal platform and requires the expenditure of considerable technical resources to effectuate the change throughout the multiple systems that constitute the Federal platform.

Applying the formulary drug list, network adequacy, meaningful difference, and essential community providers standards will ensure that all QHPs on HealthCare.gov meet a consistent minimum standard and that consumers obtaining coverage as a result of applying through HealthCare.gov are guaranteed plans that meet these minimum standards. HHS has designed and implemented policy and operations for the FFE such that shoppers at HealthCare.gov can experience a consistent standard of service. We proposed that SBE–FPs that wish to rely on the HealthCare.gov platform require their issuers to meet certain minimum standards as well, since their consumers are obtaining the coverage through HealthCare.gov. SBE–FPs have the flexibility to exceed these minimum standards to the extent they do not present display problems on HealthCare.gov. Although we clearly recognize that the SBE–FPs are SBEs, and thus legally distinct from FFEs, this difference will not always be apparent to HealthCare.gov consumers. Not having these standards apply may lead to consumer confusion and dilution of consumer goodwill with respect to the plans available on HealthCare.gov. The States would still be responsible for conducting QHP certification reviews for these standards.

Applying the QHP issuer compliance and compliance of delegated or downstream entities requirement at § 156.340(a)(4), which involves the maintenance of records standards of § 156.705 and the compliance reviews for QHP issuers standards of § 156.715, will ensure that the SBE–FP has authority at least as strong as that possessed by HHS to enforce compliance with these standards and will ensure that the SBE–FP and HHS are able to access all records upon request from the issuers in the SBE–FPs.

Applying the casework standards at § 156.1010 will ensure that the SBE–FP and HHS can respond to problems about which they both bear responsibility. Since SBE–FPs must use the Federally operated Health Insurance Casework System (HICS) for handling consumer casework and meeting casework resolution timeframes as part of utilizing the Federal platform for eligibility and enrollment functions, the SBE–FP would not be overseeing casework processes. However, as with all other Exchange types, State departments of insurance will still handle appropriate consumer complaints related to issuers in their States. For cases that are Exchange-related, or those in which the consumer has chosen to contact the Exchange even after contacting the appropriate department of insurance, HHS would oversee the routing and resolution of casework. HHS's intent is to work collaboratively with the SBE–FP, similar to how HHS works with SPMs.

Finally, we proposed under § 155.200(f)(3) that HHS will work with SBE–FPs to enforce the FFE standards listed under § 155.200(f)(2) directly against SBE–FP issuers or plans who do not meet these standards. In that circumstance, we proposed that HHS would have the authority to suppress a plan under § 156.815. This will ensure that consumers shopping for coverage on HealthCare.gov have access to plans that are in compliance with the FFE standards with which SBE–FP issuers must comply as a condition of offering QHPs through a State Exchange on the Federal platform.

We intend to work closely and collaboratively with SBE–FPs, and believe that our collaboration with States that currently use the Federal platform with respect to enforcement matters has been close and effective. We are finalizing our proposals as proposed.

Comment: One commenter indicated that the inability of the Federal platform to accommodate State customization for SBE–FPs is a major disincentive for SBEs to use the Federal platform. The commenter also expressed concerns about the proposed Federal platform agreement not being able to be customized by individual State, as State procurement and contracting officials may require State specific language in contracts.

Response: We are finalizing the regulations as proposed. We intend to describe the availability of new capabilities of the Federal platform that would allow for SBE–FPs to select certain Federal services to use or to customize particular functionality in future rules, through our annual rulemaking process, as well as in future versions of the Federal platform agreement. At this time we do not foresee State-specific customization of the language in the Federal platform agreement, but will engage with States as part of the process of finalizing the agreement.

Comment: We received a comment that the proposed requirement to use the Federally operated HICS system creates procedural burdens on State-based consumer advocacy staff. The commenter recommended that consumer complaints for SBE–FPs should be referred directly to the appropriate State authority for resolution.

Response: We are finalizing the regulations as proposed. The Federally operated HICS system is closely tied to the SBE–FP's utilization of the Federal platform for eligibility and enrollment functions. While SBE–FPs must rely on the Federally operated HICS system for processing casework, we are open to future possibility of HHS coordination with SBE–FP States on consumer communications pertaining to casework and complaints to the extent it is operationally feasible. Should such coordination be operationally feasible, the roles and responsibilities between HHS and the State would be specified through the Federal platform agreement.

Comment: Regarding our proposals to apply certain FFE QHP standards to SBE–FP issuers, along with our proposed requirements pertaining to the enforcement of those standards, we received some comments that were supportive and comments that were opposed. The commenters that opposed the proposed requirements stated that SBE–FP States should maintain sole authority for setting standards for, and certifying, QHPs. One commenter stated that using two sets of enforcement standards would lead to consumer harm and insurer confusion. Another commenter expressed concern that the application of FFE standards could result in inconsistent treatment of off-Exchange QHPs and recommended that SBE–FP QHPs should be governed by the same State rules as SBEs to ensure market parity. Another commenter stated that the proposed requirements may cause confusion regarding the legal

status of SBE–FPs and the true extent to which certain Federal Exchange requirements and limitations apply. One commenter recommended that we explicitly state in the final rule that the implementing guidance issued through the annual Letter to Issuers also applies to issuers on SBE–FPs.

Response: We are finalizing the rules as proposed. HHS will coordinate with the SBE–FP on enforcement of FFE standards listed under § 155.200(f)(2) through plan suppression. SBE–FP States are being required to incorporate certain FFE QHP standards into their State's QHP standards and QHP certification process; thus, there would be only one set of QHP standards that apply to all issuers in a particular SBE–FP State. An SBE–FP would have the flexibility to exceed those FFE QHP standards when setting their QHP standards and QHP certification process should they elect to. There may be differences in standards set by an SBE–FP State for QHPs that participate in the Exchange versus plans that are offered outside of the Exchange, which can also occur in SBE and FFE States. Moving forward, the annual Letter to Issuers will include implementing guidance that is specific to SBE–FPs.

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

We proposed two amendments to § 155.205 to address functions of an SBE–FP. First, because an SBE–FP relies on HHS to carry out eligibility and enrollment functions, which would include relying on the FFE call center to carry out these functions, we proposed to amend § 155.205(a) to exempt an SBE–FP from the requirement to operate a toll-free call center, and instead provide that an SBE–FP must at a minimum operate a toll-free telephone hotline to respond to requests for assistance to consumers in their State, in accordance with section 1311(d)(4)(B) of the Affordable Care Act.

Secondly, we proposed to amend § 155.205(b) by adding paragraph (b)(7) to provide that an SBE–FP must, at a minimum, operate an informational Internet Web site in accordance with section 1311(d)(4)(C) of the Affordable Care Act. The informational Web site would direct consumers to HealthCare.gov to apply for, and enroll in, coverage through the Exchange.

We are also finalizing an amendment to § 155.205(b)(1), related to standardized options. For a discussion of this amendment, please see the preamble discussion of standardized options.

Comment: Some comments stated that having SBE–FPs maintain these consumer assistance features is duplicative and would cause confusion among consumers. Commenters also recommended further clarification between a toll-free call center and a toll-free telephone hotline, and defining minimum functional requirements of a toll-free hotline. Commenters also asked that HHS clarify the minimum requirements for the SBE–FPs informational Web site.

Response: We are finalizing the proposed requirement for the SBE–FP to operate a toll-free hotline and informational Web site, as this is based on statutory minimum functional requirements that an SBE (including an SBE–FP) must meet. A toll-free call center includes capabilities for processing eligibility and enrollment actions and accessing consumer information to process these actions, whereas a toll-free hotline includes the capability to provide information to consumers and appropriately direct consumers to the Federally operated call center or HealthCare.gov to apply for, and enroll in, coverage through the Exchange. Both the toll-free hotline and the informational Web site that an SBE–FP is required to operate must include the capability to direct consumers to the Federal platform services, including the FFE call center and HealthCare.gov Web site, to apply for, and enroll in, Exchange coverage. We are finalizing the requirement for SBE–FPs to operate a toll-free hotline and informational Web site.

c. Standards Applicable to Navigators Under §§ 155.210 and 155.215; Standards Applicable to Consumer Assistance Tools and Programs of an Exchange Under § 155.205(d) and (e); and Standards Applicable to Non-Navigator Assistance Personnel in an FFE and to Non-Navigator Assistance Personnel Funded Through an Exchange Establishment Grant (§§ 155.205, 155.210 and 155.215)

To help consumers apply for and enroll in QHPs and insurance affordability programs through the Exchange, we established consumer assistance programs, including the Navigator program described at section 1311(d)(4)(K) and 1311(i) of the Affordable Care Act and § 155.210. Among other duties, Navigators are required to conduct public education activities to raise awareness of the availability of QHPs; to distribute fair and impartial information concerning enrollment in QHPs and the availability of Exchange financial assistance; to facilitate enrollment in QHPs; and to provide referrals for any enrollee with a grievance, complaint, or question regarding their health plan, coverage, or a determination under such plan or coverage. We have also established under § 155.205(d) and (e) that each Exchange must provide consumer assistance, outreach, and education functions, which must include a Navigator program and can include a non-Navigator assistance personnel program.

We proposed to amend § 155.210(e) by adding a new paragraph (e)(8) to require Navigators in all Exchanges to provide targeted assistance to serve underserved or vulnerable populations within the Exchange service area. Navigators already must have expertise in the needs of underserved and vulnerable populations, and we believe that also requiring Navigators to provide targeted assistance to these populations is critical to improving access to health care for communities that often experience a disproportionate burden of disease. We also believe that Navigators should focus their outreach and enrollment assistance efforts on harder-to-reach populations and the remaining uninsured.

Because the characteristics of underserved and vulnerable populations may vary over time and from region to region, we proposed to permit each Exchange to define and identify the underserved and vulnerable populations in its service area, and to update these definitions as appropriate. This could include an Exchange allowing its Navigator grantees to propose which communities to target, for the Exchange's approval (for example, in their grant applications). In FFEs, we proposed to identify populations as vulnerable or underserved through our Navigator funding opportunity announcements and to give FFE Navigator grant applicants an opportunity to propose additional communities to target during the grant application process. We proposed that the primary criteria used to identify such populations within the FFEs would be that the population is disproportionately without access to coverage or care, or at a greater risk for poor health outcomes. Members of these populations could be identified by age groups, demographics, disease, geography, or other characteristics as defined or approved by the Exchange. In FFEs, our proposal would apply beginning with the application process for Navigator grants awarded in 2018.

Although we did not propose to extend this requirement to certified application counselors and non-Navigator assistance personnel subject to § 155.215, we stated in the preamble to the proposed rule that we would

encourage certified application counselors and non-Navigator assistance personnel subject to § 155.215 to prioritize assisting the vulnerable and underserved populations identified by the Exchange in their communities, and we recognize that many of these assisters already focus their efforts on such populations.

Navigators would not be serving these target populations exclusively, since all Navigators are required to assist any consumer seeking assistance. As we have explained previously, all Navigators should have the ability to help any individual who seeks assistance, even if that consumer is not a member of the community or group the Navigator intends to target (*see* 78 FR 20589; 78 FR 42830; 79 FR 30270; 79 FR 30278).

We are finalizing this provision as proposed.

Comment: We received many comments supporting our proposal to require Navigators in all Exchanges to provide targeted assistance to serve underserved or vulnerable populations within the Exchange service area. Commenters agreed that reaching these populations is important to increasing awareness among remaining uninsured consumers regarding coverage options available through the Exchange, helping consumers find affordable coverage that meets their needs, and narrowing health disparities. In addition, commenters stated that Navigators are uniquely positioned to serve these populations because of established ties and pre-existing relationships. Commenters also agreed that this provision should not be extended to certified application counselors and non-Navigator assistance personnel subject to § 155.215, but said that it would be helpful for HHS to educate these assister types about this kind of targeted assistance and how they can support Navigators' efforts.

Response: We agree that requiring Navigators to target assistance to underserved and vulnerable populations is critical to improving access to health coverage. We are not extending this requirement to certified application counselors and non-Navigator assistance personnel subject to § 155.215 in this final rule, but continue to encourage these assister types to prioritize reaching and assisting the vulnerable and underserved populations identified by the Exchange in their communities, and we recognize that many of these assister types already focus efforts on such populations. HHS has previously and will continue to provide technical assistance and resources on reaching and serving a variety of vulnerable and underserved populations to all Navigators, non-Navigator assistance personnel, and certified application counselors in the FFEs.

Comment: We received several comments regarding how Exchanges should identify vulnerable or underserved populations. Many commenters suggested data sources to consult when identifying these populations. Several commenters requested that HHS provide a list of underserved or vulnerable populations, made up of populations where there was either a documented lower rate of insurance prior to the implementation of the Affordable Care Act or where current enrollment rates are lower than those of other populations. Commenters recommended specific populations for identification, including low-income individuals and families; people of color; women; people living with HIV/AIDS; people living with disabilities; rural communities; lesbian, gay, bisexual, and transgender people; people with limited English proficiency; people with transportation limitations; people with mental health needs; children and youth with special health care needs; cancer survivors; low income immigrants; patients with rare diseases; survivors of domestic violence; abandoned spouses; and pregnant women enrolled in coverage that is not minimum essential coverage. In addition, several commenters requested that HHS ensure that SBEs consult with local stakeholders when defining underserved and vulnerable populations.

Response: Because the characteristics of underserved and vulnerable populations may vary over time and from region to region, we believe that SBEs are best positioned to identify the underserved and vulnerable populations in their States who most need targeted assistance and support. Therefore, we do not intend to provide a list or otherwise identify these populations in SBEs, including SBE–FPs. We encourage SBEs to work with local stakeholders and Navigators to identify populations to target, using reliable sources of data. For FFEs, HHS will identify vulnerable or underserved populations through our Navigator funding opportunity announcements and will give FFE Navigator grant applicants an opportunity to propose additional communities to target during the grant application process, beginning with the application process for Navigator grants awarded in 2018. The primary criteria the FFEs will use to identify vulnerable or underserved populations will be if they are disproportionately without access to coverage or care, or are at a greater risk for poor health outcomes.

Comment: We received several comments requesting that HHS further explain how Navigators are expected to target or focus their work on these populations, while still fulfilling the requirement to assist any consumer seeking assistance. Commenters expressed concern that this requirement might compel Navigator organizations to limit their services to certain populations or create such a perception.

Response: This provision does not require Navigators to limit their services to the specific populations they are targeting, and we rely on Navigators' creativity and local knowledge to structure their programs so that they target one or more vulnerable and underserved populations while remaining open to all consumers. For example, a Navigator grantee might open an application and enrollment assistance location in an area populated by a community that has historically experienced heath care access barriers, and reach out to community members in ways that are culturally competent and linguistically appropriate to that community, while remaining ready to serve any consumer seeking assistance. In the FFEs, we will provide more information regarding Navigator duties, scope of activities, and program requirements in the Navigator funding opportunity announcement. SBEs, including SBE–FPs, have flexibility to provide further guidance in this area as well. Finally, we continue to remind Navigators that we interpret Navigators' duty to provide fair and impartial information and services under § 155.210(e)(2) to require that all Navigators should have the ability to help any individual who seeks assistance from the Navigator, even if that consumer is not a member of the community or group the Navigator intends to target.

Comment: We received several comments regarding the selection process for Navigator grantees. Some commenters requested that HHS encourage Exchanges to prioritize entity types (such as safety net providers) or applicants capable of reaching underserved or vulnerable populations, and some recommended specific populations of Navigator grant applicants that should be given preference. In addition, commenters requested that HHS ensure that Exchanges adjust their grant-making criteria to account for the greater time and resources necessary to reach underserved and vulnerable communities. A few commenters requested that Navigators be required or

encouraged to collaborate with providers and other organizations, such as patient-focused and community-based organizations that are also engaged in consumer health and patient education, in order to ensure that underserved and vulnerable populations are receiving assistance. A few commenters also requested that HHS develop guidance for FFE Navigators, FFE non-Navigator assistance personnel, and FFE certified application counselors on collaborating and forming partnerships with groups that are engaged in reaching populations, consumer health, and patient education.

Response: For FFEs, we will take these comments into consideration when drafting Navigator selection criteria for the Navigator funding opportunity announcements for 2018 and future years. We agree that local collaboration and leveraging community partnerships might help Navigators reach marginalized communities, and we intend to issue guidance for FFE Navigators with additional information on collaborating or partnering with other community organizations. SBEs, including SBE–FPs, are responsible for administering their own Navigator programs, including determining their own selection process, consistent with statutory and regulatory authority.

Comment: We received several comments regarding the timeframes in which these populations would be identified. Commenters requested that Exchanges regularly re-identify these populations. Some commenters requested that these populations be identified at least 3 months prior to the beginning of open enrollment and that applicants be allowed to identify new populations for each grant cycle.

Response: SBEs, including SBE–FPs, retain flexibility to administer their own Navigator programs, and we encourage SBEs to regularly revisit the ways they define and identify vulnerable and underserved populations to ensure that the results remain current and relevant. In FFEs, we will continue to prioritize publicizing and awarding Navigator grants in a transparent and timely fashion. We intend to identify these populations when each funding opportunity announcement is published, at least 60 days prior to the date applications are due.

Comment: Several commenters requested that HHS and States ensure that Navigators receive adequate resources, including funding and training, to work with vulnerable and underserved populations. Commenters urged HHS to tailor training opportunities to population-specific messages and content. Several commenters were concerned about how these activities would be funded.

Response: Under § 155.210(b)(2)(i), Navigators in all Exchanges must be trained in the needs of underserved and vulnerable populations. Under § 155.215(b)(2)(xii), Navigators in FFEs must additionally receive training on working effectively with individuals with limited English proficiency; people with a full range of disabilities; and vulnerable, rural, and underserved populations. SBEs, including SBE–FPs, are responsible for administering their own Navigator programs, including funding and budgets, and may provide or require additional training and technical assistance to address the needs of the populations they have identified as vulnerable and underserved. In FFEs, Navigator applicants will have an opportunity to propose budgets in their Navigator applications to cover the costs of these activities.

In § 155.210, we proposed to add paragraph (e)(9) to specify that Navigators in all Exchanges would be required to help consumers with certain other types of assistance, including post-enrollment assistance. We designed this proposal to ensure that consumers would have access to skilled assistance beyond applying for and enrolling in health coverage, including, for example, assistance with the process of filing Exchange eligibility appeals or with applying through the Exchange for exemptions from the individual shared responsibility payment, providing basic information about reconciliation of premium tax credits, and understanding basic concepts related to using health coverage. We discussed the statutory authority for these proposals in the preamble to the proposed rule.

We proposed at § 155.210(e)(9)(i) to require Navigators in all Exchanges to help consumers with the process of filing appeals of Exchange eligibility determinations. We did not propose to establish a duty for Navigators to represent a consumer in an appeal, sign an appeal request, or file an appeal on the consumer's behalf. We explained that we believe that helping consumers understand Exchange appeal rights when they have received an adverse eligibility determination, and assisting them with the process of completing and submitting appeal forms, would help to facilitate enrollment and would help consumers obtain fair and impartial information about enrollment, including information about available exemptions from the individual shared responsibility payment that would help consumers decide whether or not to enroll in coverage. We interpreted this proposal to include helping consumers file appeals of eligibility determinations made by an Exchange (including SHOP Exchanges) related to enrollment in a QHP, special enrollment periods, exemptions from the individual shared responsibility payment that are granted by the Exchange, participation as an employer in a SHOP, and any insurance affordability program, including eligibility determinations for Exchange financial assistance, Medicaid, the Children's Health Insurance Program (CHIP), and Basic Health Programs.

We also proposed at § 155.210(e)(9)(ii) to require that Navigators in all Exchanges help consumers understand and apply for exemptions from the individual shared responsibility payment that are granted by the Exchange. We explained that this assistance with Exchange-granted exemptions would include informing consumers about the requirement to maintain minimum essential coverage and the individual shared responsibility payment; helping consumers fill out and submit Exchange-granted exemption applications and obtain any necessary forms prior to or after applying for the exemption; explaining what the exemption certificate number is and how to use it; and helping consumers understand and use the Exchange tool to find bronze plan premiums. We explained that this duty would also include explaining the general purpose of Internal Revenue Service (IRS) Form 8965, Health Coverage Exemptions, to consumers, consistent with IRS published guidance on the topic, and explaining how to access this form and related tax information on IRS.gov.

Navigators may not provide tax assistance or interpret tax rules within their capacity as Exchange Navigators, and our proposal would not require Navigators to help consumers apply for exemptions claimed through the tax filing process. We noted that we would, however, interpret the assistance provided under § 155.210(e)(9)(ii) to include helping consumers generally understand the availability of exemptions claimed through the tax filing process and how to obtain them. We noted that this interpretation would help ensure that Navigators share information about the full scope of possible exemptions while not providing actual tax assistance or tax advice. We requested comment on whether we should require that, prior to providing this assistance and information, Navigators provide consumers with a disclaimer stating that they are not acting as tax advisers and cannot provide tax advice within their capacity as Exchange Navigators. We

also sought comment on whether a Navigator's duty to provide assistance with filing exemption applications under proposed § 155.210(e)(9)(ii) and filing appeals of exemption application denials under proposed § 155.210(e)(9)(i) should be limited, in light of the resource limitations that Navigators and their funding agencies may face. We sought comment on whether this assistance should be limited, for example, to consumers who have applied for or have been denied coverage or financial assistance, as opposed to those who only seek to avoid the individual shared responsibility payment, in order not to reduce the assistance available to consumers seeking coverage.

In addition, we proposed at § 155.210(e)(9)(iii) to require Navigators to help consumers with the Exchange-related components of the premium tax credit reconciliation process, such as by ensuring they have access to their Forms 1095–A, Health Insurance Marketplace Statement, and receive general, high-level information about the purpose of this form that is consistent with published IRS guidance on the topic. We explained that under the proposal, Navigators would be required to help consumers obtain IRS Forms 1095–A and 8962, Premium Tax Credit (PTC), and the instructions for Form 8962, and to provide general information, consistent with applicable IRS guidance, about the significance of the forms. Navigators would also be required to help consumers understand (1) how to report errors on the Form 1095–A; (2) how to find silver plan premiums using the Exchange tool; and (3) the difference between advance payments of the premium tax credit and the premium tax credit and the potential implications for enrollment and re-enrollment of not filing a tax return and not reconciling any advance payments of the premium tax credit that were paid on consumers' behalf.

As noted above, Navigators may not provide tax assistance or advice, or interpret tax rules and forms within their capacity as Exchange Navigators, but their expertise related to the consumer-facing aspects of the Exchange, including eligibility and enrollment rules and procedures, uniquely qualifies them to help consumers understand and obtain information from the Exchange that is necessary to the premium tax credit reconciliation process. We indicated that because this proposal would include a requirement that Navigators provide consumers with information and assistance understanding the availability of IRS resources, Navigators would be expected to familiarize themselves with the availability of materials on IRS.gov, including the Form 8962 instructions, IRS Publication 974 Premium Tax Credit, and relevant FAQs, and to refer consumers with questions about tax law to those resources or to other resources, such as free tax return preparation assistance from the Volunteer Income Tax Assistance or Tax Counseling for the Elderly programs.

To help ensure consumers have seamless access to Exchange-related tax information beyond the basic information that Navigators can provide, we proposed at § 155.210(e)(9)(v) that Navigators be required to refer consumers to licensed tax advisers, tax preparers, or other resources for assistance with tax preparation and tax advice related to consumer questions about the Exchange application and enrollment process, exemptions from the requirement to maintain minimum essential coverage and the individual shared responsibility payment, and premium tax credit reconciliation.

We proposed at § 155.210(e)(9)(iv) to require Navigators in all Exchanges to help consumers understand basic concepts related to health coverage and how to use it. We explained that these activities could be supported by existing resources such as the HHS *From Coverage to Care* initiative, which we encouraged Navigators to review, and which is now available in multiple languages at *https://marketplace.cms.gov/c2c.* We explained that this proposal would improve consumers' access to health coverage information both when selecting a plan and when using their coverage. We anticipated that this assistance would vary depending on each consumer's needs and goals.

To ensure that all Navigators receive training in every area for which we proposed a corresponding Navigator duty, we proposed at § 155.210(b)(2)(v) through (viii) to require all Exchanges, including SBEs, to develop and disseminate training standards to be met by all entities and individuals carrying out Navigator functions to ensure expertise in: The process of filing appeals of Exchange eligibility determinations; general concepts regarding exemptions from the requirement to maintain minimum essential coverage and the individual shared responsibility payment, including the application process for exemptions granted through the Exchange, and IRS resources on exemptions; the Exchange-related components of the premium tax credit reconciliation process and IRS resources on this process; and basic concepts related to health coverage and how to use it.

We noted that providing assistance with certain other post-enrollment issues already falls within the scope of existing required Navigator duties. We explained that we interpret the existing requirements to facilitate enrollment in QHPs under section 1311(i)(3)(C) of the Affordable Care Act and § 155.210(e)(3), and to provide information that assists consumers with submitting the eligibility application under § 155.210(e)(2), to include assistance with updating an application for coverage through an Exchange, including reporting changes in circumstances and assisting with submitting information for eligibility redeterminations.

Additionally, we explained in the proposed rule preamble our interpretation that Navigators are already permitted under existing statutory and regulatory provisions to help with a variety of other post-enrollment issues. For example, Navigators may educate consumers about their rights with respect to coverage available through an Exchange, such as nondiscrimination protections, prohibitions on preexisting condition exclusions, and preventive services available without cost sharing. Navigators may also assist consumers with questions about paying premiums for coverage enrolled in through an Exchange and help consumers obtain assistance with coverage claims denials.

We are finalizing the proposals with several modifications to paragraphs (b)(2) and (e)(9). We are revising the requirement that Navigators must provide the post-enrollment and other assistance activities described in § 155.210(e)(9) to give SBEs the option of requiring or authorizing any of these activities, and to make all of these activities required in FFEs under Navigator grants awarded in 2018 or any later year, and optional (but authorized) before then.

We are revising the training requirements under § 155.210(b)(2) to specify that in any Exchange opting to require Navigators to perform any of the assistance topics specified in paragraph (e)(9), the training topic corresponding to the required paragraph (e)(9) assistance topic would also be required. Because all assistance topics specified in paragraph (e)(9) will be required in FFEs under Navigator grants awarded in 2018 or any later year, all training topics will be required in all FFEs under Navigator grants awarded in 2018 or any later year. We are adding a training provision at § 155.210(b)(2)(ix) to ensure

that Navigators who are required under paragraph (e)(9)(v) to provide referrals to licensed tax advisers, tax preparers, or other resources are also trained on this topic.

We are adding language to §§ 155.210(e)(6)(i), 155.215(g)(1), and 155.225(f)(1) to require that, prior to providing assistance, Navigators, non-Navigator assistance personnel subject to § 155.215, and certified application counselors must provide consumers with a disclaimer stating that they are not acting as tax advisers or attorneys when providing assistance as Navigators, non-Navigator assistance personnel, and certified application counselors (respectively), and cannot provide tax or legal advice within their respective capacities as Navigators, non-Navigator assistance personnel, and certified application counselors.

We are also revising the assistance provisions at paragraph (e)(9) as follows:

- To make it more clear that Navigator assistance with Exchange eligibility appeals under paragraph (e)(9)(i) does not require Navigators to help consumers through the entire Exchange eligibility appeals process, we have added the word ''understanding'' to this provision.
- To make minor changes to paragraphs (e)(9)(ii) and (v) to ensure consistent usage of the term ''individual shared responsibility payment,'' and to make a minor change to paragraph (e)(9)(ii) to consistently use the term ''claim'' to describe how consumers apply for exemptions through the tax filing process.
- To remove ''understanding'' from the beginning of paragraph (e)(9)(iii) because we interpret assistance with Exchange-related components of the premium tax credit reconciliation process to also include helping consumers access and use certain Exchange tools and resources, and to add ''understanding'' before ''the availability of IRS resources'' in paragraph (e)(9)(iii) to more clearly specify the type of assistance with IRS resources that is included under this provision.
- To expand the assistance under paragraph (e)(9)(iv), with understanding basic concepts related to health coverage and how to use it, to also include helping consumers understand their rights related to health coverage, and to make a parallel change to the corresponding training topic at paragraph (b)(2)(viii).

Comment: Many commenters supported our proposed additional Navigator duties to provide post-enrollment and other assistance. A number of commenters agreed that assistance beyond enrollment would help Navigators maintain relationships with consumers across coverage years, which may be vital to successful enrollment, reenrollment, coverage utilization, and coverage continuity for some consumers. Several commenters stated that SBEs should have the flexibility to choose whether to require Navigators in their States to perform these additional functions. Other commenters disagreed that post-enrollment assistance falls within Navigators' statutorily authorized duties. One commenter recommended delaying implementation of these requirements for 2 years to give States time to establish and implement training requirements, and to give Navigators time to become familiar with these new requirements. Several commenters recommended making these activities optional for grantees.

Response: We agree that SBEs should have the flexibility to determine effective approaches to post-enrollment and other Navigator assistance based on local experience. For example, some SBEs make the proposed types of assistance available to consumers through different types of community-based consumer advocacy and patient advocacy organizations, and business associations and tax clinics, rather than from Navigators. We do not want to compel SBEs to disrupt or replace successful consumer assistance strategies, and therefore the final rule gives SBEs, including SBE–FPs, the flexibility to decide whether or not they will require or authorize their Navigators to provide any or all of the assistance topics listed at § 155.210(e)(9). Any SBE opting to require its Navigators to provide any or all of the types of assistance listed at § 155.210(e)(9) would also be required to provide training on the corresponding training topics at § 155.210(b)(2)(v) through (ix), and we are modifying the training topic proposals to reflect this policy.

We also agree that a 2-year delay will give FFEs more time to expand coverage of the new assistance topics in the formal FFE training materials, and give FFE Navigators more time to familiarize themselves with the new requirements. Such a delay also aligns with the timing of the next FFE Navigator funding opportunity announcement in 2018 and thus allows 2018 grant applicants to structure their proposals to meet these new requirements while not disrupting current grantee work plans and budgets. Therefore, we are specifying that the new assistance topics and the corresponding training provisions will be required in FFEs beginning with Navigator grants awarded in 2018.

However, we want to emphasize that FFE Navigator grantees will be authorized to provide assistance with any of the topics listed in § 155.210(e)(9) before 2018, when providing assistance in all those topics will be required of them. If FFE Navigator grantees choose to provide any of the assistance specified in § 155.210(e)(9) before 2018, we would expect them to familiarize themselves with related needs in their communities and build competency in the assistance activities they are providing. As we noted in the preamble to the proposed rule, under § 155.215(b)(2), Navigators in FFEs must already be trained on the tax implications of enrollment decisions, the individual responsibility to have health coverage, eligibility appeals, and rights and processes for QHP appeals and grievances. FFE Navigators are also already required under § 155.215(b)(2) to receive training on applicable administrative rules, processes, and systems related to Exchanges and QHPs. HHS will continue to build and improve its training materials in these areas, and in 2018 will expand on the formal FFE Navigator training that HHS already provides on the new assistance topics listed in § 155.210(e)(9). Until then, in addition to HHS's existing formal training, we will continue to provide FFE Navigators with additional information related to the new assistance activities through informal webinars, newsletters, and technical assistance tools like fact sheets and slide presentations. FFE Navigator grantees that opt to carry out any of the assistance activities in § 155.210(e)(9) should draw upon these materials to ensure their staff and volunteers are adequately prepared to provide that assistance.

If SBEs, including SBE–FPs, choose to authorize (but not require) their Navigators to provide the assistance topics listed at § 155.210(e)(9), we would expect them to ensure that their Navigators are sufficiently prepared to provide this assistance, either by including the corresponding training topics at § 155.210(b)(2)(v) through (ix) in their Navigator training standards, or through informal continuing education such as webinars, fact sheets, supplementary trainings and certifications, and other technical assistance. However, because we believe SBEs are in the best position to determine the extent of training that is appropriate for duties they are authorizing (but not requiring) their Navigators to perform, SBEs (including SBE–FPs) would not be required to

provide training on the topics listed in § 155.210(b)(2)(v) through (ix) unless they required the corresponding forms of assistance under § 155.210(e)(9).

Finally, in the preamble to the proposed rule we discussed the statutory authority for the assistance topics specified in § 155.210(e)(9), and we refer commenters to those discussions, at 80 FR 75520–75522.

Comment: Many commenters were concerned that requiring these new duties without additional funding would cause undue burden, discourage program participation, or detract from Navigators' time and resources to help consumers enroll in coverage. Many commenters requested that HHS invest in the Consumer Assistance Programs established under section 2793 of the PHS Act instead of, or in addition to, these requirements.

Response: We expect that providing for SBE flexibility and phasing in implementation of § 155.210(e)(9) in FFEs will mitigate some of commenters' concerns about funding sources. FFE Navigators may cover the costs of these additional activities using Navigator grant funds and will have the opportunity to propose budgets during the grant application process, and current FFE Navigators may revise their work plans if they opt to carry out these activities before they become required.

We agree that Consumer Assistance Programs established under section 2793 of the PHS Act have served an important role for consumers with health insurance concerns. We also remind commenters that § 155.210(e)(4) already requires Navigators in all States to provide referrals to any applicable office of health insurance consumer assistance or health insurance ombudsman established under section 2793 of the PHS Act, or any other appropriate State agency, for any enrollee with a grievance, complaint, or question regarding their health plan, coverage, or a determination under the plan or coverage. Many States operate an office of health insurance consumer assistance or a health insurance ombudsman. The critical assistance provided by these offices will continue to be an important complement to and resource for Navigators, and HHS will continue to explore ways to fund Consumer Assistance Programs. However, we note that this existing referral requirement is not sufficient to cover the new assistance activities under § 155.210(e)(9).

Comment: A few commenters said they believe the proposed Navigator duties duplicate services provided by issuers or agents and brokers. Several commenters requested that Navigators providing post-enrollment assistance be subject to background checks and required to be licensed, carry errors and omissions insurance, and be under the oversight of State regulators.

Response: We believe it is important for consumers to have access to a variety of assistance options. Additionally, Navigators in all States are required under § 155.210(c)(1)(iii) to meet any licensing, certification, or other standards prescribed by the State or Exchange, so long as the standards do not prevent the application of the provisions of title I of the Affordable Care Act.

Comment: A number of commenters supported our proposal that all Exchanges be required to provide training that would prepare Navigators for the additional proposed areas of responsibility. Many commenters urged us to ensure that this training be robust, supported by technical assistance, and carefully monitored and updated. Many commenters suggested that we specify additional training topics. One commenter asked how HHS would ascertain training competency.

Response: We are finalizing the new training provisions largely as proposed, but are adding introductory language so that their applicability is aligned to whether the corresponding assistance activities are required under final § 155.210(e)(9). If an Exchange (including an FFE) opts to require its Navigators to perform any or all of the types of assistance specified in paragraph (e)(9), the Exchange's training standards under paragraph (b)(2) must include corresponding training on any of the required assistance topics. For example, an Exchange opting to require its Navigators to help consumers understand the process of filing Exchange eligibility appeals under § 155.210(e)(9)(i) must ensure its Navigators have expertise in this topic by including the process of filing Exchange eligibility appeals under § 155.210(b)(2)(v) in its training standards. All of the training topics in § 155.210(b)(2)(v) through (ix) must be included in the training standards for Navigators in FFEs under Navigator grants awarded in 2018 or any later year, because that is when all the activities specified under paragraph (e)(9) will be required in FFEs, as discussed above and as specified in paragraph (e)(9). We believe this final policy will ensure that all Navigators required to perform functions under paragraph (e)(9) will be adequately trained in each required topic.

We are also adding a new § 155.210(b)(2)(ix) to correspond to the referral assistance specified in § 155.210(e)(9)(v), and are adding the words ''and rights'' to § 155.210(b)(2)(viii) to parallel a related modification to § 155.210(e)(9)(iv) that is discussed below.

Section 155.215(b)(1)(iii) already requires FFE Navigators, after completing required training, to complete and achieve a passing score on all approved certification examinations prior to carrying out any consumer assistance functions under § 155.205(d) and (e) or § 155.210. FFE Navigators must also obtain continuing education and be certified or recertified on at least an annual basis under § 155.215(b)(1)(iv). Under § 155.210(b)(2), all Exchanges, including SBEs and SBE–FPs, are required to develop training standards that ensure expertise in the topics specified at § 155.210(b)(2), but SBEs, including SBE–FPs, have flexibility in creating examination or certification requirements for their Navigators.

Comment: Many commenters said they do not believe the new Navigator post-enrollment requirements are appropriate for other assister types, such as certified application counselors or non-Navigator assistance personnel subject to § 155.215, who may have more limited time and resources. One commenter thought that these assister types should be encouraged to help consumers understand and use their coverage. Another commenter stated that certified application counselors are well positioned to provide post-enrollment assistance because many are in community health centers. A few commenters recommended that certified application counselors, non-Navigator assistance personnel subject to § 155.215, and Federally Qualified Health Center enrollment counselors should have access to the new Navigator training and resources related to post-enrollment and other assistance.

Response: We agree that non-Navigator assistance personnel subject to § 155.215 and certified application counselors may have more limited resources than Navigators, and that tailoring duties to each of these three assister types fosters a robust pool of different kinds of consumer assistance. Therefore, we are not finalizing any assistance or training requirements parallel to § 155.210(b)(2)(v)–(ix) and (e)(9) for non-Navigator assistance personnel subject to § 155.215 or certified application counselors. As we noted in the preamble to the proposed rule, the requirement under § 155.210(e)(2) to provide information that assists consumers with submitting the eligibility application (which also applies to certain non-Navigator

assistance personnel through § 155.215(a)(2)(i)), could include helping consumers report changes in circumstances and submit information for eligibility redeterminations. We also noted in the preamble to the proposed rule that under § 155.215(b), non-Navigator assistance personnel subject to § 155.215 and Navigators in FFEs are subject to the same training requirements. In addition, all FFE training modules can be accessed by the public, including by certified application counselors and non-Navigator assistance personnel subject to § 155.215. As noted in the preamble to the proposed rule, nothing prevents non-Navigator assistance personnel subject to § 155.215 or certified application counselors from helping with activities that are consistent with their existing regulatory duties.

Although we are not requiring any assistance or training requirements parallel to the new provisions under § 155.210(b)(2)(v) through (ix) and (e)(9) for non-Navigator assistance personnel subject to § 155.215 or certified application counselors, we believe that a disclaimer stating that these assisters are not acting as tax advisers or attorneys (as discussed below) is an important consumer protection that should apply regardless of whether these assisters are providing assistance on the topics specified at § 155.210(e)(9). For this reason, and to align parallel provisions requiring Navigators, non-Navigator assistance personnel subject to § 155.215, and certified application counselors to provide consumers with information about their respective functions and responsibilities, we are revising §§ 155.215(g)(1) and 155.225(f)(1) to require that, prior to providing assistance, non-Navigator assistance personnel subject to § 155.215 and certified application counselors provide consumers with a disclaimer stating that they are not acting as tax advisers or attorneys when providing assistance (respectively) as non-Navigator assistance personnel and certified application counselors, and cannot provide tax or legal advice within their (respective) capacities as non-Navigator assistance personnel and certified application counselors.

Comment: A number of commenters cautioned that Navigators should not be expected to become, or be held out as, experts in the new assistance topics specified in § 155.210(e)(9). Several commenters asked that we further define what we mean by ''assistance with'' so that Navigators can be clear about the full extent of consumer support expected from them in these areas.

Response: Each Navigator grantee and each individual Navigator should have the ability to help any individual who presents themselves for assistance. Additionally, we expect that all individuals carrying out Navigator duties would be trained to perform all of the duties of a Navigator and would be equipped to assist consumers with the activities described in § 155.210(e)(9) in Exchanges where the activities described in § 155.210(e)(9) are required or authorized. Below, we discuss examples of the kinds of assistance we interpret § 155.210(e)(9) to include.

Comment: Several commenters asked us to explain whether Navigators are permitted to collect, disclose, access, maintain, store or use personally identifiable information (PII) to carry out these additional duties. One commenter asked us to explain how consumer privacy protections will be ensured and enforced.

Response: Under their grant terms and conditions, FFE Navigators are permitted to create, collect, handle, disclose, access, maintain, store, or use consumer PII only to perform functions that they are authorized to perform under the terms of their grant, including functions authorized or required under § 155.210, or for other purposes for which the consumer provides his or her specific, informed consent. Once this rule takes effect, the activities under paragraph (e)(9) will be authorized Navigator functions in FFEs, both before and after 2018. Therefore, after this rule takes effect, FFE Navigators may create, collect, handle, disclose, access, maintain, store, and use consumer PII to perform these functions, and we will update guidance and model consent forms to reflect this. HHS has a variety of enforcement options in the event of a violation of these standards, including implementing corrective action plans or pursuing civil money penalties under § 155.206 or § 155.285, or withholding or terminating grant funds. With respect to SBEs, § 155.260(b) directs SBEs to execute a contract or agreement with Navigators that binds them to privacy and security standards that, among other things, take into consideration a Navigator's authorized duties and activities. If an SBE opts to require or authorize the activities specified in § 155.210(e)(9) after that provision takes effect, we would expect that SBE privacy and security standards would reflect SBEs' decisions to require or authorize Navigators to carry out these additional activities, and would give Navigators the ability to create, collect, handle, disclose, access, maintain, store, and use PII as needed to do so. In any event, the exact extent to which and the conditions under which each SBE may permit or require its Navigators to create, collect, handle, disclose, access, maintain, store, and use PII is a matter within the reasonable discretion of the SBE, so long as the SBE's standards comply with § 155.260 and otherwise do not act as an impediment to the performance of required or authorized Navigator duties under § 155.210.

Comment: We asked for comment on whether we should make explicit in the regulation any of our interpretations of existing statutes and regulations that would permit (but not require) Navigators to perform certain kinds of post-enrollment assistance, such as assistance with coverage claims denials. We also asked for comment on whether there are additional forms of post-enrollment assistance that Exchanges should require Navigators to provide, commensurate with their general legal authority. One commenter recommended that we specify in regulation any Navigator activities we interpret to be permitted but not required. Some commenters recommended that additional post-enrollment activities should be required, including filing complaints with regulators, assisting pregnant women enrolled in QHPs to understand their coverage options and ensure continuity of coverage, and helping enrollees pursue coverage determination appeals and formulary exceptions.

Response: Because we are sensitive to the concerns commenters expressed about Navigators' limited time and resources to perform the new activities described in § 155.210(e)(9), we are not adding provisions that require or permit any additional activities commenters recommended at this time. Instead, we have tried to limit the modifications to the proposed activities in this final rule to changes that provide additional detail about the scope of the specific post-enrollment and other new assistance activities that we proposed adding to the rule.

Comment: With respect to our proposed requirement that Navigators provide information and assistance with filing Exchange eligibility appeals, many commenters were concerned that consumers' legal rights may be compromised without proper legal representation, and stated that Navigators should serve primarily as a bridge to connect consumers with legal assistance. One commenter stated that Navigators should have the option of assisting consumers with appeals only when they have the expertise to do so.

Several asked us to clarify that Navigators may not serve as authorized representatives for consumers filing appeals. Commenters urged HHS to clearly define the types of information Navigators must provide related to appeals and create guidelines to help Navigators and consumers recognize where legal assistance becomes appropriate or necessary. Several commenters recommended that this duty be limited to making consumers aware of their right to appeal, providing basic education on the appeals process, and making appropriate referrals for legal assistance when possible. To facilitate these referrals, commenters asked HHS to help FFE Navigator grantees identify methods of establishing relationships with local legal services organizations and other State offices to help with the appeals process. One commenter suggested that Navigators should also provide information and assistance with appeal denials. One commenter asked how these proposed requirements might affect Medicaid appeals in States that have delegated the authority to make Medicaid and CHIP eligibility determinations to the Exchange. A number of commenters interpreted our proposal to mean that Navigators would be required to help consumers appeal adverse coverage decisions.

Response: We recognize that helping consumers through the entire Exchange appeals process may require more resources and expertise than many Navigators can offer. To that end, we are narrowing this provision by adding the word ''understanding'' to make clear that any assistance required under this provision is limited to activities that help consumers understand the process of filing Exchange eligibility appeals, and does not include a requirement to help consumers through the entire Exchange eligibility appeals process. It does not prevent Navigators who are authorized or required to provide assistance under this provision from providing such longer-term assistance, as long as they do not provide legal advice in their capacity as Navigators, as discussed below. We also appreciate the critical and established role that legal services organizations play in helping consumers understand and access their Exchange eligibility appeal rights, and have incorporated providing information about free and low-cost legal help into our expectations for assistance under this provision, as discussed below.

We interpret assistance under this provision to include the following activities, as relevant to consumers' needs: (1) Helping consumers identify and meet the deadline for appealing an Exchange eligibility determination; (2) helping consumers understand that they have a right to appeal eligibility determinations made by an Exchange (including SHOP Exchanges) related to enrollment in a QHP, special enrollment periods, exemptions from the individual shared responsibility payment that are granted by the Exchange, participation as an employer in a SHOP, and any insurance affordability program, including eligibility determinations for Exchange financial assistance, Medicaid, the Children's Health Insurance Program, and Basic Health Programs; (3) helping consumers understand the process of appealing those eligibility determinations and what steps to take to complete an appeal; (4) helping consumers access relevant Exchange resources, such as appeal request forms and mailing addresses for appeals, and Exchange guidance on appeals; and (5) providing consumers with information about free or low-cost legal help in their area, including local legal aid or legal services organizations and other State offices to help with the Exchange eligibility appeals process. Assistance under this provision may also include helping consumers collect supporting documentation for the appeal (such as screenshots of relevant information from the online application).

Although the assistance under § 155.210(e)(9)(i) includes helping consumers understand the general availability of a right to appeal adverse Exchange eligibility determinations and the process for appealing them, Navigators should not, in their capacity as Navigators, cross the line into providing legal advice, such as by recommending that consumers take specific action with respect to that right. For example, Navigators could help consumers understand the difference between an appeal and an expedited appeal, but should not help them decide which one is best suited to their circumstances. We suggest that Navigators familiarize themselves with any laws defining legal advice in the States in which they operate, as this may help them ascertain when they might be taking an action that could constitute providing legal advice. We also note that we did not propose nor are we establishing a duty for Navigators to represent a consumer in an appeal, sign an appeal request, or file an appeal on the consumer's behalf, either as a legally authorized representative or otherwise. Although HHS regulations do not prohibit Navigators from serving as authorized representatives under § 155.227 outside of their capacity as Navigators, they should keep any activities as a consumer's authorized representative separate from their Navigator duties and should not use Navigator grant funds for these activities, because these activities are not authorized Navigator functions under HHS regulations.

Assistance provided under this provision does not include assistance with appeals of coverage decisions by issuers, but only assistance with appeals of eligibility determinations made by an Exchange. However, as we said in the preamble to the proposed rule, Navigators are already permitted, but not required, to help consumers obtain assistance with coverage claims denials and to educate consumers about their rights with respect to coverage available through an Exchange. Additionally, under the new language about rights that we are adding to § 155.210(e)(9)(iv), Navigators providing assistance under that paragraph should inform consumers who have questions about coverage claims denials that they have the right to appeal adverse benefit determinations and to have the appeal reviewed by an independent third party. Finally, as indicated above, helping consumers with the process of filing Exchange eligibility appeals includes, where applicable, helping consumers understand the process of filing an appeal of a modified adjusted gross income (MAGI)-based Medicaid or CHIP eligibility determination, where the State has delegated authority to the Exchange to adjudicate these appeals.

Comment: Commenters supported our proposals to require Navigators to provide consumers with information and assistance regarding exemptions. One commenter disagreed with our proposal, arguing that exemptions assistance is counter to the goal of the Affordable Care Act. The majority of commenters recommended exemptions assistance not be limited to certain consumers because helping with exemptions is minimally burdensome and because of the importance of skilled assistance to consumers who cannot access coverage. Several commenters suggested that Navigators should have the flexibility, if they are unable to fully meet consumer demand, to prioritize helping consumers apply for and enroll in coverage over helping consumers seek exemptions during open enrollment. Several commenters recommended that this duty include assistance with understanding the requirement to maintain minimum essential coverage and the individual shared responsibility payment, the general purpose of and where to access

IRS Form 8965, Health Coverage Exemptions, and how to use applicable Exchange tools to find bronze plan and second-lowest cost silver plan premiums. Several commenters recommended that Navigators' duty with respect to exemptions should be limited to education about, but not assistance with, obtaining an exemption. One commenter asked for guidance on how this requirement would apply to SBE Navigators, since most States' Exchange-granted exemptions are processed by an FFE, rather than an SBE.

Response: We are not limiting Navigator assistance with exemptions under paragraph (e)(9)(ii) to a specific consumer population because we agree that Navigator services should not be exclusively available to a predefined set of consumers and closed to others. Where resources are limited, Navigators providing assistance under this provision may prioritize helping consumers seeking to apply for and enroll in coverage. For example, during a busy enrollment event, Navigators may choose to limit exemptions assistance to directing consumers to exemptions resources on HealthCare.gov and IRS.gov, and schedule another time for consumers to return for additional assistance. But we also continue to expect that Navigators will serve all consumers seeking assistance.

We believe that the Affordable Care Act contemplates that Navigators will assist consumers with making an informed decision about whether to enroll in health coverage, and making this decision will often require consumers to have a basic understanding of available exemptions. We are finalizing § 155.210(e)(9)(ii) generally as proposed, except that for clarity and consistent use of terminology we are modifying the reference to the individual shared responsibility requirement to refer to the individual shared responsibility payment, and are changing language about ''how to apply for'' exemptions claimed through the tax filing process to ''how to claim'' them. Because exemptions assistance needs will vary among consumers, and to avoid being overly prescriptive, we are not expanding the assistance specifically required under this provision to include the activities recommended by commenters. We interpret assistance under this provision to include the following activities, as relevant to consumers' needs: (1) Informing consumers about the requirement to maintain minimum essential coverage and the individual shared responsibility payment; (2) helping consumers fill out and submit Exchange-granted exemption applications and obtain any necessary forms prior to or after applying for the exemption; (3) explaining what the exemption certificate number is and how to use it; (4) helping consumers understand the availability of exemptions from the requirement to maintain minimum essential coverage and from the individual shared responsibility payment that are claimed through the tax filing process and how to claim them; (5) helping consumers use any applicable Exchange tool to find lowest cost bronze and second-lowest cost silver plan premiums (that is, the FFE tool or any similar tool offered by an SBE); and (6) helping consumers understand the availability of IRS resources on this topic, including explaining the general purpose of and how to access IRS Form 8965, Health Coverage Exemptions, and the instructions for that form. We emphasize that explaining the general purpose of IRS Form 8965 to consumers must be done consistent with IRS published guidance on the topic, and must include providing information on where to access this form and related tax information on IRS.gov.

With respect to exemptions granted through the Exchange, we do not believe that Navigators' activities related to exemptions should be limited to education only. However, to help ensure that Navigators do not provide tax advice in their capacity as Navigators, we are finalizing the portion of this proposal that limits Navigators' required involvement in exemptions claimed through the tax filing process to providing general information and helping consumers access IRS resources, rather than assistance with claiming exemptions on the tax return or filling out IRS forms. For example, Navigators acting in their capacity as Navigators must not help consumers fill out IRS Form 8965 or help them report having minimum essential coverage on their tax return. We believe this limitation is sufficient to protect both consumers and Navigators.

In any SBEs that opt to require or authorize this assistance, Navigators will be required or authorized (respectively) to help consumers access Exchange-granted exemptions, whether consumers in that State access those exemptions through the SBE or FFEs, and, as in any Exchange, they will be limited to providing only general information about exemptions claimed on the tax return in their capacity as Navigators.

Comment: Many commenters said that Navigators should provide consumers with a disclaimer stating that they are not acting as tax advisers and cannot provide tax advice within their capacity as Navigators. One commenter stated that requiring a disclaimer was unnecessary because Navigators do not provide tax advice and many already provide a disclaimer to this effect. Some commenters recommended that we require a similar disclaimer that Navigators are not acting as legal representatives and cannot provide legal advice or legal representation within their capacity as Navigators. Some commenters recommended that the disclaimer be required to be written, provided in a linguistically appropriate manner, or included in our model authorization form for FFE Navigators.

Response: We agree that prior to providing assistance, Navigators should provide consumers with a disclaimer stating that they are not acting as tax advisers or attorneys when providing assistance as Navigators, and cannot provide tax or legal advice in their capacity as Navigators. We are therefore adding language to § 155.210(e)(6)(i) to specify that such a disclaimer must be included as part of the information provided to applicants about the Navigator's functions and responsibilities and that both the disclaimer and the information provided about Navigator functions and responsibilities must be provided prior to providing assistance. We do not interpret this requirement to mean that Navigators must provide such a disclaimer prior to providing general outreach and education. Although we do not specify the method of delivering the disclaimers, we plan to add these disclaimers to our model authorization form for FFE Navigators. The requirement under § 155.210(e)(5) that Navigators must provide information in a manner that is culturally and linguistically appropriate to the needs of the population being served by the Exchange and accessible to people with disabilities will apply to these disclaimers. Finally, as discussed above, we are adding a parallel disclaimer requirement for non-Navigator assistance personnel subject to § 155.215 and certified application counselors, under §§ 155.215(g)(1) and 155.225(f)(1) (respectively).

Comment: Many commenters supported our proposal to require Navigators to provide consumers with assistance with understanding the Exchange-related components of the premium tax credit reconciliation process, and the availability of IRS resources on this process. Commenters agreed that although Navigators should not provide tax advice, informing

consumers of the tax implications of receiving advance payment of the premium tax credit is an essential component of helping consumers enroll. Several commenters recommended that we specify that this assistance entails helping consumers: (1) Access and understand IRS Forms 1095–A, –B, and –C, (2) understand how to report Form 1095 errors, (3) understand how to use applicable Exchange tools to find silver plan premiums, and (4) understand the purpose of IRS Form 8962. A few commenters suggested that Navigators should also provide information about reliable resources on this process from sources other than the IRS. Other commenters were concerned that our proposal would stretch Navigators' capacity and distract from enrollment, and that tax professionals, not Navigators, are best suited to assist consumers with tax-related issues. Some commenters asked us to clarify the prohibition on providing tax advice, one commenter requested that we add this prohibition to § 155.210(d), and another asked how it will be enforced.

Response: We are finalizing this provision largely as proposed. Because not all consumers will require information and assistance with each of the topics commenters recommended that we include in this provision, we are not expanding the final rule to include them. However, we interpret assistance under this provision to include helping consumers with the following, as relevant to their needs: (1) The Exchange-related components of the premium tax credit reconciliation process; (2) accessing and understanding the general purpose of IRS Form 1095–A; (3) understanding how to report Form 1095–A errors; (4) using any applicable Exchange tool to find second-lowest cost silver plan premiums (that is, the FFE tool or any similar tool offered by an SBE); and (5) understanding the availability of IRS resources on this process, including the general purpose of and how to access IRS Form 8962, and the instructions for that form. To avoid confusion about the scope of this provision, we are removing the word ''understanding'' from the beginning of the provision, because Navigators' assistance with the Exchange-related components of the premium tax credit reconciliation process would include not only helping consumers understand Exchange tools and resources but also helping consumers access and use these tools and resources. We are also adding ''understanding'' before the provision's description of Navigators' assistance with respect to the availability of IRS resources on this process, to better capture our interpretation that Navigators are not authorized to interpret those resources, and can instead only direct consumers to them. This edit also helps align this provision with the similar requirement in § 155.210(e)(9)(ii) that Navigators help consumers understand the availability of IRS resources on exemptions.

Where Navigators are also tax professionals, they might be in a position to assist clients with both the Exchange-related and the tax filing components of the premium tax credit reconciliation process, but should keep these duties separate and not perform any tax assistance within their capacity as Navigators or using Navigator grant funds. As part of Navigators' assistance with Form 1095–A, they may, for example, explain to consumers why they received the form and what the information on the form means, explain why they may have received more than one copy of the form, help them find the form in their online account or get a copy of the form, explain what they should do if they think the form may have gone to the wrong address, or if they think the information on their form is incorrect or does not include a dependent they added to their coverage. On the other hand, Navigators who are acting in their capacity as Navigators should not, for example, help consumers fill out IRS Form 8962, advise consumers about whether to file an amended tax return, or help them complete their income tax return. We believe it is critically important to ensure that consumers are provided with the most authoritative, accurate, and up-to-date resources related to premium tax credit reconciliation, and thus IRS-approved resources must be the primary resource to which Navigators refer consumers.

We disagree with commenters that Navigators should be required to help consumers access and understand IRS Forms 1095–B and 1095–C. Form 1095–B, Health Coverage, is an annual form issued by providers of minimum essential coverage to report certain information to the IRS and to taxpayers about individuals who had coverage during the year. Form 1095–C, Employer-Provided Health Insurance Offer and Coverage, is an annual form issued by certain large employers to report to the IRS and to taxpayers information about offers of employer-sponsored coverage for the year. Unlike the Form 1095–A, these forms are not issued by an Exchange. The IRS has resources that explain the purpose of these forms, how they relate to the tax filing process, how to request copies of the forms, and how to request corrections to the forms. Navigators should be able to help consumers access IRS resources relating to these forms. However, we are not requiring Navigators providing assistance under this provision to help consumers access these forms or report errors.

Comment: We received support from commenters for our proposal to require Navigators to help consumers understand basic concepts related to health coverage and how to use it. Several commenters recommended that this assistance include helping consumers understand their rights related to health coverage. Some recommended that we specify topics in addition to the examples we included in the preamble to the proposed rule, including helping consumers understand out-of-pocket cost calculators and provider and formulary lookup tools, common utilization management definitions, including step therapy and prior authorization, and what an Explanation of Benefits Statement is and how to read it. Other commenters stated that because this assistance will vary depending on each consumer's health insurance literacy, needs, and goals, additional specificity is unnecessary.

Response: We agree with commenters that consumers' rights with respect to coverage available through an Exchange, such as nondiscrimination protections and prohibitions on preexisting condition exclusions, are critical for consumers to understand when accessing or attempting to access coverage through an Exchange. Additionally, in the preamble to the proposed rule, we explained that the assistance provided under this provision could include helping consumers understand the right to coverage of certain preventive health services without cost sharing, and that we interpret existing HHS regulations to permit Navigators to educate consumers about their rights with respect to coverage available through an Exchange. Therefore, we are adding the phrase ''and rights'' to § 155.210(e)(9)(iv) to ensure that Navigators' activities in this area include education about these topics. However, to avoid crossing the line into providing legal advice, Navigators should not, in their capacity as Navigators, recommend that consumers take specific action with respect to these rights. We are also adding the phrase ''and rights'' to the corresponding training provision related to this duty at § 155.210(b)(2)(viii). Because the health literacy information consumers need varies depending on their circumstances, we are not

requiring Navigators to help consumers with specific health literacy topics. Instead, we interpret assistance under this provision to include, for example, helping consumers understand: (1) Key terms used in health coverage materials, such as ''deductible'' and ''coinsurance,'' and how they relate to the consumer's health plan; (2) the cost and care differences between a visit to the emergency department and a visit to a primary care provider under the coverage options available to the consumer; (3) how to identify in-network providers and how to make and prepare for an appointment with a provider; (4) how the consumer's coverage addresses steps that often are taken after an appointment with a provider, such as making a follow-up appointment and filling a prescription; and (5) the right to coverage of certain preventive health services without cost sharing.

Comment: A few commenters asked for clarification about whether the duty proposed in § 155.210(e)(9)(iv) pertains to general education about health coverage or to assisting individuals with activities such as making appointments or filling prescriptions, which they believed would be overly burdensome. Several commenters stated that there are insufficient educational resources available and asked HHS to create template materials and identify other resources on these topics. One commenter asked HHS to undertake or support a thorough assessment of consumer health insurance literacy needs. Some commenters noted that issuers often provide additional training and materials to agents and brokers about their plans, and recommended that HHS require issuers to provide Navigators with this kind of information.

Response: The assistance provided under § 155.210(e)(9)(iv) only includes providing information and assistance with *understanding* basic concepts and rights related to health coverage and how to use it; it does not include patient advocacy or case management. With respect to needs assessments, we remind Navigators in FFEs of their obligations under § 155.215(c)(1) to develop and maintain general knowledge about the racial, ethnic, and cultural groups in their service area, including each group's health literacy and other needs, and under § 155.215(c)(2) to collect and maintain updated information to help understand the composition of the communities in the service area.

Agents and brokers often receive information on health plans from the issuers with whom they have a contractual relationship. While we do not require QHP issuers to provide their affiliated agents and brokers with plan information, we continue to leverage existing practices and encourage agents and brokers to work directly with QHP issuers within whom they have a contractual relationship to obtain the necessary information on that issuer's QHPs. Navigator organizations may invite issuers in their area to share information or attend education sessions regarding plan benefits and details. As long as all issuers in the Exchange service area are invited and all applicable Navigator conflict-of-interest provisions are followed, including the rule prohibiting Navigators from receiving any consideration directly or indirectly from any health insurance issuer or stop-loss insurance issuer in connection with the enrollment of any individuals or employees in a QHP or non-QHP, such an event would not represent a conflict of interest or violate a Navigator's duty under § 155.210(e)(2) to provide information and services in a fair, accurate, and impartial manner.

Comment: Most commenters supported our proposal that Navigators be required to provide referrals to licensed tax advisers, tax preparers, or other resources for assistance with tax preparation and tax advice related to consumer questions about the Exchange application and enrollment process, exemptions from the requirement to maintain minimum essential coverage and from the individual shared responsibility requirement, and premium tax credit reconciliations. Commenters requested detail about how such a referral mechanism would work; for example, whether Navigators would be allowed to refer consumers to a specific tax professional, as opposed to a general listing of tax professionals. Other commenters asked HHS for guidance on limitations and strategies for referring and collaborating with tax preparation services, legal services organizations, community experts, patient-focused and community-based organizations, and other State offices. One commenter questioned the term ''licensed tax adviser,'' noting that IRS does not provide such a license. Another asked HHS to specify IRS's Volunteer Income Tax Assistance (VITA) and Tax Counseling for the Elderly (TCE) programs as appropriate points of referral. And one commenter asked HHS to partner with the Internal Revenue Service (IRS) to provide training and education to tax preparers.

Response: All referrals from a Navigator to other organizations must be consistent with applicable statutory and regulatory requirements, including the requirement at § 155.210(e)(2) that Navigators provide information and services in a fair, accurate, and impartial manner, and the conflict of interest provision at § 155.210(d)(4) prohibiting Navigators from receiving any consideration directly or indirectly from any health insurance issuer or issuer of stop loss insurance in connection with the enrollment of any individuals or employees in a QHP or a non-QHP. We interpret the requirement under § 155.210(e)(2) that Navigators provide information and services in a fair, accurate, and impartial manner to mean that Navigators must not accept payment in exchange for providing a referral or recommending the services of another organization. We intend to issue guidance for FFE Navigators with additional information on collaborating or partnering with other organizations.

The referrals discussed under this provision include referrals to licensed tax advisers, tax preparers, or other resources for assistance with tax preparation and tax advice. Licensed tax advisers are one type of tax professional, but not the only type. ''Licensed'' can mean any type of professional license that qualifies someone to prepare taxes, and could include certified public accountants and attorneys. We agree that VITA and TCE programs may often be the best resources for referral under this provision.

To ensure that Navigators who are required under paragraph (e)(9) to provide referrals to licensed tax advisers, tax preparers, or other resources for assistance with tax preparation and tax advice are also trained on this topic, we are adding a corresponding training provision at § 155.210(b)(2)(ix). We are also replacing a reference in paragraph (e)(9)(v) to the individual shared responsibility requirement with a reference to the individual shared responsibility payment, to ensure consistent use of terminology.

We also proposed to amend §§ 155.205(d) and 155.215(b)(1)(i) to specify that any individual or entity carrying out consumer assistance functions under § 155.205(d) and (e) or § 155.210, in both SBEs and FFEs, would be required to complete training prior to performing any assister duties, including before conducting outreach and education activities, as well as before providing application and enrollment assistance. Section 155.215(b) already requires Navigators and non-Navigator assistance personnel in FFEs and non-Navigator assistance personnel funded through Exchange Establishment grants under section

1311(a) of the Affordable Care Act to obtain certification by the Exchange prior to carrying out any consumer assistance functions under § 155.205(d) and (e) or § 155.210. We proposed to amend § 155.215(b)(1)(i) to specify that the consumer assistance functions referenced in that provision would include outreach and education activities. In addition, we proposed to amend § 155.205(d) to require that training be completed not only before providing the assistance described in that paragraph, but also before conducting the outreach and education activities specified in paragraph (e).

This proposal sought to ensure that individuals and organizations subject to §§ 155.205(d) and (e), 155.210, and 155.215 do not perform any Exchange outreach and education activities or application and enrollment assistance while identifying as or holding themselves out to the public as Exchange-approved Navigators or non-Navigator assistance personnel, prior to completing Exchange requirements, including training and certification. The proposed amendments would not apply to certified application counselors, but § 155.225(d)(1) already requires certified application counselors to complete and achieve a passing score on all Exchange approved certification examinations prior to functioning as certified application counselors.

We are finalizing these amendments as proposed.

Comment: The majority of commenters supported our proposal to require that Navigators and non-Navigator assistance personnel complete training prior to performing any assister duties, including before conducting outreach and education activities, as well as before providing application and enrollment assistance. These commenters also recommended exempting Navigators in FFEs and non-Navigator assistance personnel subject to § 155.215 who are eligible to be recertified from the requirement in § 155.215(b) to complete recertification training prior to conducting outreach and education. A few commenters expressed concern regarding the availability and content of training. Commenters also were concerned that this provision would prevent Navigators and non-Navigator assistance personnel subject to § 155.215 from conducting year-round outreach education, if training is not available year round, or recommended that training be available at least 2 months prior to open enrollment so that new assisters subject to this requirement can complete the training and begin assisting consumers.

Response: We appreciate the support for this proposal and agree that it is essential that consumers trust that Navigators and non-Navigator assistance personnel are properly informed and trained when consumers seek out their services, whether those services include assistance with an Exchange application or education about the Exchange. We recognize commenters' concerns that the timing of the FFE Navigator and non-Navigator assistance personnel training may prevent some Navigators and non-Navigator assistance personnel in FFEs from conducting outreach and enrollment work during periods when training is being updated and relaunched prior to the start of a new open enrollment period for the individual market. We will continue to strive to complete FFE training updates prior to FFE Navigator and non-Navigator assistance personnel certification deadlines. We believe there is great value in ensuring that Navigators in FFEs and non-Navigator assistance personnel subject to § 155.215 complete recertification training prior to providing any outreach or assistance to consumers because there are often changes in Exchange operations and policy from year to year and we want to ensure that these assisters are providing the most up to date and accurate information to consumers. Therefore, we are not exempting Navigators in FFEs and non-Navigator assistance personnel subject to § 155.215 who are eligible to be recertified from this requirement.

Comment: A few commenters requested clarification regarding individuals who are not yet certified or are not acting as Navigators or non-Navigator assistance personnel at Navigator and non-Navigator assistance personnel organizations but who may be serving as spokespeople and conducting public education activities about the Exchange and the Exchange assistance available from the organization. One commenter requested that HHS allow newly hired, but not fully trained or certified Navigators to conduct outreach, as long as they disclose they are not yet certified to conduct enrollment assistance and immediately refer consumers to a fully trained and certified Navigator. A few commenters opposed our proposal due to concern that it would prohibit such activities.

Response: As explained in the proposed rule preamble, nothing in the Exchange regulations prohibits individuals who are not trained and certified as Exchange-approved Navigators, non-Navigator assistance personnel, or certified application counselors from conducting outreach about Exchanges and providing application and enrollment assistance. These individuals may of course conduct outreach and education about Exchanges as long as they do not represent themselves as Exchange-approved Navigators, non-Navigator assistance personnel, or certified application counselors.

Comment: One commenter expressed concern about how this provision could reasonably be enforced.

Response: Exchanges have discretion to pursue a variety of enforcement options in the event of Navigator or non-Navigator assistance personnel noncompliance with any applicable statutory or regulatory requirements or prohibitions. These options include implementing corrective action plans or pursuing civil money penalties under § 155.206 or withholding or terminating grant or contract funds. FFE Navigators and FFE non-Navigator assistance personnel who wish to file a complaint or grievance against other FFE Navigators or FFE non-Navigator assistance personnel can contact their Project Officer or point of contact at CMS. FFE certified application counselors should direct complaints or grievances to the certified application counselor inbox at *CACQuestions@cms.hhs.gov.* We also rely on communication with State regulatory agencies (such as Departments of Insurance) and CMS Regional Offices regarding FFE Navigator and FFE non-Navigator assistance personnel conduct.

Section 155.210(d)(6) currently prohibits Navigators from providing to an applicant or potential enrollee any gifts unless they are of nominal value; or any promotional items that market or promote the products or services of a third party, when those promotional items are being used as an inducement for enrollment. Through a cross-reference to § 155.210(d) in § 155.215(a)(2)(i) and a parallel provision in § 155.225(g)(4), this prohibition also applies to non-Navigator assistance personnel subject to § 155.215, and to certified application counselors.

To reduce confusion about when gifts and promotional items can be provided to applicants and potential enrollees, we proposed to amend §§ 155.210(d)(6) and 155.225(g)(4) to specify that gifts of any value (including third-party promotional items of any value) should never be provided to applicants or potential enrollees as an inducement for enrollment. We also proposed to specify that gifts that are not provided as an inducement for enrollment may be provided to applicants and potential enrollees if they do not exceed nominal

value.[40] We proposed that this nominal value restriction would apply both to each individual gift and to the cumulative value of multiple gifts, including promotional items. We further proposed that the nominal value restriction on the cumulative value of multiple gifts would only apply to single encounters between the assister and an individual, and not to multiple encounters, so that assisters would not have to collect PII as a means of tracking the number and value of gifts provided to an individual consumer across multiple encounters, such as all encounters in a single calendar year or enrollment season. We noted that we would consider a single outreach or educational event to be a ''single encounter''; that is, the assisters subject to the proposed requirement would not be permitted to provide multiple gifts to the same consumer at the same outreach event if the cumulative value of those gifts exceeded nominal value.

We proposed to define ''gifts,'' for purposes of §§ 155.210(d)(6) and 155.225(g)(4), to include gift items, gift cards, cash cards or cash, as well as promotional items that market or promote the products or services of a third party. Language in §§ 155.210(d)(6) and 155.225(g)(4) currently provides that gifts, gift cards, or cash may exceed nominal value for the purpose of providing reimbursement for legitimate expenses incurred by a consumer in an effort to receive Exchange application assistance, such as travel or postage expenses. We proposed to amend this language to indicate that the reimbursement of legitimate expenses, such as travel and postage expenses, when incurred by a consumer in an effort to receive Exchange application assistance, would not be considered a gift, and therefore, would not be subject to the proposed restrictions on providing gifts.

Finally, existing regulations under §§ 155.210(d)(7) and 155.215(a)(2)(i) already prohibit the use of Exchange funds by Navigators and by non-Navigator assistance personnel subject to § 155.215 to purchase gifts or gift cards, or promotional items that market or promote the products or services of a third party, that would be provided to any applicant or potential enrollee. We did not propose to amend this provision.

[40] We have previously defined ''nominal value'' as a cash value of $15 or less, or an item worth $15 or less, based on the retail purchase price of the item, regardless of the actual cost. (79 FR 15807, 15831 (Mar. 21, 2014) and 79 FR 30239, 30283 (May 27, 2014).

We are finalizing the amendments to §§ 155.210(d)(6) and 155.225(g)(4) as proposed.

Comment: Many commenters supported our proposals, agreeing that the amendments clarify the rule and strike the right balance between allowing Navigators, non-Navigator assistance personnel subject to § 155.215, and certified application counselors to use gifts and promotional items in outreach while ensuring they are never used to induce enrollment. Some commenters asked for examples of permissible and impermissible gifts, promotional items, and legitimate expenses. Several commenters asked for guidance on the terms ''nominal'' and ''products or services of a third party.'' One commenter suggested that our rule may conflict with the beneficiary inducement rules that apply to Medicare and State health care programs, potentially creating difficulties for Navigators that are health care providers.

Response: As we noted in the preamble to the proposed rule, we have previously defined ''nominal value'' as a cash value of $15 or less, or an item worth $15 or less, based on the retail purchase price of the item, regardless of the actual cost (79 FR 15831 and 79 FR 30283). This nominal value limit applies to all gifts, including gift items, gift cards, cash cards, cash, and promotional items that market or promote the products or services of a third party. Some illustrative examples of permissible gifts and promotional items include pens, magnets, or key chains worth $15 or less each, including if such items bear the name or logo of a local business, or community or social service program. Such items may, for example, be provided to consumers at outreach and education events or at other forums attended by members of the general public, as long as they are not being provided as an inducement to enrollment. By ''inducing enrollment,'' we mean conditioning receipt of the items on a consumer's actually enrolling in coverage, as opposed to encouraging consumers to seek or receive application or other authorized assistance. To the extent that Federal or State health program beneficiary inducement rules apply to entities or individuals who also serve as Navigators, non-Navigator assistance personnel subject to § 155.215, or certified application counselors, those entities and individuals must comply with those rules as well as the applicable program rules under §§ 155.210(d)(6), 155.215(a)(2)(i), and 155.225(g)(4).

d. Ability of States To Permit Agents and Brokers To Assist Qualified Individuals, Qualified Employers, or Qualified Employees Enrolling in QHPs (§ 155.220)

We proposed additional standards under § 155.220 for oversight and enforcement of standards applicable to agents, brokers, and web-brokers who facilitate enrollment in the FFEs. These standards were proposed under the Secretary's authority to establish procedures for States to permit agents and brokers to assist consumers enrolling in QHPs through the FFEs, as described in sections 1312(e) of the Affordable Care Act.

In the proposed rule, we explained that we were considering an option to enhance the direct enrollment process, so that an applicant who initiated enrollment directly with a web-broker entity using the web-broker's non-Exchange Web site could remain on the web-broker's Web site to complete the application and enroll in coverage, instead of being redirected to the Exchange Web site to complete the application and receive an eligibility determination. Under the proposal, the web-broker's Web site could obtain eligibility information from the Exchange to support the consumer in selecting and enrolling in a QHP with Exchange financial assistance. Accordingly, we proposed to revise § 155.220(c)(1) to ensure that the Exchange maintained its role in determining eligibility when an applicant initiates enrollment with a web-broker on the web-broker's non-Exchange Web site, by requiring the agent or broker to ensure that the applicant completed an eligibility verification and enrollment application through the Exchange Web site, or an Exchange-approved web service using the FFE single streamlined application. Additionally, we solicited comments on the proposal to require web-broker entities to use the FFE single streamlined application without deviation from the language of the application questions and the sequence of information required for an eligibility determination or redetermination. We solicited comments on how much flexibility web-broker entities should be afforded relative to the consumer experience on its non-Exchange Web site. We also sought comment on additional matters HHS should consider to improve the direct enrollment process, such as requiring HHS approval of alternative enrollment pathway processes, additional consumer safeguard protections, additional web-broker reporting requirements, and

establishing more robust privacy and security requirements including requiring adoption of cyber security best practices and specificity as to the collection and use of consumer information. We also proposed to adopt parallel standards for the use of QHP issuer Web sites under § 156.265(b)(2)(ii). See III.G.5.c of this preamble for a discussion of the amendments to § 156.265(b)(2)(ii).

We proposed to amend paragraph (g)(2)(ii) to clarify that HHS could determine an agent or broker to be noncompliant if HHS finds that the agent or broker violated any term or condition of the agreement with the FFEs required under paragraph (d) of this section, or any term or condition of an agreement with the FFEs required under § 155.260(b). We proposed to add § 155.220(g)(5) to address suspension or termination of an agent's or broker's agreements with the FFEs in cases involving potential fraud or abusive conduct. We proposed in § 155.220(g)(5)(i)(A) that if HHS reasonably suspected that an agent or broker may have engaged in fraud or abusive conduct using PII of an Exchange applicant or enrollee, or in connection with an Exchange enrollment or application, HHS could suspend the agent's or broker's agreement and accompanying registration with the FFEs for up to 90 calendar days, with the suspension effective as of the date of the notice to the agent or broker. We further proposed under § 155.220(g)(5)(i)(B) if the agent or broker failed to submit information during this 90-day period, HHS could terminate the required agreements for cause effective immediately upon expiration of the 90-day period, under § 155.220(g)(5)(ii). In § 155.220(g)(5)(ii), we proposed that if HHS reasonably confirmed the credibility of an allegation that an agent or broker engaged in fraud or abusive conduct using personally identifiable information of Exchange enrollees or applicants, or in connection with an Exchange enrollment or application, or was notified by a State or law enforcement authority of the State or law enforcement authority's finding or determination of fraud or behavior that would constitute abusive conduct in such a circumstance, HHS would notify the agent or broker and terminate, immediately and permanently, the agent's or broker's agreements with the FFEs. In § 155.220(g)(5)(iii), we proposed that during the 90-day suspension period, as well as following the termination of the FFE agreements, the agent or broker would not be registered with the FFEs, or be permitted to assist with or facilitate enrollment through the FFEs, or assist individuals in applying for Exchange financial assistance for QHPs. For consistency with these proposed termination standards, we proposed corresponding updates to paragraphs (g)(3) and (4), and proposed amending paragraph (f)(4) to remove the unnecessary reference to paragraph (g).

We proposed adding paragraph § 155.220(j) to establish standards of conduct for agents and brokers that assist consumers to enroll in coverage through the FFEs to protect consumers and ensure the proper administration of the FFEs. In § 155.220(j)(1)(i) through (iii), we proposed that an agent or broker that assisted with or facilitated enrollment of qualified individuals, qualified employers, or qualified employees through an FFE, or assisted individuals in applying for Exchange financial assistance for QHPs sold through the FFEs, would have to: (1) Execute the required agreement under § 155.260(b)(2); (2) register with the FFEs as described in paragraph (d)(1) of this section; and (3) comply with the FFE standards of conduct proposed in this paragraph. In § 155.220(j)(2), we proposed that the agents and brokers described in paragraph (j)(1) would have to: (1) Provide consumers with correct information, without omission of material fact, regarding the FFEs, QHPs (including SADPs [41]) offered through the FFEs and insurance affordability programs, and refrain from marketing or conduct that is misleading or coercive, or discriminates based on race, color, national origin, disability, age, sex, gender identity, or sexual orientation; (2) provide the FFEs with correct information under section 1411(b) of the Affordable Care Act; (3) obtain the consent of the individual, employer, or employee prior to assisting with or facilitating enrollment in coverage through an FFE, or prior to assisting with the application for financial assistance for QHPs sold through the FFEs; (4) protect consumer PII in accordance with § 155.260(b)(3) and the agreement described in § 155.260(b)(2); and (5) comply with all applicable Federal and State laws and regulations. In § 155.220(j)(3), we proposed that an agent or broker would be considered to be in compliance with the standard of conduct requirements to provide consumers and the FFEs with correct information if HHS determined that the agent or broker had a reasonable cause for any failure to provide correct information and that the agent or broker acted in good faith. We also proposed that the violation of these standards could result in the termination for cause of the agent's or broker's agreements with the FFEs as described in § 155.220(g), or the imposition of other penalties as authorized by law.

In § 155.220(k), we proposed penalties for agents and brokers registered with the FFEs other than termination of the agreements with the FFEs. In § 155.220(k)(1), we proposed that if HHS determined that an agent or broker failed to comply with the requirements of § 155.220 he or she could be denied the right to enter into an agreement with the FFEs in future years, and could be subject to CMPs as described in § 155.285 if the violation involved the provision of false or fraudulent information to an Exchange or the improper use or disclosure of information. In § 155.220(k)(2), we proposed that the denial of the right to enter into an agreement with the FFEs in future years would be subject to 30 calendar days' advance notice and the reconsideration process established in § 155.220(h). The imposition of CMPs for the provision of false or fraudulent information to an Exchange or the improper use or disclosure of information would be subject to the advance notice and appeals process described in § 155.285.

Finally, in § 155.220(l) we proposed that an agent or broker who enrolled qualified individuals, qualified employers, or qualified employees in coverage in a manner that constituted enrollment through an SBE–FP, or assisted individual market consumers with submission of applications for Exchange financial assistance through an SBE–FP would have to comply with all applicable FFE standards in § 155.220.

Comment: The proposal for the enhanced direct enrollment process received broad support by many commenters, who stated they believe enabling the applicant to remain on a web-broker's or issuer's non-Exchange Web site would improve the consumer experience by supporting more seamless transitions than the existing direct enrollment functionality. One commenter stated the proposal would increase enrollment, as the current direct enrollment functionality requires a consumer to be directed back and forth between the direct enrollment Web site and HealthCare.gov, leading some

[41] As detailed in the Exchange Establishment Rule (77 FR 18309, 18315) (Mar. 27, 2012), with some limited exceptions, SADPs are considered a type of QHP. We expect agents, brokers, and web-brokers registered with the FFEs to comply with applicable rules and requirements in connection with SADPs, just as they must comply with those rules in connection with medical QHPs.

consumers to drop out of the process before completing enrollment out of frustration over operational ineffeciencies or duplication. Commenters also broadly supported our proposal for the Exchange to continue being the entity responsible for making eligibility determinations and to continue to be the system of record for enrollment. Other commenters opposed the proposal, citing the increased risk of consumers receiving inaccurate or misleading information that might affect eligibility determinations and consumer choice. Some commenters urged HHS to take several considerations into account before moving forward with the proposal, including the potential negative impact on Medicaid-eligible populations.

FFE single streamlined application. We proposed to require web-brokers to use the single streamlined application without deviation from the language of the application questions and the sequence of information required for an eligibility determination. In support of the proposal, a few commenters stated that HHS should grant entities flexibility in the application process to enable integration into existing processes, and enable more innovation for a better consumer experience. Some commenters recommended that HHS instead use the FFE single streamlined application as a baseline, and allow web-brokers the opportunity to tailor applications for specific target populations. One commenter stated that consumers should only be required to answer questions that are relevant to their personal circumstances, so as to reduce consumer burden and application time. Another commenter stated that allowing minor changes to the wording of specific questions could help enhance the consumer experience, so long as the overall meaning of the question is maintained.

Other commenters called HHS's proposal to require web-brokers and issuers to strictly adhere to existing eligibility Exchange language a ''prudent safeguard,'' citing concerns that enhanced direct enrollment would increase the risk of consumers receiving inaccurate or misleading information that might affect eligibility determinations and consumer choice, and the potential for consumer confusion around communication with Exchanges.

HHS approval of alternative enrollment pathway processes. HHS solicited comments on requiring HHS approval of alternative enrollment processes in the proposed rule. Some commenters urged that HHS implement the approval process in a collaborative and flexible manner, with clear and concise guidelines. Other commenters strongly recommended that HHS confirm that all web-brokers adhere to certain criteria prior to offering enhanced direct enrollment services, including ensuring web-broker's application questions and flows provide accurate eligibility assessments and meet other requirements, such as providing appropriate consumer support, displaying all plan information fully and accurately, and demonstrating compliance with privacy and security standards via regular audits. One commenter asked HHS to adopt a ''check-list and review of required plan choice elements'' template that would enable HHS to validate the entities' plan choice displays, tools, and elements of their application. Another commenter encouraged HHS to minimally require web-brokers to submit a Minimum Acceptable Risk Standards for Exchanges ''(MARS–E) Compliance Manual'' as a pre-condition to offering the enhanced direct enrollment eligibility service, which would detail how they manage and comply with MARS–E compliance processes. One commenter stated that HHS should require web-based entities to seek prior approval for alternative direct enrollment processes by presenting their alternatives to HHS for review, before using any display features or tools that vary from those available on the Exchange Web site.

Timing. We received many comments on the timing related to implementation of the enhanced direct enrollment proposal. Some commenters wanted an aggressive implementation timeline, urging HHS to finalize and implement the FFE single streamline application process early in 2016 so that testing could occur well in advance of the 2017 Individual Market Open Enrollment period. Other commenters recommended HHS pursue a more measured approach, noting that developing, testing, and implementing the enhanced process will be a significant undertaking for HHS, web-brokers, and QHP issuers. One commenter stated that a measured approach would allow entities to use the Exchange approved web service for a transitional period alongside the traditional direct enrollment pathway. Another commenter urged that HHS wait several years before implementing the proposal, and gather and analyze data on the consumer experience with web-based entities during 2016, conduct an examination of its oversight of web-brokers and QHP issuers in 2017, and then propose any expansion with sufficient detail for implementation no earlier than 2018.

Response: Based on the comments received, we are finalizing the proposal to enhance the direct enrollment process with some modifications, as noted below.

We appreciate the many comments and recommendations on the direct enrollment proposal we received. While we believe that an enhanced direct enrollment process will provide a more seamless consumer experience, we agree with commenters that implementing the proposal will be a significant undertaking for HHS, web-brokers, and issuers, and that such an effort will require sufficient time for operational planning and preparation, such as identifying and testing the Exchange-approved web services under § 155.220(c)(1) that can be used to support the enhanced direct enrollment process, and ensuring privacy and security risks are addressed and mitigated. HHS will not provide such an option during the individual market open enrollment period for 2017 coverage, but seeks to make this option available for the individual market open enrollment period for 2018 coverage. We intend to supplement the framework we are finalizing in this rule with more specific guidance and requirements in future rulemaking, such as specific guidelines for a pre-approval process under § 155.220(c)(4)(i)(F), and requirements for privacy and security. Until then, web-brokers must continue to comply with the current direct enrollment process, through which a consumer is directed to HealthCare.gov to complete the eligibility application, and all associated guidance. This means direct enrollment entities are not permitted at this time to use non-Exchange Web sites to complete the Exchange eligibility application or automatically populate data collected from consumers into HealthCare.gov through any non-Exchange Web site. Completion of the Exchange eligibility application on a non-Exchange Web site, or collection of data through a non-Exchange Web site that is then used to complete the eligibility application, will be considered a violation of the direct enrollment entity's agreement with the FFEs.

While enhanced direct enrollment will not be available in the individual market open enrollment period for 2017 coverage, we are finalizing our proposal to revise § 155.220(c)(1) to enable web-broker entities who use HHS-approved direct enrollment processes to facilitate enrollment through the FFEs to either ensure the applicant's completion of an eligibility verification and enrollment

through the Exchange Internet Web site as described in § 155.405, or ensure that the eligibility application information is submitted for an eligibility determination through an Exchange-approved web service. This will allow applicants to complete the entire Exchange application and enrollment process on the web-broker's non-Exchange Web site. We believe this process will grant direct enrollment entities the operational flexibility to expand front-end, consumer-facing channels for enrollment, and provide consumers with a more seamless experience.

However, we also share commenters' concerns that allowing this flexibility without additional protections in place may increase the risk of imprecise, inaccurate, or misleading eligibility results. In light of those considerations and the accompanying comments received, we are adding new § 155.220(c)(3)(ii)(A) through (D) to clearly articulate the requirements associated with completing an Exchange eligibility application on a web-broker's non-Exchange Web site. These requirements may be amended over time as implementation activities begin and once experience is gained under the new process (once implemented).

Consistent with the proposal in the proposed rule, § 155.220(c)(3)(ii)(B) requires all language related to application questions, and the sequence the questions are presented on the direct enrollment entity's non-Exchange Web site to be identical to that of the FFE Single Streamlined Application. We acknowledge the comments requesting deviations from the FFE single streamlined application to enhance the consumer experience, and are finalizing language permitting such deviations with HHS approval. We will only approve minor modifications that do not change the intent or meaning of the questions, decrease the probability of accurate answers and eligibility determinations, or affect the dependencies and structure of the dynamic application.

We are also adding new § 155.220(c)(3)(ii)(C), which sets out a more general requirement that any non-Exchange Web site facilitating the completion of an Exchange eligibility application ensure that all information necessary for the completion of the application related to the consumer's applicable eligibility circumstance are submitted through an Exchange-approved web service. New § 155.220(c)(3)(ii)(D) requires that the process used for consumers to complete the eligibility application on the non-Exchange Web site comply with all applicable Exchange standards, including Exchange notice requirements under § 155.230 and Exchange privacy and security standards related to handling PII under § 155.260(b).

We have also renumbered the current requirements that apply when an Internet Web site of an agent or broker is used to complete the QHP selection process in new § 155.220(c)(3)(i). No changes were made to these existing requirements or the accompanying regulatory text. We note that, as outlined in § 155.220(c)(3)(ii)(A), these requirements would also apply when an Internet Web site of an agent or broker is used to complete the Exchange eligibility application.

We agree with commenters that urged HHS to adopt an approval process to ensure that the web-broker non-Exchange Web site seeking to offer stand-alone direct enrollment eligibility services meets all applicable requirements in order to protect consumers. Accordingly, we have added § 155.220(c)(4)(i)(F) to outline a process for HHS to verify that these entities have met all of the applicable requirements of this section before the non-Exchange Web site is used to complete the Exchange eligibility application.

The primary objective of the new requirements outlined in § 155.220(c)(3)(ii) and (c)(4)(i)(F) is to ensure that the Exchange is able to produce an accurate eligibility determination from an eligibility application completed by a direct enrollment entity on a non-Exchange Web site for enrollment in a QHP offered through the Exchange, including eligibility for advance payments of the premium tax credit and cost-sharing reductions, as well as enrollments in Medicaid, CHIP or the Basic Health Program. Alignment with the FFE Single Streamlined Application regarding sequence and language on a non-Exchange Web site to the FFE application is critical to ensuring that the information provided to the Exchange through the Exchange approved web-service represents a complete understanding of a consumer's circumstance, and is directly tied to ensuring accurate eligibility results. As noted above, HHS will consider allowing minor deviations from the standardized language, in order to improve readability or the consumer experience. We will provide guidance on the process for seeking approval to deviate from the standardized language.

We clarify that the requirements related to the direct enrollment process rules are applicable to FFEs (including FFEs where States perform plan management functions) and SBE–FPs only, and would not apply to SBEs that do not use the HealthCare.gov platform, nor alter any State-specific rules related to Medicaid eligibility.

Comment: HHS solicited feedback on experiences with enrollment through web-brokers, including any concerns with privacy and security of the information transmitted through web-brokers by expanding direct enrollment to incorporate the FFE single streamlined application and suggestions for improvements, including requiring additional information display requirements (such as the lowest cost plan at each metal level) beyond those outlined in § 155.220(c)(3) to ensure that consumers understand basic information about cost and availability of qualified health plans. We received several comments opposing HHS implementing additional consumer protection and privacy and security standards with respect to the use of the enhanced direct enrollment process. Some commenters stated that existing web-broker requirements are sufficient to ensure appropriate consumer protections. One commenter said issuers and web-brokers should not be required to display the lowest-cost plan in each metal level because existing decision support tools can filter plans based on customer input. However, one commenter suggested requiring conspicuous notice to consumers to ensure they are aware they are applying for Exchange coverage. Several commenters provided specific recommendations to ensure that consumers understand that they are applying for Exchange coverage, including creating standardized application ID numbers that enable consumers to create HealthCare.gov accounts that would link to their web-broker accounts. Several commenters did not support requiring branding on web-brokers' sites, since many web-brokers build platforms for their strategic partners with an expectation of maintaining brand continuity. Others supported specific branding requirements, recommending a consumer-tested ''seal of approval'' to demonstrate that the web-broker's application was approved by HHS. One commenter suggested that direct enrollment non-Exchange Web sites display a standard disclaimer that notifies consumers that eligibility determinations for Exchange coverage are made by the Exchange and not the web-broker or issuer, and directing that any questions, concerns, or appeals related to an eligibility determination be submitted to the Exchange.

Commenters generally agreed that web-brokers should continue to follow

existing privacy and security standards, including the Minimum Acceptable Risk Standards for Exchanges (MARS–E). Specific suggestions include requiring approval from CMS's Chief Information Security Officer, and the CMS Chief Technology Officer, providing CMS with a current MARS–E Compliance Manual and SSP System Security Plan (SSP) subject to verification via a pre-delegation audit by CMS, and appointing a designated, dedicated Privacy Officer responsible for attesting to the organization's adherence to privacy standards as outlined in the web-broker's agreement with HHS.

Other comments raised several concerns about the privacy and security of consumers' personally identifiable information, particularly citizenship and immigration status, and asked HHS to clarify how these entities would collect, store, and use PII. Some commenters wanted HHS to clarify that web-based entities will not gather and store data beyond that necessary for HealthCare.gov, State-based Exchanges, and Medicaid eligibility and enrollment via ''cookies'' or other tracking tools, and would not store or use information gathered from consumers in the application process for marketing other products.

Response: We agree that implementing the proposal will be a significant undertaking for HHS, and that privacy and security risks must be addressed prior to implementation. We intend for the standards outlined in this section to provide a framework to prepare for the implementation to support use of the enhanced direct enrollment option in future years. We will continue to consider commenters' recommendations on ensuring consumers are protected, and intend to propose further protections in future rulemaking.

Comment: HHS also solicited comments on about the current agent and broker provisions in § 155.220 as applied to web-brokers, including suggestions for improvements in the future, such as increased monitoring and oversight activities. Commenters supported HHS conducting regular audits over web-brokers. Additionally, some commenters supported ongoing monitoring of plan selection and enrollment patterns through comprehensive data analysis. Others stated that audits need to be conducted ''equitably,'' and that HHS should assist web-brokers in coming into compliance if violations are identified.

Response: We agree with commenters that supported HHS conducting regular audits of agents and brokers under this section to ensure ongoing compliance with applicable standards. We are adding § 155.220(c)(5), which authorizes HHS to periodically monitor and audit agents and brokers approved under this subpart. This audit authority would extend to agents or brokers who follow the current direct enrollment pathway that uses a non-Exchange Web site to complete QHP selection, as well as agents or brokers who follow the enhanced direct enrollment pathway that uses a non-Exchange Web site to complete the Exchange eligibility application.

Comment: One commenter stated that there was a drafting error in paragraph (f)(4). That paragraph relates to termination without cause, but the language in that paragraph uses the phrase ''for cause.''

Response: We confirm the drafting error—we are correcting the paragraph to read ''without cause.''

Comment: While many commenters supported the proposal for suspension and termination of an agent's or broker's agreements with the FFEs in cases of potential fraud or abusive conduct, several commenters opposed the proposal as an encroachment on, or preemption of, State law. These commenters asked that HHS refer instances of fraud and abuse to the State, encouraged the FFE to work closely with the State regulator to ensure consumers are protected, and urged HHS to allow the States to regulate agents licensed do business in their State ''without interference.'' Commenters also requested that HHS coordinate with issuers on issues of agent and broker fraud, and inform issuers when HHS has notified a State's department of insurance regarding specific fraud or misconduct issues.

Response: The proposal we are finalizing relating to agent or broker suspension or termination if HHS reasonably suspects fraud or abusive conduct pertains only to agents' and brokers' agreements and registration with the FFEs to assist consumers with enrollments through the FFEs; it does not otherwise interfere with any State authority to regulate agents or brokers who are licensed to business in their jurisdiction. While HHS may suspend or terminate the FFE agreements with an agent or broker, this suspension or termination would not impact State licensure of an agent or broker. As stated in the preamble to the proposed rule, the investigations and enforcement related to the conduct of agents and brokers with respect to enrollments through or interactions with the FFEs will be conducted in coordination with States. We are finalizing paragraph (g)(5)(ii) to clarify that HHS will limit terminations without 30-days advance notice to those situations where there is a finding or determination by a Federal or State entity that an agent or broker has engaged in fraud, or abusive conduct that may result in imminent or ongoing consumer harm. In response to comments received from the public on this matter, we are also adding paragraph (g)(6) to clarify that the State department of insurance or equivalent State producer licensing authority will be notified by HHS in cases of a suspension or termination of the agent's or broker's agreements and registration with an FFE effectuated under paragraph (g). HHS will also coordinate with affected QHP issuers if it will not impede any State or Federal law enforcement investigation and as permitted under applicable Federal or State law.

Comment: Several commenters were concerned that the proposal did not afford sufficient due process protections to agents and brokers, and pointed out that a 90-day suspension period could prevent a wrongly accused agent or broker from participating in most or all of an individual market open enrollment period for a given plan year. These commenters urged HHS to provide notice and opportunity to respond before implementing a suspension, as well as provide further guidance on what would define 'fraud' or 'abusive conduct.' Commenters proposed measures such as suspending or terminating based on clear, unequivocal, and convincing evidence, a threat of immediate consumer harm, and the opportunity for an appeal hearing before an administrative law judge. Some commenters suggested that a 90-day suspension period may not be sufficient to conduct a full investigation, and suggested a longer timeframe for suspension as well as a reference to § 155.1210 to emphasize the record retention obligation of an agent along with HHS's ability to access or audit agent and broker records.

Response: Section 1313(a)(5) of the Affordable Care Act provides the authority to implement any measure or procedure that the Secretary determines is appropriate to reduce fraud and abuse in the administration of the Exchanges. We believe that a 90-day suspension is not an unreasonable timeframe where there is suspected fraud or abuse by an agent or broker, who may sell plans through the FFE not only during open enrollment but throughout the year. We note that a similar requirement for Medicare providers, 42 CFR 405.371, gives HHS the authority to suspend payments for at least 180 days where

there is reliable information that an overpayment exists, or there is a credible allegation of fraud. HHS intends to use this suspension and termination authority to stop further FFE enrollment activity by the agent or broker in cases where the misconduct may cause imminent or ongoing consumer harm. Further, we are modifying paragraph (g)(5)(i)(B) to require HHS to review and make a determination whether to lift the suspension within 30 days of receipt of evidence to rebut the allegation of fraud or abusive conduct. This provides an opportunity to limit the length of the suspension with the timely submission of rebuttal evidence.

We are finalizing the proposed paragraphs (g)(5)(i)–(ii) so that suspension or termination will be effective starting on the date of the notice in cases of actions related to suspected fraud, or abusive conduct that may cause imminent or ongoing consumer harm; for other terminations for cause under paragraph (g)(1), agents and brokers will receive 30 days' notice with opportunity to respond prior to termination as currently described in paragraph (g)(3). We are finalizing proposed paragraph(g)(5)(i)(B) with modification, so that in cases where the agent or broker submits evidence during the suspension period, HHS will review it and make a determination whether to lift the suspension within 30 days of receipt of the evidence; if the rebuttal evidence fails to convince HHS to lift the suspension, or if the agent or broker fails to submit rebuttal evidence during the 90-day suspension period, HHS may terminate for cause the agent or broker's agreements with the FFEs under paragraph (g)(5)(ii).

We note that § 155.1210 applies to Exchanges and agents of Exchanges, but not agents of QHP issuers. However, agents and brokers are downstream entities of QHP issuers, and they should be bound by their agreement with the QHP issuer to provide access to records, under § 156.340(b)(4), and maintain records in accordance with the standard at § 156.705, and HHS may request those records as part of an investigation or audit.

Comment: Commenters generally agreed with the standards of conduct proposed in § 155.220(j) for agents and brokers as important consumer protections. One commenter suggested HHS go further in implementing standards for protecting PII, protected health information (PHI), and Federal tax information. Other commenters suggested that agents should be able to maintain flexibility to answer consumers' questions in a manner that is best understood by the consumers they serve, which may result in minor inaccuracies in the information provided to FFEs, and asked HHS to adopt a standard of good faith without the necessity of a finding of reasonable cause. Two commenters requested clarification of the requirement for consumer consent. Commenters also requested clarification on the prohibition on the use of the words ''exchange'' and ''marketplace'' in business names and Web sites since the words ''exchange'' and ''marketplace'' are common and have been part of the names of Web addresses of many long-standing insurance-related businesses that pre-date the Exchanges and are not intentionally misleading.

Response: In addition to the standards of conduct requirements in § 155.220(j), the FFE privacy and security agreement contains specific requirements for protecting PII, PHI, and Federal tax information. The requirement to provide accurate information to consumers is not intended to target generalities or minor imprecisions, but rather misrepresentations of material information that would affect a consumer's choice of coverage or subsidies. As described in preamble to the proposed rule,[42] we would interpret § 155.220(j)(2)(i), which requires agents, brokers and web-brokers to refrain from marketing or conduct that is misleading, to require that agents, brokers, and web-brokers avoid the use of the terms Marketplace or Exchange or other words in the name of a business or Web site if doing so could reasonably cause confusion with a Federal program or Web site. We intend to provide further information on the requirements for consumer consent under § 155.220(j)(2)(iii) in future guidance.

Comment: While several commenters approved of extending the FFE standards for agents and brokers to SBE–FP States, others wanted more flexibility for SBE–FP States to train, register, and provide oversight of agents and brokers. Commenters suggested allowing SBE–FPs to design and administer their own individual training and certification program with treatment of State-specific requirements and regulations that may not be adequately addressed by FFE training and registration. One commenter suggested that State-specific regulations and training materials should be made available for voluntary incorporation by the individual SBE–FP. Another commenter requested that all allegations of agent misconduct in SBE–FP States be referred to the State so State regulators can investigate the misconduct to see if additional consumer harm has occurred in off-Exchange sales.

Response: Because agents and brokers will be accessing the Federal platform to enroll consumers in SBE–FP QHPs, we are finalizing § 155.220(l), to require that they be registered with HHS (which includes training through HHS or an HHS-approved vendor as described in § 155.222 for agents and brokers serving individual market consumers), and that that they comply with all applicable FFE standards in § 155.220. As stated above, HHS will work closely with State departments of insurance (or equivalent State regulators of agents and brokers) in SBE–FP States in oversight of agents and brokers. The roles and responsibilities of HHS and the State will be specified through the Federal platform agreement. While HHS will consider future alternatives that would allow SBE–FPs to provide Exchange training, we note that States may require licensed agents and brokers to receive State-specific SBE–FP training as part of their continuing education to maintain a State license.

We are finalizing these provisions as proposed, with the following modifications. We are finalizing § 155.220(c)(1) to require agents or brokers to ensure an applicant's completion of an eligibility verification and enrollment application through an Exchange Internet Web site, or through an Exchange-approved Web service, subject to meeting the requirements under new paragraphs § 155.220(c)(3)(ii) and (c)(4)(i)(F). To ensure that the information provided to the Exchange through non-Exchange Web sites represents a complete and accurate determination of a consumer's eligibility for enrollment through the FFEs, we are adding § 155.220(c)(3)(ii)(B) to require all language related to application questions, and the sequence of questions presented on the agent or broker's non-Exchange Web site, to use the same language as the FFE single streamlined application in § 155.405. We are also adding § 155.220(c)(3)(ii)(C) to require all information for the consumer's applicable eligibility circumstances are submitted through an Exchange-approved Web service; and § 155.220(c)(3)(ii)(D) to require the process used for consumers to complete the eligibility application to comply with all applicable Exchange standards, including §§ 155.230 and 155.260(b). To ensure maximum consumer protection, we are also adding new § 155.220(c)(4)(i)(F) to outline a process for HHS to verify entities meet all requirements of this section prior to

[42] 80 FR 75526 (December 2, 2015).

using a non-Exchange Web site to complete the Exchange eligibility application. In addition, we are adding § 155.220(c)(5) to enable HHS to periodically monitor and audit entities to assess compliance with standards in this section. We are correcting an error in paragraph (f)(4) to change ''for cause'' to ''without cause.'' We are finalizing (g)(5)(i)(A) to add ''that may cause imminent or ongoing consumer harm'' after ''abusive conduct.'' To clarify the process for submitting evidence to rebut the allegation of fraud or abusive conduct, we are amending paragraph (g)(5)(i)(B) to add that if the agent or broker submits such evidence during the suspension period, HHS will review the evidence and make a determination whether to lift the suspension within 30 days after HHS's receipt of evidence. If the rebuttal evidence does not persuade HHS to lift the suspension, or if the agent or broker fails to submit rebuttal evidence during the suspension period, HHS may terminate the agent's or broker's agreements required under paragraph (d) of this section and under § 155.260(b) for cause under paragraph (g)(5)(ii) of this section. We are changing the language in paragraph (g)(5)(ii), relating to grounds for termination without notice. The proposed rule stated that if HHS reasonably confirms the credibility of an allegation that an agent or broker engaged in fraud or abusive conduct (or is notified by a State or law enforcement authority of the State or law enforcement authority's finding or determination of fraud or behavior that would constitute abusive conduct). Based on comments discussed above, we are revising this provision in order to clarify the grounds for termination without advance notice and the role of the State.

We are also eliminating a redundancy within the proposed rule. Paragraph (g)(5)(ii), as originally proposed, described the termination of the agent's or broker's agreement with the Exchange under § 155.260(b) as of the date of the notice. Consequently, to reduce duplication, we are deleting a similar sentence from (g)(5)(iii). We are adding paragraph (g)(6) so that the State department of insurance or equivalent State agent or broker licensing authority will be notified in cases of suspensions or terminations effectuated under paragraph (g).

Finally, we have made a small number of non-substantive changes to the rule to make language consistent as well as to clarify the date on which the 30-day window for reconsideration requests begins.

e. Standards for HHS-Approved Vendors of FFE Training for Agents and Brokers (§ 155.222)

In the proposed rule, we proposed changes to the standards for HHS-approved vendors of FFE training for agents and brokers outlined in § 155.222. To prevent duplication with HHS functions, we proposed eliminating the requirement that vendors perform information verification functions, including State licensure verification and identity proofing, as well as other changes to improve the vendor training model.

To reflect that HHS-approved vendors would no longer be required to perform information verification functions, we proposed amending § 155.222(a)(1) to provide that a vendor must be approved by HHS, and removing the reference to information verification. We also proposed in § 155.222(a)(2) to remove the requirement that vendors must require agents and brokers to provide proof of valid State licensure. Consistent with these changes, we proposed amending § 155.222(b)(1) through (5) and (d) to remove standards for information verification, identity proofing, verification of agents' and brokers' valid State licensure, and all related standards that support these functions. We proposed to eliminate the requirements in paragraphs (b)(1)(i) through (ii) to submit an application demonstrating prior experience with verification of State licensure and identity proofing, and instead combine into paragraph (b)(1) the existing requirements to demonstrate prior experience with online training and technical support for a large customer base. In paragraph (b)(2) we proposed to eliminate the requirement to adhere to HHS specifications for content, format, and delivery of information verification. In paragraph (b)(4) we proposed to amend the standards for the agreement that vendors must execute with HHS, to eliminate the requirement that vendors implement information verification processes. We proposed amending § 155.222(b)(5) and (d) to remove references to information verification.

Other proposed changes to this section incorporated the proposed standards for SBE–FPs, privacy and security measures, and technical support requirements. In paragraph (b)(2), we proposed to include SBE–FP States in the requirement to offer continuing education units (CEUs) in five FFE States. In paragraph (b)(3) we proposed to eliminate the requirement that vendors collect, store, and share with HHS all data from agent and broker users of the vendor's training; instead we proposed that vendors would only be required to collect, store and share with HHS FFE training completion data. We also proposed adding a paragraph (b)(6) to require vendors to provide technical support to agent and broker users of the vendor's FFE training as specified by HHS. In preamble, we noted that HHS has the authority to require approved vendors to provide technical support, as well as FFE training, in accordance with HHS guidelines and in a manner and format that complies with Section 508 of the Rehabilitation Act of 1973.[43] We also proposed that, the World Wide Web Consortium's Web Content Accessibility Guidelines (WCAG) 2.0 Level AA standards[44] could also be considered an acceptable national standard for Web site accessibility.

Comment: Commenters supported the proposed improvements to standards for vendors that wish to be approved by HHS to offer agent and broker FFE training. They supported the proposed change to § 155.222 that would eliminate the requirement that vendors conduct identity-proofing, as the current years' experience indicated that it was not needed and was duplicative of existing Exchange practices. They also supported the proposed requirement that vendors offer tier one help desk support for agent and broker users. One commenter requested that vendors be able to provide an additional level of help desk support (that is, tier two support) to brokers who were having trouble navigating the CMS Enterprise Portal. The commenter also suggested that scripted responses, reflecting vendor input, be provided to vendors at least two weeks prior to the FFE training launch. One commenter supported the provisions at § 155.222(b)(3) that require vendors to share only training completion data with HHS, as opposed to all data about users, and asked that HHS use that data to provide consumers with information about the availability of the assistance that agents and brokers provide.

Response: HHS will continue to work with approved vendors to enhance customer service and technical support to agents and brokers. Requirements for vendors' customer support and help desks will be included in guidance provided to conditionally approved vendors. All agents and brokers who successfully complete FFE training through an approved vendor or the CMS Marketplace Learning Management System (MLMS), in addition to other

[43] 80 FR 75487, 75528 (December 2, 2015).

[44] For more information see, the WCAG Web site at *http://www.w3.org/TR/WCAG20/*.

FFE registration steps, will be added to Find Local Help if they choose to make their contact information publicly available.

We are finalizing these provisions as proposed.

f. Standards Applicable to Certified Application Counselors (§ 155.225)

We proposed to amend § 155.225(b)(1) to provide that certified application counselor designated organizations must, as a condition of their designation as certified application counselor organizations by the Exchange, provide the Exchange with information and data related to the number and performance of the organization's certified application counselors, and about the consumer assistance being provided by the organization's certified application counselors, upon request, in the form and manner specified by the Exchange.

We explained that § 155.225(b)(1)(ii) already requires certified application counselor designated organizations to maintain a registration process and method to track the performance of certified application counselors, but it does not specify the type of performance information that must be tracked, nor does it require that information be provided to the Exchange. We stated that our proposed amendment would give Exchanges valuable information that will aid in their oversight of certified application counselor programs and improve Exchanges' understanding of the scope of consumer assistance being provided in the Exchange service area. The requirement would also improve the consumer assistance functions of the Exchange in other significant ways, for example, by providing information that could help an Exchange focus its outreach and education efforts, target its recruitment of certified application counselor organizations, and identify the need for increased technical assistance and support for certified application counselor organizations.

We explained that under this proposal, Exchanges could establish reporting standards tailored to their own specific needs and objectives. In States with FFEs, we proposed that HHS would collect information and data from certified application counselor designated organizations on a monthly basis beginning in January 2017. We proposed that the FFEs would require these organizations to report, at a minimum, data regarding the number of individuals who have been certified by the organization; the total number of consumers who received application and enrollment assistance from the organization; and of that number, the number of consumers who received assistance applying for and selecting a QHP, enrolling in a QHP, or applying for Medicaid or CHIP. We anticipated that the monthly reports submitted to the FFEs would provide information and data from the preceding month, and would be submitted electronically, through HIOS or another electronic submission vehicle. We also said that we expected that some of the data that FFEs would require from certified application counselor designated organizations would be similar to what is collected from Navigator grantees in the FFEs.[45] We explained that we did not expect this information collection to include consumers' PII. We requested comments on our proposal, on the scope of information and data that Exchanges should collect, and on HHS's specific proposals for collecting information and data from certified application counselor organizations in the FFEs, including the proposed scope and timing of reports by these organizations to the FFEs.

We are finalizing this provision largely as proposed, with a modification to the frequency and timing of reporting required by FFEs, from a monthly basis beginning in January 2017, to a quarterly basis beginning with reports for the third quarter of calendar year 2017.

Comment: We received mixed comments related to our proposal to collect data from certified application counselor organizations. Many commenters supported the proposal, noting the value of tracking performance data. Many commenters also requested that we coordinate with the Health Resources and Services Administration (HRSA), which has reporting requirements related to their Affordable Care Act Health Center Outreach and Enrollment Assistance grants, in order to reduce duplication and administrative burden for Federally Qualified Health Centers that are both HRSA grantees and serving as FFE-designated certified application counselor organizations. We also received several specific suggestions for data elements to be collected by Exchanges, including metrics related to re-enrollment, assistance to consumers with limited English proficiency, and post-enrollment activities. One commenter requested that we develop a means for certified application counselor organizations to voluntarily report additional information that falls outside of the proposed performance measures.

Response: We agree that in general, tracking performance data will enhance the Exchanges' ability to oversee and support certified application counselor organizations, target outreach and education efforts, and identify training needs. In FFEs, we believe the information and data reporting we proposed aligns well with HRSA's Affordable Care Act Health Center Outreach and Enrollment Assistance grant reporting metrics. We also appreciate commenters' suggestions for additional FFE data elements to be reported. However, to minimize the burden on certified application counselor organizations, we are not adding to or changing the kind of information and data to be collected in FFEs.

Comment: A few commenters opposed this proposal, arguing that the requirements would be overly burdensome and could lead some certified application counselor organizations to discontinue their programs. Many commenters urged us to minimize the burden associated with certified application counselor performance data reporting. Commenters expressed concern that unfunded reporting burdens would further reduce the number of organizations able to provide critical enrollment assistance. Several commenters expressed concern regarding the scope and frequency of the proposed FFE reporting requirements, and recommended requiring less frequent reporting.

Response: We intend that any FFE information collection be straightforward, and place little burden on certified application counselor organizations, particularly given the resource constraints faced by many certified application counselor organizations. We recognize that certified application counselor organizations are not expected or required to be funded by Exchanges. In FFEs, to help minimize any burden on certified application counselors and certified application counselor organizations, while still providing FFEs enough information to meaningfully improve oversight of certified application counselor programs, we are finalizing a quarterly, rather than monthly, reporting schedule, beginning with reports for the third quarter of calendar year 2017, and are otherwise finalizing the provision as

[45] The data collection requirements for FFE Navigator grantees in 2015–2016 are specified in the Information Collection Request (OMB control number 0938–1215) under the Cooperative Agreement to Support Navigators in Federally-facilitated and State Partnership Exchanges (see the Paperwork Reduction Act package associated with 80 FR 36810). *http://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201507-0938-001.*

proposed. Quarterly reporting submitted to the FFEs will be aligned with calendar year quarters (that is, Quarter 1: January 1–March 31; Quarter 2: April 1–June 30; Quarter 3: July 1–September 30; and Quarter 4: October 1–December 31). Quarterly reports submitted to the FFEs should provide information and data from the quarter and will be due 30 days after the end of the quarter. For example, the first report that will be due under this rule, the third quarter report for calendar year 2017, will cover the period from July 1, 2017 through September 30, 2017, and will be due October 30, 2017. This quarterly reporting period and deadline will generally align with both the FFE Navigator grant metrics and HRSA's Affordable Care Act Health Center Outreach and Enrollment Assistance grant reporting metrics. FFE Navigator quarterly reports are also due 30 days after the end of the quarter, and the quarterly reports under HRSA's grants are due approximately 10–15 days after the end of the quarter. We believe that quarterly reports will provide the FFEs with sufficient information to meaningfully improve oversight of certified application counselor programs.

We believe our final rule strikes the right balance between minimized burden and effective monitoring, and that it will improve the consumer assistance functions of the Exchange by providing Exchanges with information that could help focus their outreach and education efforts, target recruitment of certified application counselor organizations, and identify the need for increased technical assistance and support for certified application counselor organizations. We also remind SBEs (including SBE–FPs) that this provision gives them the option, but does not require them, to establish reporting standards and collect data from certified application counselor organizations, because the rule only requires organizations to provide data and information to the Exchange upon the Exchange's request.

Comment: We received many comments requesting additional guidance regarding performance metrics and the submission process for FFE reporting. Commenters requested clear guidance and instructions on defining the specific data elements to ensure that organizations can easily and consistently report data. In addition, commenters requested that the system for FFE reporting be easy to understand and access, and that HHS provide adequate training and support for the system. We received many comments suggesting that the FFE leverage existing IT and data collection platforms to avoid duplicative efforts. For example, commenters noted that certified application counselors working in FFEs provide their identification number and organization number on applications submitted through HealthCare.gov and that this number should be used to quantify the number of clients who received application assistance. Commenters also suggested that the FFEs track the number of certified application counselors through the FFE online training system.

Response: In FFEs, additional guidance on the reporting requirements will be published through instructions and trainings. We anticipate that quarterly reports submitted to FFEs would provide information and data from the preceding quarter, and would be submitted electronically, through HIOS or another electronic submission vehicle. We have considered commenters' suggestions related to alternative collection methods, but have significant concerns with the quality, completeness, and accuracy of data collected using these methods. The certified application counselor identification number field on applications submitted through HealthCare.gov is not a required field, and therefore is underreported. In addition, this number would not account for assistance certified application counselors provide to consumers who do not complete an application through HealthCare.gov. Tracking the number of certified application counselors in FFEs through our online training system only tracks who has completed the FFE training, not who has been formally certified. In FFEs, designated certified application counselor organizations, not FFEs, certify individual certified application counselors, and completion of the FFE training may be only one of several criteria prerequisite to certification. For example, certified application counselor organizations may require additional employee training, and some States have additional requirements that must be met before an individual can be certified as a certified application counselor. By collecting more accurate information, we believe FFEs will be better positioned to ensure adequate assistance is available to consumers.

Comment: A few commenters agreed that SBEs should have the option to establish their own reporting requirements to align with their needs. A few commenters requested that SBEs be allowed an exemption from this proposal if they determine that the administrative costs are too burdensome. One commenter requested that HHS establish limits on both the scope and frequency of performance data reporting requirements in all Exchanges. Commenters also noted that certified application counselor organizations that operate under the umbrella of national organizations would benefit from standardized reporting requirements across all Exchanges.

Response: In SBEs, including SBE–FPs, this provision only requires that organizations submit information and data to the SBE upon request, in the form and manner specified by the SBE, and therefore affords SBEs the flexibility to establish standards appropriate to their own specific needs and objectives. SBEs, including SBE–FPs, may weigh any increased administrative costs of requiring regular reports against the benefits of having additional information about the consumer assistance landscape in their State and decide whether, how, and when to collect data from certified application counselor organizations. In addition, we encourage SBEs to take into consideration the impact their reporting requirements will have on organizations that also serve as certified application counselor organizations in States with an FFE. We encourage SBEs to consider using, at a minimum, the data elements used by the FFEs, in order to minimize the burden on organizations that also serve as certified application counselor organizations in States with an FFE, but they are not required to do so if they do not believe that doing so fits their State's circumstances.

As discussed earlier in this preamble, in the discussion of the amendments to § 155.210(d)(6), we proposed to amend § 155.225(g)(4), which prohibits certified application counselors in all Exchanges from providing certain kinds of gifts and promotional items to an applicant or potential enrollee. For the same reasons discussed above, we proposed to amend § 155.225(g)(4) consistent with our proposed amendments to § 155.210(d)(6). Based on comments received, discussed above with the amendments to § 155.210(d)(6), we are finalizing this provision as proposed.

g. Privacy and Security of Personally Identifiable Information (§ 155.260)

Section 155.260(a)(1) refers to insurance affordability programs, as defined in § 155.20. We proposed to make a technical correction to this paragraph so that § 155.300, which contains the definition of insurance affordability programs, is referenced instead. We are finalizing this provision as proposed.

h. Oversight and Monitoring of Privacy and Security Requirements (§ 155.280)

Section 155.280(a) permits HHS to oversee and monitor the FFEs and non-Exchange entities associated with FFEs to ensure compliance with the privacy and security standards established and implemented by an FFE under § 155.260. Section 155.280(a) also provides authority for HHS to monitor State Exchanges for compliance with the privacy and security standards established and implemented by the State Exchanges under § 155.260. We proposed amending paragraph (a) to permit HHS to also oversee and monitor SBE–FPs' compliance with the privacy and security standards established and implemented by an FFE under § 155.260.

Comment: We received only a few comments on this proposal. A few commenters supported extending HHS's authority to oversee and monitor privacy and security standards to SBE–FPs, but expressed concern that since SBE–FPs conduct some operations themselves, HHS should be required to oversee and monitor SBE–FPs to ensure protection of consumer PII.

Response: We agree with the commenter that it is critical to ensure protection of consumer's PII, as well as ensure cybersecurity generally, across all Exchange models. We are committed to continue working with States to ensure compliance with all State and Federal requirements related to Exchanges, including Exchange privacy and security standards. We are finalizing the rule as proposed.

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

a. Options for Conducting Eligibility Determinations (§ 155.302)

We proposed to amend § 155.302(a) by adding an option for an SBE–FP to satisfy the requirement of conducting eligibility determinations by relying on HHS to carry out eligibility determination activity and other requirements within subpart D, through a Federal platform agreement. We did not receive any comments on this proposal, and are finalizing it as proposed.

b. Eligibility Process (§ 155.310(h))

We proposed to amend § 155.310(h), which currently directs the Exchange to notify an employer that an employee has been determined eligible for Exchange financial assistance. We proposed to revise this requirement so that the Exchange must notify an employer that an employee has been determined eligible for Exchange financial assistance only if the employee has also enrolled in a QHP through the Exchange. We also proposed to revise paragraph (h)(2) so that a notice sent in accordance with § 155.310(h) must indicate that an employee has been determined eligible for Exchange financial assistance and has enrolled in a QHP through the Exchange. We clarified that for purposes of § 155.310(h), an employee is determined eligible for cost-sharing reductions when the employee is determined eligible for cost-sharing reductions based on income in accordance with § 155.305(g) or § 155.350(a).

With regard to the timing of the employer notification required under paragraph (h), we proposed that the Exchange may choose to either (a) notify employers on an employee-by-employee basis as eligibility determinations are made for Exchange financial assistance and enrollment in a QHP through the Exchange, or (b) notify employers for groups of employees who are determined eligible for Exchange financial assistance and enroll in a QHP through the Exchange. Under both options, the Exchange must notify employers within a reasonable timeframe following any month an employee was determined eligible for either form of Exchange financial assistance and enrolled in a QHP, with the goal to notify employers as soon as possible to provide the greatest benefit to enrollees. We sought comment on these proposals.

Comment: Many commenters supported the requirement that an Exchange must notify an employer that an employee has been determined eligible for Exchange financial assistance only if the employee has also enrolled in a QHP through the Exchange. A few commenters stated that the proposed change would reduce consumer confusion and minimize administrative burden.

Response: We are finalizing § 155.310(h) as proposed.

Comment: Several commenters expressed concern that employer notices may contribute to employer retaliation and requested that HHS expressly prohibit employer retaliation and include such language on employer notices and elsewhere.

Response: Section 1558 of the Affordable Care Act amended the Fair Labor Standards Act of 1938 to provide that no employer may discharge or in any manner discriminate against any employee with respect to his or her compensation, terms, conditions, or other privileges of employment because the employee (or an individual acting at the request of the employee) has received financial assistance under the Affordable Care Act. We intend to include language referencing section 1558 of the Affordable Care Act in notices from the FFEs under § 155.310(h) for 2016, and we encourage SBEs to do the same.

Comment: We received comments supporting both the policy that notices be sent in groups of employees and that notices be sent on an employee-by-employee basis. For example, one commenter expressed concern that notifying employers in groups of employees could delay the notification process. Another commenter supported the proposal that the Exchange may choose the manner and timing by which to send notices.

Response: To allow for operational flexibility and the varying needs of different Exchanges, we are finalizing the proposed language allowing an Exchange to choose to send notices on an employee-by-employee basis or in groups of employees. We note, however, that for 2016, the FFEs intend to send notices in groups of employees.

Comment: A few commenters requested that we further define the requirement to notify employers within a reasonable timeframe following any month an employee was determined eligible for Exchange financial assistance and enrolled in a QHP through the Exchange. They stated that that failure to send notices within one month could result in adverse tax consequences for the employee.

Response: While we understand the concerns that the commenters expressed, we are finalizing this provision as proposed in order to provide the Exchange with flexibility to make decisions based on its operational capabilities. As we stated in the proposed rule, the Exchange must notify employers within a reasonable timeframe following any month an employee was determined eligible for either form of Exchange financial assistance and enrolled in a QHP through the Exchange, *with the goal to notify employers as soon as possible to provide the greatest benefit to enrollees* (Emphasis added). The goal of the Exchange must be to send notices as soon as possible. We remind stakeholders that tax liability is determined by the IRS, and is not affected by these notices or the employer appeals process.

Based on the comments received, we are finalizing paragraph (h) as proposed. The FFEs intend to publish a sample notice that complies with § 155.310(h)

for the benefit of employers, employees, SBEs, and other stakeholders.

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

In § 155.320(c), we proposed to allow an Exchange to establish a reasonable threshold at which the Exchange must follow the alternate verification process where the applicant's attested projected annual household income is sufficiently below the annual income computed in accordance with § 155.320(c)(3)(ii)(A). Currently, an applicant enters the alternate verification process if the attested annual household income submitted by the applicant is more than 10 percent less than income data received from trusted data sources, or if no data is available from trusted data sources. Under the proposal, in place of the 10 percent threshold, the Exchange would establish a reasonable threshold in guidance that must be approved by HHS, must not be less than 10 percent, and can also include a threshold dollar amount.

We are finalizing this rule as proposed.

Comment: Commenters overwhelmingly supported adjusting the threshold in § 155.320(c). Commenters stated that the current 10 percent threshold is too restrictive and causes too many applicants to enter the alternate verification process. Commenters stated that the alternate verification process is burdensome to applicants because providing proof of projected income can be difficult. Some commenters suggested that a reasonable threshold should not be less than 20 percent or 25 percent. Other commenters recommended that HHS also do more to assist applicants in the resolution of annual income data matching issues.

Response: HHS will continue to study what threshold may be most appropriate, taking into account normal fluctuations in applicants' annual household income and experience with the tax reconciliation process. HHS will release guidance for Exchanges on what constitutes a reasonable threshold and to clarify the process for an Exchange to receive approval from HHS. HHS believes that clear outreach and notice for applicants related to the annual household income attestation process is critical. To that end, HHS released a new guide for applicants with annual household income data matching issues. The guide is available at the HHS Web site: *https://marketplace.HHS.gov/outreach-and-education/household-income-data-matching-issues.pdf.*

Comment: One commenter recommended against adjusting the threshold because it would result in adverse tax consequences for applicants. Instead, the commenter suggested that HHS should broaden the time period it uses when checking income from trusted data sources during the verification process like Equifax Workforce Solutions from 90 to 360 days.

Response: HHS may examine the proposal for expanding data used as part of the electronic data service for upfront verification of income as part of consumers' initial application submission.

Comment: One commenter suggested that an Exchange use the same standard for entering the alternate verification process as the Exchange uses to resolve applicants with annual household income data matching issues.

Response: The two processes are different since they are comparing different data elements. The purpose of the alternate verification process is to examine the difference in an applicant's attested projected annual household income and information from trusted data sources, whereas the resolution of data matching issues depends on an examination of whether an applicant's submitted documentation is satisfactory evidence to support their attested projected annual household income.

Comment: One commenter suggested that applicants be allowed to provide an explanation for discrepancies in their income, and that a standardized form should be provided for applicants to attest to their income as a means of verifying their income in the alternate verification process.

Response: HHS believes the use of written explanations that include sufficient information to calculate an annual income are a valuable tool for applicants, and has implemented procedures for handling explanations of income that accompany documentation of income.

Comment: The majority of commenters expressed support for granting the Exchanges flexibility in setting a reasonable threshold to meet varying Exchange needs, including related to State demographics. One commenter stated that all Exchanges should use the same threshold for applicants entering the alternate verification process.

Response: HHS supports granting Exchanges flexibility to establish a reasonable threshold, but all thresholds are subject to the same reasonability standard.

Comment: One commenter suggested that as a strategy to help applicants avoid repayment of advance payments of the premium tax credit (APTC) at tax time, Exchanges should set the default applied APTC amount at 85 percent. The commenter stated that this would allow for some flexibility for income changes during the year, and protect applicants against repayment during tax reconciliation.

Response: HHS believes that it is important to educate applicants about how changes in their income affect their eligibility for the premium tax credit. During plan selection, applicants are notified that they can accept the full amount of advance payments of the premium tax credit for which they have been determined eligible, accept a smaller amount, or accept no advance payments and claim any premium tax credit they are eligible for on their tax returns. Applicants are also notified that they may have to pay money back through the tax reconciliation process if the APTC they receive exceeds the PTC they can claim on their tax return.

Comment: One commenter suggested allowing for additional flexibility in verification for annual household income for certain occupations that have greater variability in their income such as self-employed merchants, artists, and small business owners.

Response: HHS understands that projecting annual household income can be difficult, particularly for applicants who have occupations that have high variability in income. HHS has worked to improve the resolution of annual household income data matching issues for these applicants by performing outreach and creating educational materials with instructions for verifying variable income.

In § 155.320(d), we made certain proposals related to alternative processes relating to verification of enrollment in an eligible employer-sponsored plan and eligibility for qualifying coverage in an eligible employer-sponsored plan. In paragraph (d)(3), we proposed to redesignate paragraph (d)(3)(i) as (d)(3)(ii) and redesignate paragraph (d)(3)(ii) as (d)(3)(i). To preserve the accuracy of the redesignated paragraph (d)(3)(ii), we proposed to update the cross-reference to paragraph (d)(3)(ii) with (d)(3)(i), and paragraph (d)(3)(iii) with (d)(4)(i), discussed below. We also proposed to modify the requirement that the Exchange select a statistically significant random sample of applicants for whom the Exchange does not have data as specified in paragraphs (d)(2)(i) through (iii) and take steps to contact any employer identified on the application for the applicant and the members of his or her household to

verify whether the applicant is enrolled in an eligible employer-sponsored plan or is eligible for qualifying coverage in an eligible employer-sponsored plan for the benefit year for which coverage is requested. This process is referred to as sampling. We proposed to modify this requirement as described in our in our discussion of proposed paragraph (d)(4) of the proposed rule. These proposed changes were intended to organize and simplify the regulatory text.

We proposed to add paragraph (d)(4), proposing that for any benefit year for which an Exchange does not reasonably expect to obtain sufficient verification data, the Exchange must follow the procedures described in paragraph (d)(4)(i) or, in the alternative, for benefit years 2016 and 2017, the Exchange may establish an alternative process approved by HHS. For the purposes of this section, the Exchange reasonably expects to obtain sufficient verification data for any benefit year when, for the benefit year, the Exchange is able to obtain data about enrollment in and eligibility for qualifying coverage in an eligible employer-sponsored plan from at least one electronic data source that is available to the Exchange and has been approved by HHS, based on evidence showing that the data source is sufficiently current, accurate, and minimizes administrative burden.

In paragraph (d)(4)(i), we proposed that the Exchange may conduct sampling. This paragraph is substantially the same as current paragraph (d)(3)(iii), with three differences described in the proposed rule: we proposed to (1) remove the absolute requirement to conduct sampling, and, for benefit years 2016 and 2017, allow the Exchange to implement an alternative process approved by HHS; (2) remove the language that appears in current paragraph (d)(3)(iv), which discusses relief that is no longer applicable; and (3) appropriately update internal cross-references. We proposed moving the sampling requirement from paragraph (d)(3) and adding it to new paragraph (d)(4) to more accurately reflect the role of the sampling process. In paragraph (d)(4)(ii), we proposed to permit an Exchange the option to implement an alternate process to sampling approved by HHS for the benefit years 2016 and 2017.

Comment: Commenters generally supported the proposal to permit an Exchange to implement an alternate process to sampling approved by HHS for the benefit years 2016 and 2017. A few SBEs opposed the sunset for the alternate process to sampling.

Response: We understand that certain SBEs may prefer the flexibility to implement either sampling or an alternate process indefinitely. However, the alternate process should be used as an interim measure to gather information about the verification process as Exchanges improve their long-term verification programs. We will take these comments under advisement for future rulemaking.

Comment: We also received several comments pertaining more broadly to verification of enrollment in an eligible employer-sponsored plan and eligibility for qualifying coverage in an eligible employer-sponsored plan.

Response: We agree with commenters on both the benefits of a comprehensive verification system for employer sponsored coverage, and on the considerable operational challenges of creating one.

We are finalizing the changes to § 155.320(d) as proposed.

d. Medicare Notices

We recognize the importance of a smooth transition to Medicare coverage, and sought comment on whether and how to implement a notification that an enrollee may have become eligible for Medicare. For example, for enrollees in an FFE, we considered pop up text on HealthCare.gov for individuals who are going to turn 65 during the benefit year. We sought comment on this and other ways to promote smooth coverage transitions.

Comment: All commenters supported implementation of the pop-up text on HealthCare.gov for individuals who are going to turn 65 during the benefit year. Most commenters also expressed a desire for more robust notice and screening requirements. Several commenters requested that the FFE implement a screening process to identify QHP enrollees who are Medicare-eligible or who will be reaching Medicare eligibility during the benefit year. Several commenters suggested that the FFE provide additional education to QHP enrollees nearing Medicare eligibility, including information related to Medicare enrollment, penalties for not timely enrolling in Medicare, the requirement to return to the FFE in order to terminate financial assistance for which Medicare beneficiaries no longer are eligible or to terminate their QHP enrollments, and options for those automatically enrolled into a Medicare Advantage plan. Most commenters also requested that the option of a pop-up screen on HealthCare.gov be augmented by notices sent to QHP enrollees nearing eligibility to enroll in Medicare (including those QHP enrollees whose eligibility to enroll in Medicare is due to disability or end stage renal disease). Commenters had varied suggestions related to the form and content of the notices, but most suggested notices containing information related to deadlines for Medicare enrollment and penalties for late enrollment, instructions on how to terminate enrollment in a QHP or to remove a Medicare beneficiary from an enrollment group prior to enrolling in Medicare, and instructions on how to terminate financial assistance, such as APTC, for which Medicare beneficiaries are no longer eligible. Some commenters had specific suggestions related to identifying and notifying QHP enrollees who are eligible for Medicare benefits due to disability or end stage renal disease. Finally, some commenters requested information related to how State-based Exchanges would be affected by new Medicare notice requirements.

Response: We appreciate the comments related to this issue. We are working to incorporate additional online content to help clarify for consumers who may be close to aging into Medicare, or who may already be eligible for Medicare or receiving Medicare benefits, to provide better clarity around how Medicare and Exchange coverage are intended to work, and options consumers may have as they transition into Medicare coverage from Exchange coverage. In addition, we are working on enhancing consumer communications on how to transition from Exchange coverage to Medicare, and helping consumers understand where to find helpful resources for both programs. We welcome further input and assistance as we work towards implementing a framework to ease QHP enrollees' transition from coverage through the Exchanges to Medicare enrollment.

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

a. Annual Eligibility Redetermination (§ 155.335(j))

In the 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 final rule (79 FR 52994, 53000 (Sept. 5, 2014)), we established a renewal and re-enrollment hierarchy at § 155.335(j) to minimize potential enrollment

disruptions. To further minimize potential disruptions of enrollee eligibility for cost-sharing reductions, we proposed to amend § 155.335(j)(1) to create a new re-enrollment hierarchy for all enrollees in a silver-level QHP that is no longer available for re-enrollment. Specifically, if such an enrollee's current silver-level QHP is not available and the enrollee's current product no longer includes a silver-level QHP available through the Exchange, we proposed that the enrollee's coverage would be renewed in a silver-level QHP in the product offered by the same issuer that is the most similar to the enrollee's current product, rather than in a plan one metal level higher or lower than his or her current silver-level QHP, but within the same product. Transitioning enrollees in this manner is an operationally efficient way to maintain continuity for enrollees eligible for cost-sharing reductions, and, because the benchmark plans for establishing the amount of the premium tax credit for which an eligible taxpayer is eligible is a silver-level plan, continued enrollment in a silver-level plan, as opposed to enrollment in a plan at a different metal level but in the same product is likely to be more consumer protective.

We also sought comment on whether the hierarchy, together with rules related to guaranteed renewability, should permit a QHP enrollee to be automatically re-enrolled into a plan not available through an Exchange, and under what circumstances such a re-enrollment should occur.

As in the 2016 Payment Notice proposed rule, we also noted that we are exploring a change to the re-enrollment hierarchy at § 155.335(j), which currently prioritizes re-enrollment with the same issuer in the same or a similar plan.

In the proposed rule, we stated we were considering an approach under which an enrollee in an FFE would be offered a choice of re-enrollment hierarchies at the time of initial enrollment, and could opt into being re-enrolled by default for the subsequent year into a low-cost plan, rather than his or her current plan or the plan specified in the current re-enrollment hierarchy.

Comment: Many commenters supported our proposal with respect to silver-level QHPs, agreeing that it assists enrollees in those plans in maintaining access to cost-sharing reductions. These commenters stressed that access to that financial assistance can be of vital importance to many enrollees. Several commenters expressed concern that automatically re-enrolling a silver-level plan enrollee into a different product might affect the enrollee's provider network, benefits, and continuity of care, or stand-alone dental coverage. Some commenters stated that education and proper notices could help ensure that enrollees actively re-enroll in coverage if they are automatically re-enrolled in a plan that does not fit their needs. Several commenters stressed that issuers, who have the experience and information necessary to ensure enrollees are matched with a product that most closely fits their needs while minimizing potential disruptions in coverage and cost-sharing reductions, are in the best position to determine which available plans are the most similar to plans that are no longer available.

Response: We are sympathetic to the comments stating that enrollees should return to the FFEs to actively re-enroll in the coverage that best fits their needs. We recognize, however, that automatic re-enrollment hierarchies must exist to help those who do not take advantage of the opportunity actively to choose coverage for the benefit year. Therefore, while we acknowledge that re-enrollment between products can result in disruption to provider networks, benefits, and continuity of care, we believe it is important to maintain enrollees' access to cost-sharing reductions in silver plans, which might be vital to their ability to pay for coverage or care. We are finalizing this provision of the rule as proposed, except that for the purpose of clarity we are finalizing a slight modified version of the language in paragraph (j)(1).

Comment: We received many comments regarding the proposed alternative re-enrollment hierarchy, many of them mirroring comments made to our proposal in the 2016 Payment Notice. Commenters who opposed permitting an alternative low-cost enrollment hierarchy stated that, in most cases, the plan a consumer chooses during open enrollment is one that the consumer has shopped for and has determined best meets his or her needs. Additionally, commenters said that low-cost premiums do not necessarily lead to lower overall cost of coverage because deductibles, copayments, coinsurance, and out-of pocket limits may be higher in QHPs with low premiums. A minority of commenters supported the proposal's emphasis on low premiums.

Response: We appreciate the many comments received regarding alternative re-enrollment hierarchies and are sensitive to the concerns raised by commenters. We recognize that consumers consider many factors in addition to premium when selecting health coverage, including the provider network, cost-sharing, deductibles, and other factors that affect overall costs, continuity of care, and the consumer experience. We are not finalizing this proposed additional re-enrollment hierarchy.

Comment: Many commenters responded unfavorably to the suggestion that enrollees in QHPs could be automatically re-enrolled into off-Exchange plans because they would lose any advance payments of the premium tax credit or cost-sharing reductions they had been receiving. Several stressed that such a plan would cause consumer confusion.

Response: In response to these comments, and in order in to maintain coverage with advance payments of the premium tax credit and cost-sharing reductions for the majority of Exchange enrollees who are receiving them, we are finalizing a rule that would provide for auto-reenrollment through the Exchange, as opposed to permitting auto-reenrollment outside the Exchange. Under this rule, an enrollee could automatically be re-enrolled into a QHP from a different issuer through the Exchange. Such reenrollments would be conducted as directed by the applicable State regulatory authority, or, where the applicable State's regulatory authority declines to act, to the extent permitted by applicable State law, in a similar QHP as determined by the Exchange. With regard to how Exchanges will determine which plans such enrollees should be auto-reenrolled into, we note that this policy provides considerable flexibility to Exchanges to implement this rule, in recognition of the operational realities of implementing a re-enrollment hierarchy in the often unique circumstances in which an issuer is not returning to the Exchange. However, whenever feasible, the Exchange should, and the FFE will attempt to, re-enroll enrollees in silver metal-level QHPs no longer available through the Exchange into the silver metal-level QHP offered by another issuer through the Exchanges of the same product network type with the lowest premium. If the QHPs that have become unavailable are in metal levels other than silver, then whenever feasible, the Exchange should and the FFE will seek to re-enroll the affected enrollees in the QHP available on the Exchange of the same metal level of the same product network type with the lowest premium. Exchanges should, and the FFEs will endeavor to, implement such a re-enrollment process for enrollees of QHPs whose issuers are discontinuing their coverage, for as many groups as is feasible given the short timelines and complex operations

that could be required in these scenarios. Those groups for which such reenrollment is not feasible will need to make an active plan selection to remain enrolled in a QHP through the Exchange. We note that such a re-enrollment generally would require a binder payment from a consumer in order to be effectuated. In future guidance, we intend to update the Federal standard notices that address how issuers that no longer have plans available through the Exchange should communicate with consumers. We anticipate providing that an issuer that no longer has plans available through the Exchange may notify its enrollees of that fact, and may encourage them to enroll in the issuer's off-Exchange plans, but may not automatically enroll them in those plans, to avoid automatic enrollment in more than one plan. We intend to provide additional guidance on the application of the rules related to guaranteed renewability to this type of situation in the future.

Comment: We received a few comments requesting more information regarding how the proposed alternative re-enrollment hierarchy would affect stand-alone dental plans. Some commenters stated that the process for re-enrolling in a SADP should be independent from re-enrollment in a QHP.

Response: Because we will not implement the proposed alternative reenrollment hierarchy at this time and the policy for consumers whose issuer exited the Exchange would not apply to SADPs, we are not addressing how this policy would affect SADPs. However, we appreciate the comments raising this issue and, if the proposal is revisited in the future, we will address concerns regarding SADPs then.

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

(1) Rules for First Month's Premium Payments for Individuals Enrolling With Regular, Special, and Retroactive Coverage Effective Dates

We proposed to amend § 155.400(e) related to the payment of the first month's premium (that is, binder payments), including deadlines, to codify previously released guidance in section 8.2 of the updated Federally-facilitated Marketplace and Federally-facilitated Small Business Health Options Program Enrollment Manual,[46] that specified our interpretation of these requirements. Specifically, we proposed to amend § 155.400(e)(1)(i) and (ii) to provide that, for prospective coverage, the binder payment must consist of the first month's premium. To provide added flexibility for issuers, we also proposed that the deadline for a binder payment related to prospective coverage with a prospective special effective date, would have to be no earlier than the coverage effective date and no later than 30 calendar days from the date the issuer receives the enrollment transaction or the coverage effective date, whichever is later. This would align the requirement for enrollments with prospective special effective dates with the requirement for enrollments with regular effective dates. We proposed to add § 155.400(e)(1)(iii) to reflect our interpretation, intended to limit the risk that issuers would provide retroactive coverage without receiving sufficient premium payments from enrollees, that applicants requesting coverage being effectuated under retroactive effective dates, such as coverage in accordance with a special enrollment period or a successful eligibility appeal, must pay a binder payment that consists of all premium due (meaning the premium for all months of retroactive coverage). If the applicant pays only the premium for one month of coverage, we proposed that the issuer would be required to enroll the applicant in prospective coverage in accordance with regular effective dates. We also proposed to specify that the deadline for payment of all premium due must be no earlier than 30 calendar days from the date the issuer receives the enrollment transaction or notification of the enrollment. This change to the binder payment rules was intended to allow issuers flexibility to set a reasonable deadline for enrollees to submit payment of retroactive premium, the total amount of which may consist of payment for several months of coverage.

Based on our experience implementing the grace period provisions under our previous rulemaking, particularly in cases involving advance payments of the premium tax credit, we identified the need for additional flexibility for issuers to establish reasonable policies regarding premium collection that would allow issuers to collect a minimal amount of premium less than that which is owed without necessarily triggering the consequences for non-payment of premiums. For example, in the Exchange Establishment Rule, we established that enrollees receiving advance payments of the premium tax credit must make full payment on all outstanding premiums owed in order to avoid entering a grace period or having their coverage terminated. In response to requests from issuers, we proposed to add flexibility to this rule to allow issuers the option to adopt a premium payment threshold policy to avoid situations in which an enrollee who owes only a *de minimis* amount of premium has his or her enrollment terminated for non-payment of premiums.

Accordingly, at new § 155.400(g), we proposed to codify a provision related to premium payment threshold policies that would allow additional issuer flexibility regarding when amounts collected will be considered to satisfy the obligation to pay amounts due, so long as issuers implement such a policy uniformly and without regard to health status, and the premium payment threshold adopted is reasonable. This would allow issuers flexibility to effectuate an enrollment, not to place an enrollee in a grace period for failure to pay 100 percent of the amount due, and not to terminate enrollments after exhaustion of the applicable grace period for enrollees. We are finalizing these policies as proposed.

Comment: We received several comments regarding the proposal to set deadlines for payment of the first month's premium (binder payments). Some commenters appreciated the flexibility that such a proposal gives to issuers to set such deadlines while others commented that the proposal would resolve ambiguity revolving around the binder payment deadlines for special and retroactive effective dates. Several commented that the guidelines would provide consumer protection by not allowing payment due dates before the effective date of coverage. One commenter suggested that the final rule allow issuers flexibility to offer consumers coverage effective dates that would be more generous than those contained in the proposal and another commenter stated that issuers should be permitted to set a binder payment deadline no later than the coverage effective date.

Response: The final rule allows issuers flexibility to set binder payment deadlines within a set of parameters we believe balances concerns about consumer protection and issuers' desire to have flexibility regarding business decisions. While we are sympathetic to the desire to give consumers a generous amount of time to pay binder payments, we believe that the final rule allows issuers to set payment deadlines in such a way that consumers have ample time

[46] Federally-facilitated Marketplace and Federally-facilitated Small Business Health Options Program Enrollment Manual (eff. Oct. 1, 2015), available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Updated_ENR_Manual.pdf.*

to effectuate coverage. We also note that the final rule allows issuers to set the binder payment deadline on the coverage effective date, but not on a date earlier than the coverage effective date.

Comment: Some commenters were confused about the additional language to allow first month's premium payments after the coverage effective date, thinking that a person's coverage could be effectuated prior to the person making their payment. These commenters opposed allowing more individuals to appear to have effective coverage and then have the coverage not be effectuated due to non-payment of premium by the payment deadline.

Response: As we previously have stated, payment for first month's premium is required prior to coverage being effectuated. For the FFE, in cases where an enrollee, consistent with an issuer's payment policy, makes his or her premium payment after the coverage effective date, but before the premium payment deadline set by the issuer, the enrollee would receive a retroactive effective date. Issuers may pend claims while waiting for the first month's premium payment and either deny or reverse those claims based on whether the enrollee makes the first month's payment by the premium payment deadline. We believe that it is appropriate to allow payments, if the issuer chooses, after the coverage effective date.

Comment: One commenter recommended a modification to § 155.400(e)(1)(iii) to give consumers requesting retroactive coverage effective dates more flexibility. The commenter felt that requiring a binder payment consisting of all premium due would be a hardship to lower-income enrollees and, in order to avoid such hardship, issuers should be required to accept payment plans when consumers enroll with a retroactive effective date.

Response: While we understand it might be difficult for some consumers to pay all premium due to effectuate with a retroactive effective date, we believe that such a policy is necessary to minimize the risk that providers and issuers would honor claims during, potentially, several months of retroactive coverage without receiving corresponding premium payments from consumers. The proposed rule allows consumers who might have difficulty paying for retroactive coverage to enroll with prospective coverage only. It is our interpretation of § 155.400(e)(1)(iii) that a binder payment for retroactive coverage consists of all premium due, or a payment sufficient to satisfy the issuer's premium payment threshold, if applicable.

Comment: One commenter expressed concern about the proposed binder payment rules for coverage with retroactive effective dates, noting that if an issuer receives only the premium for one month of coverage, the enrollees would effectuate for prospective coverage with a regular effective date. The commenter thought this proposal to be inconsistent with the FFE's current guidance related to altering coverage effective dates without instruction to do so from the FFE, which generally, but not always, requires a transaction from the FFE in order to set or alter enrollees' coverage effective dates.

Response: Although issuers generally should not grant or alter coverage effective dates without a transaction from the FFE, there are cases where FFE guidance is sufficient to give rise to such an alteration. For example, current FFE guidance allows issuers to cancel coverage, without any directive from the FFE, for enrollees who have not paid their binder payments by the applicable due date. We believe that allowing enrollees who make a binder payment insufficient to satisfy all premium due but sufficient to effectuate prospective coverage to effectuate prospectively with a regular effective date protects consumers and promotes the goal of getting consumers into coverage while not conflicting with current regulations or FFE policies.

Comment: Several organizations commented on the proposal to codify the provision related to premium payment threshold policies which allows additional issuer flexibility regarding when amounts collected will be considered to satisfy the obligation to pay amounts due, so long as issuers implement such a policy uniformly and without regard to health status and that the premium payment threshold adopted is reasonable. Most commenters saw the proposal as providing important consumer protections and allowing sufficient flexibility for issuers to tailor the threshold as they wished, within the parameters set by HHS. A few of the commenters, however, claimed that the proposed rule would cause providers to bear the burden of claims, subsequently reversed by issuers, incurred during the second and third months of a grace period for enrollees receiving APTC.

Response: We do not believe that codifying the premium payment threshold will lead to additional uncompensated claims. The purpose of the threshold, which issuers may utilize at their option, is to keep enrollees from entering a grace period or having their enrollments terminated for non-payment of premium when the amount they owe is within a reasonable threshold. Issuers' adoption of the premium payment threshold could serve as a method to avoid terminating enrollments for non-payment of premium for enrollees who only owe a small amount of premium. We do not believe this policy will have the effect of increasing the number of consumers who enter the grace period or who are terminated from coverage for non-payment, the predicate for pended claims that are not eventually paid.

Comment: One commenter sought clarification that, under the premium payment threshold policy proposed in the rule, unpaid premium within a reasonable threshold tolerance, is still an amount owed by the enrollee and cannot be forgiven by the issuer.

Response: Any amount that is unpaid but within the tolerance of a reasonable premium payment threshold established by an issuer remains an amount owed by the enrollee and cannot be forgiven by the issuer. This remains true whether the premium payment threshold is utilized for any of the following payments: binder payments, regularly-billed payments, or amounts owed by an enrollee while in a grace period.

Comment: Two commenters requested that, due to that the complexity of creating the necessary operations framework to institute the premium payment threshold policy, the regulation should not be effective until 2017 or 2018. One commenter requested that the final rule provide for implementation of a threshold based, at an issuer's discretion, on a flat dollar amount or a percentage of the total member responsible portion of premium owed.

Finally, one commenter requested that we amend the proposed rule to make the premium payment threshold mandatory for all issuers. Additionally, the commenter sought a change to the proposed rule setting a 90 percent percentage of member responsible portion of premium as the mandatory threshold for all issuers.

Response: The proposed rule included flexibility for issuers to implement a premium payment threshold to suit their specific business, provided the threshold adopted is reasonable. We did not consider utilizing a flat dollar amount threshold rather than a percentage of premium owed to be reasonable, because such an approach would not take into account the possibility that even a low flat dollar amount may represent a large portion of an enrollee's portion of premium after application of APTC. We previously have recommended a premium payment

threshold of 95 percent,[47] which we consider to be reasonable. Although we understand the desire to provide uniformity of consumer protections across the FFEs, we do not wish to make the premium payment threshold a mandatory policy nor to set a mandatory threshold at a fixed percentage, as specific facts may justify a higher or lower one. Finally, because the premium payment threshold policy is implemented at the option of each issuer, we do not believe there is a reason to delay implementation of the regulation due to operational complexity.

(2) Reliance on HHS to Carry Out Enrollment and Related Functions

We also proposed to amend § 155.400 by adding a new paragraph (h) to reflect that SBE–FPs must agree to rely on HHS to implement the functions related to eligibility and enrollment within subpart E, through the Federal platform agreement. This reflects that eligibility and enrollment functions must be performed together in the FFE, and that neither function can be performed separately by an SBE–FPs at this time. We did not receive any comments on this proposal and are finalizing the policy as proposed.

c. Annual Open Enrollment Period (§ 155.410)

We proposed to amend paragraph (e) of § 155.410, which provides the dates for the annual open enrollment period in which qualified individuals may apply for or change coverage in a QHP. We proposed to amend paragraph (e)(2) to define the open enrollment period for coverage year 2017 to be November 1, 2016, through January 31, 2017. We also proposed to amend the annual open enrollment period coverage effective date provisions in paragraphs (f)(2)(i) through (iii) to include the coverage effective dates for 2017.

We proposed this time period and these coverage effective dates to remain consistent with the 2016 open enrollment period. This timeframe will continue to partially overlap with the annual open enrollment period for Medicare and most employer offerings, which will benefit consumers by facilitating smooth transitions between coverage and creating process efficiencies for issuers handling enrollments and re-enrollments during the same period.

We also sought comment on what the open enrollment period for coverage year 2018 and subsequent years should be.

We are finalizing the open enrollment period for coverage year 2017 as proposed.

In response to comments received, we are similarly defining, at § 155.410(e)(2), the open enrollment period for coverage year 2018 to be November 1, 2017 through January 31, 2018. These are the same start and end dates as for the open enrollment periods for the 2016 and 2017 benefit years. We define the coverage start dates for all open enrollment periods beginning with the open enrollment period for the 2016 benefit year, in three paragraphs at § 155.410(f)(2). Accordingly, for example, for the 2018 coverage year, the Exchange must ensure that coverage is effective January 1, 2018, for QHP selections received by the Exchange on or before December 15, 2017; February 1, 2018, for QHP selections received by the Exchange on or before January 15, 2018; and March 1, 2018, for QHP selections received by the Exchange on or before January 31, 2018, and similarly for other coverage years. We believe that this open enrollment period provides sufficient time for operational readiness by the FFE and issuers, and provides consistency for consumers and sufficient time for them to enroll in coverage. However, as further explained below, we plan to shift to an earlier open enrollment end date for future open enrollment periods, starting with the open enrollment period for the 2019 coverage year, and are therefore finalizing at § 155.410(e)(3) an open enrollment period for all future coverage years to run from November 1 through December 15 of the year prior to the coverage year, with coverage effective the first day of the coverage year.

Comment: We received support from most commenters for maintaining the same open enrollment period for coverage year 2017 as for coverage year 2016, as it provides consistency for consumers, reduces consumer confusion about coverage effective dates, and continues to partially overlap with the open enrollment period for Medicare and for most employer offerings. We received several comments requesting an earlier open enrollment period that ends prior to the start of the benefit year and several comments requesting a later open enrollment period that continues through the Federal tax-filing season. Several commenters requested shortening the open enrollment period for the 2017 coverage year by two weeks, while other commenters requested lengthening the open enrollment period by a month or through part of the Federal tax filing season.

Response: After consideration of the comments, we are finalizing the open enrollment period for coverage year 2017 as proposed, for consistency with the 2016 open enrollment period, as discussed above.

Comment: We received varied comments regarding the open enrollment period for coverage year 2018 and for future coverage years. Many commenters recommended shifting to an earlier open enrollment period that starts and ends prior to the start of the coverage year, so that all consumers have a full year of coverage. Among these commenters, some recommended shortening the open enrollment period by two weeks for an open enrollment period that starts on October 1 and runs through December 15. Some of these commenters recommended shortening the duration of the open enrollment period from 3 months to 2 months for an open enrollment period that starts on October 15 and runs through December 15. Other commenters recommended shortening the duration of the open enrollment period to about six weeks, so it starts on November 1 and runs through December 15. Several commenters recommended an open enrollment period that starts on October 15 and runs through either December 7 or December 15 in order to align the Exchange and Medicare open enrollment periods.

Commenters opposed to an earlier open enrollment period start date expressed concerns about providing sufficient time for plans to be certified and for plans to be previewed prior to the start of the open enrollment period. Those opposed to an earlier open enrollment period end date expressed concern about consumer confusion over the enrollment deadline. And, those opposed to shortening the duration of the open enrollment period expressed concerns about the workforce constraints of assisters, such as Navigators and certified application counselors, agents, and brokers who provide enrollment assistance throughout the open enrollment period.

Several commenters recommended a gradual shift to an earlier open enrollment period. These commenters stressed the importance of enabling consumers to enroll in coverage in January, since many consumers travel or are otherwise occupied during the last few months of the year. Among these commenters, some recommended maintaining the same open enrollment period duration of 3 months for an open

[47] Federally-facilitated Marketplace and Federally-facilitated Small Business Health Options Program Enrollment Manual, updated October 1, 2015, section 6.1, available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Updated_ENR_Manual.pdf.*

enrollment period that starts on October 15 and runs through January 15. Other commenters recommended shortening the open enrollment period by approximately two weeks and keeping the same open enrollment start dates as for coverage years 2016 and 2017, for an open enrollment period that starts on November 1 and runs through January 15. Lastly, some of these commenters recommended shortening the open enrollment period to 2 months for one that starts on November 15 and runs through January 15.

Several other commenters recommended maintaining the same open enrollment period for 2018 and for future coverage years as for coverage years 2016 and 2017. Doing so, these commenters point out, would allow for better planning and consistency. Many of these commenters also recommended that HHS establish an open enrollment period for all future benefit years, which would enable issuers to engage in longer term planning, assist with outreach and enrollment efforts, and reduce consumer confusion.

Lastly, many commenters recommended a later closing of the open enrollment period to better align with the Federal tax filing season. These commenters noted that it is through the Federal tax filing process that many consumers have learned about the individual shared responsibility coverage requirement. While all of these commenters agreed that the duration of the open enrollment period should be extended, commenters were divided about whether the start of the open enrollment period should be the same as for the 2016 and 2017 coverage years, November 1, or should start slightly later on November 15. These commenters were also divided about whether the open enrollment period should continue through most of the tax filing season by continuing through March 15 or whether the open enrollment period should continue past the April tax-filing deadline to run through April 30. However, the majority of these commenters recommended an open enrollment period that begins on November 15 and runs through March 15.

Response: After consideration of the comments received, we are finalizing an open enrollment period for 2018 that starts on November 1, 2017 and runs through January 31, 2018. Maintaining the same open enrollment period start and end dates for coverage years 2016 through 2018, will provide consistency for consumers and will avoid putting new pressure on the QHP certification timeline for issuers. An open enrollment period end date of January 31 ensures that consumers are enrolled by March, which supports coverage for most consumers for the majority of the 2018 coverage year and does not put any new burdens on assisters, such as Navigators and certified application counselors, agents, brokers, and others providing enrollment assistance. However, to support a full year of coverage for most consumers, we plan to shift to an earlier open enrollment end date for the 2019 open enrollment period and all future open enrollment periods. Starting with the 2019 coverage year and beyond, we are setting an open enrollment period that runs through December 15. This change achieves our goals of shifting to an earlier open enrollment so that all consumers who enroll during this time will receive a full year of coverage and this will reduce selection risk for issuers. We believe that shifting the open enrollment period end date to December 15 for the 2019 coverage year provides sufficient time for all entities involved in the annual open enrollment period process, including Exchanges and issuers, to make the necessary adjustments to meet this earlier deadline. We also believe that, as the Exchanges grow and mature, a month-and-a-half open enrollment period provides sufficient time for consumers to enroll in or change QHPs for the upcoming coverage year.

d. Special Enrollment Periods (§ 155.420)

Special enrollment periods are available to consumers under a variety of circumstances as described in § 155.420. We stated in the proposed rule that we had heard concerns regarding abuse of special enrollment periods, and we sought comments and data regarding existing special enrollment periods.

In order to review the integrity of special enrollment periods, the FFE will be conducting an assessment under which we collect and review documents from consumers to confirm their eligibility for the special enrollment periods under which they enrolled. We note that where an Exchange undertakes such a review, the Exchange may either retroactively or prospectively end coverage, consistent with Exchange regulations, if the Exchange determines that the special enrollment period was improperly granted under § 155.420.

Comment: We received many comments related to amending the number and scope of special enrollment periods. Several commenters requested the addition of new special enrollment periods, including special enrollment periods for pregnancy and for individuals facing the individual shared responsibility payment at tax time. Other commenters requested the expansion of existing special enrollment periods, including adding provider network and drug formulary errors to the special enrollment period for plan or benefit display errors under paragraph (d)(4) of this section, allowing dependents of Indians to enroll in or change enrollments along with the Indian through the special enrollment period in paragraph (d)(8) of this section, and allowing for a retroactive coverage start date for consumers who qualify for the special enrollment period due to a loss of minimum essential coverage in paragraph (d)(1) of this section. Several commenters requested expansions to the timeframe and applicability of special enrollment periods, including extending the length of time in which a consumer may enroll after qualifying for a special enrollment period from 60 to 90 days, and extending all special enrollment periods offered through the Exchange to the off-Exchange market.

Other commenters requested restrictions in the number and availability of special enrollment periods. One commenter requested the elimination of all special enrollment periods that do not align with those special enrollment periods offered by Medicare or are not required by HIPAA, while another commenter stated that special enrollment periods should be limited to certain life-changing events. One commenter requested restricting the eligibility of the special enrollment period for gaining access to new QHPs as a result of a permanent move to only consumers who were previously enrolled in other minimum essential coverage, and only allowing the new dependent to enroll in or change his or her enrollment into a new QHP under the special enrollment period described in paragraph (d)(2). One commenter requested that States with SBE–FPs have the flexibility to establish State-specific special enrollment periods to address the particular needs of consumers in their State.

Response: We are not finalizing new qualifying events, eliminating current qualifying events, or changing the scope of current qualifying events for special enrollment periods at this time, but are continuing to study this issue. As explained in guidance released on January 19, 2016,[48] HHS has removed

[48] Special Enrollment Periods No Longer Utilized by the Federally-facilitated Marketplaces and State-based Marketplaces using the Federal Platform and Future CMS Actions (Jan. 19, 2016), available at *https://www.regtap.info/uploads/library/ENR_RetiredSEPs_011916_v1_5CR_011916.pdf;* see also FAQs on the Marketplace Residency Requirement

certain special enrollment periods that were available in 2014 and 2015 because the specified time period has ended, the situation it addressed has been resolved, or needed system updates have been made. HHS continues to review rules and guidance related to special enrollment periods.

Comment: Commenters expressed concerns about current misuse or abuse of special enrollment periods, including consumers who inappropriately obtain a special enrollment period on the basis of a loss of minimum essential coverage after being terminated from coverage due to a failure to pay premiums in violation of § 155.420(e)(1). Some commenters supported more clearly defining the eligibility parameters of existing special enrollment periods, as well as the consequences for inappropriately utilizing a special enrollment period to enroll in coverage.

In response to our request for comment and data to assess whether special enrollment periods are being abused and to minimize potential misuse and abuse of special enrollment periods, commenters expressed strong support for the Exchange to take actions to verify consumer eligibility for special enrollment periods moving forward, including requesting documentation supporting consumers' eligibility for special enrollment periods. Several commenters requested that the Exchange require consumers to submit documentation to either the Exchange or issuers to verify their eligibility for a special enrollment period. Some commenters noted that requesting such documentation at the time of the eligibility determination and before coverage has begun is least burdensome for consumers and is preferred by issuers. To aid in verification of special enrollment period eligibility, one issuer suggested implementing an online directory for issuers of consumers who have been terminated due to nonpayment of premiums. Some commenters requested that, until such verification has taken place, coverage not be effectuated under the special enrollment period. Other commenters suggested that the coverage of consumers who were ultimately found to be ineligible for special enrollment periods which they used to enroll in coverage or did not submit the necessary documentation in a timely manner should be canceled as of the date the enrollment became effective.

Conversely, other commenters expressed concern about the elimination or limitation of existing special enrollment periods without documented proof of abuse. Commenters stressed the important role special enrollment periods play in providing access to needed coverage for consumers throughout the year. Commenters encouraged HHS to analyze how consumers access special enrollment periods by using available data sources, and encouraged HHS to look at the findings by SBEs that have already conducted similar analyses. In addition, commenters cautioned against ending a consumer's coverage unless fraud has been proven.

Response: We appreciate the important concerns being raised regarding this issue. We believe it is important that consumers and others providing enrollment assistance understand the eligibility criteria for special enrollment periods, and so we will consider providing additional clarification around existing special enrollment periods. We continue to be interested in better understanding how consumers are accessing special enrollment periods and whether they are doing so in an appropriate and accurate way. In light of the strong support commenters expressed for verifying eligibility for special enrollment periods, we intend to conduct an assessment of QHP enrollments that have been made through special enrollment periods in the FFE to ensure that consumers properly accessed coverage and will require documentation for select SEPs going forward, as described in recent guidance posted on February 24, 2016.[49]

e. Termination of Coverage (§ 155.430)

Under current rules, § 155.430(b)(1) requires an Exchange to permit an enrollee to cancel or terminate his or her coverage in a QHP following appropriate notice to the Exchange or the QHP issuer. We proposed to add paragraph (b)(1)(iv) to allow an enrollee to retroactively cancel or terminate his or her enrollment in a QHP through the Exchange in very limited circumstances. For enrollees whose enrollment or continued enrollment in a QHP resulted from an error, misconduct, or fraud committed by an entity other than the enrollee, we aim to increase flexibility under the regulations to permit such enrollees to avoid the consequences of that entity's actions by canceling the QHP coverage. To this end, we proposed to redesignate current paragraph (b)(2)(vi) as (b)(2)(vii) and add a new paragraph (b)(2)(vi) to permit the Exchange to cancel an enrollee's enrollment in a QHP under certain circumstances. This rule would permit cancellations of fraudulent enrollments that the Exchange discovers, even if the enrollee is never aware of the enrollment.

We proposed new paragraph (b)(1)(iv)(A), which would permit an enrollee to retroactively terminate his or her coverage or enrollment if he or she demonstrates to the Exchange that he or she attempted to terminate his or her coverage or enrollment and experienced a technical error that did not allow the enrollee to effectuate termination of his or her coverage or enrollment through the Exchange. Such an enrollee would have 60 days after he or she discovered the technical error to request retroactive termination.

We proposed a new paragraph (d)(9), which would provide that the retroactive termination date under paragraph (b)(1)(iv)(A) would be no sooner than 14 days after the earliest date that the enrollee could demonstrate that he or she contacted the Exchange to terminate his or her coverage or enrollment through the Exchange, unless the issuer agrees to an earlier effective date as set forth in § 155.430(d)(2)(iii).

We proposed in paragraph (b)(1)(iv)(B) to provide for cancellation for an enrollee who demonstrates to the Exchange that his or her enrollment in a QHP through the Exchange was unintentional, inadvertent, or erroneous and was the result of the error or misconduct 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. Such an enrollee would have 60 days from the point he or she discovered the unintentional, inadvertent, or erroneous enrollment to request cancellation. In determining whether an enrollee has demonstrated to the Exchange that his or her enrollment meets the criteria for cancellation under this paragraph, the Exchange would examine the totality of the circumstances surrounding the enrollment, such as whether the enrollee was enrolled in other minimum essential coverage at the time of his or her QHP enrollment and whether he or she submitted claims for services rendered to the QHP. These factors would serve to indicate the intentions of the enrollee and whether the enrollment really was undesired and unintended and would be weighed in making a

and the Special Enrollment Period due to a Permanent Move (Jan. 19, 2016), available at *https://www.regtap.info/uploads/library/ENR_FAQ_ResidencyPermanentMove_SEP_5CR_011916.pdf.*

[49] 2017 Final HHS Notice of Benefit and Payment Parameters Fact Sheet. February 24, 2016. Available at, *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/index.html#Premium.*

determination whether a cancellation is warranted. We sought comment on what other factors are indicative of an enrollee's bona fide intent and could limit gaming and should be considered in this analysis.

In new paragraph (b)(1)(iv)(C), we proposed to allow cancellations for enrollees who are enrolled in a QHP without their knowledge or consent due to the fraudulent activity of any third party, including third parties who have no connection with the Exchange. Such an enrollee would have 60 days from the point at which he or she discovered the fraudulent enrollment to request cancellation.

We proposed new paragraph (d)(10), which would provide that for cancellation or retroactive terminations granted in accordance with paragraphs (b)(1)(iv)(B) and (C), the cancellation or termination date would be the original coverage effective date or a later date, as determined appropriate by the Exchange, based on the circumstances of the cancellation or termination.

Finally, under our current rules, § 155.430(b)(2) allows the Exchange to initiate termination of an enrollee's coverage or enrollment in a QHP through the Exchange, and permits a QHP issuer to terminate such coverage or enrollment in certain circumstances. We proposed to amend paragraph (b)(2)(ii)(A) to reflect the change to § 156.270(d) and (g) that gives an enrollee who, upon failing to timely pay premium, is receiving APTC, a 3-month grace period.

We also proposed in new paragraph (b)(2)(vi) that the Exchange could cancel an enrollee's enrollment that the Exchange determines was due to fraudulent activity, including fraudulent activity by a third party with no connection with the Exchange. New paragraph (d)(11) would provide that for cancellations granted in accordance with paragraph (b)(2)(vi), the cancellation date would be the original coverage effective date. The Exchange only would send the cancellation transaction following reasonable notice to the enrollee (recognizing that where no contact information or false contact information is available that notice may be impossible or impracticable).

We noted that our current guidance recognizes that at some point, the Exchange must discontinue the ability for enrollees to retroactively adjust coverage for the preceding coverage year. We stated that we are considering codifying a deadline for requesting cancellations or retroactive terminations.

We received the following comments concerning the proposed provisions around retroactive terminations and cancellations.

Comment: Most commenters supported the proposed ''60-days from discovery'' window for requesting the termination, while a few commenters suggested shorter windows (30–45 days). A few commenters agreed with the importance of providing a date after which retroactive terminations and cancellations will no longer be granted for the preceding coverage year.

Response: We chose 60 days to align with our standard 60-day special enrollment period window under § 155.420. We recognize the need to discontinue the ability for enrollees to retroactively adjust coverage for the preceding coverage year at some point. To that end, HHS issued a cut-off date in 2015 after which retroactive terminations through the FFE for 2014 coverage would no longer be granted, with the exception of those cases adjudicated through the appeals process. In determining the cut-off date for terminations of enrollments through FFEs and SBE–FPs for future years, we want to balance the operational needs of issuers and potential future functionality changes to the FFEs' enrollment system against the need to provide adequate time to identify and address erroneous, unknown, or nonconsensual enrollments through retroactive terminations and cancellations. Accordingly, we are codifying a provision permitting the Exchange to set a date after which retroactive terminations and cancellations will no longer be granted for the preceding coverage year, with the exception of those cases adjudicated through the appeals process, based on these factors.

Comment: Many commenters supported our proposal to permit retroactive terminations for enrollees who experienced a technical error by the Exchange that prevented them from terminating their coverage. Some supporters noted enrollees sometimes face challenges in terminating coverage timely. Two commenters suggested we make the effective date of termination the date of the demonstrated attempt, rather than 14 days following the attempt. A few commenters expressed concerns about potential gaming.

Response: This 14-day window proposed aligns with the regulation on voluntary, enrollee-initiated prospective terminations, and we note that issuers may permit earlier effective dates of terminations under § 155.430(d)(2)(iii). To minimize any opportunities for gaming, the Exchange will make these determinations based on research performed by HHS caseworkers.

Comment: Many commenters endorsed our proposal to permit retroactive terminations and cancellations for enrollees whose enrollment was unintentional, inadvertent, or erroneous and was the result of Exchange error or misconduct, citing examples of enrollments occurring under these circumstances and stressing the importance of this protection for consumers against undue financial burden. One commenter felt the provision did not go far enough to adequately protect a Medicaid-eligible enrollee who is unaware of his or her Medicaid eligibility or unaware of his or her ineligibility for the premium tax credit. A few commenters expressed concern about harm to the risk pool and the stability of the Exchanges through gaming. They noted limitations in the Exchange's ability to verify eligibility for special enrollment periods. One commenter recommended that enrollees only be permitted to initiate retroactive terminations or cancellations when permitted under State law or in the case of death. A few others recommended no retroactive terminations or cancellations be granted if premiums were paid or claims were incurred.

Response: We understand issuers' concerns regarding adverse selection if retroactive terminations or cancellations are granted without merit. Our aim is to provide these types of retroactive terminations or cancellations only for enrollees who were clearly harmed by an error or misconduct. It is not intended for enrollees who either simply did not understand the rules of their enrollment when they enrolled and want to reduce any tax liability they face due to ineligibility for the premium tax credit, or who wish to retroactively drop coverage when they realize they did not use it. We expect these terminations and cancellations to be granted rarely and only following thorough research of the facts and circumstances. To that point, the FFE will make these determinations only based on research performed by HHS caseworkers.

Comment: Several commenters commented on our provisions around granting enrollee-initiated and Exchange-initiated retroactive cancellations in cases involving fraudulent activity. Supporters cited examples of enrollee harm due to fraudulent activity by agents and brokers. A few commenters noted that coverage would not be effectuated without a binder payment and that member materials would be sent that would signify enrollment. A few commenters felt this authority is already permitted under issuers' rescission

authority (§ 147.128(a)(1)). One recommended we align the language with the language around agent and broker fraud in § 155.220. Others recommended that we clearly define fraud and ensure verification of instances of fraud.

Response: These proposed rules around cancellations for fraudulent activity are intended, in part, to address concerns regarding individuals who may have been enrolled without their knowledge or consent, potentially resulting in adverse tax consequences. In some cases, the enrollee may not discover the enrollment in time to request cancellation on his or her own behalf.

We recognize the legal and administrative complexities involved in determining fraud and we understand the importance of making this rule narrow enough to prevent abuse, but not so narrow that it could never be used. To that end, we are finalizing paragraphs (b)(1)(iv)(C), (b)(2)(vi), and (d)(11), except that we are replacing references to fraud with references to enrollments performed without enrollee ''knowledge or consent.'' In addition, in paragraph (b)(1)(iv)(C), we are adding that the enrollee must ''demonstrate to the Exchange'' that he or she was enrolled without his or her knowledge or consent.

Comment: Some commenters suggested retroactive terminations or cancellations in circumstances other than those we proposed. For example, a few commenters recommended that the Exchange retroactively terminate or cancel enrollments granted under special enrollment periods for which the enrollee was not truly eligible. Another commenter recommended we not permit retroactive cancellation when a consumer does not pay his or her premium in the fourth quarter, and then moves to a different plan during open enrollment with coverage effective January 1. Another commenter recommended we create parameters to permit retroactive terminations or cancellations in instances of credit card theft. Finally, one commenter recommended we allow termination without penalty to auto-enrollees in the first 60 days of the year, or due to confusion over covered benefits or providers.

Response: We understand the commenters' concerns; however, this proposed rule was limited to scenarios involving technical errors, misconduct or fraudulent activity. We address some of our future activities around special enrollment periods elsewhere in this rule. We are finalizing the provisions proposed in § 155.430 of the proposed rule with a few modifications. Specifically, as discussed above, we are eliminating references to fraud in paragraphs (b)(1)(iv)(C), (b)(2)(vi), and (d)(11) and referring instead to enrollments performed without the enrollee's knowledge or consent. We believe that in certain cases a retroactive termination can be justified where the enrollment was performed without knowledge or consent, even if fraud did not occur. In paragraph (b)(2)(vi), we also clarify that the enrollment performed without the enrollee's knowledge or consent could be performed by a third party that has no connection with the Exchange. In addition, for consistency with paragraphs (b)(1)(iv)(A) and (B), in paragraph (b)(1)(iv)(C), we are requiring that the enrollee ''demonstrates to the Exchange'' that he or she was enrolled without his or her knowledge or consent. Finally, as described in response to comments above, we are adding a new paragraph (d)(12) permitting the Exchange to establish a timeframe during which retroactive terminations and cancellations for the preceding coverage year must be initiated.

6. Appeals of Eligibility Determinations for Exchange Participation and Insurance Affordability Programs

a. General Eligibility Appeals Requirements (§ 155.505)

In § 155.505, we made certain proposals related to the general eligibility appeals requirements. We proposed to add paragraph (b)(1)(iii) to state more clearly that applicants and enrollees have the right to appeal a determination of eligibility for an enrollment period. We also proposed to add paragraph (b)(5) to clarify the existing right under § 155.520(c) that applicants and enrollees have to appeal a decision issued by the State Exchange appeals entity. In paragraph (b)(4), we proposed to correct a typographical error by replacing the word ''or'' with the word ''of,'' and to replace ''pursuant to'' with ''under.''

We are finalizing the changes as proposed.

Comment: Commenters all supported the proposal to clarify the existing rights to appeal a determination of eligibility for an enrollment period and appeal a decision issued by the State Exchange appeals entity. One commenter sought clarification that the change to § 155.505(b)(5), related to the right to appeal a decision issued by a State Exchange appeals entity, applies only to Exchange decisions related to eligibility for enrollment in a qualified health plan and financial assistance through the Exchange, but not Medicaid or CHIP.

Response: In certain circumstances, it is possible that a State Exchange appeals entity appeal decision regarding eligibility for Medicaid, CHIP, or the BHP could be escalated to and adjudicated by the HHS appeals entity. However, as discussed below, at the time of publication of this final rule, no State agency administering Medicaid, CHIP, or the BHP has delegated appeals to the State Exchange appeals entity in a manner that would permit the HHS appeals entity to adjudicate these appeals. Therefore, we confirm that the right to appeal a decision issued by a State Exchange appeals entity under § 155.505(b) currently is limited to decisions related to eligibility for enrollment in a qualified health plan through the Exchange (including enrollment periods), Exchange financial assistance, exemptions from the individual shared responsibility requirement, and denials of requests to vacate dismissals by the State Exchange appeals entity.

As we explained in the final rule in the July 15, 2013 **Federal Register** (78 FR 42160), States may choose to delegate authority to conduct Medicaid fair hearings for MAGI-based eligibility determinations to the Exchange operating in the State regardless of whether the Exchange is an FFE, State Exchange, or a State Partnership Exchange, in accordance with the Medicaid regulations at 42 CFR 431.10(c) and (d). If a State agency delegates authority to conduct MAGI-based eligibility appeals to an Exchange, including a State Exchange, in accordance with 45 CFR 431.10(c) and (d), such a delegation would extend to the HHS appeals entity, if the State Exchange appeals entity's appeal decision were escalated under § 155.505(c)(2)(i).

However, States with State Exchanges that are State governmental agencies may also coordinate appeals, beyond delegation under our rules, through a waiver granted under the Intergovernmental Cooperation Act. If a State delegates authority to conduct fair hearings through an Intergovernmental Cooperation Act waiver to another State agency, including a State Exchange or State Exchange appeals entity, Medicaid appeal decisions made by that entity could not be escalated to the HHS appeals entity (78 FR 42,160, 42,165 (July 15, 2013)).

As of this publication, all State Exchanges have coordinated appeals through an Intergovernmental Cooperation Act waiver, and therefore Medicaid appeal decisions made by a

State Exchange appeals entity are not appealable to the HHS appeals entity under § 155.520(c) or § 155.505(b)(5).

b. Appeals Coordination (§ 155.510)

We proposed to revise § 155.510(a)(1) to allow the appeals entity, the Exchange, or the agency administering insurance affordability programs to request information or documentation from the appellant that the appellant already has provided if the agency does not have access to such information or documentation and cannot reasonably obtain it. Currently, § 155.510(a)(1) prohibits the appeals entity or agency administering insurance affordability programs from asking an appellant to provide information or documentation that the appellant already provided in order to minimize the burden on the appellant.

We are finalizing our proposal, with an addition as described below.

Comment: Commenters all supported the proposed change to § 155.510(a)(1). A few commenters cautioned that the proposed amendment to paragraph (a)(1) should not overly burden appellants and recommended that it be used as a time-limited, interim measure until system functionality improves.

Response: We agree that proposed paragraph (a)(1) should not overly burden appellants. As proposed, paragraph (a)(1) permits the appeals entity, Exchange, or agency administering insurance affordability programs to request information or documentation from the appellant if the agency does not have access to such information or documentation and cannot reasonably obtain it. To further ensure that paragraph (a)(1) does not overly burden appellants, we are finalizing paragraph (a)(1) to also require that the information or documentation requested is necessary to properly adjudicate the appellant's appeal. We believe that the addition of this language will minimize any unnecessary burden on the appellant while also ensuring that appeals are adjudicated accurately.

c. Appeal Requests (§ 155.520)

We proposed to add paragraph (d)(2)(i)(D), concerning appellants whose appeal request is determined invalid for failure to request an appeal by the date determined in paragraph (b) or (c) of this section. The proposed addition would require the appeals entity to notify an appellant that, in the event the appeal request is invalid because it was not timely submitted, the appeal request may be considered valid if the applicant or enrollee demonstrates within a reasonable timeframe determined by the appeals entity that failure to timely submit was due to exceptional circumstances and should not preclude the appeal.

We proposed that the appeals entity may determine what constitutes an exceptional circumstance that should not preclude an appeal notwithstanding the appellant's failure to timely submit an appeal request. We also proposed that the appeals entity may determine what is considered a reasonable timeframe for an appellant to demonstrate an exceptional circumstance.

We are finalizing the provision as proposed.

Comment: Commenters supported the proposed change to § 155.520(d)(2)(i)(D). A few commenters requested additional examples or guidelines as to what constitutes an ''exceptional circumstance'' such that failure to timely submit an appeal request should not preclude an appeal. Commenters also requested additional guidance on what constitutes a ''reasonable timeframe'' to demonstrate an exceptional circumstance. One SBE supported the proposed amendment as long as Exchange appeal entities have the flexibility to determine what constitutions an exceptional circumstance and a reasonable timeframe.

Response: In the proposed rule, we provided several examples of situations that might constitute an exceptional circumstance under proposed paragraph (d)(2)(i)(d). We stated that a weather emergency, such as a blizzard, hurricane or tornado, may constitute an exceptional circumstance. We discussed scenarios in which severe weather causes a power outage making it impossible to prepare, mail, or fax appeal requests to the appeals entity, and situations when a disaster may cause consumers to lose access to the documents they need to complete and submit appeal requests. We also noted that if a consumer suffers a catastrophic medical event and is consequently unable to submit an appeal request on time, the appeals entity may determine that this constitutes an exceptional circumstance under the proposed exception.

We also provided guidance in the proposed rule as to what constitutes a reasonable timeframe to demonstrate an exceptional circumstance. We stated that if an appellant was unable to send an appeal request on time due to a snow storm and power outage and sent the request four months after the snow storm and power outage had been resolved, the appeals entity may find that the appellant experienced an exceptional circumstance as contemplated by the proposed rule, but that the appellant waited an unreasonable amount of time to demonstrate it.

The examples above provide guidance to appellants and representatives as to what the appeals entity may consider an exceptional circumstance such that failure to timely submit an appeal request should not preclude an appeal, and a reasonable timeframe to demonstrate an exceptional circumstance. We intend for these examples to be illustrative and not exhaustive, and believe that the appeals entity should decide on a case-by-case basis whether an appeal request that is invalid due to untimely submission nevertheless should be allowed to proceed under paragraph (d)(2)(i)(d).

d. Dismissals (§ 155.530)

We proposed to revise § 155.530(a)(4) to allow an appeal to continue when an appellant dies if the executor, administrator, or other duly authorized representative of the estate requests to continue the appeal.

Comment: Commenters supported the proposed change to § 155.530(a)(4). A few commenters also recommended allowing a spouse, partner, parent, or guardian of a deceased appellant to continue an appeal. They believed this may be necessary when an appellant, especially a child or incapacitated adult, has not gone through the legal process of establishing an executor, administrator, or other duly authorized representative. In such cases, the commenters recommend allowing a family member to step into the shoes of the deceased appellant to prevent the dismissal of an appeal from imposing a financial hardship on the surviving members of the family.

Response: We agree with the commenters. Therefore, we are clarifying that if a deceased appellant has not designated an executor, administrator, or other duly authorized representative, and one has not been appointed by the court, the deceased appellant's spouse, legal civil or domestic partner, or for a minor or unmarried incapacitated appellant, parent or legal guardian, is considered a duly authorized representative and may continue the appeal.

We are finalizing § 155.530(a)(4) as proposed.

e. Informal Resolution and Hearing Requirements (§ 155.535)

In § 155.535, we proposed amendments to the informal resolution and notice of hearing requirements. In § 155.535(a), we proposed a change to

clarify that the requirements of the informal resolution process described in paragraphs (a)(1) through (4) apply to both the HHS appeals entity and a State Exchange appeals entity.

In § 155.535(b), we proposed providing two exceptions to the requirement that the appeals entity must send written notice to the appellant of the date, time, and location or format of the hearing no later than 15 days prior to the hearing date. In paragraph (b)(1), we proposed an exception when an appellant requests an earlier hearing date. In paragraph (b)(2), we proposed an exception to the notice requirement under paragraph (b) when a hearing date sooner than 15 days is necessary to process an expedited appeal, as described in § 155.540(a), and the appeals entity and appellant have mutually agreed to the date, time, and location or format of the hearing. These proposals were intended to create a more agreeable experience for the appellant overall while also improving efficiency for the appeals process.

Comment: The comments received on these proposed changes were largely supportive. Commenters recommended that if written notice is not sent to an appellant under paragraph (b)(2), then the appeals entity must contact both the appellant and the appellant's authorized representative, if any, to agree upon a date, time, and location or format of the hearing.

Response: We agree with the commenter's recommendation. The simple act of contacting the appellant's authorized representative could reduce the likelihood of an unintended failure to appear that could harm both the appellant and the overall efficiency of the appeals process. This may be especially true for limited-English proficient appellants who should not suffer the harsh consequences because of a language barrier.

We are finalizing § 155.535(a) and (b)(1) as proposed. We are finalizing § 155.535(b)(2) to allow an exception to the notice requirement under paragraph (b) when a hearing date sooner than 15 days is necessary to process an expedited appeal, as described in § 155.540(a), and the appeals entity, has contacted the appellant and appellant's authorized representative, if any, to schedule a hearing on a mutually agreed to date, time, and location or format.

f. Appeal Decisions (§ 155.545)

In paragraph (b)(1), we proposed to remove the third appearance of the word ''of'' to correct a typographical error. We proposed to revise paragraph (c)(1)(i) to include cross references to § 155.330(f)(4) and (5), which aligns with our proposed change § 155.505(b) to clarify that applicants and enrollees have the right to appeal a determination of eligibility for an enrollment period. Finally, we proposed to revise § 155.545(c)(1)(ii) so that the coverage effective date for eligible appellants requesting a retroactive appeal decision effective date is the coverage effective date that the appellant did receive or could have received if the appellant had enrolled in coverage under the incorrect eligibility determination that is the subject of the appeal.

Comment: Commenters all supported the proposed changes to § 155.545. Some commenters recommended that, in the event the appeals entity takes more than 90 days to process an appeal through no fault of the appellant, the appellant may choose a coverage effective date that falls between the initial eligibility determination date and the date of the appeals decision. They pointed out that while waiting for an appeal to be adjudicated, an appellant may have experienced a health issue for which retroactive coverage would be helpful, but may not be in the financial situation to pay back premiums for more than a limited number of months.

Response: To remain consistent with other effective date regulations, we cannot permit an appellant to choose a coverage effective date that falls between the initial eligibility determination date and the date of the appeal decision, except in the limited circumstance described below. Existing effective date regulations including those at §§ 155.410(f), 155.330(f), and 155.420(b) allow for prospective or retroactive coverage effective dates, as appropriate, based on a triggering event such as an eligibility determination or the birth of a child. The special coverage effective dates for certain special enrollment periods under § 155.420(b)(2)(iii), which requires the Exchange to ensure a coverage effective date that is appropriate based on the circumstances of the special enrollment period, must be tied to a triggering event and may not be chosen by the qualified individual or enrollee.

In the event an appeals entity finds that an eligibility determination, as described in § 155.505(b)(1), was incorrect, and the appellant had more than one coverage effective date available in the enrollment period that the eligibility determination was made, the appellant may be permitted to choose a coverage effective date associated with the enrollment period. For example, if the appeals entity determines that an eligibility determination made on November 25, 2015 for the 2016 coverage year was incorrect, the appellant may choose a retroactive coverage effective date of January 1, 2016, February 1, 2016, or March 1, 2016 because the appellant would have had the opportunity to make a QHP selection between November 25, 2015 and January 31, 2016 and receive one of those coverage effective dates (depending on when the QHP was selected). Even in this situation, the appellant may choose only from among those coverage effective dates that would have been available under the original enrollment period, and may not chose any coverage effective date between the initial eligibility determination date and the date of the appeals decision.

Accordingly, we are finalizing paragraph (c)(1)(ii) as proposed, with one modification. Under the final regulation, an appeals entity may only implement an appeal decision retroactively to the coverage effective date the appellant did receive or could have received if the appellant had enrolled in coverage under the incorrect eligibility determination that is the subject of the appeal. We are changing the phrase ''would have received'' to ''could have received'' to clarify that an eligible appellant may choose from among the coverage effective dates that would have been available under the original enrollment period.

g. Employer Appeals Process (§ 155.555)

We proposed to make a technical correction to § 155.555(e)(1) by removing the cross-reference to paragraph (d)(3) of this section, which does not exist, and replacing it with paragraph (d)(1)(iii).

We also proposed to amend § 155.555(l) by revising paragraph (l) and adding paragraphs (l)(1) and (2) to give the Exchange more operational flexibility in implementing an employer appeal decision. Currently under § 155.555(l), when an employer appeal decision affects an employee's eligibility, the Exchange is directed to redetermine the employee's eligibility and the eligibility of the employee's household members, if applicable. We proposed to amend § 155.555(l) so that, after receipt of the notice from the appeals entity under paragraph (k)(3) of this section, the Exchange must follow the requirements in either paragraph (l)(1) or (2) if the appeal decision affects the employee's eligibility. Under proposed paragraph (l)(1), the Exchange must promptly redetermine the employee's eligibility and the eligibility of the employee's household members, if applicable, in accordance with the standards specified in § 155.305, as currently provided in paragraph (l).

Under proposed paragraph (l)(2), the Exchange must promptly notify the employee of the requirement to report changes in eligibility as described in § 155.330(b)(1). We sought comment on the addition of the option described in paragraph (1)(2), and whether it would help ensure the most accurate redetermination of eligibility for insurance affordability programs by giving employees the opportunity to report any additional changes in their eligibility information.

We are finalizing § 155.555(l), and the technical correction to § 155.555(e)(1), as proposed.

Comment: Commenters generally supported the proposed addition of § 155.555(l)(2). Several commenters supported this change because it would give consumers the opportunity to update their application with any other changes that could affect eligibility which would result in a more accurate eligibility determination. One commenter provided an example of an applicant who had employer-sponsored coverage through his or her spouse at the time of applying for coverage through the Exchange, but later received a legal separation. One commenter who disagreed with the proposed addition of paragraph (l)(2) expressed concern that an employee who fails to update his or her eligibility may face a greater tax liability when filing his or her Federal tax return.

Response: As described in § 155.330(b)(1), an enrollee is required to report any change with respect to the eligibility standards specified in § 155.305 within 30 days of such change. Before enrolling in coverage through the Exchange, applicants for coverage must confirm their understanding that they must notify the entity administering the program they enroll in if information on their application changes, and that such changes may affect the eligibility for member(s) of their household. Nevertheless, we agree with commenters that the proposed change in § 155.555(l)(2) would give employees another opportunity to update their application with changes that affect their eligibility or the eligibility of household members when an appeal decision under § 155.555 affects the employee's eligibility. We are finalizing § 155.555(l) as proposed to permit the Exchange, after receipt of the notice under paragraph (k)(3) of this section, to follow either the requirements in either paragraph (l)(1) or (2) if the appeal decision affects the employee's eligibility. As stated in the proposed rule, for the 2016 benefit year, the FFE intends to implement appeal decisions that affects the employee's eligibility by following the procedure described in paragraph (1)(2).

Comment: One commenter who supported the proposed changes to § 155.555(l) wrote that, in order for the option described in paragraph (l)(2) to be meaningful, employees must have very clear instructions on how to update their application.

Response: We agree that a notice under § 155.555(l)(2) must provide clear instructions to the employee in order to be effective. For notices submitted by the FFE, we intend to provide guidance on reporting changes in information with respect to eligibility through the online application and the Marketplace Call Center, instructions on updating the online application questions to reflect that the employee has an offer of employer-sponsored coverage that provides minimum value and is affordable for the employee, and instructions on terminating enrollment in a QHP through the Exchange for those who want to terminate enrollment upon being redetermined ineligible for Exchange financial assistance.

Comment: Commenters suggested that the Exchange be required to follow the procedures outlined in both paragraphs (l)(1) and (2). They recommended that the Exchange send a notice under paragraph (l)(2) and, if an employee does not update his or her application within a specified period of time, the Exchange follow the procedure described paragraph (l)(1) to redetermine the employee's eligibility and the eligibility of the employee's household members, if applicable.

Response: We are concerned that such a policy would cause considerable operational burden to the Exchange while providing minimal benefit to the employee. We believe that the policy as proposed balances the need for employees to receive an updated eligibility determination after an appeal decision affects the employee's eligibility, with the need to provide operational flexibility to the Exchange. Accordingly, we are finalizing this provision as proposed, to give the Exchange the option to follow either paragraph (l)(1) or (2) after receipt of the notice under paragraph (k)(3) of this section.

Comment: One commenter expressed concern that an employee who does not report his or her change in eligibility could place the employer at greater risk for an assessable payment under section 4980H of the Code.

Response: We disagree with the proposition that an employee who does not report his or her change in eligibility could place the employer at greater risk for being liable for an assessable payment under section 4980H of the Code. An employee is subject to the requirement to report a change in his or her eligibility under § 155.330(b)(1) when the appeals entity determines that his or her employer offered employer-sponsored coverage that provides minimum value and is affordable for the employee. Independently, the Internal Revenue Service (IRS) will determine whether an employer is liable for an employer shared responsibility payment based on the employer shared responsibility provisions.[50] If the IRS, in its own review, determines that an employee of an applicable large employer is ultimately not eligible for the premium tax credit under section 36B of the Code, then, in general, the employer will not owe an employer shared responsibility payment with respect to that full-time employee, even if the employee enrolled in a QHP with APTC (regardless of whether the employee reported a change with respect to eligibility to the Exchange following the outcome of an employer appeal).

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

a. Eligibility Standards for Exemptions (§ 155.605)

In § 155.605, we proposed to clarify and streamline policies related to exemptions. Consistent with prior guidance, we proposed to permit any applicant whose gross income is below his or her applicable filing threshold to qualify for a hardship exemption and claim the exemption through the tax filing process. In addition, we proposed to permit individuals eligible for services from an Indian health care

[50] In general, an applicable large employer (an employer with at least 50 full-time employees, including full-time equivalent employees) will owe an assessable payment to the IRS under section 4980H(a) of the Code if the employer fails to offer coverage to its full-time employees (and their dependents) and at least one full-time employee receives the premium tax credit. An assessable payment under section 4980H(a) of the Code is calculated based on the employer's number of full-time employees, without regard to how many full-time employees receive the premium tax credit. An applicable large employer will owe an assessable payment under section 4980H(b) of the Code if it offers coverage to its full-time employees (and their dependents) but at least one full-time employee receives the premium tax credit, which could occur if the coverage offered did not provide minimum value or was not affordable. (For purposes of section 4980H, coverage may be considered affordable under an affordability safe harbor even if the coverage is not affordable for purposes of section 36B of the Code. 26 CFR 54.4980H–5(e)(2)). An assessable payment under section 4980H(b) of the Code is calculated based on the number of full-time employees who receive the premium tax credit.

provider to claim a hardship exemption through the tax filing process. We proposed that for the 2016 tax year and later that the Exchange no longer issue exemption certificate numbers (ECNs) for the following exemption types: members of a Health Care Sharing Ministry, individuals who are incarcerated, members of Federally recognized tribes, and individuals who are eligible for services from an Indian health care provider. We also proposed to codify a list of other hardship exemptions previously established in prior guidance and to clarify operational standards for timeframes of hardship events and the duration of certain hardship exemptions. We are finalizing the policy of streamlining of exemptions offered through the tax filing process as proposed; however, at this time, we will not codify the list of hardship exemptions established in prior guidance and will not finalize the proposal to permit an individual to obtain a hardship exemption for a hardship experienced within 3 years of the date of application.

Comment: We received comments in favor of eliminating unnecessary paperwork for individuals seeking an exemption due to their State not expanding Medicaid coverage. Commenters also supported streamlining the exemption process for members of a Health Care Sharing Ministry, members of Federally recognized Indian tribes and individuals eligible for services from an Indian health care provider, and individuals who were incarcerated by delegating these exemption types fully to the IRS.

Response: In this final rule, we are finalizing the proposal to streamline the exemption application process for consumers and to minimize paperwork requirements for consumers in States that did not expand Medicaid coverage. We are finalizing the proposal to no longer require a denial notice for the hardship exemption for applicants ineligible for Medicaid because their State did not expand Medicaid coverage. In addition, we are finalizing the proposal to streamline exemption processing for members of a Health Care Sharing Ministry, individuals who are incarcerated, members of Federally recognized Indian tribes, and individuals who are eligible for services from an Indian health care provider.

Comment: We received comments supporting and opposing our proposal to codify hardship criteria established in regulatory guidance. Commenters stated that any expansion of the hardship exemption criteria could weaken the individual shared responsibility provision and create instability in insurance risk pools. In addition, we received a request for clarification of factors that an Exchange would examine in order to approve a hardship exemption.

Response: We will continue to examine these comments and will not codify the list of hardship exemptions previously established in public guidance at this time.

Comment: We received comments both in support of and against the proposal to allow individuals to apply for a hardship that occurred up to 3 calendar years in the past. Commenters who supported this proposal thought that it would provide greater flexibility for Exchanges to approve hardship exemptions. Commenters who did not support the proposal stated that 3 years was overly broad and could lead to a destabilization of a health insurance risk pool by providing an additional incentive for healthy consumers to claim an exemption in lieu of obtaining health coverage.

Response: In response to the concerns raised by commenters, we will not finalize § 155.605(d)(2) at this time. Similarly, we will not finalize the last sentence of the introductory paragraph of § 155.605(d)(1), which establishes a maximum length of any hardship exemption of the month before the circumstance, the remainder of the calendar year, and the next calendar year.

Comment: We received a suggestion that the Exchange establish an exemption for people who are erroneously determined ineligible for APTC and who do not enroll in a qualified health plan as a result.

We also received one comment that our proposal to codify the existing hardship exemption time period related to an appeal in § 155.605(d)(2)(xiv) should be expanded to include the date of application, rather than a consumer's potential coverage effective date. The commenter stated that the current timeframe is too narrow for individuals who were unable to file an appeal of an eligibility determination within 90 days due to the fact that a data inconsistency generated during the application process must be adjudicated before a consumer may file an appeal.

Response: We are not codifying § 155.605(d)(2)(xiv) at this time, but will continue to consider these issues and comments for future rulemaking.

b. Required Contribution Percentage (§ 155.605(e)(3))

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. 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 (the 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) (redesignated as § 155.605(d)(2) in this final rule), 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) (redesignated as § 155.605(d)(5) in this final rule), 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 individual 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.

Section 5000A established the 2014 required contribution percentage at 8 percent. For plan years after 2014, section 5000A(e)(1)(D) of the Code and 26 CFR 1.5000A–3(e)(2)(ii) provide that the required contribution percentage is the percentage determined by the Secretary of HHS 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.

We established a methodology for determining the excess of the rate of premium growth over the rate of income growth for plan years after 2014 in the 2015 Market Standards Rule (79 FR 30302), and we said future adjustments would be published annually in the HHS notice of benefit and payment parameters.

Under the HHS methodology, the rate of premium growth over the rate of income growth for a particular calendar year is the quotient of (x) 1 plus the rate of premium growth between the preceding calendar year and 2013, carried out to ten significant digits, divided by (y) 1 plus the rate of income growth between the preceding calendar year and 2013, carried out to ten significant digits.[51]

As the measure of premium growth for a calendar year, we established in the 2015 Market Standards Rule that we

[51] We also defined the required contribution percentage at § 155.600(a) to mean the product of 8 percent and the rate of premium growth over the rate of income growth for the calendar year, rounded to the nearest one-hundredth of one percent.

would use the premium adjustment percentage. The premium adjustment percentage is based on projections of average per enrollee employer-sponsored insurance premiums from the National Health Expenditure Accounts (NHEA), which are calculated by the CMS Office of the Actuary.[52] (Below, in § 156.130, we finalize the proposed 2017 premium adjustment percentage of 1.1325256291 (or an increase of about 13.3 percent) over the period from 2013 to 2016. This reflects an increase of about 4.9 percentage points (1.1325256291–1.0831604752) for 2015–2016.)

As the measure of income growth for a calendar year, we established in the 2015 Market Standards Rule that we would use per capita Gross Domestic Product (GDP), using the projections of per capita GDP used for the NHEA, which is calculated by the Office of the Actuary. We also stated in the 2015 Market Standards Rule (79 FR 30304), that we would-consider alternative measures of income and premium growth should projections of those measures become available. Subsequently, as part of its projections of National Health Expenditures, the Office of the Actuary published projections of personal income (PI) for the first time in September 2014 and subsequently in July 2015. As a result, in the proposed rule we said we were considering substituting this new measure of per capita PI for per capita GDP in the calculation for the required contribution percentage. We received one comment in support of our proposal to substitute per capita PI for per capita GDP in the calculation to establish the rate of income growth for the required contribution percentage, and are finalizing it here. As stated in the proposed rule, we believe per capita PI better aligns with the statutory intent of measuring the income of an individual than per capita GDP. The projections of PI published by the Office of the Actuary are consistent with the measure published by the Bureau of Economic Analysis, which reflects income received by individuals from all sources, including income from participation in production. Specifically, it includes compensation of employees (received), supplements to wages and salaries, proprietors' income with adjustments for inventory valuation and capital consumption, personal income receipts on assets, rental income, and personal current transfer receipts, less contributions for government social insurance.

The Office of the Actuary's PI projection is generated using the University of Maryland's Long Term Inter-industry Forecasting Tool. The Long Term Inter-industry Forecasting Tool model is a macro-economic model that is based on the historical relationships that exist between PI growth, GDP growth, and changes in other macro-economic variables. For instance, the correlation between PI and GDP is influenced by fluctuations in taxes and government transfer payments, depreciation of capital stock, and retained earnings and transfer payments of private business.[53] Estimates of GDP in the NHE projections reflect economic assumptions from the 2015 Medicare Trustees Report and are updated to incorporate the latest available consensus data from the monthly Blue Chip Economic Indicators. These same economic assumptions are used for producing projections of PI and employer-sponsored insurance premiums, so using this estimate will generate an internally consistent estimate of the growth in premiums relative to growth in income.

As stated in the proposed rule, we will continue to consider other changes to the measures of income per capita and premium growth as additional information becomes available and as we gain experience with the current measures; we received no comments on other indices that we should develop or consider.

Since updating the required contribution percentage for 2017 requires calculating the cumulative difference between premium growth and income growth between the preceding calendar year and 2013, we also proposed in the proposed rule to replace per capita GDP with per capita PI for all years beginning in 2013 and then calculate cumulative income growth through 2016. We received no comments on this retrospective approach, and are finalizing it here; as stated in the proposed rule, a retrospective approach allows for consistency across all years with the most recent data available. We note that potential future changes based on new data that are not available for 2013 may be made on a prospective basis.

Therefore, under the approach finalized here, and using the NHEA data, the rate of income growth for 2017 is the percentage (if any) by which the most recent projection of per capita PI for the preceding calendar year ($49,875 for 2016) exceeds the per capita PI for 2013, ($44,925), carried out to ten significant digits. The ratio of per capita PI for 2016 over the per capita PI for 2013, using the finalized approach for both years, is estimated to be 1.1101836394 (that is, per capita income growth of about 11.0 percent). This reflects an increase of about 3.0 percentage points (1.1101836394–1.0798864830) for 2015–2016.

Thus, using the 2017 premium adjustment percentage finalized in this rule, the excess of the rate of premium growth over the rate of income growth for 2013–2016 is 1.1325256291/1.1101836394, or 1.0201245892. This results in a required contribution percentage for 2017 of 8.00*1.0201245892, or 8.16 percent, when rounded to the nearest one-hundredth of one percent, an increase of 0.27 percentage points from 2016 (8.16100–8.13399). The excess of the rate of premium growth over the rate of income growth also is used for determining the applicable percentage in section 36B(b)(3)(A) and the required contribution percentage in section 36(c)(2)(C).

c. Eligibility Process for Exemptions (§ 155.610)

In § 155.610, we proposed adding new paragraph in § 155.610(k) which describes how the Exchange will handle incomplete exemption applications. We proposed that the Exchange will handle incomplete exemption applications in a similar manner to the procedure for handling incomplete health coverage applications established under § 155.310(k). Specifically, when the Exchange receives an application that does not contain sufficient information to make an eligibility determination, the Exchange will: (1) Provide notice to the applicant indicating that information necessary to complete an eligibility determination is missing, specify the missing information, and provide instructions for submitting the missing information; (2) provide the applicant with a period of no less than 10 and no more than 90 days starting from the date on which the notice is sent to the applicant to provide the information needed to complete the application to the Exchange; and (3) if the Exchange does not receive the requested information, then the Exchange will

[52] For any given year the premium adjustment percentage is the percentage (if any) by which the most recent NHEA projection of per enrollee employer-sponsored insurance premiums for the current year exceeds the most recent NHEA projection of per enrollee employer-sponsored insurance premiums for 2013.

[53] For projections of PI and GDP, see Table 1 at Centers for Medicare & Medicaid Services. National Health Expenditure Data: Projected, available at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html.*

notify the applicant that the Exchange will not process the application and will provide appeal rights to the applicant. We sought comment on this proposal.

Comment: We received comments which supported this proposal to handle incomplete exemption applications, however many commenters found the 10-day minimum timeframe to be too short and recommended a minimum of 30 days to submit missing information to the Exchange instead.

Response: We accept this recommendation, and will amend the regulation text to establish a minimum of 30 days from the date on which the notice is sent to an applicant to provide required information to the Exchange.

d. Verification Process Related to Eligibility for Exemptions (§ 155.615)

In § 155.615, we proposed to delete § 155.615(c), (d), (e), and (f)(3) to conform with a proposal under § 155.605 that would remove the ability for consumers to obtain an ECN from the Exchange for certain exemptions. We also proposed conforming redesignations of the remaining paragraphs under § 155.615. Elsewhere in this final rule, we are finalizing the relevant proposals under § 155.605. Accordingly, we are finalizing as proposed the deletions of paragraphs (c), (d), (e), and (f)(3) from § 155.615 and the conforming redesignations.

Comment: We received comments both in support of and against the 3-year period for exemption criteria under the proposed rule at § 155.605(d)(3) and the conforming amendment to § 155.615(c)(2).

Response: We will continue to consider the issues presented by commenters, and will not finalize § 155.615(c)(2) at this time.

e. Options for Conducting Eligibility Determinations for Exemptions (§ 155.625)

We proposed to amend § 155.625(a)(2) and (b) to remove the deadline after which a State Exchange would be required to process exemption applications for residents of the State by the start of open enrollment for 2016, and to instead permit an Exchange to adopt the exemption eligibility determination service operated by HHS indefinitely. Based on HHS's operation of this service to date, we have determined that the HHS exemption option is an efficient process for State Exchanges that has minimized confusion for consumers. This proposal follows an FAQ published on July 28, 2015 in which HHS stated that it will not take any enforcement action against State Exchanges that continue to use the HHS service for exemptions beyond the start of open enrollment for 2016.

Comment: We received one comment about this section that supports the recommendation to permit States to elect to use the HHS service for exemptions. This commenter also suggested that an SBE should be able to grant the hardship exemption established in § 155.605(d)(2) for lack of affordable coverage even if it does not process other exemptions, because the State would have the eligibility information needed to determine whether an individual qualifies for this exemption from an individual's health coverage application.

Response: We accept this comment and have amended the regulation text to permit a State Exchange to grant a hardship exemption to consumers the Exchange determines unable to afford coverage based on their projected annual household income under § 155.605(d)(2) regardless of whether the Exchange will grant other exemption types.

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

a. Functions of a SHOP (§ 155.705)

In § 155.705, we proposed to add new paragraphs (b)(3)(viii) and (ix) to specify that the FF–SHOPs would provide additional options for employer choice for plan years beginning on or after January 1, 2017, namely a ''vertical choice'' option for QHPs and SADPs. Under this option, employers will be able to offer qualified employees a choice of all plans across all available levels of coverage from a single issuer. We noted that existing SHOP regulations at § 155.705(b)(3)(i)(B) and (b)(3)(ii)(B) provide State-based SHOPs with the flexibility to provide employers with vertical choice or other employer choice options in addition to ''horizontal choice,'' in which an employer selects a single actuarial value coverage level and makes all plans at that coverage level available to qualified employees. We did not propose to alter State-based SHOPs' flexibility in this regard, unless the State-based SHOP was relying on the Federal platform for SHOP enrollment functions.

We also sought comment on whether the FF–SHOPs should make other employer choice options available, including allowing participating employers to select an actuarial value level of coverage, after which employees could choose from plans available at that level and at the level above it, which we refer to below as ''contiguous choice.'' We also sought comment on whether to give the State in which the FF–SHOP is operating an opportunity to recommend whether the FF–SHOP in that State should implement any additional model of employer choice. However, in all States, the FF–SHOPs would continue to give employers the option of offering a single QHP (or single SADP) as well as the option of offering a choice of all QHPs (or SADPs) at a single actuarial value level of coverage, and States would not be given an opportunity to recommend that these options not be implemented in their State.

We also proposed adding new paragraph § 155.705(b)(3)(x) to provide that the employer choice models available through the FF–SHOP platform would be available for SBE–FPs utilizing the Federal platform for SHOP enrollment functions. We discussed how, if we gave States with FF–SHOPs an opportunity to recommend implementation of additional employer choice models, States with SBE–FPs would be given the same opportunity.

Additionally, we proposed to amend paragraph (b)(4)(ii)(B) to specify the timeline under which qualified employers in an FF–SHOP must make initial premium payments. We proposed to add paragraph (b)(4)(ii)(B)(*1*) to specify that in the FF–SHOPs, payment for the group's first month of coverage must be received by the premium aggregation services vendor on or before the 20th day of the month prior to the month that coverage begins. We explained that electronic payments would have to be completed or the premium aggregation services vendor must have receipt of any hard copy check on or before the 20th day of the month prior to the month that coverage would begin. We also explained that if an initial premium payment is not received by the premium aggregation services vendor on or before the 20th day of the month prior to the month that coverage would begin, coverage would not be effectuated. We further explained that grace period and reinstatement opportunities under § 155.735(c)(2), which are provided to groups that do not make timely payments after coverage has taken effect, are not relevant in this context, and we proposed amendments to introductory language at § 155.735(c)(2) to reflect this.

In circumstances where an FF–SHOP would be retroactively effectuating coverage for qualified employer groups, the FF–SHOP would need to receive payment prior to effectuating coverage. We sought comment on the timing of when a premium payment should be

required to be received by an FF–SHOP when coverage is effectuated retroactively, and explained that we were considering a policy under which payments for the first month's coverage and all months of the retroactive coverage would have to be received and processed no later than 30 days after the event that triggers the eligibility for retroactive coverage.

At paragraph (b)(4)(ii)(C)(*2*), we proposed to correct a cross reference to § 155.705(b)(4)(ii)(B)(*1*) that should have been updated to cross-reference § 155.705(b)(4)(ii)(C)(*1*) when paragraph (b)(4)(ii)(A) was added in the 2016 Payment Notice.

We also proposed amendments to § 155.705(b)(11)(ii) to provide for FF–SHOPs to use a ''fixed contribution methodology'' in addition to the reference plan methodology set forth in the current regulation. We proposed to specify that when an employer decides to offer a single plan to qualified employees, the employer would be required to use the fixed contribution methodology. We also proposed to permit employers to choose between the reference plan contribution methodology and the proposed fixed contribution methodology when offering a choice of plans. Additionally, we proposed to add language to § 155.705(b)(11)(ii) explaining that a tobacco surcharge, if applicable, would be added to the monthly premium after the employer contribution is applied to the premium. Finally, we proposed to streamline the discussion of the reference plan contribution methodology described in § 155.705(b)(11)(ii) and proposed removing § 155.705(b)(11)(ii)(D) because the FF–SHOPs are currently not able to support basing employer contributions on calculated composite premiums.

We are finalizing the provisions regarding the FF–SHOP's authority to provide vertical choice, but will provide States with FF–SHOPs an opportunity to recommend that the FF–SHOP in their State not offer vertical choice in their State. States with SBE–FPs utilizing the Federal platform for SHOP enrollment functions will have the authority to opt out of making vertical choice available in their States. Information about whether vertical choice will be available in specific States with an FF–SHOP or SBE–FP will be made public prior to the deadline for QHP certification application submissions for the applicable year. We are also making a minor modification to add ''stand alone dental'' to the first sentence of § 155.705(b)(3)(ix)(C).

Comment: We received several comments concerning the additional proposed employer choice options. Many commenters supported the additional employer choice options because they would enhance the appeal of FF–SHOPs for both employees and employers. One commenter encouraged HHS to expand its proposal by allowing FF–SHOP employees to select from a wider variety of plans. Some commenters did not support adding vertical choice as an additional employer choice option, expressing concern about adverse selection because vertical choice could lead smaller employer groups with enrollees in need of more medical services to enroll in higher metal level QHPs. Additionally, there is concern that even if vertical choice is available to employers, an employer could still select horizontal choice or a single plan causing adverse selection. Commenters recommended that HHS consider the impact on selection and resulting changes in plan pricing when considering offering vertical choice in an FF–SHOP. One commenter recommended that FF–SHOP members only be allowed to enroll in one plan with one carrier to reduce complexity in the FF–SHOPs. Some commenters recommended that HHS promote the existing employer choice options instead of adding new employer choice options at this time. Other commenters believed that additional changes to employer choice will create confusion, add complexity, and create administrative challenges which would discourage participation in FF–SHOPs. One commenter also expressed concern about employer choice options, stating that if employers are required to select a specific issuer to offer coverage to the group, provider networks for employees could potentially be disrupted. To address this, the commenter recommended that HHS open all QHPs to employees enrolling in coverage through an FF–SHOP.

Response: We are finalizing the proposal to provide for a vertical choice option in FF–SHOPs, for plan years beginning on or after January 1, 2017. We agree with commenters that additional employer choice options can enhance the appeal of the FF–SHOPs, and intend to work with stakeholders to minimize any confusion stemming from the introduction of vertical choice. Due to operational limitations, at this time we are not offering a wider variety of employer choice options. We appreciate the concerns raised about adverse selection, but believe the fact that our proposal limits vertical choice to a single issuer's plans will help allow the issuer to manage the risk of adverse selection. Offering multiple plans to a qualified employer group allows an issuer to enroll a greater share of the group than if multiple issuers offering coverage in a single coverage level were vying for members of the group. Issuers would thus likely enroll a more diverse risk pool from the qualified employer's group. While qualified employers may still choose to offer their qualified employees horizontal choice or a single plan, the availability of the additional vertical choice option may help to mitigate the risk for adverse selection. To mitigate concerns raised by commenters and because we believe States are best positioned to understand the small group market dynamic in their State, HHS will provide States with an FF–SHOP an opportunity to recommend that the FF–SHOP in their State not make vertical choice available in their State. For similar reasons, States with SBE–FPs utilizing the Federal platform for SHOP enrollment functions will be able to opt out of making vertical choice available in their States. In States where vertical choice is available, a qualified employer would have a choice of three employer choice options for both QHPs and SADPs: A single plan, all available plans at a single level of coverage (horizontal choice, as provided for by the statute), and a choice of all plans offered by a single issuer across all levels of coverage (vertical choice). In States where vertical choice is not an available option for qualified employers, the single plan option and horizontal choice option would continue to be available to qualified employers.

Comment: We received several comments supporting adding contiguous choice as an additional employer choice option because employers would have more QHP options available to offer to their employees. One commenter recommends that HHS consider the additional administrative costs of allowing additional choice options.

Response: As stated, we believe additional employer choice options could enhance the appeal of the FF–SHOPs, and we will continue to explore adding the option of contiguous choice in the future, but are not adding a contiguous choice option at this time, so that we can further consider the potential for adverse selection that could result from that option.

Comment: One commenter recommended that States should not be permitted to make the decision on whether to implement new approaches for employer choice in FF–SHOPs and that it should be at the issuer's option about which QHPs and SADPs to make available to qualified employees. The

commenter recommended that HHS require States to conduct an assessment on the actuarial impact of various employer choice approaches, and determine safeguards that will protect against adverse selection. Other commenters also stated they do not agree with allowing States to opt in and out of offering vertical choice, and supported standardizing employer choice options across all States that have an FF–SHOP or that rely on the Federal platform for SHOP enrollment. Another commenter encouraged HHS to only allow additional employer choice options in States where the same option currently exists in the off-Exchange market, to prevent possible adverse selection while promoting a stable small group market.

Response: In order to provide for State-specific evaluations of the impact of vertical choice on adverse selection and resulting changes in plan pricing, and to provide for more uniform small group market coverage options both on and off-Exchange, States with an FF–SHOP will be given an opportunity to recommend that the FF–SHOP in their State not offer vertical choice. States with SBE–FPs utilizing the Federal platform for SHOP enrollment functions will be able to opt out of making vertical choice available in their States. We believe that States are best positioned to assess the impact of additional employer choice options based on local market conditions. A State with an FF–SHOP that wishes to recommend against offering vertical choice in that State must submit a letter to HHS in advance of the annual QHP certification application deadline, by a date to be established by HHS, describing and justifying the State's recommendation, based on the anticipated impact vertical choice would have on the small group market and consumers. A State-based Exchange utilizing the Federal platform for SHOP enrollment functions may decide against offering vertical choice by notifying HHS of that decision.

HHS is requiring that a State with an FF–SHOP that wishes to recommend against offering vertical choice in that State make its recommendation to the FF–SHOP by submitting a letter to HHS in advance of the annual QHP certification application deadline, by a date to be established by HHS. The State's letter must describe and justify the State's recommendation, based on the anticipated impact this additional option would have on the small group market and consumers. This deadline will give issuers sufficient time to make informed decisions about whether to participate in the FF–SHOP, and will give the FF–SHOPs sufficient time to implement the State's recommendation. States with FF–SHOPs will be able to make recommendations regarding vertical choice on an annual basis. For plan years beginning in 2017 only, we strongly recommend that States with FF–SHOPs submit their recommendations to HHS on or before March 25, 2016, via email to *shop@cms.hhs.gov.* States that meet this deadline will provide the FF–SHOPs sufficient time to review and implement State recommendations. HHS anticipates that its decisions regarding State recommendations for plan years beginning in 2017 would be made by April 1, 2016, which would provide issuers with sufficient time to determine their involvement in the FF–SHOPs for the following year.

For these same reasons, we are finalizing our proposal to add a new paragraph at § 155.705(b)(3)(x) to provide that the employer choice models available through the FF–SHOP platform will be available for SBE–FPs utilizing the Federal platform for SHOP enrollment functions, except that SBE–FPs may decide against offering the employer choice models specified in paragraphs (b)(3)(viii)(C) and (b)(3)(ix)(C). Under the final rule, a State with an SBE–FP must notify HHS of its decision against offering vertical choice in that State in advance of the annual QHP certification application deadline, by a date to be established by HHS. Again, this deadline will give issuers sufficient time to make informed decisions about whether to participate in the SHOP, and will give us sufficient time to implement the State's decision. States with SBE–FPs will be able to make decisions regarding vertical choice on an annual basis. For plan years beginning in 2017 only, we strongly recommend that States with an SBE–FP utilizing the Federal platform for SHOP enrollment functions notify HHS of their decisions on or before March 25, 2016, via email to *shop@cms.hhs.gov.* Again, States that meet this deadline will provide the FF–SHOPs sufficient lead time to implement the State's decision. HHS anticipates that it will announce the SBE–FP States that have decided against offering vertical choice for plan years beginning in 2017 on or around April 1, 2016, which would provide issuers with sufficient time to decide whether to participate in the SHOP for the following year.

Additional guidance will be provided to States regarding the notification or recommendation time frames for plan years beginning in 2018 and beyond.

Comment: Some commenters believe that requiring employer groups to make initial premium payments by the 20th day of the month prior to the month that coverage begins increases the potential for issuers not to receive the initial premium payment until after the first month of effectuated coverage. These commenters recommended that issuers not be required to effectuate coverage without payment from the FF–SHOP.

Response: We are finalizing the provision with a modification to specify that a similar policy also applies under circumstances of retroactive coverage. Under § 156.285(c)(8)(iii), FF–SHOP issuers are required to effectuate coverage unless the FF–SHOP sends a cancellation notice prior to the coverage effective date. Section 156.285(c)(8)(iii) does not require issuers to effectuate coverage if the FF–SHOP does not receive a premium payment by the deadline established for the FF–SHOP. If payment is not received by the FF–SHOP prior to that deadline, the FF–SHOP will issue a cancellation notice.

We are finalizing the following premium payment policies for circumstances where an FF–SHOP would be retroactively effectuating coverage. These policies differ somewhat from the policies we explained we were considering in the preamble to the proposed rule, because for operational reasons, premium payments must be received by the FF–SHOP premium aggregation services vendor by a certain date in order to be processed in a timely manner. When coverage is effectuated retroactively, as discussed in the proposed rule preamble, payment for the first month's coverage and all months of the retroactive coverage must be received and processed no later than 30 days after the event that triggers the eligibility for retroactive coverage. Additionally, however, in order for coverage to be effectuated by the first day of the following month, the employer must also make this payment by the 20th day of the preceding month. If payment is made after the 20th day of a month, coverage will take effect as of the retroactive coverage effective date, but coverage will not be effectuated until the first day of the second month following the payment, and the payment must include the premium for the intervening month. Regardless, in order to effectuate retroactive coverage for a qualified employer or qualified employee, such as under an appeal decision, all premiums owed must be paid in full, including any prior premiums owed for coverage back to the retroactive coverage effective date, as well as a premium pre-payment for the next month's coverage.

These policies also apply to SBE–FPs that are utilizing the Federal platform

for SHOP enrollment and premium aggregation functions, because premium aggregation is an integral part of the eligibility and enrollment functions managed through the FF–SHOP platform.

Comment: We received a comment expressing concern that employer groups will not be able to make the full premium payment within 30 days after the event that triggers eligibility for retroactive coverage, depending on how many months of retroactivity are covered. The commenter recommended that issuers not be required to effectuate retroactive coverage without full payment.

Response: We believe that 30 days after the event that triggers eligibility for retroactive coverage is sufficient time for employer groups to make their full premium payment in order to have retroactive coverage. This policy also ensures that issuers receive payments in a timely manner. Issuers are not required to effectuate coverage if an employer's full payment is not received by the deadline set by the FF–SHOP. Issuers should not cancel an enrollment transaction unless the FF–SHOP sends a cancellation transaction.

Comment: We received no comments regarding our proposal to correct the cross reference from § 155.705(b)(4)(ii)(B)(*1*) to § 155.705(b)(4)(ii)(C)(*1*).

Response: We are finalizing this provision as proposed.

Comment: With respect to our proposals to amend § 155.705(b)(11)(ii), one commenter recommended that HHS clarify that any tobacco surcharge would be paid to the FF–SHOP and not to issuers separately. Another commenter recommended that the tobacco surcharges should be spread across the costs of coverage for an entire group, rather than for the tobacco users only.

Response: Any applicable tobacco surcharges will continue to be paid directly to the FF–SHOP as part of the group's total premium payment and will not be paid to issuers separately. We disagree that the tobacco surcharge should be spread across the entire group. The surcharge is a cost borne by the tobacco user and other enrollees in a group should not be responsible for sharing in its cost. We are finalizing the proposed amendments to § 155.705(b)(11)(ii) with a modification to the language about tobacco surcharges for clarity. We are also modifying the proposed language about the contribution methodologies available to employers that offer a choice of plans to replace a reference to ''the level of coverage offered'' with a reference to the ''plans offered,'' to reflect the possibility that employers might offer vertical choice under the amendments finalized in this rule.

Comment: With respect to our proposals to amend § 155.705(b)(11)(ii), we received one comment stating that if the FF–SHOP cannot support basing employer contributions on calculated composite premiums, employers may lose interest in participating in FF–SHOPs. Another commenter stated that because this feature is widely available off-Exchange, removing this option would put FF–SHOPs at a competitive disadvantage. Several commenters urged HHS to continue seeking feedback on this feature.

Response: Because of operational limitations, FF–SHOPs are not currently able to support basing employer contributions on calculated composite premiums. However, we appreciate the concerns expressed by commenters and we are therefore not finalizing the removal of this provision as proposed. Instead, we are modifying the provision at § 155.705(b)(11)(ii)(D) to state that an FF–SHOP may permit employers to base contributions on a calculated composite premium for employees, for adult dependents, and for dependents below age 21, which gives the FF–SHOPs the flexibility to implement this approach in the future. We are also removing the reference to ''the reference plan'' in this provision to reflect the availability of the fixed contribution methodology under the amendments finalized in this rule. We will continue to examine supporting employer contributions based on calculated composite premiums in the FF–SHOPs.

b. Eligibility Determination Process for SHOP (§ 155.715)

In order to align with our interpretation of guaranteed availability and guaranteed renewability, we proposed to specify that the termination described in § 155.715(g)(1) would be a termination of the employer group's enrollment through the SHOP, rather than a termination of a group's coverage. In many circumstances, an employer may offer to continue the same coverage outside of the SHOP, in which case the issuer should not terminate the coverage. We are finalizing this provision as proposed.

Comment: Some commenters support removing automatic terminations of SHOP coverage in order to be consistent with guaranteed renewability requirements. One commenter recommended that if an employer no longer has SHOP coverage, the employer should be able to make no contribution toward the cost of employee coverage through the SHOP. Employees would be responsible for paying the full premium amount. Another commenter stated that making the coverage available outside of the SHOP and requiring employers to make payments and send data directly to issuers will introduce complexity, undue burden, and unnecessary confusion due to the differing issuer and SHOP data and payment methods. We also received one comment recommending that HHS wait to implement terminations of SHOP enrollment, rather than a termination of the group's coverage, until the infrastructure exists to automate the process.

Response: In order to align with regulations around guaranteed availability and guaranteed renewability, we are finalizing the provision as proposed. Employers can decide whether to contribute toward the cost of employee coverage regardless of whether the employee has coverage through a SHOP. Employer groups wishing to maintain their small group coverage outside of a SHOP are encouraged to work directly with issuers to do so. If an employer offers coverage outside of a SHOP, enrollment and payment functions will be between the group and the specific issuer, and not through the SHOP. SHOPs are encouraged to work directly with issuers and groups to address any questions and concerns about the transfer of responsibility from the SHOP to the issuer. SHOPs, and not issuers, initiate all terminations of a group's enrollment through the SHOP, and this is how the FF–SHOP currently operationalizes terminations of group enrollments. FF–SHOPs are not able to automate the process of terminating FF–SHOP enrollment because it requires information from issuers and groups to ensure a transfer of responsibility should a group's coverage continue outside of the FF–SHOP.

c. Enrollment Periods Under SHOP (§ 155.725)

In § 155.725, we proposed to amend paragraph (c). Specifically, we proposed to delete paragraph (c)(1) because it is outdated, redesignate current paragraph (c)(2) as introductory text to paragraph (c), and redesignate the remaining paragraphs to reflect the new structure of paragraph (c).

We also proposed to redesignate § 155.725(e) as § 155.725(e)(1), and add paragraph (e)(2) to specify that qualified employers in the FF–SHOP must provide qualified employees with an annual open enrollment period of at least 1 week. Like all of § 155.725(e), this amendment would only apply to renewals of SHOP participation.

Additionally, we proposed amendments to § 155.725(h)(2) to specify that in the case of an initial group enrollment or renewal, the event that triggers the group's coverage effective date in an FF–SHOP is not the plan selection of an individual qualified employee being enrolled as part of the group enrollment, but the employer's submission of all plan selections for the group, which we refer to in rule text as the group enrollment. This amendment would permit qualified employers to set initial and annual enrollment periods for their qualified employees that could include qualified employee plan selections both before and after the 15th day of the month. We also proposed to permit employers to select a coverage effective date up to 2 months in advance, provided that small group market rates are available for the quarter in which the employer would like coverage to take effect. Under the proposal, if an employer submits its group enrollment by the 15th day of any month, the FF–SHOP would ensure a coverage effective date of the first day of the following month, unless the employer opts for a later effective date for which rates are available. If an employer submits its group enrollment between the 16th day of the month and the last day of the month, we proposed that the FF–SHOP ensure a coverage effective date of the first day of the second following month, unless the employer opts for a later effective date for which rates are available. We note that the effective date of coverage selected by a qualified employer remains subject to the limit on waiting periods under § 147.116.

We also proposed to amend § 155.725(i)(1) to provide that a SHOP be permitted to, but not be required to, provide for auto-renewals of qualified employees. We also proposed to amend the language of the provision for consistency with our interpretation of guaranteed renewability. Specifically, if a SHOP does not provide for auto-renewals for qualified employees, qualified employees would have to review and provide a response to the employer's renewal offer of coverage. If auto-renewal is available in a SHOP, qualified employees would not be required to take any action to continue in the prior year's coverage through the SHOP.

Finally, we proposed to amend § 155.725(j)(2)(i) to remove a reference to § 155.420(d)(10), which was deleted in the 2016 Payment Notice. We also proposed to specify that there would not be a SHOP special enrollment period when a qualified employee or dependent of a qualified employee experiences an event described in § 155.420(d)(1)(ii), which provides for a special enrollment period for individuals enrolled in a non-calendar year group health plan or individual health insurance coverage.

We are finalizing these amendments as proposed.

Comment: We received several comments about the length of a qualified employee's annual open enrollment period for renewals. Some commenters stated they believe the proposed minimum annual open enrollment period of one week is insufficient. One commenter recommended that employees be provided with a 30-day annual open enrollment period, or at a minimum, a two-week annual open enrollment period.

Response: The proposed amendment would not prevent a qualified employer from offering annual enrollment periods to qualified employees that are longer than one week. This regulation specifies only the minimum length of the annual open enrollment period for qualified employees. We are finalizing this provision as proposed because it would enable qualified employers and qualified employees, especially at very small companies, to finalize their annual renewal process more quickly.

Comment: We received one comment supporting our proposal to allow employers to opt for a coverage effective date up to 2 months in advance. The commenter stated that this amendment increases employer flexibility and may improve the consumer's experiences with SHOP.

Response: We are finalizing the provision as proposed. We note that the effective date of coverage selected by a qualified employer remains subject to the limit on waiting periods under § 147.116.

Comment: One commenter supported the proposed change to allow SHOPs to offer auto-renewals of qualified employees. However, another commenter did not support this automated process because of the risk of error.

Response: Auto-renewals provide a more streamlined, efficient way to renew coverage with minimal risk for error, and our rule will permit SHOPs to do so. We note that the FF–SHOPs are not able to support this feature at this time. Additional guidance will be provided if auto-renewal becomes available in the FF–SHOPs.

Comment: We received one comment supporting the proposal that there not be a SHOP special enrollment period when a qualified employee or dependent of a qualified employee is enrolled in a non-calendar year group health plan or individual health insurance coverage.

Response: We are finalizing the provision as proposed.

d. Termination of SHOP Enrollment or Coverage (§ 155.735)

To align with proposed amendments to § 155.705(b)(4), we proposed to modify the introductory language of § 155.735(c)(2) to specify that the provisions related to termination of employer group health coverage for non-payment of premiums in FF–SHOPs under paragraph (c)(2) do not apply to premium payments for the first month of coverage. We did not receive any comments regarding this proposal, and are finalizing it as proposed.

We also proposed amendments to § 155.735(d) to specify that if an enrollee changes from one QHP to another during the annual open enrollment period or during a special enrollment period, the last day of coverage would be the day before the effective date of coverage in the enrollee's new QHP.

Additionally, we proposed at § 155.735(d)(2)(iii) to require FF–SHOPs to send advance notices to qualified employees before their dependents age off of their plan. The notice would be sent 90 days in advance of the date when the child dependent enrollee is no longer eligible for coverage under the plan the employer purchased through the FF–SHOP because he or she has reached the maximum child dependent age for the plan. The notice would include information about the plan in which the dependent is currently enrolled, the date the dependent would age off the plan, and information about next steps. In the FF–SHOPs, a dependent aging off of the plan loses eligibility for dependent coverage at the end of the month of the dependent's 26th birthday or at the end of the month in which the issuer has set the maximum dependent age limit (but in some cases might have the option to keep the coverage for a period of time after that date under applicable continuation coverage laws). This notice is intended to be a courtesy notice as enrollees would still receive a termination notice when their coverage through the SHOP is terminating.

We are finalizing these provisions generally as proposed, with the exception of a technical correction to paragraph (d)(2)(ii) to replace the citation to § 155.420(b)(2) with a citation to § 155.725(j)(5), the SHOP rule under which SHOP enrollments are effectuated pursuant to special enrollment periods. Section

155.725(j)(5) cross-references § 155.420(b), and thus also cross-references the retroactivity possible under § 155.420(b)(2).

Comment: We received one comment supporting our proposal to send qualified employees 90 days advance notice of when a child dependent is no longer eligible for coverage under the plan the employer purchased through the FF–SHOP because he or she has reached the maximum child dependent age for the plan. The commenter notes that it is important to recognize that the age-off date may go well beyond a dependent's twenty-sixth birthday, depending on State dependent coverage laws.

Response: We are finalizing the provision as proposed. If a State or issuer sets maximum dependent age limits greater than 26 years, the FF–SHOPs will send the notice 90 days in advance of when the child dependent is no longer eligible for coverage under the plan the employer purchased through an FF–SHOP. The FF–SHOPs will be able to accommodate issuer-specific and State-specific maximum dependent age limits.

e. SHOP Employer and Employee Eligibility Appeals Requirements (§ 155.740)

In § 155.740, we proposed amendments relating to SHOP appeals. We proposed to provide that employers and employees may file an appeal not only if a SHOP fails to provide an eligibility determination in a timely manner, but also if a SHOP fails to provide timely notice of an eligibility determination. We also proposed to allow employers and employees who successfully appeal a denial of SHOP eligibility to select whether the effective date of coverage or enrollment through the SHOP under their appeal decision will be retroactive to the effective date of coverage or enrollment through the SHOP that the employer or employee would have had if they had correctly been determined eligible, or prospective from the first day of the month following the date of the notice of the appeal decision. Additionally, we proposed that if eligibility is denied under an appeal decision, the appeal decision would be effective on the first day of the month following the date of the notice of the appeal decision.

Comment: Some commenters said they believe that if an employer only adds eligible employees to the roster, then the SHOP will have no knowledge of ineligible employees. Therefore, the process of employees appealing to the SHOP will never be a valid scenario because no ineligibility notification will ever be sent by the SHOP to the employee. Another commenter suggested that HHS retain the current regulatory language about the coverage effective date after a successful appeal decision or adopt an effective date that is the first of the month following the appeal decision, but not allow each group to choose. Some commenters stated that only those who had retroactive claims would select the retroactive date. Commenters also recommended that coverage should never take effect more than a month retroactively, or that coverage should start immediately.

Response: We are finalizing as proposed our proposal that employers and employees may file an appeal not only if a SHOP fails to provide an eligibility determination in a timely manner, but also if a SHOP fails to provide timely notice of an eligibility determination. SHOPs may send a notice of ineligibility if the information provided by an employee does not match the information provided by the qualified employer. An FF–SHOP might send a notice of ineligibility to an employee, for example, if the employee inaccurately enters his or her unique participation code in the FF–SHOP employee application. We note that employers do not make SHOP eligibility determinations for employees. The SHOPs make all eligibility determinations for employees. Employers must offer SHOP coverage to all full-time employees; other employees and former employees added to the employee roster are also eligible for SHOP coverage.

We are making a minor modification to our proposal allowing employers and employees to select either a retroactive or prospective coverage or enrollment effective date if the appeal decision finds the employer or employee eligible, to specify that individual employees may select an effective date only when the appeal is of an individual employee's eligibility determination (rather than an appeal of a determination of eligibility for an employer, which affects coverage or enrollment for the entire group). We believe that if an employer or employee applied for coverage or enrollment with the intention that coverage would be effective on a specific date, received a denial of eligibility, and successfully appealed the decision, the employer or employee should be provided with the option to select retroactive or prospective coverage or enrollment, because the employer or employee was found to be eligible for SHOP coverage and the group or employee could have had SHOP coverage as early as the original desired date had the original eligibility determination been correct. Regardless of whether the group or employee has incurred claims, to provide maximum flexibility to consumers, we believe that the decision about whether to select a retroactive or prospective coverage or enrollment effective date should be the employer's or employee's. While we acknowledge issuers' concerns about who might select retroactive coverage, we note that retroactive coverage would be effectuated only if the requisite premium payment is made in accordance with § 155.705(b)(4)(ii)(B)(2), as finalized here. In the FF–SHOPs, premiums owed for employees that are found eligible under an employee appeal decision will be collected from employers as part of the next monthly invoice for the group.

We are finalizing § 155.740(l)(3)(iii), regarding the effective date of a denial of eligibility under an appeal decision, with a revision specifying that the appeal decision would be effective as of the date of the notice of the appeal decision. This is the same effective date that applies under the current version of § 155.740(l)(3), so there will not be any change in policy regarding the effective date of a denial of eligibility under an appeal decision under this rule. We have decided to maintain the current policy because if an employer or employee is denied eligibility and their appeal is also denied, the employer or employee might never have had enrollment or coverage through the SHOP, and even if they did, would not have been entitled to it. The SHOP should therefore be able to make the appeal decision effective as of the date of the notice of the appeal decision.

9. Exchange Functions: Certification of Qualified Health Plans

a. Certification Standards for QHPs (§ 155.1000)

(1) Denial of Certification

Section 1311(e)(1)(B) of the Affordable Care Act states that Exchanges may certify a health plan as a QHP if such health plan meets the requirements for certification as promulgated by the Secretary and the Exchange determines that making available such health plan through such Exchange is in the interests of qualified individuals and qualified employers. Section 1311(e)(1)(B) thereby affords Exchanges the discretion to deny certification of QHPs that meet minimum QHP certification standards, but are not ultimately in the interests of qualified individuals and qualified employers. In the proposed rule, we

stated that we interpret the ''interest'' standard to mean QHPs should provide quality coverage to consumers to meet the Affordable Care Act's goals.

Section 155.1000 provides Exchanges with broad discretion to certify health plans that otherwise meet the QHP certification standards specified in part 156. HHS expects to continue to certify the vast majority of plans that meet certification standards. HHS will focus denials of certification in the FFEs based on the ''interest of the qualified individuals and qualified employers'' standard on cases involving the integrity of the FFEs and the plans offered through them. Examples of issues that could result in non-certification of a plan include concerns related to an issuer's material non-compliance with applicable requirements, an issuer's financial insolvency, or data errors related to QHP applications and data submissions. Under this approach, HHS could consider an assessment of past performance, including with respect to oversight concerns raised through compliance reviews and consumer complaints received, and the frequency and extent of any data submission errors. In exercising this authority, HHS intends to adopt a measured approach that would take into consideration several factors, including available market competition and the availability of operational resources.

We noted that the Office of Personnel Management (OPM) has the sole discretion for contracting with multi-State plans and as such retains the authority to selectively contract with multi-State plans.

Comment: Several commenters opposed HHS's proposal to deny certification to plans based on the interest standard, stating ''additional'' or ''new'' HHS certification authority would reduce competition and innovation, lead to arbitrary, inconsistent, and capricious certification decisions, and interfere with State reviews. Other commenters agreed that HHS has existing authority to deny certification and supported the proposal. Those commenters believe that the use of such authority could promote the availability of high-value health plans and innovative health care delivery system reforms, encourage insurers to minimize annual rate increases, and enable FFEs to become a ''trusted source of quality coverage for consumers.''

Response: The interest standard was previously codified in § 155.1000 (77 FR 18467); thus, we did not propose new or additional certification authority.

Comment: Some commenters stated HHS should work with plans to address concerns and meet certification requirements rather than denying certification, and denials should only be used when a health plan is financially impaired. They also recommended HHS make specific requirements and examples available for comment (for example, clarifying how consumer complaints would be used to assess past performance) before finalizing any criteria. Other commenters agreed that HHS should use factors outlined in the proposed rule, such as consumer complaints and past performance, as criteria for denying certification. Some States shared information on their models. Other commenters wanted HHS to take additional factors into account, such as a ''history of repeated or egregious violations'' of nondiscrimination standards and network adequacy requirements. Another commenter asked HHS to consider safe harbors for innovative plan designs that provide incentives to reduce the cost of health care to consumers while providing EHB and meeting or exceeding minimum value (MV).

Response: As stated above, while we have existing authority to deny certification based on the interest standard, we are not including any specific requirements or criteria in this final rule. HHS will continue to focus on cases involving the integrity of the FFEs and the plans offered through them, and, as discussed in the proposed rule, will consider factors such as an issuer's material non-compliance with applicable requirements, an issuer's financial insolvency, or data errors related to QHP applications and data submissions. We expect to continue to certify the vast majority of plans that meet certification standards.

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

1. Standardized Options

In order to provide a new option that could further simplify the consumer plan selection process, we proposed six standardized options that issuers could choose to offer in the individual market FFEs in plan year 2017. At § 156.20, we proposed to define a standardized option as a QHP with a cost-sharing structure specified by HHS. Each standardized option consists of a fixed deductible; fixed annual limitation on cost-sharing; and fixed copayment or coinsurance for a key set of EHB that comprise a large percentage of the total allowable costs for an average enrollee (these are the EHB in the Actuarial Value Calculator with the addition of urgent care). We proposed one standardized option at each of the bronze, silver (and the three associated silver CSR plan variations), and gold levels of coverage. We proposed that an issuer could offer a standardized option at one or more levels of coverage, with the exception that if it offers a silver standardized option, it must also offer the three associated standardized silver CSR plan variations. We did not propose a standardized option at the platinum level of coverage since only a small proportion of QHP issuers in the FFEs offer platinum plans.

We proposed that an issuer could offer more than one plan for each standardized option within a service area, subject to the meaningful difference requirements defined at § 156.298. This could be accomplished, for example, if the issuer offers an HMO standardized option at a particular level of coverage as well as a PPO standardized option at the same level of coverage. We also proposed that issuers would retain the flexibility to offer an unlimited number of non-standardized plans and that we would not limit the total number of QHPs that may be sold through an FFE in a rating area or county, outside of any limitations under the meaningful difference and other applicable QHP certification requirements.

We encouraged issuers to offer at least one standardized option, particularly at the silver level of coverage (and the associated silver CSR plan variation levels). This would simplify the consumer shopping experience for the greatest number of FFE QHP enrollees, since silver plans are the most common and popular plans in terms of enrollment in the FFEs.

We designed the standardized options to be as similar as possible to the most popular (weighted by enrollment) QHPs in the 2015 FFEs in order to minimize market disruption and impact on premiums.

We proposed that standardized options have the four drug tiers currently utilized in our consumer-facing applications—generic, preferred brand, non-preferred brand, and specialty drug tiers—with the option for issuers to offer additional lower-cost tiers if desired, since slightly more than half (56 percent) of the proposed 2016 FFE QHPs had more than four drug tiers.

We proposed that standardized options have no more than one in-network provider tier since varying cost sharing by provider tier affects the actuarial value of a plan, making it difficult to standardize a cost-sharing

structure. Additionally, only 14 percent of FFE enrollees in 2015 were enrolled in QHPs with more than one in-network tier, and only 6 percent of enrollees were covered by an issuer that did not offer a single-tier plan in addition to a multi-tier plan in the same county.

We proposed that the standardized options would exempt from the deductible certain routine services, such as primary care, specialist visits (at the silver and gold metal levels), and generic drugs, to ensure that access to coverage translates into access to care for routine and chronic conditions and that enrollees receive some up-front value for their premium dollars. Among 2015 FFE QHPs, more than 85 percent of silver plan enrollees and more than 50 percent of bronze plan enrollees selected plans that cover certain services prior to application of the deductible. (The figure for gold plan enrollees was more than 90 percent. However, many gold plans have a $0 deductible, in which case, the concept of deductible-exempt services would not be meaningful.) Primary care and generic drugs are the services most likely to be covered without a deductible at all metal levels. Other services that are also likely to be covered prior to the deductible, particularly by silver and gold plans, include specialist visits and mental/behavioral health and substance use disorder outpatient services.

We proposed that the standardized options balance consumer preference for copayments over coinsurance with the potential impact on premiums. Research shows that consumers often prefer copayments to coinsurance because copayments are more transparent and make it easier for consumers to predict their out-of-pocket costs. On the other hand, setting fixed copayments on a national level for high-cost services could lead to disparate premium effects due to regional and issuer-specific cost differences, or it could lead to premium increases or require corresponding increases in other forms of cost sharing, if set too low.

To reduce operational complexity, we proposed to not vary the standardized options by State or by region. We proposed one set of standardized options for all FFEs, including those in which States perform plan management functions, recognizing that some States regulate the level of cost sharing applied to certain benefits, such as emergency room services and specialty drugs.

We noted that we would be conducting consumer testing to help us evaluate ways in which standardized options, when certified by an FFE, could be displayed on our consumer-facing plan comparison features in a manner that makes it easier for consumers to find and identify them, including distinguish them from non-standardized plans. We noted that we anticipate differentially displaying the standardized options to allow consumers to compare plans based on differences in price and quality rather than cost-sharing structure as well as providing information to explain the standardized options concept to consumers. We also noted that we are considering whether to require QHP issuers or web-brokers to differentially display standardized options when a non-FFE Web site is used to facilitate enrollment in an FFE.

We noted that multi-State plan issuers may use the standardized options, but that OPM, at its discretion, may design additional standardized options applicable only to multi-State plan issuers. We would not display the OPM-designed standardized options applicable only to multi-State plan issuers in a differential manner, however, in order to preserve consistency in the standardized options identified by HHS in the FFEs.

We are finalizing the HHS-specified standardized options, but as further described below, we are specifying some changes to the standardized options' cost sharing, including one technical correction. These changes remain consistent with the general features and principles of standardized options described in the preamble to the proposed rule. We will make any additional changes to the standardized options in future rulemaking. The plans finalized in this rule apply beginning with the 2017 plan year and until any future changes are finalized.

In addition, we are adding to § 155.205(b)(1) a new provision codifying the Exchange's authority to differentially display standardized options on our consumer-facing plan comparison and shopping tools. (How standardized options will be displayed will take into consideration the results of consumer testing, which is currently in process.) We do not intend to require QHP issuers or web-brokers to adhere to differential display requirements of standardized options when using a non-Exchange Web site to facilitate enrollment in a QHP through an Exchange at this time, but will consider whether we should propose such a standard in the future. Additionally, because the provision in § 155.205(b)(1) refers to standardized options, we will finalize the definition of standardized option at § 155.20, which specifies the definitions for part 155, instead of at § 156.20, which specifies definitions for part 156.

Overall, commenters were supportive of the specific standardized plan designs, but suggested some modifications. The proposed 2017 bronze standardized option closely resembled a catastrophic plan, with a $6,650 deductible, an annual limitation on cost sharing equal to the maximum allowable annual limitation on cost sharing for 2017 (proposed to be $7,150), and 50 percent coinsurance for most types of benefits. Primary care visits (for the first three visits) and mental health/substance use outpatient services were exempt from the deductible with a copayment of $45. Generic drugs were also exempt from the deductible with a copayment of $35. The top three drug tiers each had a 50 percent coinsurance rate. We are making a change to the cost sharing for each of the top three drug tiers in the bronze standardized option. In response to commenters who noted the relative paucity of bronze plans on the FFEs with 50 percent coinsurance rates for drugs, the preferred brand drug tier now has a 35 percent coinsurance; the non-preferred brand drug tier now has a 40 percent coinsurance; and the specialty drug tier now has a 45 percent coinsurance. We are also making a technical correction to the Bronze plan's AV calculation to ensure that the deductible and coinsurance apply correctly after the first three primary care visits, to align with the Final 2017 AV Calculator User Guide instructions. Making this technical correction and the above changes to drug coinsurance rates raises the AV for the plan to 61.88. Thus, the AV for the final bronze standardized option is 0.06 percent higher than the AV of the proposed bronze standardized option, which was 61.82 (rounded to 61.8). The coinsurance rate for each of the top three drug tiers more closely reflects the average coinsurance rate for each of the top three drug tiers in the most popular (weighted by enrollment) QHPs in the 2015 FFEs, which were 25 percent, 35 percent, and 45 percent, respectively. The new bronze standardized option also addresses commenters' concerns that the proposed design was inconsistent with the principle of having four different drug tiers. Non-generic drugs would all have had a 50 percent coinsurance rate with the proposed version of the bronze standardized option.

The proposed 2017 silver standardized option had a $3,500 deductible, an annual limitation on cost sharing equal to the maximum allowable annual limitation on sharing

for 2017, and a 20 percent enrollee coinsurance rate. Primary care visits, mental health/substance use outpatient services, specialist visits, urgent care visits, and all drug benefits were exempt from the deductible, and all of the deductible-exempt benefits had copayments instead of coinsurance, except for the specialty drugs tier, which had a 40 percent coinsurance rate. Emergency room services were subject to the deductible, with a $400 copayment applicable after the deductible.

In the final rule, we are making a change to the proposed silver standardized option in response to comments. The proposed silver standardized option and gold standardized option had the same copayment value for generic drugs. We are increasing the copayment for generic drugs to $15 for the silver standardized option to more closely reflect the average copayment rate for generic drugs in the most popular QHPs in the 2015 FFEs (weighted by enrollment). The actuarial value of the new standardized silver option is 70.63 percent (0.37 percent lower than the AV of the proposed version).

The proposed silver cost-sharing reduction standardized options reduced all cost sharing parameters successively to meet the 73 percent, 87 percent, and 94 percent AV requirements. Where possible, the cost-sharing reduction standardized options and the non-cost-sharing reduction standardized silver option maintain similar differentials between the cost sharing for certain benefits like primary care and specialty visits. We are finalizing the three standardized options at the silver cost-sharing reduction variation levels.

The proposed 2017 gold standardized option, which we are also finalizing as proposed, has a $1,250 deductible, a $4,750 annual limitation on cost sharing, and a 20 percent coinsurance rate for most types of benefits. Primary care visits, mental health and substance use outpatient services, specialist visits, urgent care visits, and all drug benefits are not subject to the deductible. All of the benefits not subject to the deductible have copayments except for specialty drugs.

TABLE 9—FINAL 2017 STANDARDIZED OPTIONS

	Bronze	Silver	Silver 73% actuarial value variation	Silver 87% actuarial value variation	Silver 94% actuarial value variation	Gold
Actuarial Value (%)	61.88	70.63	73.55	87.47	94.30	79.98.
Deductible	$6,650	$3,500	$3,000	$700	$250	$1,250.
Annual Limitation on Cost Sharing.	$7,150	$7,150	$5,700	$2,000	$1,250	$4,750.
Emergency Room Services.	50%	$400 (copay applies only after deductible).	$300 (copay applies only after deductible).	$150 (copay applies only after deductible).	$100 (copay applies only after deductible).	$250 (copay applies only after deductible).
Urgent Care	50%	$75 (*)	$75 (*)	$40 (*)	$25 (*)	$65 (*).
Inpatient Hospital Services.	50%	20%	20%	20%	5%	20%.
Primary Care Visit	$45 (* first 3 visits, then subject to deductible and 50% coinsurance).	$30 (*)	$30 (*)	$10 (*)	$5 (*)	$20 (*).
Specialist Visit	50%	$65 (*)	$65 (*)	$25 (*)	$15 (*)	$50 (*).
Mental Health/Substance Use Disorder Outpatient Services.	$45 (*)	$30 (*)	$30 (*)	$10 (*)	$5 (*)	$20 (*).
Imaging (CT/PET Scans, MRIs).	50%	20%	20%	20%	5%	20%.
Rehabilitative Speech Therapy.	50%	20%	20%	20%	5%	20%.
Rehabilitative OT/PT.	50%	20%	20%	20%	5%	20%.
Laboratory Services	50%	20%	20%	20%	5%	20%.
X-rays	50%	20%	20%	20%	5%	20%.
Skilled Nursing Facility.	50%	20%	20%	20%	5%	20%.
Outpatient Facility Fee.	50%	20%	20%	20%	5%	20%.
Outpatient Surgery Physician/Surgical.	50%	20%	20%	20%	5%	20%.
Generic Drugs	$35 (*)	$15 (*)	$10 (*)	$5 (*)	$3 (*)	$10 (*).
Preferred Brand Drugs.	35%	$50 (*)	$50 (*)	$25 (*)	$5 (*)	$30 (*).
Non-Preferred Brand Drugs.	40%	$100 (*)	$100 (*)	$50 (*)	$10 (*)	$75 (*).
Specialty Drugs	45%	40% (*)	40% (*)	30% (*)	25% (*)	30% (*).

(*) = not subject to the deductible.

Comment: Many commenters supported our proposal to establish standardized options in the individual market FFEs in plan year 2017, as a step towards simplifying the consumer experience, both when shopping for

health insurance and when making cost-sharing payments to use covered health care services. Some commenters opposed our standardized options proposal, arguing that it will hamper innovation and limit competition and choice, and that differential or preferential display of standardized options could inadvertently steer consumers with specific or special health care needs towards selecting standardized options that are designed for the average QHP enrollee and not for a specific population. These commenters expressed their concern that our proposal represents a first step toward ultimately limiting or excluding non-standardized plans. These commenters stated that making standardized options mandatory in the future could stifle innovation in plan design, including value based insurance design offerings, as well as competition in the case that standardized options are sorted above non-standardized plans on our consumer-facing plan comparison and shopping tools. Among those who supported the standardized options proposal, many urged that offering them should be mandatory, even in 2017.

Response: We believe that standardized options can simplify the consumer shopping experience and are therefore finalizing the proposal for issuers to be able to offer standardized options if they choose. We recognize that these cost-sharing structures may not be appropriate for all issuers or all markets. We are not requiring issuers to offer standardized options, nor limiting their ability to offer other QHPs, and as a result, we do not believe that standardized options will hamper innovation or limit choice. Additionally, we will seek to mitigate the risk that consumers with special health care coverage needs incorrectly choose a standardized option through the use of tools that explain to consumers which cost-sharing features are standardized, and how they may differ from one another and from non-standardized plans, as well as how they can be used to simplify the shopping experience. We believe that most consumers with specialized health care needs will carefully shop for coverage that provides the right mix of cost-sharing protections, benefits, and networks.

Comment: Several commenters agreed with the features of our proposed standardized options, including the inclusion of certain deductible-exempt services, a single in-network provider tier, four drug tiers with the option of lower-cost tiers, and copayments in place of coinsurance where possible. We also received many recommended specific changes to the standardized option designs, particularly with respect to prescription drugs. Some commenters opposed the use of coinsurance for the specialty drug tier across all metal levels without the inclusion of specific and reasonable dollar level caps. Some commenters noted that the proposed bronze standardized option in effect has only two tiers, since the generic drug tier has a proposed copayment of $35 while the top three drug tiers all have the same coinsurance rate of 50 percent. Some commenters noted that the proposed copayments for generic drugs were set at the same copayment rate ($10) for both the gold standardized option and the silver standardized option and recommended that the generic copayment be lower in the gold plan than in the silver plan. Some commenters asked that all four drug tiers be exempt from the deductible, while others asked that drugs be subject to a separate deductible. Some commenters asked that we clarify that the copayment amounts for the drug tiers are for thirty-day retail fills. Some commenters asked that we clarify that issuers are permitted to create lower cost tiers for any of the four drug tiers, not just for the generic drugs tier. For example, commenters suggested that issuers should be permitted to create a preferred specialty tier with lower cost sharing than the specialty tier. Some commenters ask that we clarify that preferred and non-preferred pharmacies are permitted with differential cost sharing and that differential cost sharing is permitted for mail-service and retail pharmacies, such that the standardized cost sharing could represent cost sharing at non-preferred retail pharmacies, with lower cost sharing available at preferred retail or mail-service pharmacies.

Response: We are finalizing the standardized options as proposed except for the changes to the bronze and silver standardized options discussed above and the following clarifications. We clarify that that copayment amounts listed for the drug tiers are for thirty-day prescription fills at retail pharmacies and that issuers (or their prescription benefit managers) may offer a lower cost-sharing rate for mail order prescription fills, as is the most common practice in the current market. We also clarify that issuers may create a lower cost tier for the generic drugs tier for standardized options, but may not do so for the three higher drug tiers in the standardized options.

Comment: One commenter recommended that we create standardized options for family plans in addition to individual plans.

Response: We clarify that issuers may offer the standardized options as family plans by doubling the maximum annual limitation on cost-sharing and setting the family (other than self-only) deductible at twice the deductible provided here.

Comment: Some commenters urged that we exempt habilitative and rehabilitative outpatient services from the deductible in the standardized options. Some commenters also encouraged the creation of a standardized platinum option. Some commenters opposed designing the standardized options to be as similar as possible to the 2015 QHPs, noting that in their opinion, the 2015 QHPs often did not meet the needs of people with chronic conditions.

Response: We designed the plans to be as similar as possible to the 2015 QHPs (as measured on an enrollment-weighted basis) in order to minimize disruption to the market and impact on premiums. Only a minority of these plans exempted habilitative and rehabilitative outpatient services from the deductible. We will consider more deductible exempt services in future years depending on changes in the QHP markets, enrollment patterns, and other considerations.

Comment: Several commenters expressed concern with our proposal to establish a set of standardized options that would apply in all States in which an FFE is currently operating, noting that States may have established or may wish to establish their own standardized plans specific to their State-wide markets.

Response: As we note in the preamble to § 156.350 in this final rule, it is not possible at this time for the Federal platform to accommodate State customization, such as State-specific display elements on Plan Compare. State-defined standardized plans that are different from HHS's standardized options will not be displayed in the same manner as HHS's standardized options on the Federal platform because of the limitations described above.

Further, in a State that has required standardization of certain cost-sharing features of its QHPs or is considering doing so in 2017 or beyond, issuers must comply with State law, which may mean that issuers in those States will be unable to offer some or all of the standardized options established through this rule-making. At this time, the FFEs will not be able to give differential display to QHPs that differ from the standardized options finalized in this final rule, even if the only differences are to comply with State

laws. We will consider whether we may be able to do so in the future, however.

Comment: HHS solicited comments on whether it should require QHP issuers or web-brokers to differentially display standardized options when using a non-Exchange Web site to facilitate enrollment in a QHP through the Exchange. Commenters voiced concerns that web-brokers already have to comply with existing plan display requirements, such as displaying all plans sold on the Exchange, and not displaying plans based on compensation, and that should HHS adopt this policy, web brokers would need clear guidance and sufficient time to prepare.

Response: We recognize that currently, web-brokers are expected to comply with display requirements under § 155.220(c)(3), which includes disclosing and displaying all QHP information provided by the Exchange or directly by QHP issuers consistent with the requirements of § 155.205(b)(1) and (c), providing consumers the ability to view all QHPs offered through the Exchange, and displaying all QHP data provided by the Exchange. We are not requiring QHP issuers or web-brokers to adhere to differential display requirements of standardized options when using a non-Exchange Web site to facilitate enrollment in a QHP through an Exchange at this time. We will consider whether such a standard should apply to non-Exchange Web sites in the future. Web-brokers and issuers should continue to comply with all existing plan display requirements.

2. FFE User Fee for the 2017 Benefit Year (§ 156.50)

Section 1311(d)(5)(A) of the Affordable Care Act permits an Exchange to charge assessments or user fees on participating health insurance issuers as a means of 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 specify 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 FFEs 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 to 2016, issuers seeking to participate in an FFE in benefit year 2017 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. Activities performed by the Federal government that do not provide issuers participating in an FFE with a special benefit will not be covered by this user fee.

OMB Circular No. A–25R further states that user fee 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 proposed to set the 2017 user fee rate for all participating FFE issuers at 3.5 percent. This user fee rate assessed on FFE issuers is the same as the 2014 to 2016 user fee rate. We are finalizing the 2017 user fee rate for all participating FFE issuers as proposed. In addition, OMB Circular No. A–25R requires that the user fee charge be sufficient to recover the full cost to the Federal government of providing the special benefit. An exception was in place for the 2014 to 2016 user fee rates, to ensure that FFEs could support the goals of the Affordable Care Act, including improving the health of the population, reducing health care costs, and providing access to health coverage. We have sought an exception to this policy again for 2017.

Comment: Some commenters requested conversion of the FFE user fee assessment from percent of premium to a per member per month amount to decouple the user fee from medical inflation. We received one comment asking whether the user fees collected in 2017 will exceed the costs of the FFE. We also received comments stating that the user fee rate is likely too low to cover the full costs of the FFE.

Response: We will continue to assess the FFE user fee as a percent of the monthly premium charged by issuers participating in an FFE, in particular as it relates to the adequacy of funding for ongoing marketing and outreach. In accordance with OMB Circular No. A–25R, issuers are charged the user fee in exchange for receiving special benefits beyond those that are offered to the general public. Setting the user fee as a percent of premium ensures that the user fee generally aligns with the business generated by the issuer as a result of participation in an FFE. Additionally, the user fee rate is set to collect costs incurred for the special benefits, no more or less, and user fee collections are used solely to support FFE user fee eligible functions.

Additionally, we proposed under §§ 155.106(c) and 155.200(f) to allow State Exchanges to enter into a Federal platform agreement with HHS so that the State Exchange may rely on the Federal platform for certain Exchange functions to enhance efficiency and coordination between State and Federal programs, and to leverage the systems established by the FFE to perform certain Exchange functions. We proposed in § 156.50(c)(2) to charge SBE–FP issuers a user fee for the services and benefits provided to the issuers by HHS. For 2017, these functions will include the Federal Exchange information technology and call center infrastructure used in connection with eligibility determinations for enrollment in QHPs and other applicable State health subsidy programs, as defined at section 1413(e) of the Affordable Care Act and enrollment in QHPs under § 155.400. As previously discussed, 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. We are finalizing our proposals under § 155.106(c) and § 155.200(f), and issuers seeking to participate in an SBE–FP in benefit year 2017 and beyond will receive special benefits not available to the general public: The ability to sell health insurance coverage through a State Exchange that realizes efficiencies by using the Federal platform to enroll

individuals determined eligible for enrollment in a QHP, including individuals who may be eligible for insurance affordability programs that may support premiums paid to issuers offering plans through the State Exchange by way of the Federal platform (HealthCare.gov), and the ability to sell health insurance coverage to small employers eligible to purchase QHPs for its employees through a SHOP Exchange. Other services that will be provided to issuers offering plans through an SBE–FP include the Federal Exchange information technology and call center infrastructure used in connection with eligibility determinations for enrollment in QHPs and other applicable State health subsidy programs. We proposed to charge issuers offering QHPs through an SBE–FP a user fee rate of 3.0 percent of the monthly premium charged by the issuer for each policy under a plan offered through an SBE–FP. This fee would recover funding to support FFE operations incurred by the Federal government associated with providing the services described above.

The proposed user fee rate was calculated based on the proportion of FFE costs that are associated with the FFE information technology infrastructure, the consumer call center, and eligibility and enrollment services, and allocating a share of those costs to issuers in the relevant SBE–FPs. A significant portion of expenditures for FFE services are associated with the information technology, call center infrastructure, and personnel who conduct eligibility determinations for enrollment in QHPs and other applicable State health subsidy programs as defined at section 1413(e) of the Affordable Care Act, and who perform the functions set forth in § 155.400 to facilitate enrollment in QHPs. We intend to review the costs incurred to provide these special benefits each year, and revise the user fee rate for issuers in SBE–FPs accordingly in the annual HHS notice of benefit and payment parameters.

Comment: Commenters requested a one-year delay in assessing the user fee on issuers operating in an SBE–FP or a reduction of the user fee for 2017, particularly noting that SBE–FPs require additional time to integrate the user fee into their State's budget, and also that the impact of this user fee on premiums in SBE–FP States will be significant. Commenters also noted charging SBE–FP issuers the full user fee rate would allow the State to make a fully informed decision on the type of model to use for 2017. We also have received questions as to why we have not charged the SBE–FP user fees until now.

Response: While a user fee rate of 3.0 percent reflects HHS's actual costs, we recognize that State Exchanges that are currently using the Federal platform may find the abrupt change of the proposed user fee in 2017 challenging for their health insurance markets. Therefore, for the 2017 benefit year, we have sought a waiver from OMB to the requirement that the user fee with respect to SBE–FPs cover the full share of costs incurred by the FFE for providing these services, and, if we receive this waiver, would reduce the user fee rate by one-half for the issuers in an SBE–FP, to provide these States additional transition time to support the costs incurred by the FFE. That is, for the 2017 benefit year, issuers operating in an SBE–FP will be charged an amount equal to 1.5 percent of premiums in the SBE–FP.

We expect, in future rulemaking, to propose that SBE–FP issuers would be charged the full user fee rate covering the full share of costs incurred by the Federal platform for the special benefits provided to issuers in SBE–FPs. We note that we did not immediately assess a user fee on SBE–FP issuers because we did not establish our authority and intent to do so through rulemaking in time for rate-setting. We are drawing on our experience with SBE–FP operations in the 2014 and 2015 benefit years to establish a regulatory structure for SBE–FPs and to help determine an appropriate cost estimate for the SBE–FP user fee. As was the case with the FFEs, the user fee will not fully capture our costs, so that we can ease the transition for States and their issuers to adapt to these higher fees. We note that we similarly sought a waiver from OMB from the requirement that FFE user fees fully account for costs in the early years of the FFEs.

Comment: Some commenters requested that HHS implement the user fee in SBE–FP States by invoicing the State directly for the costs incurred or setting up a different methodology for recouping the costs incurred. These commenters indicated that a State that wishes to fund its Exchange operations by assessing a fee on all insurance carriers selling individual market major medical policies, both on and off Exchange, the Federal user fee structure would require the SBE–FP to execute a complex reconciliation process.

Response: We will assess the user fee rate as a percent of monthly premiums charged by issuers operating in an SBE–FP, as established in prior rulemaking. Setting the user fee as a percent of premium charged by issuers ensures that the user fee generally aligns with the business generated by the issuer as a result of the special benefits provided. We recognize that SBE–FPs may have elected to cover Exchange costs differently. Therefore, at an SBE–FP's written request, HHS will collect from the SBE–FP the total amount that would result from the user fee collected from issuers based on the percent of monthly premiums charged by invoicing the State for the total user fee charge, and not by collecting the fee directly from SBE–FP issuers.

Comment: One commenter requested unbundling of the costs of the Federal platform, as States may not utilize all aspects of the Federal platform bundle. We also received comments urging HHS to set a limit on the State's portion of the assessment for covering the State's costs. Commenters' suggestions for the user fee limit ranged from 3.5 percent to 5 percent of premiums for combined Federal and State user fee charges.

Response: As we discuss in § 155.106, HHS will not—at this time—offer a menu of Federal services from which an SBE–FP may select some but not other services on the Federal platform. As such, we are finalizing the SBE–FP user fee eligible costs as a bundle as proposed, and do not at this time anticipate unbundling the costs for each Federal service. We will also continue assessing the user fee by market. This means that, if an SBE–FP is not utilizing Federal services for the SHOP Exchange, the user fee would not be charged on SHOP issuers. Additionally, we do recognize the benefits of States operating their own plan management and customer support functions, and do not intend to limit the State's ability to generate revenue to support these functions.

Comment: One commenter sought confirmation that if a State is currently developing its own SBE platform, but later decides instead to rely on the Federal platform under the SBE–FP model, the SBE–FP model would be available to the State. Additionally, the commenter requested that in such a situation the State be charged the same user fee as charged to existing SBE–FPs.

Response: The SBE–FP model option will be available per the timelines and conditions we describe in § 155.106. The SBE–FP user fee for a particular benefit year, established through rulemaking, will apply to all States that use the SBE–FP for that benefit year, including those States that do not currently use the SBE–FP model. All issuers on SBE–FPs for the 2017 benefit year would receive the reduced 1.5 percent transitional rate. Additionally, we note that nothing restricts a State

from using its own revenue to support developing its own SBE platform.

Comment: Other commenters stated that the FFE and SBE–FP user fee rates are likely too low to provide all of the necessary functions for consumers, and that the assumption that FFE spend only 15 percent of user fee collections on marketing, outreach, and plan management is too low.

Response: Our current user fee rates for issuers in an FFE and an SBE–FP are based on our current anticipated contract costs for providing the special benefits. Our cost distributions are based on larger estimated enrollment through FFEs, and are not comparable to what individual States may spend on these functions. Further, to ensure FFEs can support many of the goals of the Affordable Care Act, we continuously assess our operational strategy for FFE functions to maximize access to health insurance coverage, and could seek, through notice and comment rulemaking, to change the user fee rate in future years to accommodate increased or decreased spending on areas such as marketing and consumer outreach.

Additionally, to ease administrative burdens on issuers and States, HHS proposed to offer States the option to have HHS collect an additional user fee from issuers at a rate specified by the State to cover costs incurred by the State-based Exchange for the functions the State retains. HHS would undertake this collection under the Intergovernmental Cooperation Act of 1968 (IGCA) if a written request is made by a State. If HHS agrees to provide such services, States may be required to reimburse HHS any additional costs that are associated with HHS's provision of such service. This coordination between the State and Federal programs would reduce administrative burden on issuers as well as the SBEs–FP. We did not receive any comments on this proposal for HHS to collect an additional user fee from issuers on behalf of the State. We will provide additional guidance if we receive such a request.

3. Single Risk Pool (§ 156.80)

We proposed to codify that any new rates set by an issuer in the small group market as part of a quarterly rate change would apply for new or renewing coverage on or after the rate effective date, and would apply for the entire the plan year. This policy is consistent with the preamble to the second Program Integrity Rule (78 FR 65067). We also proposed to make non-substantive changes to the wording of that paragraph, including to delete an outdated reference to when quarterly rate changes could first be implemented.

We also reiterated that a health insurance issuer may vary the plan-adjusted index rate for a particular plan from its market-wide index rate adjusting only for the explicitly stated factors in § 156.80(d)(2). Any plan level adjustment not specifically stated, including adjusting for morbidity of plan enrollees, is not permissible.

We received no comments on these specific issues and are finalizing the provisions as proposed.

4. Essential Health Benefits Package

a. Provision of EHB (§ 156.115)

In the 2016 final Payment Notice, we finalized regulation text at § 156.115(a)(5) that discussed habilitative services and devices. Due to a technical error in the amendatory instructions, the current CFR does not reflect this finalized language, and instead retains the language that was finalized prior to being amended by the 2016 Payment Notice; therefore, we are including regulation text in this rulemaking to make a technical correction to update the CFR to language that was previously finalized.

b. Prescription Drug Benefits (§ 156.122)

In the proposed rule, we discussed three proposals related to prescription drug benefits. First, § 156.122(c) requires plans providing EHB to have processes in place that allow an enrollee, an enrollee's designee, or the enrollee's prescribing physician (or other prescriber) to request and gain access to clinically appropriate drugs not covered by the plan. Such procedures must include a process to request an expedited review based on exigent circumstances meeting the requirements under § 156.122(c)(2). For plan years beginning in 2016 and thereafter, these processes must also include certain processes and timeframes for the standard review process, and have an external review process if the internal review request is denied. The costs of the non-formulary drug provided through the exceptions process must count towards the annual limitation on cost sharing and AV of the plan. As discussed in the 2016 Payment Notice (80 FR 10750), the exceptions process established in this section is distinct from the coverage appeals process established under § 147.136. Specifically, the drug exceptions process applies to drugs that are not included on the plan's formulary drug list, while the coverage appeals regulations apply if an enrollee receives an adverse benefit determination for a drug that is included on the plan's formulary drug list. Because these two processes serve different purposes, we reaffirmed our belief that they are not duplicative and we did not propose to change these definitions. However, we also clarified in the 2016 Payment Notice that ''nothing under this policy (§ 156.122(c)) precludes a State from requiring stricter standards in this area.'' We stated in the proposed rule that we received additional comment regarding States' coverage appeals laws and regulations and non-formulary drugs. In our discussion, we noted that if a State is subjecting non-formulary drugs to the standards under § 147.136 as opposed to § 156.122(c), the State's coverage appeals laws or regulations would provide the enrollee with a different process for review, and as a result a different process for obtaining coverage of the non-formulary drug. Specifically, § 147.136 has separate requirements for its external review process and allows for a secondary level of internal review before the final internal review determination for group plans.

As a result, if the State is subjecting non-formulary drugs to § 147.136 and the health plans are also required to comply with § 156.122(c), the health plan may have to satisfy two standards for non-formulary drugs. Therefore, we proposed amending § 156.122(c) to establish that a plan, in a State that has coverage appeals laws or regulations that are more stringent than or are in conflict with our exceptions process under § 156.122(c), and that include reviews for non-formulary drugs, the health plan's exception process satisfies § 156.122(c) if it complies with the State's coverage appeals laws or regulations. The purpose of § 156.122(c) is to ensure that an enrollee has the ability to request and gain access to clinically appropriate drugs not covered by the plan. Regardless of whether a State's coverage appeals laws or regulations satisfy § 156.122(c) or if the health plan meets § 156.122(c) through its exception process, we would expect that an enrollee would retain the ability to request and gain access to clinically appropriate drugs not covered by the plan. Therefore, we solicited comments on the scope of application of State appeals laws or regulations that include determinations for non-formulary drugs for this purpose, especially under medical necessity provisions. We also sought comment as to whether these provisions would allow the enrollee the ability to request and gain access to clinically appropriate drugs not covered by the plan in all cases through a State's coverage appeals laws or regulations. As

the State generally is the primary enforcer of the EHB requirements, the State would determine whether its coverage appeals laws or regulations would satisfy § 156.122(c) and therefore, would allow the health plans in the State to defer to the States' coverage laws or regulations. We noted that we consider multi-State plans that comply with OPM's coverage appeals requirements to satisfy § 156.122(c). We considered codifying this interpretation.

Second, we proposed amending the process at § 156.122(c) to allow for a second level of internal review. For example, we considered using the same timelines as the first level of internal review, 72 hours for the standard review request and 24 hours for the expedited review request.

Lastly, we sought comment on whether the substance use disorder requirement under EHB needs additional clarification with regard to medication assisted treatment (MAT) for opioid addiction.

We are finalizing one provision under this final rule to allow a State to determine that the health plans in the State satisfy § 156.122(c) when the health plans are required to adopt an exceptions process under the State's coverage appeals laws and regulations that include review of non-formulary drugs, and the exceptions process contains requirements at least as stringent as those under § 156.122(c).

Comment: Some commenters supported allowing the State to determine that health plans in the State comply with § 156.122(c) by virtue of the State's coverage appeals laws and regulations applying to non-formulary drugs, as long as the health plans treat the denied formulary exception as an adverse coverage determination under § 147.136. These commenters believed that this proposal is within the State's scope and would avoid duplication and potential operational and financial burdens of having the two different external review processes. Other commenters stated that HHS should require States to prove that they have a stronger standard than that required by the exception process and wanted HHS to make the determination as to whether a State has a stronger standard. Commenters wanted to know what would make a State law ''in conflict with'' the Federal standard and wanted HHS to study the issue to define the problem. These commenters were generally concerned with the timeframe differences between §§ 156.122(c) and 147.136. Some commenters also wanted the State to certify that their laws comply with § 156.122(c), such as with a tool, and to make the determinations publically available. Similarly, commenters supported or had concerns with the OPM clarification with regard to satisfying § 156.122(c). Some commenters requested additional clarification as to whether drugs count towards the annual limitation on cost sharing, such as cases when a State's coverage appeals laws and regulations are applying to non-formulary drugs. Some commenters wanted clarification that this exceptions process is different from the preventive services' exceptions process. Other commenters submitted comments about other prescription drug related issues beyond the scope of the proposed rule.

Response: We are finalizing our proposal that a State may determine that health plans in the State satisfy the requirements of § 156.122(c) if the health plans have a process through the State's coverage appeals laws and regulations to allow an enrollee to request and gain access to clinically appropriate drugs not otherwise covered by the health plan under standards at least as stringent as the requirements at § 156.122(c). To meet this standard, the process must include an internal review, an external review, the ability to expedite the reviews, and timeframes that are the same as or shorter than timeframes established under paragraphs (c)(1)(ii) and (c)(2)(iii) of this paragraph. In the event that an exception request is granted under § 156.122(c)(4), the excepted drug(s) are treated as an EHB including counting any cost-sharing towards the plan's annual limitation on cost-sharing under § 156.130.

While we appreciate commenters' concerns about potential confusion if two processes apply, we do not believe that applying timeframes less stringent than those in the current § 156.122(c) would benefit enrollees. We understand that States may not be able to meet these timeframes under their current coverage appeals laws and regulations and that States may have to change their laws and regulations in order to align the timeframes under § 156.122(c), if the State wishes to use its current laws and regulations to streamline processes and create efficiencies. The State is not required to undertake this option. We also reaffirm that we consider multi-State plans that comply with OPM's coverage appeals requirements to satisfy § 156.122(c). Lastly, we note that the exceptions process under § 156.122(c) is separate from other exceptions process required under applicable Federal or State law. In particular, compliance with the exceptions process under § 156.122(c) does not constitute compliance with the exceptions process for contraceptive services as clarified in guidance under section 2713 of the PHS Act, both of which apply to non-grandfathered individual and small group market plans that are required to provide EHB.[54]

Comment: Some commenters supported a second level of internal review and noted that including two levels of internal review is consistent with current practices, improves administrative efficiency, and ensures enrollees obtain medically necessary medications as soon as possible. The commenters noted that having only one level of internal review means more enrollees will rely on the external review process, which is costly. Some commenters sought additional time for the second level of review. Other commenters opposed a second level of internal review altogether and were primarily concerned that the second level of review could delay access and could burden enrollees. Some commenters wanted evidence that the second level of review would help enrollees, since the health plan conducts the internal review, as opposed to a third party. Some commenters wanted clarification as to whether this revised rule would be effective for the 2016 plan year or apply with enforcement discretion. Other commenters were concerned that the rule would apply different standards in 2016 versus 2017 (one level of internal review versus two).

Response: We are not finalizing new requirements in this area. A health plan, at its election, may conduct a concurrent second internal review in the standard review process and the expedited review process within the timeframes established under § 156.122(c)(1) and (2), but the health plan is not required to do so. As discussed in the preamble of the 2016 Payment Notice (80 FR 10818), all of the timeframes begin when the health plan or its designee receives a request. An enrollee or the enrollee's prescribing physician (or other prescriber) should strive to submit a completed request; however, health plans should not fail to commence review if they have not yet received information that is not necessary to begin review. Therefore, we interpret § 156.122(c)'s reference to receipt of the request to mean that the health plan must begin the review following the receipt of information

[54] See the section entitled ''Coverage of Food and Drug Administration (FDA)-approved Contraceptives'' in FAQS about Affordable Care Act Implementation (PART XXVI), (May 11, 2015), available at *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf.*

sufficient to begin the review. We note that the processes specified in § 156.122(c) are only required in connection with requesting and gaining access to clinically appropriate non-formulary drugs, and are not required in connection with utilization management processes for drugs on the plan's formulary drug list. We also note that § 156.122(c) only applies to non-grandfathered individual and small group market plans that are required to provide EHB under section 2707(a) of the PHS Act and section 1302 of the Affordable Care Act, as well as to QHPs under §§ 156.200(b)(3) and 156.20. We will continue to monitor the implementation of the drug exceptions processes to determine whether further guidance on these processes is needed.

Comment: We received many comments supporting requiring coverage of medication assisted treatment for opioid addiction as an EHB. These comments cited cost effectiveness, clinical evidence, and inability to interchange MAT options in support of requiring that all MATs be covered as an EHB. Commenters noted a lack of covered providers and related services limiting access to appropriate MAT; a lack of and variation in coverage of specific types of treatments, such as methadone; utilization management practices for MAT as areas of concern and reasons to require coverage of MAT. Commenters also noted the lack of MAT coverage by certain new State base-benchmark plans, including explicit exclusions. Other commenters were not supportive of additional clarification on MAT coverage for substance use disorders or wanted to review a specific proposal for additional coverage, as MAT is required to be covered under certain United States Pharmacopeia (USP) categories and classes at § 156.122(a)(1). Commenters were also concerned about setting a precedent in which MAT coverage is treated differently from other EHB or drugs, noting that EHBs are required under the statute to be equal to the scope of benefits provided under a typical employer plan. Some commenters supported the use of Pharmacy & Therapeutics (P&T) Committees in making drug coverage determinations and stated they were concerned that any coverage requirements could restrict and impede P&T Committees' clinical judgment. Others commented that requiring MAT coverage could increase premiums.

Response: In October 2015, the President issued a Memorandum directing Federal Departments and Agencies to identify barriers to medication-assisted treatment for opioid use disorders and develop action plans to address these barriers. Both the EHB requirement and Federal mental health and substance use disorder parity requirements apply to QHP coverage of medications to treat opioid dependence. Because these requirements extend beyond QHPs, we anticipate issuing separate guidance with respect to MAT in the near future.

c. 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 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. 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.

Under the methodology established in the 2015 Payment Notice and amended in the 2015 Market Standards Rule for estimating average per capita premium for purposes of calculating the premium adjustment percentage, the premium adjustment percentage is calculated based on the projections of average per enrollee employer-sponsored insurance premiums from the NHEA, which is calculated by the Office of the Actuary. Accordingly, using the employer-sponsored insurance data, the premium adjustment percentage for 2017 is the percentage (if any) by which the most recent NHEA projection of per enrollee employer-sponsored insurance premiums for 2016 ($6,076) exceeds the most recent NHEA projection of per enrollee employer-sponsored insurance premiums for 2013 ($5,365).[55] Using this formula, we proposed and are finalizing the premium adjustment percentage for 2017 at 13.25256291 percent. We note that the 2013 premium used for this calculation has been updated to reflect the latest NHEA data. We are also finalizing the following cost-sharing parameters for calendar year 2017 based on our finalized 2017 premium adjustment percentage.

Maximum Annual Limitation on Cost Sharing for Calendar Year 2017. Under § 156.130(a)(2), for the 2017 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 2017, 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 13.25256291 percent for 2017 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 are finalizing the 2017 maximum annual limitation on cost sharing as proposed at $7,150 for self-only coverage and $14,300 for other than self-only coverage.

Comment: Two commenters said the annual rate of increase in the MOOP ($300 for individuals this year after a $250 increase last year, and $600 for other than self-only coverage this year on top of a $500 increase last year) is unsustainable and negatively affects enrollees' willingness to use prescription drugs, which in turn affects health outcomes. The commenters asked HHS to engage with stakeholders to develop an alternative methodology to calculate the maximum annual limitation on cost sharing.

Response: As discussed above, the maximum annual limitation on cost sharing is calculated based on the premium adjustment percentage for the

[55] See Projections of National Health Expenditures: Methodology and Model Specifications (Jul. 28, 2015), available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ProjectionsMethodology.pdf;* Projections of National Health Expenditures: Methodology and Model Specification (Sept. 18, 2013), available at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ProjectionsMethodology2012.pdf;* and Table 17: Health Insurance Enrollment and Enrollment Growth Rates (Jul. 22, 2015), available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html* (located in the NHE Projections 2014–2024—Tables link). For additional information, see, also, National Health Expenditure Projections 2012–2022, available at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Proj2012.pdf.*

[56] *See:* IRS, 26 CFR 601.602: Tax forms and instructions (May 2, 2013), available at *http://www.irs.gov/pub/irs-drop/rp-13-25.pdf.*

benefit year. The methodology established in 2015 to calculate the premium adjustment percentage is based on a projection of annual increases in per enrollee employer-sponsored insurance premiums from the National Health Expenditure Accounts (estimated by the CMS Office of the Actuary). HHS believes it is the best available source of projected growth for premium given statutory requirements and interaction with other measurements. However, as discussed in the 2015 Notice of Benefits and Payment Parameters (79 FR 13802), HHS intends to review the methodology for calculating annual premium growth after the initial years of reform-driven changes to benefits and plan design, after the premium trend is more stable, and as data on premiums become available.

Comment: One commenter expressed concern over a growing gap between the Affordable Care Act's maximum annual limitation on cost sharing and the Internal Revenue Service's out-of-pocket limit for high deductible health plans (HDHPs) used with health savings accounts. (The 2016 HHS maximum out-of-pocket limitation for other than self-only coverage was $600 above the 2016 IRS out-of-pocket limit on high deductible health plans for other than self-only coverage.) The commenter also expressed concern that the IRS limit is not announced for some months after the HHS limit is known, leading issuers to price products conservatively, and higher than they might otherwise if the IRS limit had been known.

Response: HHS and IRS are bound by different statutory parameters when calculating annual out-of-pocket limits. HHS uses the premium adjustment percentage described above to adjust the maximum out-of-pocket limit, and the IRS uses the Consumer Price Index, a measure of inflation, to adjust its out-of-pocket limitation.

d. 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 section 1402(c)(1)(B)(i) of the Affordable Care Act (that is, 73 percent, 87 percent, or 94 percent, depending on the income of the enrollee). 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 2017 maximum annual limitation on cost sharing would be $7,150 for self-only coverage and $14,300 for other than self-only group 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 2017 benefit year and our proposed results.

Consistent with our analysis in the 2014, 2015, and 2016 Payment Notices, we developed three test silver level QHPs, and analyzed the impact on AV of the reductions described in the Affordable Care Act to the estimated 2017 maximum annual limitation on cost sharing for self-only coverage ($7,150). The test plan designs are based on data collected for 2016 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 Exchanges. For 2017, the test silver level QHPs included a PPO with typical cost-sharing structure ($7,150 annual limitation on cost sharing, $2,175 deductible, and 20 percent in-network coinsurance rate), a PPO with a lower annual limitation on cost sharing ($4,800 annual limitation on cost sharing, $2,775 deductible, and 20 percent in-network coinsurance rate), and an HMO ($7,150 annual limitation on cost sharing, $3,000 deductible, 20 percent in-network coinsurance rate, and the following services with copayments 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 test QHPs meet the AV requirements for silver level health plans.

We then entered these test plans into the proposed 2017 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) (2/3 reduction in the maximum annual limitation on cost sharing), and 150 and 200 percent of the FPL (2/3 reduction), would not cause the AV of any of the model QHPs to exceed the statutorily specified AV level (94 and 87 percent, respectively). In contrast, the reduction in the maximum annual limitation on cost sharing specified in the Affordable Care Act for enrollees with a household income between 200 and 250 percent of FPL (1/2 reduction), would cause the AVs of two of the test QHPs to exceed the specified AV level of 73 percent. As a result, we proposed that the maximum annual limitation on cost sharing for enrollees in the 2017 benefit year with a household income between 200 and 250 percent of FPL be reduced by approximately 1/5, rather than 1/2. We further proposed 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 2/3, as specified in the statute, and as shown in Table 10. 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 noted 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 level. We did not receive comments on this proposal, and are finalizing the

reductions in the maximum annual limitation on cost sharing for 2017 as proposed.

We note that for 2017, 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 10—REDUCTIONS IN MAXIMUM ANNUAL LIMITATION ON COST SHARING FOR 2017

Eligibility category	Reduced maximum annual limitation on cost sharing for self-only coverage for 2017	Reduced maximum annual limitation on cost sharing for other than self-only coverage for 2017
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(i) (that is, 100–150 percent of FPL)	$2,350	$4,700
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(ii) (that is, 150–200 percent of FPL)	2,350	4,700
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(iii) (that is, 200–250 percent of FPL)	5,700	11,400

e. AV Calculation for Determining Level of Coverage (§ 156.135)

Section 2707(a) of the PHS Act and section 1302 of the Affordable Care Act direct issuers of non-grandfathered health insurance in the individual and small group markets, including QHPs, to ensure that plans meet a level of coverage specified in section 1302(d)(1) of the Affordable Care Act and codified at § 156.140(b). On February 25, 2013, HHS published the EHB Rule (78 FR 12833), implementing section 1302(d) of the Affordable Care Act, which required that, to determine the level of coverage for a given metal tier level, the calculation of AV be based upon the provision of EHB to a standard population. Section 156.135(a) establishes that AV is generally to be calculated using the AV Calculator developed and made available by HHS for a given benefit year. In the 2015 Payment Notice (79 FR 13743), we established at § 156.135(g) provisions for updating the AV Calculator in future plan years and in the proposed rule, we proposed to amend those provisions to allow for additional flexibility in our approach and options for updating of the AV Calculator in the future.

Specifically, we proposed that HHS will update the AV Calculator annually for material changes that may include costs, plan designs, the standard population, developments in the function and operation of the AV Calculator and other actuarially relevant factors. Under the amended regulation, we will continue to make updates to the AV Calculator, as we have in previous years, including updates to the trend factor, algorithms changes, and user interface changes. We will also update the claims data and demographic distribution being used in the AV Calculator as needed, and continue to update the AV Calculator's annual limitation on cost sharing based on a projected estimate to allow for compliance with § 156.130(a). Therefore, the major difference that we proposed under the revised § 156.135(g) was that the methodology, data sources, and trigger for making updates in the AV Calculator would be more flexible than the previous § 156.135(g). This amended provision will allow us more options in considering approaches to making changes in the AV Calculator, particularly as the health insurance market and the AV Calculator evolve, new methodological approaches are developed, and new data becomes available.

We would also not be required to make each of these changes each year, although we could include these types of material changes in our annual updating of the AV Calculator. We proposed that in developing the annual updates to the AV Calculator, we would continue to take into consideration stakeholder feedback on needed changes to the AV Calculator (through *actuarialvalue@cms.hhs.gov*) and to publicly release a draft version of the AV Calculator and the AV Calculator Methodology for comment before releasing the final AV Calculator. We are finalizing these provisions as proposed.

Comment: Commenters were concerned about the timing of the release of the AV Calculator, and wanted the AV Calculator to be available sooner. Certain commenters did not support the revised language without a timeframe. Commenters generally wanted the final AV Calculator to be available around January 1 of the preceding benefit year, in anticipation of State filing deadlines.

Response: We are finalizing the provision as proposed. One reason for changing § 156.135(g) is to provide HHS with the flexibility to update the AV Calculator sooner. We understand the importance for issuers and States to have time to use the final version of the AV Calculator to develop and adjust plan designs in advance of State filing deadlines. We believe that revised § 156.135(g) will give HHS added flexibility in changing the AV Calculator, which may result in HHS releasing the final AV Calculator earlier, such as by January 1 of the preceding benefit year. Regardless, we anticipate releasing the final AV Calculator no later than the end of the first quarter of the preceding benefit year.

Comment: Some commenters supported the flexibility for the trend factor calculation. Others expressed wanting predictable and consistent updates, wanting less frequent updates, and wanting an increase to the *de minimis* range.

Response: We recognize the importance of ensuring that the AV Calculator accurately reflects the current market and that changes to the AV Calculator minimize disruption to current plan designs through keeping AVs stable. We intend to carefully weigh these factors when making changes. We do not intend to make changes to the *de minimis* range at this time. The *de minimis* range is intended to allow plans to float within a reasonable range of +/− 2 percent.

We will also continue to work with stakeholders on the development of the AV Calculator updates. As noted above, in developing the annual updates to the AV Calculator, we will continue to take into consideration stakeholder feedback on needed changes to the AV Calculator (through *actuarialvalue@cms.hhs.gov*) and to publicly release a draft version of the AV Calculator and the AV Calculator Methodology for comment before releasing the final AV Calculator.

Additionally, we also intend to consult as needed with the American Academy of Actuaries and the NAIC on needed changes to the AV Calculator.

Comment: One commenter was concerned that the AV Calculator does not take into account the scope of networks and formularies. Other commenters asked for the Minimum Value Calculator to be updated consistently and discussed issues for large group plans that use the MV Calculator, such as accounting for the annual limitation on cost sharing.

Response: AV measures a plan's cost sharing generosity on the basis of the EHB being provided to a standard population (and without regard to the population to which that plan may actually provide benefits) to determine the level of coverage. AV is not intended to measure the scope of a network or formulary. All plans required to comply with AV must comply with EHB requirements (which establish the scope of benefits, including the formulary, being offered) and State and, in the case of QHPs, Federal laws and regulations establish a plan's network requirements.

We will work with the Department of Treasury and the Internal Revenue Service to consider whether further guidance is needed with regards to the MV Calculator. Updates to the MV Calculator are beyond the scope of this rulemaking.

f. Application to Stand-Alone Dental Plans Inside the Exchange (§ 156.150)

At § 156.150, we proposed revisions to increase the annual limitation on cost sharing for SADPs. To make adjustments to the annual limitation on cost sharing in subsequent years to keep pace with inflation, we proposed in paragraph (a)(1) that for a plan year beginning after 2016, the dollar limit applicable to a SADP for one covered child be increased by an amount equal to the product of that amount and the quotient of consumer price index for dental services for the year 2 years prior to the benefit year, divided by the consumer price index for dental services for 2016. In paragraph (a)(2), we proposed that the dollar limit for two or more covered children be twice the dollar limit for one child described in paragraph (a)(1) of this section. We sought comment on whether the premium adjustment percentage defined in § 156.130(e) should be used instead.

In paragraph (c), we proposed to define the dental CPI, which is a sub-component of the U.S. Department of Labor's Bureau of Labor Statistics Consumer Price Index specific to dental services. We would use the annual dental CPI published by the Department of Labor. In paragraph (d), we proposed that increases in the annual dollar limits for one child that do not result in a multiple of $25 will be rounded down, to the next lowest multiple of $25.

We are finalizing the provision with modifications to paragraphs (a)(1) and (2) to apply the indexing formula to plan years beginning after 2017 and with a modification of the language of the formula for increasing the annual limitation on cost sharing for purposes of clarity.

Comment: Several commenters supported our proposed approach to raise the annual limitation on cost sharing over time using the CPI for dental services. Some commenters asked that the proposal be implemented sooner than for plan years beginning after 2016. Others requested using the 2014 CPI for dental services rather than the 2016 in order to have the annual limitation on cost sharing increase in the next few years. Others asked that we also consider increasing the annual limitation on cost sharing to a set level and then applying the indexing formula via the CPI for dental services in order to meet HHS's stated interest in providing preventive care without cost sharing. We also received several comments requesting clarification of the formula.

Response: When we established specific values for the annual limitation on cost sharing for SADPs in previous rules,[57] we intended to eventually index the limitation to keep pace with inflation and moderate potential increases in premiums, similar to the annual limitation on cost sharing for medical QHPs. Without such an increase, over time we could see an increase in SADP premiums and fewer affordable dental options for consumers. We believe that this formula balances the need to establish a process to increase the annual limitation on cost sharing over time against concerns with increasing the maximum financial liability to consumers.

In the regulatory impact assessment in the proposed rule, we noted our desire for consumers to have access to preventive services without cost sharing. We acknowledge that this may be difficult to achieve at the low AV level of 70 percent. However, we believe that to implement a one-time increase to the annual limitation on cost sharing by a significant amount would be overly burdensome for consumers.

Accordingly, we are finalizing the proposal as proposed, with minor modifications. We are modifying paragraphs (a)(1) and (2) to apply the indexing formula to plan years beginning after 2017 rather than 2016. We acknowledge that applying the indexing formula to plan years beginning after 2017 will ensure that the first application of the formula, for the 2018 benefit year, will result in neither an increase nor a decrease in the annual limitation on cost sharing for that benefit year. However, we are seeking to balance stability in plan designs with the desire to increase the annual limitation on cost sharing to keep pace with inflation. We will continue to monitor the increase over time to ensure we are working towards our stated goals. As noted in the proposed rule, we will propose and finalize the annual increase to the dental annual limitation on cost sharing according to the formula specified here in the annual Payment Notice.

We did not receive any comments suggesting that we use the premium adjustment percentage defined in § 156.130(e) instead. We did not receive any comments opposing our proposal to increase the annual limitation on cost sharing in $25 increments and will finalize this provision as proposed.

We also are making a modification to the wording of the formula, though not to its meaning. Under this final rule, as under the proposal, the annual limitation on cost sharing will be increased by the same percentage the CPI for dental services increased between 2016 and the year that is 2 years prior to the applicable benefit year.

Comment: A commenter asked that we clarify that the annual limitation on cost sharing would never be reduced. Another requested clarification whether the provisions would be applied to off-Exchange SADPs.

Response: We are clarifying that the proposed formula will not be used to reduce the annual limitation on cost sharing for SADPs. The updated formula language in paragraph (a)(1) specifically notes that the annual dollar limit is *increased* by the percent increase of the consumer price index for dental services. We do not include a provision that would require a reduction.

We also note that all Exchange-certified SADPs must meet the same certification standards, including the annual limitation on cost sharing, regardless of whether they are offered on or off Exchanges.

[57] Exchange Establishment Rule, 77 FR 18309 (Mar. 27, 2012); EHB Rule, 78 FR 12833 (Feb. 25, 2013).

5. Qualified Health Plan Minimum Certification Standards

a. Network Adequacy Standards (§ 156.230)

At § 156.230, we established the minimum criteria for network adequacy that health and dental plan issuers must meet to be certified as QHPs, including SADPs, in accordance with the Secretary's authority in section 1311(c)(1)(B) of the Affordable Care Act. Section 156.230(a)(2) requires all issuers to maintain a network that is sufficient in number and types of providers to assure that all services will be accessible without unreasonable delay. Section 156.230(b) sets forth standards for access to provider directories requiring issuers to publish an up-to-date, accurate, and complete provider directory for plan years beginning on or after January 1, 2016, and § 156.230(c) requires QHPs in the FFE to make this provider directory data available on its Web site in an HHS-specified format and also submit this information to HHS in a format and manner and at times determined by HHS.

(1) State Selection of Minimum Network Adequacy Standards

The NAIC's Network Adequacy Model Review Subgroup has completed significant work in the area of network adequacy, which includes finalization of a Network Adequacy Model Act, which can be found at *http://www.naic.org/store/free/MDL-74.pdf,* that States can adopt in whole or in part. We will continue to monitor the work of the NAIC in this area and of States' implementation of these standards, and look forward to partnering with States and the NAIC in developing and promulgating network adequacy protections. In the interest of furthering this work, we proposed a number of standards related to network adequacy.

In recognition of the traditional role States have in developing and enforcing network adequacy standards, we proposed that FFEs would rely on State reviews for network adequacy in States in which an FFE is operating, provided that HHS determined that the State uses an acceptable quantifiable network adequacy metric commonly used in the health insurance industry to measure network adequacy.

We proposed that HHS would determine that a State's network adequacy assessment methodology meets the standard above if the State selects one or more standards from a list of metrics provided by HHS and applies them prospectively to the QHP issuers in the State. We anticipated including at least the following metrics in the list:

- Prospective time and distance standards at least as stringent as the FFE standard.
- Prospective minimum provider-covered person ratios for the specialties with the highest utilization rate for its State.

We proposed that after HHS discussed with States their selection to determine whether the State's network adequacy standard would be acceptable under the standard above, we would notify issuers via regulatory guidance about whether the State standards or Federal default standard would apply.

We proposed that when HHS determined that a State's network adequacy standard is acceptable under the standard above, the State would certify to the FFE which plans meet the network adequacy standard, and the FFE in that State would rely on the State's review for purposes of determining whether a QHP meets the requirements under § 156.230(a)(2), although those issuers would still be required to submit to HHS provider data, attest to the HHS network adequacy certification requirements, and meet other applicable HHS standards, including the other standards under § 156.230.

In the proposed rule, we stated that for States that do not review for network adequacy, or do not select a standard as described above, the FFE would conduct an independent review under a Federal default standard. We proposed the Federal default standard to be a time and distance standard. For the certification cycle for plan years beginning in 2017, we stated that we anticipated evaluating the QHP issuer networks under this standard based on the numbers and types of providers, in addition to their general geographic location. The standard proposed involved using a time and distance standard at the county level. We also stated that we were considering using standards similar to those used in Medicare Advantage, utilizing the National Provider Identifier database, and focusing on the specialties that enrollees most generally use. Further, we explained that HHS was also carefully considering other network standards, including those of individual States, accrediting entities, and Federal health care programs, as it developed the time and distance standards for the FFEs.

We also stated that the proposed county-specific time and distance parameters that plans would be required to meet, including specifications for specific provider and facility types, would be detailed annually in conjunction with the Letter to Issuers.

We also proposed that issuers that did not meet the specified standards would be able to submit a justification to account for any variances, and that the FFE would review the justification to determine whether the variance is reasonable based on circumstances, such as the availability of providers and variables reflected in local patterns of care.

We explained that we did not intend in establishing these default standards to prohibit certification of plans with narrow networks or otherwise impede innovation in plan design. Instead, we stated that we intended to establish a minimum floor consistent with the levels generally maintained in the market today, so that generally a very small number of plans would be identified as having networks deemed inadequate. Our discussion of the Federal default standard was intended to provide issuers with more transparency regarding our certification processes. In that discussion, we clarified that the process would be designed and implemented to achieve results similar to those yielded by the reviews conducted by the FFEs in prior certification cycles. We explained that we believed this standard would promote predictability for issuers in the course of certification. We noted in the proposed rule that multi-State plan options will be considered to meet the network adequacy requirements under § 156.230(a)(2) if they meet network adequacy standards established by OPM.

For the reasons noted below, we are not finalizing § 156.230(d) as proposed at this time and will continue to work with States to determine how to best ensure reasonable access while preventing duplicate review.

Comment: Many commenters raised concerns about the use of a time and distance Federal default standard, and stated the new NAIC Network Adequacy Model Act does not include time and distance standards. Commenters also raised concerns that the proposed standard could increase health care costs, would not adequately address network adequacy issues in all areas, and would not fit all types of plans, and numerous commenters asked that HHS give States time to enact the new NAIC Network Adequacy Model Act rather than implementing the standard in the final rule.

Response: We appreciate the concerns raised and in response are declining to finalize § 156.230(d) as proposed for the 2017 plan year. Our intention is to give States time to adopt the NAIC Network

Adequacy Model Act provisions. We note in particular that the NAIC Network Adequacy Model Act highlights ''specific quantitative standards to ensure adequate access that carriers must, at a minimum, satisfy in order to be considered to have a sufficient network,'' and these include provisions requiring a minimum numbers of providers, and setting limits on travel times and wait times. The Act explains how these standards can be incorporated either in statute or in regulation. Further, we note that the NAIC Network Adequacy Model Act was approved unanimously by all States and Washington, DC, and the NAIC has stated that it will be a priority of the organization to have a majority of States adopt the NAIC Network Adequacy Model Act within 3 years. We note our expectation that all States, including FFE States, will actively implement these provisions, and we look forward to monitoring States' progress this year, with a particular view to avoiding duplicative Federal and State review processes. We will revisit this proposal in future rulemaking. We will continue the process used in previous years to review network adequacy as part of the annual certification process, and will review network data for reasonable access.

For transparency, we are publishing separately details of the FFEs' internal QHP certification process for network adequacy, including the metric used for the internal review, to assess plans for network adequacy.[58] These standards are consistent with those we have used in the past to assess potential QHPs for compliance with the network adequacy requirements; we believe that providing additional transparency about these standards will help issuers with their network planning.

Comment: Many commenters expressed support for the proposed time and distance standards, and many requested specific standards for specific types of specialty care including pediatrics, cancer centers, women's health, and transplant providers. Commenters also requested that additional standards be added to the quantitative standards, including requirements regarding wait times, language services, telehealth, disability accessibility and reasonable access being provided at the lowest cost sharing tier. Some commenters also expressed concerns about the applicability of time and distance to dental issuers and urged that other standards be used. Some commenters supported the use of time and distance standards for SADPs. Some commenters requested that the time and distance standards be expanded to SBEs and multi-State plans, and that they be used as the required standards, not a default.

Response: We appreciate the comments; however, we are not finalizing the default time and distance standard at this time. As discussed above, our intention is to give States time to adopt the NAIC Network Adequacy Model Act provisions and implement associated standards.

Comment: Many commenters offered suggestions for changing and expanding the State metrics listed in the preamble, including keeping or removing the time and distance metric and provider-covered person ratios, adding the network sufficiency metrics from the recently completed NAIC Network Adequacy Model Act, adding a metric related to standards for wait times, and altering the two listed metrics to specify that they apply to specialties and subspecialties. Some commenters suggested we implement an effective network access review standard comparable to the effective rate review standard by State.

Response: We are not finalizing our proposal establishing a minimum quantitative State network adequacy measurement at this time. We wish to provide States time to adopt the NAIC Network Adequacy Model Act provisions and associated standards.

Comment: Some commenters suggested that HHS provide that only providers available through the plan's lowest tier of cost-sharing be counted for purposes of determining a network's adequacy.

Response: We intend to monitor the practice of tiering of providers and will consider implications of the practice for network adequacy review in the future. We remind all issuers, including those that use tiered networks, that they must continue to meet the current requirement in § 156.230(a)(2) to provide reasonable access to all covered services at all times throughout the plan year.

As States continue their work to implement the NAIC Network Adequacy Model Act, we will continue to use quantitative time-distance standards in our review of plans for QHP certification on the FFEs, and will be providing details of the criteria for review in the annual Letter to Issuers.

We are finalizing a number of policies relating to network adequacy. We are finalizing two provisions to address provider transitions in the FFE and a standard for all QHPs governing cost sharing that would apply in certain circumstances when an enrollee receives EHB provided by an out-of-network ancillary provider at an in-network setting. We are also finalizing our proposed policy regarding standardized categorization of network breadth for QHPs on the Federal platform.

(2) Additional Network Adequacy Standards

Under proposed § 156.230(e), which we are finalizing as paragraph (d), we proposed two new requirements to address provider transitions. First, we proposed new § 156.230(e)(1) to require QHP issuers in all FFEs to notify enrollees about a discontinuation in their network coverage of a contracted provider. We proposed that a QHP in an FFE be required to make a good faith effort to provide written notice of a discontinued provider, 30 days prior to the effective date of the change or otherwise as soon as practicable, to all enrollees who are patients seen on a regular basis by the provider or receive primary care from the provider whose contract is being discontinued, irrespective of whether the contract is being discontinued due to a termination for cause or without cause, or due to a non-renewal.

We also proposed that a discontinued provider include both a provider that is being involuntarily removed from the network, and a provider that is voluntarily leaving the network. To satisfy this requirement, we stated that we expect the issuer to try to work with the provider to obtain the list of affected patients or to use its claims data system to identify enrollees who see the affected providers. We said that we would encourage issuers, as part of the notice to consumers, to notify the enrollee of other comparable in-network providers in the enrollee's service area, provide information on how an enrollee could access the plan's continuity of care coverage, and encourage the enrollee to contact the plan with any questions.

Second, we proposed a new § 156.230(e)(2) to require that QHP issuers in all FFEs ensure continuity of care for enrollees in cases where a provider is terminated without cause. Specifically, we proposed to require the issuer, in cases where the provider is terminated without cause, to allow an enrollee in active treatment to continue treatment until the treatment is complete or for 90 days, whichever is shorter, at in-network cost-sharing rates. We proposed the following definition of active treatment in paragraph (e)(2): (1) An ongoing course of treatment for a life-threatening condition; (2) an

[58] Final 2017 Letter to Issuers in the Federally-facilitated Marketplaces (Feb. 29, 2016).

ongoing course of treatment for a serious acute condition; (3) the second or third trimester of pregnancy; or (4) an ongoing course of treatment for a health condition for which a treating physician or health care provider attests that discontinuing care by that physician or health care provider would worsen the condition or interfere with anticipated outcomes. In relation to the proposed definition of active treatment, we stated that an ongoing course of treatment includes treatments for mental health and substance use disorders that fall within the proposed definition. For the purposes of the active treatment definition, we proposed to interpret a life-threatening condition as a disease or condition for which likelihood of death is probable unless the course of the disease or condition is interrupted; and a serious acute condition as a disease or condition requiring complex on-going care which the covered person is currently receiving, such as chemotherapy, post-operative visits, or radiation therapy. Finally, we proposed under paragraph (e)(2)(ii) that any decisions made for a request for continuity of care be subject to the issuer's internal and external grievance and appeal processes in accordance with applicable State or Federal law or regulations. We solicited comments on several issues related proposed § 156.230(e), such as the definitions of key terms and timeframes, when these provisions should apply, whether exceptions should be allowed for States that already have requirements, whether additional provisions should be allowed for continuity of care in cases of pregnancy as far as extending beyond 90 days and whether that care should limited to obstetric care and whether other provisions are needed to protect an enrollee when a provider contract is terminated.

We are finalizing these requirements as proposed, with certain modifications to better align with the NAIC Network Adequacy Model Act, including extending continuity of care coverage for the second or third trimester of pregnancy through the postpartum period and codifying the definitions of life-threatening condition and serious acute condition. Additionally, we note that these standards are not intended to, and do not, preempt State provider transition notices and continuity of care requirements, and that we intend to defer to a State's enforcement of substantially similar or more stringent standards.

Comment: Many commenters supported deferring to State provider transition policies instead of the proposals in the proposed rule, with some commenters only supporting deference when the State has stronger consumer protections. Justifications for deferring to State provider transition policies included problems with conflicting State law and the associated burden with conflicting requirements. In the absence of applicable State laws, some commenters recommended aligning standards to those in the NAIC Network Adequacy Model Act that are administratively feasible or allow issuers to maintain their current practices.

Response: We are finalizing these proposed provider transition policies in § 156.230(d), but note that these standards are not intended to, and do not, preempt State provider transition notices and continuity of care rules, and that we would defer to a State's enforcement of substantially similar or more stringent requirements. This flexibility would apply to any State that chooses to enact these parts of the NAIC Network Adequacy Model Act under section 6(L).[59] We recognize that the NAIC Network Adequacy Model Act differs in certain respects from our requirements under § 156.230(d)(1) and (2); we intend to monitor States' implementation of the NAIC Network Adequacy Model Act and may consider revisions to this policy in the future if needed.

Comment: Some commenters wanted more than 30 days' notice, or asked that the timeframes align with the NAIC Network Adequacy Model Act. Some commenters supported requiring all enrollees of a primary care provider to be required to be notified. Other commenters stated that the notices should not be required if providers are leaving a practice with other in-network providers from that practice available. Some commenters advocated for the development of enrollee registries through which enrollees can be informed of changes or receive a list of providers being discontinued. Some commenters expressed concern about the value of notifications, and others expressed concern about the confidentiality of provider notices.

Response: We are finalizing the notice requirements at § 156.230(d)(1) as proposed. While our notice requirements are not the same as those in the NAIC Network Adequacy Model Act, we did consider these notice requirements and requirements from other programs in proposing § 156.230(d)(1). We understand that issuers need timely notification from the provider leaving the network in order to meet the 30-day timeframe, but as the issuer has the contracting relationship with the provider, the issuer is in the best position to require providers to provide a termination notice to the issuer.

We note that paragraph (d)(1) requires that the issuer make a good faith effort to provide the required notification. We understand that there are certain situations that cannot be anticipated, and in those cases, we would expect the issuer to send the notice to the enrollee as soon as practically possible. Issuers can send the notification to the enrollee electronically or by mail. In response to comments, we clarify that when the provider is leaving a practice, and as a result will no longer belong to the issuer's network, but other providers from the practice remain in-network, paragraph (d)(1) would not require the issuer to provide notice to the enrollees. We believe in those cases the provider's practice is better positioned to provide notification to the enrollee.

Comment: Comments on the appropriate definition of ''regular basis'' generally either preferred to leave the definition to the discretion of the issuer or suggested that we define it to include an enrollee that has received services from the provider within one year. Some commenters specifically wanted the definitions related to primary care from the NAIC Network Adequacy Model Act to be incorporated in the rule to clarify how the provisions under paragraph (d)(1) should apply. Some commenters wanted additional protections in cases of provider transitions, such as special enrollment periods for provider terminations, or limits on the ability of issuers to terminate providers mid-year (or recourse for the providers in the event of such a termination), while other comments expressed concern about the difficulty in coordinating with providers to identify affected enrollees. Other commenters wanted issuers to be required to include information in the notice about other comparable in-network providers and to inform the enrollee of rights to receive continuity of coverage.

Response: The purpose of § 156.230(d)(1) is to ensure that enrollees are notified of changes to their provider network on a timely basis. At this time, we are not extending this provision to include additional requirements. However, notwithstanding a provider termination, all QHP issuers are required under § 156.230(b) to maintain a network that is sufficient in number and types of providers, including providers that specialize in mental health and substance abuse services, to assure that

[59] See *http://www.naic.org/store/free/MDL-74.pdf.*

all services will be accessible without unreasonable delay. For purposes of paragraph (d)(1), we will not finalize a uniform definition of regular basis at this time, and will permit issuers to implement a reasonable definition of that term. The NAIC Network Adequacy Model Act similarly did not include a definition of regular basis. For purposes of paragraph (d)(1), we note that, in alignment with the NAIC Network Adequacy Model Act, we generally understand primary care to mean health care services for a range of common physical, mental or behavioral health conditions provided by a physician or non-physician primary care provider, and a provider of primary care to mean a participating health care professional designated by the issuer to supervise, coordinate, or provide initial care or continuing care to an enrollee, and who may be required by the issuer to initiate a referral for specialty care and maintain supervision of health care services rendered to the covered person, but that an issuer may implement reasonable definitions of these terms. To identify enrollees who see a provider who is terminating, we expect the issuer to work with the provider to obtain the list of affected patients, use its claims data system to identify enrollees who see the affected providers, or use another reasonable method. The issuer does not need to use more than one method. For the written notice required under paragraph (d)(1), we encourage issuers to notify the enrollee of other comparable in-network providers in the enrollee's service area, provide information on how an enrollee may access the plan's continuity of care coverage, and encourage the enrollee to contact the plan with any questions.

Comment: Some commenters stated that continuity of care should cover non-renewals and terminations without cause; other commenters disagreed. Commenters sought clarifications regarding the cost sharing during the continuity of care period, and some commenters asked us to adopt provisions from the NAIC Network Adequacy Model Act, including providing that the issuer is only required to provide the continuity of care if the provider agrees to accept the previously contracted in-network rate and to ensure protections against balance billing. Some stated that failure to include such a request could increase premiums.

Response: While we expect issuers to negotiate with a provider for payment for services under § 156.230(d)(2), issuers would only be responsible for paying to a provider what was previously being paid under the same terms and conditions of the provider contract, including any protections against balance billing, if the provider agrees to provide care under § 156.230(d)(2). We cannot require non-contracted providers to accept a particular payment rate under § 156.230(d)(2). Therefore, nothing under § 156.230(d)(2) would prohibit balance billing for non-contracted providers in accordance with section 1302(c)(3)(B) of the Affordable Care Act and § 155.20. This means that an enrollee could be balance billed for the services under § 156.230(d)(2), absent another prohibition on balance billing in this situation, and those balance billing amounts would not be required to count toward the plan's annual limitation on cost sharing established at § 156.130.

In response to comments, we are limiting paragraph (d)(2) to cases where the provider is terminated without cause, including non-renewals without cause, and clarify that § 156.230(d)(2) does not apply in cases where the contract is terminated or not renewed with cause. A termination or non-renewal without cause could be initiated by either the issuer or the provider or could be mutual. In any of these cases, enrollee continuity of care should be ensured. Furthermore, we clarify that if the enrollee remains in the same plan across plan years, § 156.230(d)(2) will apply across plan years. However, if an enrollee switches plans, § 156.230(d)(2) would not apply, since there would not necessarily be an expectation that the same provider would be available under the new plan.

Comment: Some commenters sought clarifications or expansions of the proposed definition of the course of active treatment, such as changes that would require inclusion of certain conditions or transitional coverage of drugs. While some commenters sought clarifications on the definition of active treatment or wanted the issuer's medical director to make the determination of whether an enrollee was in the course of active treatment, commenters generally supported the proposed definition of ''active treatment'' and our proposal that would make the continuity of coverage rule subject to internal and external appeal processes. Commenters supported requiring continuity of coverage for pregnancy through the post-partum period. Some commenters also sought 90 days as the minimum transitional period, not the maximum period for continuity of care coverage, or urged us to adopt a longer or shorter period.

Response: We are not making changes to the definition of ''active treatment'', except to amend the definition to ''active course of treatment'' to align with the language in the NAIC Network Adequacy Model Act. This change is not intended to alter the meaning of the proposed rule. We are also finalizing, to align with the NAIC Network Adequacy Model Act, the definitions of a life-threatening condition as a disease or condition for which likelihood of death is probable unless the course of the disease or condition is interrupted; and a serious acute condition as a disease or condition requiring complex ongoing care which the covered person is currently receiving, such as chemotherapy, radiation therapy, or post-operative visits. For the purposes of the active course of treatment definition, an ongoing course of treatment includes treatments for mental health and substance use disorders that fall within the definition of active course of treatment. Additionally, if the enrollee has successfully transitioned to a participating provider, if the benefit limitations of the plan are met or exceeded, or if care is not medically necessary, § 156.230(d)(2) would no longer apply to the enrollee.

In response to comments supporting the extension of this policy to cases of pregnancy, we are revising the definition of active course of treatment to include the second or third trimester of pregnancy through the postpartum period. We are leaving the definition of what constitutes ''postpartum period'' and the scope of related services to the reasonable interpretation of the issuer.

At § 156.230(f), which we are now finalizing as paragraph (e), we proposed to require, notwithstanding § 156.130(c) of the subpart, that for a network to be deemed adequate, each QHP that uses a provider network must count cost sharing paid by an enrollee for an EHB provided by an out-of-network provider in an in-network setting under certain circumstances towards the enrollee's annual limitation on cost sharing. Alternatively, we proposed that the plan could provide a written notice to the enrollee at least 10 business days before the provision of the benefit that additional costs may be incurred for EHB provided by an out-of-network provider in an in-network setting, including balance billing charges, unless such costs are prohibited under State law, and that any additional charges may not count toward the in-network annual limitation on cost sharing.

We solicited comments on whether 10 business days' advance notice is the appropriate timeframe. We also sought comment on whether issuers should be

required to provide customized information to the consumer (including information on potential in-network providers) or if a form notification would be sufficient. We proposed that this policy would apply to all QHP issuers, in all Exchanges.

We are finalizing our proposed policy, with four modifications. First, we provide that this policy would only apply to cost sharing paid by an enrollee for an EHB provided by an out-of-network *ancillary* provider in an in-network setting. Second, we are shortening the timeframe from 10 business days to the longer of the issuer's prior authorization timeline (that is, when the issuer would typically respond to a prior authorization request submitted timely) or 48 hours prior to the scheduled service. Third, we are finalizing this proposal so that it will take effect beginning for the 2018 benefit year. Fourth, we are making a minor edit for clarity.

Comment: Many commenters supported HHS's efforts to address surprise out-of-pocket costs for consumers. Other commenters supported the proposal, but felt that it did not go far enough to protect consumers, and stated that HHS should consider including a prohibition on balance billing or otherwise restricting consumer financial responsibility in these scenarios. Other commenters thought that it may be difficult for consumers to locate an in-network provider within this timeframe. Commenters also suggested expanding the proposal to include situations in which an in-network provider is not available, when the provider directory is not up to date, and emergency care.

Several commenters did not support our proposal, and asked that States be given the time and discretion to implement network adequacy standards. Others requested that HHS adopt NAIC Network Adequacy Model Act provisions instead. Other commenters were concerned that the proposal may have unintended consequences, such as disincentivizing providers from contracting with issuers in order to be able to balance bill consumers, or incentivizing consumers and out-of-network providers to elect to perform procedures at an in-network facility.

Response: We are finalizing, for the 2018 and later benefit years, a modified § 156.230(e) to count services provided by an out-of-network ancillary provider in an in-network facility towards the in-network annual limitation on cost sharing if the issuer does not provide timely notice, with the modifications described above. We did not propose to prohibit balance billing by out-of-network providers or limit the financial liability associated with out-of-network services to consumers. Our intent in establishing this policy beginning for the 2018 benefit year is to permit us to monitor ongoing efforts by issuers and providers to address the complex issue of surprise out-of-network cost sharing at in-network facilities across all CMS programs in a holistic manner, and amend our policy in the future to accommodate progress on this issue, if warranted.

While not a solution to all adverse financial consequences of receiving treatment from an out-of-network provider in this situation, we believe the policy we are finalizing will help provide transparency and ensure that consumers receive notice of the possible consequences where an out-of-network ancillary provider may be seen and are provided some mitigation of these consequences where proper, timely notice is not provided by the issuer. We believe that this policy provides a measure of financial protection for consumers against surprise out-of-network cost sharing, while maintaining the larger part of the QHP's cost-sharing structure and avoids significant impacts on premiums.

We are making a modification to this policy to limit its application to ancillary providers (that is, the provider of a service ancillary to what is being provided by the primary provider, such as anesthesiology or radiology) rather than the services supplied by the primary provider. In response to comments, we were concerned that the proposed policy could have had the unintended consequence of providing for reduced cost sharing for a primary provider, such as a surgeon *known* to be out-of-network. We acknowledge commenters' concerns that as previously written, the policy could allow for a consumer who has selected an out-of-network provider to deliberately seek to have the services rendered in an in-network facility in order to reduce cost sharing. We believe that this modification will address this concern.

We intend to continue to monitor these situations, including issuers' timely compliance with this provision to consider whether further rulemaking is needed. Lastly, as we stated in the proposed rule, this proposal is not intended to, and does not, preempt any State laws on this topic.

Comment: Some commenters supported the requirement that issuers notify consumers of the potential for additional cost-sharing from out-of-network providers, but did not support the exception for issuers to not count the cost sharing towards the annual limitation on cost sharing. Others thought that the notification timeframe of 10 days was arbitrary, not long enough for consumers to arrange in-network care, or too long because prior authorization frequently happens closer to service delivery. Some commenters requested that facilities be required to notify consumers about whether or not providers were in-network for a consumer. Others noted that the 10 days' notice timeframe prior to the service may incentivize issuers to delay approval to utilize the notification exception.

Commenters also provided feedback on the type of information that should be included in a notice—many suggested that issuers be required to include information on available network providers, information on costs, and how a consumer could appeal a determination. Other commenters thought the notification process was overly burdensome for issuers, especially if customized information was required.

Response: In response to comments, we are modifying the 10-day timeline to account for issuers' prior authorization timelines. We are requiring notice from issuers by the longer of the issuer's prior authorization timeline (that is, when the issuer would typically provide the prior authorization) or 48 hours. This new timeline is more in line with existing issuer prior authorization timelines and will be less administratively burdensome for QHP issuers to implement, while providing consumers with the same time period to adjust their plans that they would have with respect to notification of prior authorization.

We are also finalizing our proposal that a form notice be provided to the enrollee in these circumstances indicating that additional costs may be incurred for an EHB provided by an out-of-network ancillary provider in an in-network setting, including balance billing charges, unless such costs are prohibited under State law, and that any additional charges may not count toward the in-network annual limitation on cost sharing. While customized information for each consumer is preferable, we understand that creating such a notice may be burdensome to QHP issuers and may delay the notification process. Additionally, the provider directories that QHP issuers must provide may ease the burden on the enrollee to find an appropriate in-network provider. Therefore, while we are not requiring that customized information be provided to the enrollee in these circumstances, including

information on available network providers, costs, and how a consumer could appeal a determination, we strongly encourage QHP issuers to provide that information.

Comment: Commenters asked if § 156.230(e), which was proposed § 156.230(f), would apply to QHPs with tiered networks or QHPs that do not provide out-of-network services. Another commenter asked for clarification on whether this provision would apply to QHPs on and off Exchanges. Other commenters asked HHS to clarify that this does not apply to emergency services which are already covered by § 147.138(b).

Response: We clarify that § 156.230(e) applies to QHPs, both on and off Exchanges, and to QHPs with tiered networks, but it does not apply to QHPs that do not cover out-of-network services. It also does not apply to emergency services, which are governed by other Federal regulations.

Comment: Several commenters requested that § 156.230(d) and (e) not apply to SADPs as the NAIC determined that these types of standards were not necessary for dental plans. The commenters stated that the structure of SADPs and the services covered by SADPs are different from medical plans as dental services are scheduled well ahead of time, the course of treatment does not include more serious conditions, and services are almost uniformly provided in the dentist's office.

Response: While we agree that these provisions are more suitable to medical services, § 155.1065 provides that SADPs must meet QHP certification standards, except for any certification requirement that cannot be met because the SADP is an excepted benefit that provides only a limited scope of coverage. However, we also believe due to the nature of these policies and the services provided by SADPs that any instances in which a SADP would need to apply these provisions would be rare.

(3) Other Comments on the Preamble to § 156.230

In the proposed rule, we solicited comments on a number of other network adequacy standards, including standards included in the work being done by the NAIC's Network Adequacy Model Review Subgroup. Our solicitation of comment included:

- Whether a QHP in an FFE should have a network resilience policy for disaster preparedness. Network resilience refers to the provider network's capacity to withstand and recover from natural or man-made disasters that may threaten enrollees' continuous access to quality care.
- Whether measuring network adequacy based on enrollee wait times for scheduled appointments, including the variation in wait times depending on the type of provider, such as for primary care or non-primary care services, and whether we should add a wait time standard as an option under the proposed permissible State standards mentioned in the proposed rule, or if we should apply a broad wait time standard across QHPs in the FFEs.
- Whether an issuer should be required to survey all of its contracted providers on a regular basis to determine if a sufficient number of network providers are accepting new patients.
- Whether issuers should be required to make available their selection and tiering criteria for review and approval by HHS and the State upon request.

We also stated that we were considering providing on HealthCare.gov a rating of each QHP's relative network coverage. This rating or classification would be made available to a consumer when making a plan selection. We explained that such a rating would help an enrollee select the plan that best meets his or her needs, and that we anticipated that this analysis would compare the breadth of the QHP network at the plan level as compared to the breadth of the other plan networks for plans available in the same geographic area.

We stated that we anticipated analyzing the QHP network by calculating the number of specific providers that are accessible within specified time and distance standards. We explained that we would then classify the QHP networks into three categories. We stated that we were considering performing the calculation based on the provider information submitted by all QHP issuers in the existing network adequacy FFE QHP certification template.

In the proposed rule, we explained that this network breadth rating would allow an enrollee to better understand plans' designs, and, like other consumer tools, could help improve plan satisfaction. We stated that we anticipated providing additional details about how we would classify networks in the Letter to Issuers and in the QHP certification instructions, and we solicited comments on what types of methods should be used to identify each network's breadth, what specific specialties should be included in the analysis, what sorts of adjustments should be made to address provider shortages, and other possible data sources to obtain information about available providers in the area. We also welcomed comments on the best way to make this information available to consumers. We intend to implement this proposal for open enrollment for the 2017 benefit year, if following consumer testing we determine that we can display this information in a manner useful to consumers. At this time, we plan to provide the classifications of network breadth for each plan at the county level. These classifications will be determined by calculating the percentage of providers in a plan's network, compared to the total number of providers in QHP networks available in a county. We plan to provide additional details on this methodology in the Letter to Issuers.

Comment: Commenters had concerns about Federal requirements on network resilience, such as geographic variation issues. Others generally support network resilience policies offering recommendations, such as broad standards, deferring to States if they have strong standards, or Medicare standards.

Response: We intend to work with stakeholders to consider best practices for network resilience policies. We want to ensure that any standards that we consider in this area are reasonable and operationally feasible, and take into account geographical variation.

Comment: Some commenters had concerns about requiring providers to be surveyed on whether they are accepting new patients because of concerns about accuracy of this reporting, the associated difficulty and burden on issuers and providers, the risk of undermining current efforts by stakeholders to improve data quality, and concerns about ''accepting new patients'' being a poor standard for determining network sufficiency. Other commenters generally supported requiring issuers to survey providers on whether they are accepting new patients, as the information could be used to update the provider directory.

Response: In the 2016 Payment Notice, we finalized requirements under § 156.230(b) 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. We also stated that all the required data, including information on whether a provider is accepting new patients, are critical for consumers to

make educated decisions about their health coverage. While we believe that it is important that enrollees have access to providers who are willing to accept new patients and issuers should ensure providers are available within the network, we intend to continue to monitor this issue, including industry's efforts in this area, to consider whether further requirements are needed.

Comment: Some commenters had concerns about issuers being required to provide selection and tiering criteria, noting the information is proprietary and that greater regulatory authority over network adequacy could have a chilling effect on network and product design. Other commenters supported such a provision. Many noted concerns that issuers are currently only making selection and tiering determinations on costs and not quality, and oversight of this criteria could prevent discrimination.

Response: We encourage issuers to be more transparent about selecting and tiering criteria. We believe that transparency of selecting and tiering criteria would help enrollees and providers better understand how the issuer designed its network, which could help enrollees use the network more effectively and efficiently.

Comment: Some commenters opposed a wait time standard, stating it is difficult to measure and assess consistently across providers, operationally and technically challenging for issuers, does not take into account quality, and would be problematic to apply across all FFEs given State variation. Other commenters supported requiring issuers to comply with wait time standards. Many supported applying such a requirement to all QHPs or all QHPs in FFEs.

Response: We understand that a Federal wait time standard would need to take into consideration market and geographical variation of States. We intend to continue to monitor the use of and development of wait time standards.

Comment: Some commenters supported providing network breadth information to consumers at the time of plan selection, and supported the implementation we described. Other commenters raised concerns about a rating system, believing it might be problematic because it does not factor in quality and could be confusing. Some commenters requested comprehensive consumer testing. Some commenters also requested that the rating information should include both physicians and hospitals.

Response: We plan to proceed with providing information about each QHP's relative network breadth on HealthCare.gov. We will base the rating information of the network data for each QHP that is submitted as part of the certification process. This rating will be made available to a consumer when making a plan selection. We are conducting consumer testing to help inform how to display the rating in a way that will assist the consumer in selecting the plan that best meets his or her needs. We anticipate providing details about what specialties the ratings will include in the 2017 Final Letter to Issuers and in the QHP certification instructions.

Comment: Commenters provided comments on other network adequacy issues, such as wanting additional requirements on provider directories, provider non-discrimination, access to specialized care, strong oversight and enforcement of network adequacy standards, and standards for material network changes. Other commenters wanted the proposed provisions to apply to all QHPs instead of QHPs in FFEs only.

Response: We are not implementing additional network adequacy related provisions at this time. Our intention is to give States time to adopt the NAIC Network Adequacy Model Act provisions and potentially reconsider this area in the future. Therefore, we are finalizing new § 156.230(d) to apply to all QHPs in an FFE only, and new § 156.230(e) to apply to all QHPs.

b. Essential Community Providers (§ 156.235)

On June 5, 2015, we proposed through a Paperwork Reduction Act (PRA) notice a provider petition process to update the ECP list against which issuer compliance with the ECP standard is measured. We completed this data collection for the 2017 benefit year and will provide additional opportunities for ECPs to submit provider data to HHS for benefit years beyond 2017. The degree of provider participation in this data collection effort has allowed HHS to assemble a more complete listing of ECPs.

In the proposed rule, we proposed that, for the 2017 QHP certification cycle, HHS would continue to credit a health plan seeking certification to be offered through an FFE 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. For QHP certification cycles beginning with the 2018 benefit year, we sought comment on whether we should revise § 156.235(a)(2)(i) and (b)(2)(i) to credit issuers for multiple contracted full-time equivalent (FTE) practitioners at a single location, up to the number of available FTE practitioners reported to HHS by the ECP facility through the ECP petition process. We proposed to apply this FTE count to the numerator of an issuer's percentage satisfaction of the general ECP standard described in paragraphs (a)(1) and (2) of § 156.235 and the alternate ECP standard described in paragraphs (b)(1) and (2) of that section. We proposed that the denominator of an issuer's percentage satisfaction of the ECP standard would reflect the number of available FTE practitioners reported to HHS by each ECP facility located in the issuer's plan service area.

In the proposed rule, we stated that our analysis of the available ECPs in each of the additional ECP subcategories previously considered for disaggregation (that is, children's hospitals, rural health clinics, freestanding cancer centers, community mental health centers, and hemophilia treatment centers) does not support further disaggregation of these categories at this time. We explained that there are too few ECPs within each of these additional ECP categories appearing on our ECP list to afford issuers sufficient flexibility in their contracting. We stated that we may revisit this consideration in the future, and encouraged QHP issuers to include in their networks these additional providers to best meet the needs of the populations they serve.

We are finalizing the provisions under § 156.235 as proposed.

Comment: We received numerous comments in support of our proposal for benefit year 2017 to continue crediting a health plan seeking certification to be offered through an FFE 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. Other commenters urged that HHS credit issuers for multiple contracted FTE practitioners at a single location.

We received many comments in support of our proposal for QHP certification cycles beginning with the 2018 benefit year to credit issuers that qualify for the general and alternate ECP standard for *multiple* contracted FTE practitioners at a single location, up to the number of available FTE practitioners reported to HHS by the ECP facility. These commenters stated that the wide variability in the number of available practitioners at each ECP facility and broad range of health care services that ECPs provide favor this position, and urged that ECP facilities

should not all be credited equally toward an issuer's satisfaction of the 30 percent ECP standard. In addition, they stated that many issuers contract with multiple unaffiliated providers that rent space in the same building and should be credited for more than one ECP at that location. Some of these commenters stated that while they support crediting issuers for multiple ECPs at a given site, they urged us to not rely solely on issuer satisfaction of the 30 percent ECP threshold to ensure adequate access to care for low-income medically underserved individuals.

We also received comments in opposition to this proposal for benefit year 2018. Many of the commenters stated that issuers do not always know how many FTE practitioners are available at a specific provider facility, and it would be burdensome for issuers to be required to collect such provider data. Many commenters opposed the proposal due to concerns that the policy might not ensure geographic distribution of ECPs and an adequate range of health care services provided by ECPs.

A few commenters stated that FTE practitioners at a facility often fluctuate, or they divide their time among several facilities, and so FTEs might be an unpredictable measure of an issuer's satisfaction of the ECP standard.

Response: On December 9, 2015, HHS launched its ECP petition initiative to give providers an opportunity to request to be added to our ECP list, update their provider data on our ECP list, and provide missing provider data, including FTE practitioner data that issuers rely upon to identify qualified ECPs for inclusion in their provider networks. The web-based ECP petition link is available at *https://data.healthcare.gov/cciio/ecp_petition.* HHS anticipates that this provider data collection initiative will require several months of provider outreach in order to collect the requisite FTE practitioner data. For benefit year 2017, we are finalizing our proposal at § 156.235(a)(2)(i) to count multiple providers at a single location 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.

For QHP certification cycles beginning with the 2018 benefit year, we are finalizing our proposal at § 156.235(a)(2)(i) to credit issuers for multiple contracted FTE practitioners at a single location, up to the number of available FTE practitioners reported to HHS by the ECP facility through the ECP petition process. As HHS collects the number of FTE practitioners from providers via the ECP petition for purposes of the benefit year 2018 certification cycle, HHS intends to clarify to issuers through guidance that issuers must report on their ECP template only the number of FTE practitioners at each ECP facility that the issuer has included in its provider networks for its member enrollees. That number must not exceed the number of available FTE practitioners reported to HHS by the ECP facility through the ECP petition process. Due to the wide variability in the number of available practitioners at each ECP facility and broad range of health care services that ECPs provide, HHS believes that this methodology for calculating an issuer's satisfaction of the ECP standard will provide a more accurate representation of the issuer's ECP participation in its provider networks.

For benefit years 2017 and beyond, HHS will continue to require issuers to satisfy the separate ECP requirement to offer a contract in good faith to at least one ECP per ECP category, where an ECP in that category is available, within each county in the plan's service area. In addition, issuers must continue to offer a contract to all available Indian health care providers in the plan's service area. In previous years, HHS relied in part on crediting a health plan with multiple providers at a single location as a single ECP toward the issuer's satisfaction of the ECP participation standard to better ensure geographic distribution of ECPs. For benefit year 2018, HHS expects to have collected the necessary ECP category-specific data directly from all qualified providers on our ECP list via the ECP petition initiative, so that reliance on counting multiple providers at a single location as a single ECP will no longer be necessary for purposes of ensuring geographic distribution of ECPs. We expect that the ECP category per county contract offering requirement will serve to better ensure geographic distribution of ECPs and an adequate range of health care services.

In order to address fluctuations in FTE practitioners at a facility, HHS intends to keep the ECP petition submission window open throughout the year, permitting providers to report the fluctuations and for issuers to view these updates in preparation for the following benefit year contract negotiations. For provider facilities that employ or contract with practitioners who divide their time among several facilities, the ECP should divide their FTE counts among the facilities when completing the ECP petition. For instance, an ECP should report a practitioner who practices half time at two separate facilities as 0.5 FTE at each facility to ensure a more accurate count of FTEs at each facility. Lastly, HHS has instructed providers to submit only one ECP petition for each facility location using the facility-level National Provider Identifier (NPI), rather than each individual practitioner at the facility submitting a separate ECP petition. Therefore, HHS intends to continue reflecting only facility-level ECPs on its ECP list, although some facilities may be composed of a solo practitioner beginning with the 2017 benefit year ECP list.

For the reasons stated above, we are finalizing our proposal to revise § 156.235(a)(2)(i) and § 156.235(b)(2)(i) to credit issuers that qualify for the general or alternate ECP standard described in § 156.235 that seek certification to be offered through an FFE (or SBE–FP) for multiple contracted FTE practitioners at a single location toward the issuer's satisfaction of the ECP standard, beginning with the 2018 benefit year. In addition, we are finalizing our proposal that for the 2017 benefit year, HHS will continue to credit an issuer that qualifies for the general or alternate ECP standard and is seeking certification to be offered through an FFE 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.

Comment: Several commenters urged that HHS disaggregate the providers listed in the ''Hospitals'' ECP category and the ''Other ECP Providers'' category. These commenters stated that by grouping together providers such as hemophilia treatment centers, community mental health centers, and rural health clinics into one ECP category, HHS runs the risk that low-income, underserved enrollees will have inadequate access to key providers that are uniquely suited to meet their specialized health needs. These commenters urged that HHS modify the ECP categories to separate the distinct entities and require contracting with each of them. Several commenters expressed concern that children's hospitals are grouped with hospitals that do not specialize in children's health care services. These commenters emphasized that children's hospitals are uniquely suited to meet the needs of children with complex medical conditions, and they urged HHS to establish a separate ECP category for children's hospitals. Some commenters expressed concern that HHS might be underestimating the number of providers in each of these ECP

subcategories, because the ECP categories reflected on the benefit year 2016 ECP list combine these providers with other provider types, rather than classifying them separately. One commenter recommended that HHS require that health plans offer contracts to all ECPs from each of the categories in each county that is in a health professional shortage area (HPSA), with the Health Resources and Services Administration serving as a resource for identifying those areas. In contrast, several health plans supported not disaggregating the ECP categories, expressing concern that issuers would not have sufficient flexibility in contracting.

Response: Based on our analysis of the available ECPs in each of the additional ECP subcategories previously considered for disaggregation (that is, children's hospitals, rural health clinics, freestanding cancer centers, community mental health centers, and hemophilia treatment centers), we believe that too few ECPs appear on the ECP list to afford issuers sufficient flexibility in their contracting. In order to address this concern, HHS launched its ECP Petition initiative on December 9, 2015, to give providers an opportunity to request to be added to the ECP list, update their provider data on the ECP list, and provide missing provider data. Provider participation in this ECP petition initiative is critical to ensure that issuers are aware of a provider's ECP status and that accurate provider data are reflected on the ECP list, including ECP category classifications. We believe that HHS's network adequacy standards, coupled with the ECP standards, including the 30 percent inclusion standard and the requirement that issuers offer a contract to at least one ECP in each ECP category in each county in the plan's service area, afford both providers and issuers sufficient contracting flexibility as HHS continues to update the ECP list. In addition, we continue to partner with HRSA to identify HPSAs for determining provider qualification for inclusion on the ECP list.

Comment: Several commenters urged that HHS require QHP issuers to contract with any willing provider, rather than only 30 percent of the available ECPs in a plan's service area. Some of these commenters suggested that HHS require that QHP issuers offer good faith contracts to all willing providers in specific ECP categories (that is, FQHCs, Ryan White providers, hemophilia treatment centers) in the plan's service area.

Response: While we appreciate the commenters' suggestions, we did not propose changes to the 30 percent ECP standard and consider these comments to be outside the scope of the proposed rule.

c. Enrollment Process for Qualified Individuals (§ 156.265)

Under § 156.265(b)(2), if an applicant initiates enrollment directly with the QHP issuer for enrollment through the Exchange (direct enrollment through an issuer), the QHP issuer must redirect an applicant directly to the Exchange Web site to complete the application and receive an eligibility determination. HHS requested comment on an option to enhance the direct enrollment process, like that described in this final rule in the preamble to § 155.220, such that an applicant could remain on the QHP issuer's Web site to complete the application and enroll in coverage, and the QHP issuer's Web site could obtain eligibility information from the Exchange in order to support the consumer in selecting and enrolling in a QHP. Our intent is to have this information exchange occur through an Exchange-approved Web service to provide Exchanges offering direct enrollment and QHP issuers more operational flexibility to expand front-end, consumer-facing channels for enrollment through a more seamless consumer experience. Accordingly, as in § 155.220, we proposed to revise § 156.265(b)(2)(ii) to ensure that an applicant who initiates enrollment directly with the QHP issuer for enrollment through the Exchange receives an eligibility determination for coverage through the Exchange Web site or through an Exchange-approved web service via the FFE single streamlined application. Comments regarding the enhanced direct enrollment proposal by web-brokers are discussed in this final rule in the preamble to § 155.220. We sought comment on the same direct enrollment options for issuers, including whether to expand oversight, auditing and monitoring activities, and how to best maintain privacy and security standards. We also solicited comments on whether standards should differ for a web-broker compared to a QHP issuer. We did not receive comments indicating standards should differ for a web-broker compared to a QHP issuer in regards to direct enrollment; thus, we are finalizing the proposal to require effectively the same set of standards regarding direct enrollment.

Comments on the general enhanced direct enrollment proposal, use of the FFE single streamlined application, HHS approval of alternative enrollment pathway processes, and the timing of direct enrollment are discussed in this final rule at the preamble to § 155.220(c)(3).

Comment: Commenters aligned their comments for web-brokers with comments for issuers, and a few commenters generally noted that a level playing field is essential to Exchange stability.

Response: Based on the comments received, as summarized above, we are finalizing the proposal to enhance the direct enrollment process with some modifications, as noted below.

We appreciate the many comments and recommendations on the direct enrollment proposal we received. While we believe that an enhanced direct enrollment process will provide a more seamless consumer experience, we agree with commenters that implementing the proposal will be a significant undertaking for HHS, web-brokers, and issuers, and that such an effort will require sufficient time for operational planning and preparations, such as identifying and testing the Exchange-approved web services under § 156.265(b) that can be used to support the enhanced direct enrollment process, and ensuring privacy and security risks are addressed and mitigated. HHS will not provide such an option during the individual market open enrollment period for 2017 coverage, but intends to provide the option by the open enrollment period for 2018 coverage. We intend to supplement the framework we are finalizing in this rule with more specific guidance and requirements in future rulemaking, such as specific guidelines for a pre-approval process under § 156.265(b)(3), and requirements for privacy and security. Until then, issuers must continue to comply with the current direct enrollment process, through which a consumer is directed to HealthCare.gov to complete the eligibility application, and all associated guidance. This means direct enrollment entities are not permitted at this time to use non-Exchange Web sites to complete the Exchange eligibility application or automatically populate data collected from consumers into HealthCare.gov through any non-Exchange Web site. Completion of the Exchange eligibility application on a non-Exchange Web site, or collection of data through a non-Exchange Web site that is then used to complete the eligibility application will be considered a violation of the direct enrollment entity's agreement with the FFEs.

See preamble to § 155.220(c)(3), above, for a discussion of the existing direct enrollment requirements.

While enhanced direct enrollment will not be available in the individual

market open enrollment period for 2017 coverage, we are finalizing our proposal to revise § 156.265(b)(2)(ii) to enable issuers who use HHS-approved direct enrollment processes to facilitate enrollment through the FFEs to either ensure the applicant's completion of an eligibility verification and enrollment through the Exchange internet Web site as required by § 155.405, or ensure that the eligibility application information is submitted for an eligibility determination through an Exchange-approved web service. This will allow applicants to complete the entire Exchange application and enrollment process on the web-broker's non-Exchange Web site. We believe this process will grant direct enrollment entities the operational flexibility to expand front-end, consumer-facing channels for enrollment.

However, we also share commenters' concerns that allowing this flexibility without additional protections in place may increase the risk of imprecise, inaccurate, or misleading eligibility results. In light of those considerations and the accompanying comments received, we are adding new paragraphs (b)(3)(i) through (iii) to clearly articulate the requirements associated with completing an Exchange eligibility application on a direct enrollment entity's non-Exchange Web site. These requirements may be amended over time as implementation activities begin and once experience is gained under the new process (once implemented).

Consistent with the proposal in the proposed rule, § 156.265(b)(3)(i) requires all language related to application questions, and the sequence in which the questions are presented on the direct enrollment entity's non-Exchange Web site to be identical to that of the FFE Single Streamlined Application. We acknowledge the comments requesting deviations from the FFE single streamlined application to enhance the consumer experience, and, as we are for web-brokers, we are finalizing language permitting such deviations with HHS approval. We will only approve minor modifications that do not change the intent or meaning of the questions, decrease the probability of accurate answers and eligibility determinations, or affect the dependencies and structure of the dynamic application.

We are also adding new § 156.265(b)(3)(ii), which sets out a more general requirement that any non-Exchange Web site facilitating the completion of an Exchange eligibility application ensure that all information necessary for the completion of the application related to the consumer's applicable eligibility circumstance are submitted through the Exchange-approved web service. New § 156.265(b)(3)(iii) requires that the process used for consumers to complete the eligibility application on the non-Exchange Web site comply with all applicable Exchange standards, including Exchange notice requirements under § 155.230 and Exchange privacy and security standards related to handling PII under § 155.260(b).

We also agree with commenters that urged HHS to adopt an approval process to ensure that the non-Exchange Web site seeking to offer stand-alone direct enrollment eligibility services meets all applicable requirements in order to protect consumers. Accordingly, we have added § 156.265(b)(4) to outline a process for HHS to verify entities meet all requirements of this section prior to using a non-Exchange Web site to complete the Exchange eligibility application.

See preamble under § 155.220 for a discussion on the primary objective of these changes.

We clarify that the requirements related to the direct enrollment process rules are applicable to FFEs (including FFEs where States perform plan management functions) and SBE–FPs only, and would not apply to SBEs that do not use the Federal platform, nor alter any State-specific rules related to Medicaid eligibility.

Comment: Commenters generally supported HHS conducting regular audits on issuers and requiring issuers to adhere regulatory standards for direct enrollment activities.

Response: We agree with commenters that supported HHS conducting regular audits of issuers under this section to ensure ongoing compliance with applicable standards and are adding § 156.265(b)(5), which enables HHS to periodically monitor and audit entities to assess compliance with standards in this section.

Comment: One commenter stated HHS should work with issuers as it develops new direct enrollment functionality, leverage existing security standards as much as possible, and leave sufficient time for testing and implementation of any requirements. Other comments raised several concerns about the privacy and security of consumers' personally identifiable information, particularly citizenship and immigration status, and asked HHS to clarify how these entities would collect, store, and use PII. Some commenters wanted HHS to clarify that web-based entities will not gather and store data beyond that necessary for the Federal platform, State-based Exchanges, and Medicaid eligibility and enrollment via ''cookies'' or other tracking tools, and would not store or use information gathered from consumers in the application process for marketing other products.

Response: We agree that implementing the proposal will be a significant undertaking for HHS, and that privacy and security risks must be addressed prior to implementation. We intend for the standards outlined in this section to provide a framework to prepare for the implementation to support use of the enhanced direct enrollment option in future years. We will continue to consider commenters' recommendations on ensuring consumers are protected, and intend to propose further protections in future rulemaking.

d. Termination of Coverage or Enrollment for Qualified Individuals (§ 156.270)

We proposed to amend § 156.270(d) to specify that a QHP issuer must provide a 3-month grace period to an enrollee who, upon failing to timely pay his or her premiums, is receiving advance payments of the premium tax credit. Because we believe that changing the length of an enrollee's grace period during the middle of the grace period would be confusing to enrollees and could result in otherwise avoidable terminations for failure to pay premiums, enrollees receiving APTC who enter a grace period for failing to timely pay premiums and who also lose their eligibility for APTC for any reason during the grace period would be able to complete the remaining portion of the grace period as though the loss of eligibility for APTC did not occur. Although the length of the grace period would continue as though the loss of eligibility for APTC did not occur, payment of APTC would terminate through normal Exchange operations as a result of the loss of eligibility. The proposed amendment to § 156.270(d) also would eliminate language limiting the 3-month grace period for enrollees who are receiving APTC to only those enrollees who made a payment during the benefit year. This would permit enrollees renewing coverage that does not require a binder payment who fail to pay January premiums in full (or fail to pay within an issuer's premium payment threshold policy, if applicable) to receive the full grace period of 3 months. This change would align more closely with our interpretation of the interaction between grace periods, guaranteed availability and renewability, and the binder payment requirement, that a binder payment is

not necessary when an enrollee enrolls, either actively or passively, in a plan within the same insurance product, and would prevent enrollees who re-enroll in the same plan or product from unfairly losing their right to a grace period because they do not make a payment for January coverage. Finally, we proposed to codify with regard to the grace period standards our policy described in the preamble for § 155.400 of this part that if an enrollee receiving advance payments of the premium tax credit can satisfy the requirement to pay all outstanding premiums, or if the enrollee satisfies an issuer's premium payment threshold implemented under § 155.400(g), if applicable, the QHP issuer must not terminate for non-payment of premium the enrollee's enrollment through the Exchange. This change to the rule would reflect the extension of the premium threshold policy to enrollees who are in a grace period for non-payment of premium.

Comment: Many commenters supported the proposed rule because it offers an important consumer protection and reduces confusion about the length of an enrollee's grace period if the enrollee had his or her APTC adjusted to $0 during the 3-month grace period for enrollees receiving APTC. Several commenters, however, stated that the proposed rule would cause providers to bear the burden of claims, subsequently reversed by issuers, incurred during the second and third months of a grace period for enrollees receiving APTC. Some, opposing the proposed rule, preferred that enrollees losing their APTC during a 3-month grace period revert to State rules to determine the length of the remainder of the grace period. Several other commenters approved of the proposed rule so long as providers were guaranteed to be reimbursed for claims incurred during the second and third months of the 3-month grace period. Finally, several commenters offered suggestions relating to enhancing the requirement contained in § 156.270(d)(3) that issuers notify providers of the possibility for denied claims when an enrollee is in the second and third months of the grace period.

Response: We recognize that the proposed rule could allow for claims to be submitted and pended during the second and third months of a grace period that, absent this amendment to the rule, would have been disallowed for lack of coverage if the length of the enrollee's remaining grace period had been shorter under State rules. However, the proposed standard is consistent with our current rules, and because of the importance we attach to the consumer protection inherent in the proposed rule, we are finalizing the proposal as proposed.

Comment: One commenter requested clarification that non-payment of a binder payment would not give rise to a grace period under the proposed rule. Other commenters requested clarification that, under the proposed rule, an enrollee is not eligible to receive a 3-month grace period for non-payment of premium for a plan which is not being paid, at least in part, by APTC. One commenter requested that, due to the complexity of creating the systems operations necessary to implement the rule, the proposed rule not go into effect, until after the date it is finalized.

Response: The changes to § 156.270(d) do not conflict with or change the binder payment rule at § 155.400(e), which states that Exchanges may, and the Federally-facilitated Exchange will, require payment of the first month's premium to effectuate an enrollment. Likewise, the changes to the binder payment rule at § 155.400(e) do not eliminate the need for an enrollee to pay a binder payment to effectuate coverage. The rule also does not change the existing rule that an enrollee is not eligible to receive a 3-month grace period for non-payment of premium for a plan which is not being paid, at least in part, by APTC. Similarly, the rule does not make any change to the rules related to the gain or loss of APTC. As with the other parts of this rule, the amendments to § 156.270(d) would be effective only after the effective date, identified at the beginning of this rule.

Comment: While some commenters expressed support for the codification of our interpretation that our rules do not require a binder payment when an enrollee enrolls, either actively or passively, in a plan within the same insurance product (but does require a binder payment when a consumer enrolls in a new product or with a new issuer), several commenters raised objections to the proposed rule's amendment of § 156.270(d) to eliminate language limiting the 3-month grace period for enrollees who are receiving APTC to only those enrollees who made a payment during the benefit year. Some commenters stated that such a change would have an adverse actuarial effect on the risk pool, and encourage enrollees to neglect their premium payments in favor of receiving free coverage during the 3-month grace period for enrollees receiving APTC.

Response: We do not interpret our rules to require a binder payment for re-enrollment from an enrollee who is enrolling with the same issuer in the same plan or product. We characterize such a re-enrollment as a renewal of coverage, which, according to our interpretation of our rules, is treated the same as a regularly-billed monthly premium payment. Because a binder payment is not required by our rules in such circumstances, we do not believe that an enrollee receiving APTC who is re-enrolling, either actively or passively, into the same plan or product should be denied a 3-month grace period if he or she does not make full payment (or a payment within the issuer's premium payment threshold, if any) for January of a benefit year. Additionally, we do not believe that this causes actuarial risk to the coverage pool or an enticement to game the system any more than such dangers would exist during any other part of the benefit year. Because we believe that this amendment offers an important consumer protection, we are finalizing the proposed rule as written. At the same time, we will carefully monitor consumer use of grace periods and make any necessary changes in future rules or guidance.

e. Additional Standards Specific to SHOP (§ 156.285)

In § 156.285(c)(5), we proposed to specify additional details about how a QHP issuer offering a QHP through an FF–SHOP should reconcile enrollment files with the FF–SHOP. Issuers would be required to send enrollment reconciliation files on at least a monthly basis according to a process and timeline established by the FF–SHOP, and in a file format specified by the FF–SHOP.

We also proposed to delete § 156.285(d)(2), to be consistent with our interpretation of guaranteed availability and guaranteed renewability. We specifically proposed that if a qualified employer withdraws from a SHOP, the SHOP, not the issuer should terminate the group's enrollment through the SHOP, and coverage might in many circumstances continue outside the SHOP.

We received no comments on these proposals. We are finalizing the amendment to delete § 156.285(d)(2) as proposed, and are finalizing the amendment to § 156.285(c)(5) with modifications to clarify that a general requirement under this provision still appliesin all SHOPs and to delete the word ''must'' because it is superfluous in light of the introductory language in § 156.285(c).

f. Meaningful Difference Standard for Qualified Health Plans in the Federally-Facilitated Exchanges (§ 156.298)

At § 156.298, we proposed modifications to the meaningful difference standard for QHPs in the FFEs. We proposed to remove the criterion in paragraph (b)(5) that otherwise identical plans would be considered meaningfully different on the basis of one QHP being health savings account (HSA) eligible. We also proposed to delete ''self-only'' and ''non-self-only'' from paragraph (b)(6). We further proposed to redesignate paragraph (b)(6) as paragraph (b)(5) and add the word ''or'' to paragraph (b)(4).

Comment: Commenters generally supported the removal of HSA eligibility as a criterion for determining meaningful difference from otherwise identical plans, so long as standard key differences in how the deductible applies will be accounted for in the existing cost sharing meaningful difference standard at § 156.298(b)(1). One commenter noted that it is important that HHS permit an issuer to offer different QHPs that look similar in terms of deductible and copayments, where one is HSA-compatible but the other is not, because certain services may be covered without a deductible.

Response: We have determined that HSA eligibility is a cost-sharing status that may be assessed by examining the QHP's cost sharing, which is included at paragraph (b)(1) and that the ''Health Savings Account eligibility'' criterion is therefore redundant.

Comment: Commenters also generally supported removing the self-only and non self-only criteria and questioned why the ''child-only'' status was retained.

Response: We are finalizing the removal of the self-only and non self-only criteria. Self-only (that is, individual) plans do not allow any dependent relationships, while non-self-only (that is, enrollee group or family) plans allow at least one dependent relationship type. An individual can enroll in individual and family plans. The allowance of dependents is the only difference between two plans if they are identified as individual only or family. These statuses alone are not indicative of meaningful differences among QHPs.

We will maintain the ''child-only'' versus non-child-only status. It is permissible for QHP issuers to offer child-only plans in which the only enrollees are individuals who have not attained the age of 21. We believe that such a child-only plan would be meaningfully different from a non child-only plan.

Comment: Several commenters asked that HHS consider other ways to strengthen meaningful difference standards, such as by adding additional quantitative standards.

Response: We are not proposing any additional meaningful difference standards at this time, but will continue to review the implementation of this policy over time.

g. Other Considerations

We reminded issuers that certain other Federal civil rights laws impose non-discrimination requirements. Issuers that receive Federal financial assistance, including in connection with offering a QHP on an Exchange, are subject to Title VI of the Civil Rights Act of 1964, the Age Discrimination Act of 1975, section 504 of the Rehabilitation Act of 1973, and section 1557 of the Affordable Care Act. The Office for Civil Rights (OCR), which enforces these statutes, published a notice of proposed rulemaking on September 9, 2015 (80 FR 54172) on the requirements of section 1557. Issuers that intend to seek certification of one or more QHPs are directed to that proposed rule and to *http://www.hhs.gov/ocr/civilrights* for additional information.

We also sought comments on fostering market-driven programs that can improve the management of costs and care. We noted that innovative issuer, provider, and local programs or strategies may be successful in promoting and managing care, potentially resulting in better health outcomes and lower rates while creating important differentiation opportunities for market participants. We sought comment on ways in which we can facilitate such innovation, and in particular on whether there are regulations or policies in place that we should modify in order to foster this innovation.

Comment: A few commenters stated that the exclusion of quality improvement activities in the MLR definition (for example, drug utilization review programs, and value-based oncology management programs) deters issuers from pursuing such innovative programs. Commenters recommended HHS revise the MLR numerator definition to include the costs of such programs.

A few commenters also suggested that HHS revisit last year's requirements requiring issuers to cover the greater of one drug in every USP category and class, or the same number of prescription drugs in each category and class as the EHB-benchmark, and also establishing P&T committees. Commenters stated that the administrative expense is significant and unnecessary.

One commenter also asked HHS to reconsider the mail order and specialty pharmacy restrictions in the 2016 final Payment Notice (§ 156.122(e) and (d)) starting for the 2017 benefit year, and instead establish less restrictive methods to achieve its policy goals, for example by requiring issuers and their prescription benefit managers (PBMs) to establish protocols that facilitate mail order delivery to enrollees with transitional living situations, multiple addresses, or other living arrangements requiring non-standard delivery. The commenter suggested that HHS could require that any mandatory mail order programs offered only apply to maintenance medications and only after a first fill of a new medication, as is common in the marketplace.

We received a comment stating that any willing provider laws can prevent selective contracting between issuers and providers as any willing provider that accepts the issuers' terms is considered in-network. The commenter stated that HHS should take into account the negative impact of such restrictions on innovation and avoid imposing similar regulatory impediments on issuers participating in the Exchange. Another commenter urged HHS to focus on addressing true drivers of costs, and avoid putting all financial responsibility on consumers. The commenter stated that consumer-based programs like reference pricing and benefit design structures are difficult for consumers to understand, particularly for those with low income literacy. Additionally, the commenter suggested addressing utilization of more evidence-based care with incentives for providers, and the need for broader efforts on price variation. Another comment requested HHS develop tools to allow consumers to pick plans based on quality and cost-effectiveness, adopt policies to increase transparency in costs (public reporting on costs for episodes), promote technology-enabled care delivery, and adopt policies to encourage total community health. We received one comment requesting that HHS not require SADPs to offer plans within its three categories (routine, basic and major), as it results in inaccurate plan representation and consumer confusion.

Another commenter suggested HHS explore options to waive the Medicaid rebate program, specifically the best price restriction, under which the Exchange QHP drug prices are included. This sets a pricing floor and prevents PBMs from negotiating lower drug prices or manufacturer rebates.

Response: We appreciate these comments and will consider them for future rulemaking.

6. Standards for Qualified Health Plan Issuers on Federally-Facilitated Exchanges and State-Based Exchanges on the Federal Platform (§ 156.350)

To make it operationally feasible for a State-based Exchange to rely on the Federal platform for eligibility and enrollment functions, issuers and plans offered on the SBE–FP must comply with rules, as interpreted and implemented in policy and guidance related to the Federal eligibility and enrollment infrastructure. These would be the same requirements related to eligibility and enrollment that are applicable to QHP issuers and plans on FFEs. For example, SBE–FP special enrollment periods must be administered within the guidelines of the FFE special enrollment periods, as it is not possible at this time for the Federal platform to accommodate State customization in policy or operations, such as State-specific special enrollment periods, application questions, display elements in plan compare, or data analysis. Additionally, if the Federal platform is to perform eligibility and enrollment functions, the Federal platform would also need to provide for certain consumer tools (for example, plan compare, premium estimator, second-lowest cost silver plan tool) to support those functions. Thus, the Federal platform would need SBE–FP QHP plan data by the dates specified in the annual Letter to Issuers to provide for adequate testing and loading of the data into the various consumer tools the FFEs offer. Issuers must also comply with certain FFE enrollment policies and operations (for example, premium payment and grace period rules, effective date logic, acceptable transaction codes, and reconciliation rules) for the Federal platform to successfully process 834 transactions with issuers and minimize any data discrepancies for reconciliation.

Therefore, we proposed to add § 156.350 to address eligibility and enrollment standards for QHP issuers participating on an SBE–FP. In paragraph (a) of new § 156.350, we proposed that QHP issuers participating in an SBE–FP must comply with HHS regulations, and guidance related to the eligibility and enrollment functions for which the State-based Exchange relies on the Federal platform. For example, those issuers would be required to comply with operational standards in the Federally-facilitated Exchange and Federally-facilitated Small Business Health Options Program Enrollment Manual. We proposed in paragraph (a) a list of provisions with which QHP issuers participating in an SBE–FP would be required to comply. These provisions relate to eligibility and enrollment functions directly, or are critical to enabling HHS to assess compliance with eligibility and enrollment functions. For example, we would require QHP issuers to comply with the requirements regarding compliance reviews of QHP issuers to the extent relating directly to applicable eligibility and enrollment functions. Without this requirement, we would be severely limited in our ability to determine whether an issuer is complying with the requirements related directly to the Federal platform's eligibility and enrollment functions. In paragraph (b), we proposed to permit these issuers to directly enroll applicants in a manner that is considered to be through the Exchange, under § 156.1230, just as QHP issuers on FFEs are permitted.

In paragraph (c), we proposed that if an SBE–FP does not substantially enforce the eligibility and enrollment standards described in paragraph (a), then HHS may enforce against the issuer or plan using the enforcement remedies and processes described in subpart I of part 156. We also proposed that the administrative review process in subpart J of part 156 would apply to enforcement actions taken against QHP issuers or plans under proposed § 156.350. Because timely compliance with paragraph (a) is vital to the smooth functioning of the Federal platform and because the Federal platform would apply a uniform compliance and enforcement regime for reasons of efficiency and speed, we believe it is appropriate that HHS have this authority in this circumstance.

Because this proposal would insert a section applicable to SBE–FPs in subpart D, which currently describes only standards for QHP issuers on the FFEs, we proposed to amend the title of subpart D to read Standards for Qualified Health Plan Issuers on Federally-Facilitated Exchanges and State-Based Exchanges on the Federal Platform.

Comment: We received comments stating the disadvantages of the Federal platform not being able to accommodate State customization. One commenter requested clarification that if a State elects to use the Federal platform for only the individual market or only for the SHOP market, the State should only be required to comply with the operational standards of the FFE for that market, not both. We also received comments supporting this proposal, noting that for issuers participating in both FFE and SBE–FP States this policy enables streamlined policies across platforms and would decrease operational burden for issuers, enrollees, and Exchanges.

Response: As we discuss above, at this time the Federal platform is not able to accommodate State customization in policy or operations. We are finalizing this policy as proposed. However, we are confirming that there is the flexibility for a State to elect to use the Federal platform for certain functions for either the individual market, or the SHOP market, or both. We are also confirming that should a State elect to use the Federal platform for certain functions for only one market, the requirements in § 156.350 would only apply for the market for which the State elects to rely on the Federal platform.

7. Enforcement Remedies in Federally-Facilitated Exchanges (§§ 156.800, 156.805, and 156.810)

In the proposed rule, we discussed four proposed rule changes. First, we proposed to revise paragraph § 156.805(d) to explain fully the effect of appealing a CMP. In the interest of aligning our CMP and decertification regulations, we proposed to rename paragraph (d) ''Request for hearing.'' We proposed to state affirmatively the issuer's right to file a request for hearing on the assessment of a CMP and we proposed to add language stating that the request for hearing will suspend the assessment of CMP until a final administrative decision on the appeal. This was similar to language in the decertification rule.

Second, we proposed to amend § 156.810 to present the appeal rights of QHP issuers and the impact of an appeal more clearly. Specifically, we added language to explain how an appeal will affect the effective date of a decertification depending on whether the decertification is standard or expedited.

Third, we proposed to remove § 156.800(c), in which we stated that sanctions will not be imposed on a QHP issuer on an FFE if it has made good faith efforts to comply with applicable requirements for calendar years 2014 and 2015. Starting in the 2016 calendar year and beyond, we proposed to impose sanctions on a QHP issuer in an FFE if the issuer fails to comply with applicable standards, even if the QHP issuer has made good faith efforts to comply with these requirements. We intend to use a progressive compliance model for determining sanctions.

Fourth, we proposed to add new bases for decertification of a QHP to § 156.810. One of the bases for decertification, § 156.810(a)(5), authorizes decertification if a QHP issuer is hindering the efficient and effective operation of a Federally-facilitated Exchange. We explained our intent to interpret hindering the efficient and effective operation of the FFEs to include impeding displaying plans properly to enrollees who purchase coverage under that plan. Where an issuer has informed HHS that it cannot continue to provide coverage under a QHP, HHS will interpret this information to mean that the efficient and effective operation of the FFE will be hindered because it will incorrectly display plans on the FFE platform. In such a case, we proposed to take all necessary steps to suppress or decertify the QHP.

We also proposed to add a basis for decertification to § 156.810 to address situations where a QHP issuer is the subject of a pending or existing State enforcement action, including a consent order, or where HHS has reasonably determined that an issuer lacks the funds to continue providing coverage to its consumers for the remainder of the plan year. Under its obligation to determine that making a plan available on the FFEs is in the interest of qualified individuals and employers, we proposed to adopt these decertification bases as a consumer protection measure.

We invited comments from affected parties on the proposal to end the good faith compliance policy and on the proposed bases for decertification.

Comment: We received comments requesting that we extend the good faith compliance policy into 2016. Some commenters only asked for an extension of the good faith compliance policy for new 2016 requirements. Commenters also requested that we clarify that any conduct occurring in 2014 and 2015 remain subject to the good faith compliance policy in the future. Others requested that, if the policy ended, we use a progressive compliance model for any compliance enforcement in the future. One commenter supported ending the policy.

Response: We are not extending § 156.800(c) to cover calendar year 2016. While there are new requirements for issuers in 2016, we believe that issuers have had sufficient time to acquaint themselves with how to comply with the fundamental regulations underpinning participation in the FFEs. We will be using a progressive compliance model for compliance conduct in the future, and may evaluate how new a particular requirement is when determining the appropriate enforcement remedy. We believe, based on past and current compliance monitoring and enforcement efforts, that issuers have gained enough experience with the FFEs to comply fully with participation standards. Of course, in all our enforcement actions, we will continue to take into account all facts and circumstances, including the reasonable good faith action of issuers.

Comment: We received comments that the expansion of bases for decertification, especially a basis for decertification based on financial solvency, falls under State, not Federal authority. One commenter expressed support for the expanded bases for decertification.

Response: We are finalizing the regulation as proposed. We believe that the added bases are necessary to provide consumers a consistent and reliable coverage experience through the FFEs. We do not believe this constitutes any infringement on State authority. While State regulators do have primary authority over whether issuers may sell coverage within the State, issuers must also comply with Federal requirements for participation in the FFEs and avoid conduct that violates Federal standards for decertification if they wish to sell QHPs on an FFE. When HHS reasonably determines, in coordination with information received from State regulators, that the issuer lacks the financial ability to provide coverage until the end of the coverage period, HHS must be able to take action to protect FFE consumers. Any action for consumers not enrolled in a QHP on an FFE generally remains the primary authority of the State regulator and outside the influence of these regulations.

8. Quality Standards

a. Patient Safety Standards for QHP Issuers (§ 156.1110)

In the proposed rule, we proposed to strengthen QHP patient safety standards at § 156.1110 in accordance with section 1311(h) of the Affordable Care Act for plan years beginning on or after January 1, 2017. We noted the importance of alignment of the QHP issuer standards with effective patient safety interventions and leveraging the successful work already being done at national, regional, and local hospital systems for health care quality improvement and harm reduction to achieve greater impact on reducing patient harm. We proposed amending § 156.1110 to capture the current patient safety standards that continue to apply for plan years beginning before January 1, 2017 in new paragraph (a)(1). We also proposed to add new paragraph (a)(2)(i)(A) to specify that for plan years beginning on or after January 1, 2017, a QHP issuer that contracts with a hospital with greater than 50 beds must verify that the hospital uses a patient safety evaluation system as defined in 42 CFR 3.20. We proposed to require, under new paragraph (a)(2)(i)(B), that for plan years beginning on or after January 1, 2017 a QHP issuer that contracts with a hospital with greater than 50 beds must ensure that the hospital implements a comprehensive person-centered discharge program to improve care coordination and health care quality for each patient. We noted that use of a data-driven approach, analytic feedback, and shared learning to advance patient safety, such as working with a Patient Safety Organization (PSO), are essential to implementing meaningful interventions to improve patient health care quality.

We also proposed to exercise the authority provided to the Secretary under section 1311(h)(2) of the Affordable Care Act to establish reasonable exceptions to the QHP issuer patient safety requirements. Specifically, in new paragraph (a)(2)(ii), for plan years beginning on or after January 1, 2017, QHP issuers can verify that a contracted hospital with greater than 50 beds implements evidence-based initiatives to reduce all cause preventable harm,[60] prevent hospital readmission, improve care coordination and improve health care quality through the collection, management and analysis of patient safety events by a means other than reporting of such information to a PSO. We noted that this would allow flexibility and promote alignment for hospitals that already engage in effective national, State, public and private patient safety programs.

We proposed to amend the documentation requirement for plan years beginning on or after January 1, 2017, from the collection of the hospital's CMS Certification Number to materials which reflect implementation of PSO activities, such as documentation of PSOs and hospitals working together to collect, report and

[60] All cause preventable harm or all adverse events-any event during the care process that results in harm to a patient, regardless of cause (Letter from Center for Clinical Standards and Quality/Survey & Certification Group to State Survey Agency Directors regarding AHRQ Common Formats—Information for Hospitals and State Survey Agencies (SAs)—Comprehensive Patient Safety Reporting Using AHRQ Common Formats (Mar. 15, 2013), available at *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-19.pdf*).

analyze patient safety events, and implementation of a comprehensive person-centered hospital discharge program to demonstrate compliance with the proposed requirements in § 156.1110(a)(2)(i); or documentation to reflect implementation of other patient safety initiatives to reduce all cause preventable harm, prevent hospital readmission, improve care coordination and improve health care quality through the collection, management and analysis of patient safety events to demonstrate compliance with the reasonable exception provision proposed to be captured in § 156.1110(a)(2)(ii).

We noted that we were considering providing that QHP issuers must ensure that their contracted hospitals as described in section 1311(h) are standardizing reporting of patient safety events with the use of the Agency for Healthcare Research and Quality (AHRQ) Common Formats. We also noted that these proposed standards would leverage the successful work already being done at national, regional, and local hospital systems for health care quality improvement and harm reduction, and align with effective patient safety interventions to achieve greater impact.

We are finalizing these proposals with the following modification. We are modifying the reasonable exceptions provision in § 156.1110(a)(2)(ii) to state that QHP issuers must verify that their applicable contracted hospitals with greater than 50 beds, if not working with a PSO, implement an evidence-based initiative, to improve health care quality through the collection, management and analysis of patient safety events, that reduces all cause preventable harm, prevents hospital readmission or improves care coordination. We acknowledge that some of the patient safety activities that a hospital performs with a PSO may be very similar, if not identical to, some of the activities that hospitals will perform as part of the initiatives described in § 156.1110(a)(2)(ii). If a provider undertakes activities to improve patient safety and health care quality, but does not do so in conjunction with a PSO, subject to the requirements of the Patient Safety and Quality Improvement Act (PSQIA) and its implementing regulation, 42 CFR part 3, the patient safety and quality information involved in such initiatives would not be subject to the PSQIA's privilege and confidentiality protections.

Comment: Most commenters generally supported our proposals and agreed with strengthening QHP issuer patient safety standards. Commenters agreed with HHS's approach of aligning existing, effective patient safety initiatives, including by requiring applicable hospitals to report to PSOs, as well as providing flexibility to allow compliance with § 156.1110 by implementing evidence-based initiatives other than working with a PSO. One commenter stated that the proposal outlined in § 156.1110(a)(2)(i)—to require a QHP issuer that contracts with a hospital with greater than 50 beds to verify that the hospital uses a patient safety evaluation system as defined in 42 CFR 3.20—should be the preferred option versus establishing reasonable exceptions in the proposed requirement in § 156.1110(a)(2)(ii). The commenter strongly supported reporting to a patient safety evaluation system because most PSOs collect all types of information from all types of health care organizations, unlike Hospital Engagement Networks (HENs) initiatives and Quality Improvement Organizations (QIOs) commissioned work, which are typically focused on certain conditions or topics. The commenter also stated that requiring hospital providers to contract with a Federally-listed PSO would decrease QHP operational burden and expenses versus the QHP burden of keeping track of multiple organizations and HEN patient safety initiatives with tenuous, variable funding.

Response: We agree with the majority of commenters and are finalizing the proposed approach of requiring QHP issuers, for plan years beginning on or after January 1, 2017 to verify that their contracted hospitals, with more than 50 beds, have current agreements with PSOs, while also providing reasonable exceptions to the PSO requirement. We believe that these requirements allow for increased alignment of QHP issuer standards with effective patient safety interventions. We agree that PSOs collect and analyze valuable information through patient safety evaluation systems to reduce harm and we believe that the requirements finalized in § 156.1110 for plan years beginning on or after January 1, 2017, will allow for both flexibility and innovation for hospitals to choose the most relevant patient safety initiative for their populations. We believe hospitals may choose to work with a PSO as their preferred option. We acknowledge that the different initiatives mentioned in the proposed rule, including HENs, QIOs and PSOs, may work on focused topic areas to reduce patient harm. Therefore, we believe that it is important for hospitals and their partners to determine and engage in the appropriate strategies reflecting the needs of their respective patient populations.

Comment: One commenter requested that HHS amend the proposed regulatory language in § 156.1110(a)(2)(ii) because it would be difficult to find any single patient safety initiative that addresses the reduction of all cause preventable harm,[61] prevention of hospital readmission, improved care coordination and improved health care quality through the collection, management and analysis of patient safety events, as currently proposed.

Response: We are finalizing the proposed requirement at § 156.1110(a)(2)(ii), with one modification. We are modifying the reasonable exceptions provision to state that for plan years beginning on or after January 1, 2017, QHP issuers must verify that their contracted hospitals with greater than 50 beds, if not working with a PSO, implement an evidence-based initiative, to improve health care quality through the collection, management and analysis of patient safety events that reduces all cause preventable harm, prevents hospital readmission or improves care coordination. We clarify that the evidence-based initiatives described in this reasonable exception provision are not intended to address all aspects of all-cause preventable harm, hospital readmission, care coordination, and health care quality in one single initiative.

Comment: Several commenters requested that HHS recognize State-level patient safety reporting programs, such as the mandatory Patient Safety Reporting System required in Pennsylvania, and Maine's Sentinel Event Reporting Program. Commenters noted that these State-level reporting programs are robust, evidence-based, effective patient safety programs that have delivered high value and improved patient safety across their regions. They recommended granting such exceptions because reporting to a PSO or other entity would be burdensome, duplicative, and would not align with reporting by hospitals in those States.

[61] All cause preventable harm or all adverse events—any event during the care process that results in harm to a patient, regardless of cause (Letter from Center for Clinical Standards and Quality/Survey & Certification Group to State Survey Agency Directors regarding AHRQ Common Formats—Information for Hospitals and State Survey Agencies (SAs)—Comprehensive Patient Safety Reporting Using AHRQ Common Formats (Mar. 15, 2013), available at *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-19.pdf*).

Response: We acknowledge that there could be local, State, or national patient safety reporting programs that meet or exceed the patient safety standards for plan years beginning on or after January 1, 2017, as outlined in § 156.1110(a)(2). Therefore, the QHP issuer patient safety requirements are intended to be broad and inclusive of various initiatives, such as State-level, evidence-based programs that improve health care quality through the collection, management and analysis of patient safety events, and that reduce all cause preventable harm, prevent hospital readmission, or improve care coordination. We describe, in the reasonable exceptions provision finalized at § 156.1110(a)(2)(ii), the key concepts characterizing an evidence-based patient safety initiative that are consistent with the National Quality Strategy and existing public and private patient safety programs. However, we do not intend to provide an exhaustive list of initiatives, to allow for flexibility and innovation for future advances in patient safety.

Comment: A few commenters suggested amending the proposed documentation requirement outlined in § 156.1110(b), and recommended allowing hospitals to attest that they participate in a patient safety activity to minimize the documentation requirement and ensure efficient, consistent mechanisms for compliance by hospitals.

Response: We maintain the documentation requirement as outlined in § 156.1110(b) and clarify that we intend the requirement for plan years beginning on or after January 1, 2017, to be broad and inclusive of examples such as hospital attestations or current agreements to partner with a PSO, HEN, or QIO. We believe that the patient safety standards support a common goal of preventing the risk of patient harm in an effective, sustainable way. We believe it is important to allow for flexibility regarding methods of complying with the new documentation requirements at § 156.1110(b)(2) in order to balance both issuer and hospital burden and to accommodate a variety of types of patient safety initiatives in which hospitals may engage. We also believe that QHP issuers and their contracted hospitals should have flexibility in how they comply with the documentation requirement as they develop their contracts.

Comment: One commenter did not agree with the proposed documentation requirement to have hospitals share their PSO agreements with QHPs because of concern of violating confidentiality provisions of sharing patient safety work products and analyses outside of the PSO per the PSQIA. Another commenter requested clarification regarding whether HHS would collect and publish data on the patient safety evaluation system as defined in 42 CFR 3.20.

Response: PSO contracts with hospitals for the purpose of receiving and reviewing patient safety work product (referred to as Patient Safety Act contracts) do not meet the definition of ''patient safety work product'', and thus, are not subject to the protections and requirements in the PSO statute and regulations. We do not intend to collect and publish data on the patient safety evaluation system nor are we generally permitted to publish patient safety work product. We clarify that these QHP issuer patient safety requirements are intended to support implementation of the PSQIA and would not violate the confidentiality provisions of patient safety work product, as defined in the PSQIA. We clarify that the QHP issuer documentation requirement in § 156.1110(b)(2) is intended to direct issuers to collect basic, administrative-type information from their contracted hospitals, with greater than 50 beds, to demonstrate compliance with the patient safety requirement for plan years beginning on or after January 1, 2017. For example, we expect such information could include current hospital agreements or attestations to partner with a PSO, which we note would not contain patient safety work product. In addition, we clarify that such information to demonstrate compliance would be submitted to an Exchange, upon request by the Exchange per the established requirement in § 156.1110(c).

Comment: Several commenters requested that HHS consider that the timeframes of hospital patient safety initiatives may not coincide with plan years, and that HHS allow flexibility so that a hospital may attest to the fact that it is already or will start to take part in a patient safety activity during the relevant plan year or base compliance on a hospital's previous year's activities. One commenter urged HHS to build a process for approving new initiatives in the future.

Response: We acknowledge that timeframes of hospital patient safety initiatives may not exactly align with plan years. We are finalizing the patient safety requirement in § 156.1110(a)(2) to state that for plan years beginning on or after January 1, 2017, issuers must verify that their applicable contracted hospitals with greater than 50 beds use a patient safety evaluation system as defined in 42 CFR 3.20, as well as implement a mechanism for comprehensive hospital discharge to improve care coordination and quality or implement an alternative evidence-based initiative. We clarify that we do not specify dates of activity regarding patient safety initiatives because we believe it is the responsibility of the issuer and contracted hospital to maintain current documentation and ensure compliance with these patient safety standards.

Comment: Several commenters supported the proposed discharge planning requirements outlined in § 156.1110(a)(2)(i)(B) that states that a QHP issuer that contracts with a hospital with greater than 50 beds must ensure that the hospital implemented a comprehensive person-centered discharge program to improve care coordination and health care quality for each patient. Commenters expressed that it is critical that the discharge planning process reflect the needs of all populations and sub-populations. Some commenters noted that HHS is already addressing hospital discharge planning requirements in a separate proposed rule, CMS 3377–P (80 FR 68125 (Nov. 3, 2015)), which should be used to meet the discharge requirements in section 1311(h) of the Affordable Care Act and to minimize unnecessary burden on QHP issuers and hospitals.

Response: We acknowledge that HHS has currently proposed implementing discharge planning requirements mandated in section 1899B(i) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act, Pub. L. 113–185) by modifying the discharge planning or discharge summary Condition of Participation requirements for hospitals. We agree with aligning discharge planning requirements to minimize burden, and clarify that continued collection of CMS Certification Numbers (CCNs) would be sufficient for issuers to comply with § 156.1110(a)(2)(i)(B). We believe there would be no additional burden because QHP issuers have already been collecting this documentation since January 1, 2015, for the initial phase of the QHP issuer patient safety standards. We are finalizing the documentation requirement in § 156.1110(b)(2) for plan years beginning on or after January 1, 2017 and clarify that the information to be collected by a QHP issuer could include CCNs to demonstrate that their contracted hospitals implement mechanisms for comprehensive person-centered hospital discharge to improve care coordination and health care quality for each patient. We also believe it is important to provide flexibility to hospitals and QHP issuers and note that

other types of information may be collected to demonstrate compliance with comprehensive person-centered hospital discharge if hospitals choose to implement this in alternative ways, other than meeting Condition of Participation requirements.

Comment: Many commenters did not support mandating the use of AHRQ Common Formats for standardizing reporting of patient safety events. They stated that requiring use of Common Formats would stifle private sector innovation and investment in the development of PSOs, would add burden and costs to PSO formation, and could cause existing PSOs to voluntary delist. Some commenters noted that hospitals that already report patient safety data in a standardized manner through other reporting systems that meet or exceed the Patient Safety and Quality Improvement Act requirements, would incur undue burden as well. Commenters urged HHS to allow flexibility to PSOs and their participants to choose the reporting format or tool they use to submit patient safety event data.

Response: We continue to strongly support hospital tracking of patient safety events using the AHRQ Common Formats,[62] which are a useful tool for a hospital regardless of what patient safety interventions are implemented for ongoing, data-driven quality assessment. We also note that use of Common Formats, and aligning with existing HHS recommendations for hospitals,[63] is integral, whether a hospital chooses to work with a PSO to comply with the proposed requirement in § 156.1110(a)(2)(i), or implements an alternative approach under the reasonable exception provision in § 156.1110(a)(2)(ii). We also remind PSOs of their requirement to collect patient safety work product in a standardized manner, as set forth in 42 CFR 3.102(b)(2)(i)(F) and (b)(2)(iii). However, we clarify that the QHP issuer patient safety standards finalized in this rule do not require the use of the Common Formats for patient safety event reporting at this time.

Comment: A few commenters provided recommendations regarding the requirement to collect and maintain CCNs and to establish quality improvement strategies.

Response: We clarify that we are finalizing requirements to transition from the first phase of patient safety standards that required, beginning on January 1, 2015, QHP issuers to verify that certain contracted hospitals meet Medicare Hospital Conditions of Participation requirements regarding a quality assessment and performance improvement program and a discharge planning process. In other words, we are finalizing the amendments to § 156.1110 to begin the second phase of the patient safety standards to require for plan years beginning on January 1, 2017, QHP issuers to verify that their contracted hospitals with greater than 50 beds use a patient safety evaluation system as defined in 42 CFR 3.20, and implement a comprehensive person-centered discharge program to improve care coordination and health care quality for each patient; or implement an evidence-based initiative, to improve health care quality through the collection, management and analysis of patient safety events that reduces all cause preventable harm, prevents hospital readmission, or improves care coordination by a means other than reporting of such information to or by a PSO. We clarify that the collection of CCNs would be sufficient under § 156.1110(b)(2) for QHP issuers to document compliance with § 156.1110(a)(2)(i)(B).

We also note that QHP issuer requirements relating to quality improvement strategies were established in the 2016 Payment Notice (80 FR 10844); therefore, comments specific to QHP issuer implementation and reporting of quality improvement strategies are out of scope of this rule. However, we expect QHP issuers would align and coordinate implementation of their contracted hospital patient safety initiatives with their QHP quality improvement strategies if applicable.

Comment: Several commenters requested clarifications regarding the timeframe for the effective date for data collection to ensure that hospitals have sufficient time to comply with the standards. One commenter suggested one year from the date of the final rule as the effective date of data collection since hospitals would need considerable time to implement activities to comply with these patient safety standards. One commenter requested more detail about how hospitals that meet the standard can be prospectively identified by plans, consumers and regulators.

Response: We believe that the majority of hospitals with greater than 50 beds already partner with a PSO, or implement an alternative national, State, public, or private evidence-based patient safety initiative that uses the collection, management and analysis of patient safety events to reduce all cause preventable harm, prevent hospital readmission, or improve care coordination. We believe that there is an adequate amount of time from the publication of this final rule for QHP issuers and their contracted hospitals to be able to comply with these patient safety standards for plan years beginning on or after January 1, 2017. We expect that issuers would continue their efforts to prospectively identify hospitals to contract with that meet all applicable Federal and State health care quality and safety requirements.

Comment: One commenter requested clarifications regarding the regulatory reference for ''a comprehensive person-centered discharge program to improve care coordination and health care quality for each patient'' and how this is tracked or published.

Response: The language being finalized at § 156.1110(a)(2)(i)(B) implements the patient safety standard captured at section 1311(h)(1)(A)(ii) of the Affordable Care Act, which refers to a mechanism to ensure that each patient receives a comprehensive program for hospital discharge that includes patient-centered education and counseling, comprehensive discharge planning, and post discharge reinforcement. We do not intend to track or publish patient safety event data regarding hospital discharge programs at this time. Instead, § 156.1110(b)(2) requires QHP issuers, for plan years beginning on or after January 1, 2017, to collect and maintain documentation to demonstrate that its contracted hospitals with greater than 50 beds meet the required patient safety standards. We also clarify that documentation to demonstrate compliance with the discharge planning requirement (for example, the hospital's CCN) would be submitted to an Exchange, upon request by the Exchange per the established requirement in § 156.1110(c).

9. Qualified Health Plan Issuer Responsibilities

a. Payment and Collections Processes (§ 156.1215)

In the 2015 Payment Notice, HHS established a monthly payment and collections cycle for insurance affordability programs, user fees, and premium stabilization programs. In 2017, as discussed elsewhere in this document, we are finalizing our proposal to charge issuers in SBE–FPs for eligibility and enrollment services a

[62] *https://www.pso.ahrq.gov/common.*

[63] Letter from Center for Clinical Standards and Quality/Survey & Certification Group to State Survey Agency Directors regarding AHRQ Common Formats—Information for Hospitals and State Survey Agencies (SAs)—Comprehensive Patient Safety Reporting Using AHRQ Common Formats (Mar. 15, 2013), available at *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-19.pdf.*

user fee for the benefits issuers in SBE–FPs will receive as a result of the SBE–FP's reliance on the Federal platform. To streamline our payment and collections process, we proposed that, for 2017 and later years, for purposes of the netting process, the reference to FFE user fees in § 156.1215(b) would be interpreted to include any fees for issuers in State-based Exchanges using the Federal platform.

In the 2015 Payment Notice, we established in § 156.1215(c) that any amount owed to the Federal government by an issuer and its affiliates is the basis for calculating a debt owed to the Federal government. In this rulemaking, we proposed that, for 2017 and later years, for purposes of calculating the debt owed to the Federal government, we would interpret the reference to FFE user fees to include any fees for issuers in State-based Exchanges using the Federal platform. We also sought comment on whether the regulations should be amended to reflect these interpretations.

We are adopting the interpretations of § 156.1215 we announced in the proposed rule by finalizing conforming amendments to paragraphs (b) and (c) of § 156.1215.

Comment: We received one comment on these proposals requesting that HHS clarify if it intends to collect user fees from issuers in State-based Exchanges using the Federal platform beginning in 2015.

Response: Our intent in this section was to establish our authority to collect the user fee from SBE–FP issuers through netting, but only once such a fee has been established. As described elsewhere in this rule, HHS will begin assessing the user fee on issuers in State-based Exchanges using the Federal platform beginning with plan years that start on or after January 1, 2017, or, at the State's request, collecting an equivalent amount from the State. We are finalizing our proposal that, for purposes of the netting process and calculating the debt owed to the Federal government, we will interpret the reference to FFE user fees at § 156.1215(b) and (c) to include any fees for issuers in SBE–FPs, beginning with plan years that start on or after January 1, 2017.

b. Administrative Appeals (§ 156.1220)

In the 2015 Payment Notice (79 FR 13818), we established an administrative appeals process for issuers. We established a three-tiered 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). In light of HHS's finalization of the proposal around SBE–FPs, we interpret this administrative appeals process to also apply to user fee payments that we collect from SBE–FP QHP issuers that offer plans on an SBE–FP.

Under § 156.1220(a), an issuer may only file a request for reconsideration based on the following: A processing error by HHS, HHS's incorrect application of the relevant methodology, or HHS's mathematical error. For example, an issuer may file a request for reconsideration that challenges the assessment of a default risk adjustment charge if the issuer believes the default charge was assessed because HHS incorrectly applied its methodology regarding data quantity and quality standards set forth in § 153.710(f); however, the issuer may not file a request for reconsideration to challenge the methodology itself. We also clarify that an issuer may not file a request for reconsideration regarding issues arising from the issuer's failure to load complete and accurate data to its dedicated distributed data environment within the data submission window. Errors by the issuer are not appealable.

In line with our proposal to delete § 153.710(d), we proposed to make conforming amendments to modify § 156.1220 to remove cross-references to the interim discrepancy reporting process. Under § 156.1220(a)(4)(ii), a reconsideration relating to risk adjustment or reinsurance may only be requested if, to the extent the issue could have been previously identified by the issuer to HHS under the final discrepancy reporting process proposed to be redesignated at § 153.710(d)(2), it was so identified and remains unresolved. As proposed to be redesignated, § 153.710(d)(2) states that an issuer must identify to HHS any discrepancies it identified in the final distributed data environment reports. We clarify that issuers may identify issues during the discrepancy reporting process under newly designated § 153.710(d)(2) that are not subject to appeal; that is, issuers may identify issues that are not processing errors by HHS, HHS's incorrect application of the relevant methodology, or HHS's mathematical errors. We clarify that, in contrast, an issuer may only request a reconsideration of unresolved issues that were identified (if they could have been so identified) under the final discrepancy reporting process proposed to be redesignated at § 153.710(d)(2), if contesting a processing error by HHS, HHS's incorrect application of the relevant methodology, or HHS's mathematical error. We also clarified that the existence of an unresolved discrepancy is not alone a sufficient basis on which to request a reconsideration.

Additionally, we clarified the grounds for appeals related to the risk corridors program. An issuer may not file a request for reconsideration to challenge the standards for the risk corridors program, including those established in §§ 153.500 through 153.540 and in guidance issued by HHS. In addition, appeals related to data for programs other than risk corridors covered in § 156.1220(a) cannot be grounds for risk corridors appeals. We proposed to clarify that the last submission of data to which the issuer has attested serves as the notification for purposes of § 153.510(d).

We also proposed to shorten the deadline for filing a request for reconsideration in § 156.1220(a)(3) from 60 to 30 calendar days.

Additionally, we proposed to clarify that an issuer must pay the full amount owed to HHS as set forth in the applicable notification, even if the issuer files a request for reconsideration under § 156.1220. Failure to pay an amount owed will result in interest accruing after the applicable payment deadline. Therefore, if an appeal is unsuccessful, and the issuer has not already remitted the charge amount owed, the issuer would owe the debt plus the interest, and administrative fees which accrue from delayed payment. If an appeal is successful, HHS will refund the amount paid in accordance with the final appeal decision. HHS is finalizing this clarification.

We are finalizing our proposal to shorten the timeframe for requesting reconsideration related to the risk adjustment, reinsurance and risk corridors programs to 30 calendar days. This final rule will become effective 60 days after it is published—that is, prior to the June 30 notification of risk adjustment and reinsurance amounts. Therefore, requests for reconsideration related to the risk adjustment, reinsurance and risk corridors programs for the 2015 benefit year must be made within 30 calendar days of notification of the payment or charge. However, HHS will maintain a 60 calendar day timeframe to request reconsideration for the APTC, CSR and user fee programs. Therefore, the request for reconsideration must be filed in accordance with the following timeframes: (1) For the premium tax credit and cost-sharing reduction portions of the advance payments, or

FFE user fee charges, within *60 calendar days* after the date of the final reconsideration notification specifying the aggregate amount of such advance payments or user fees for the applicable benefit year; (2) for a risk adjustment payment or charge, including an assessment of risk adjustment user fees, within *30 calendar days* of the date of the notification under § 153.310(e); (3) for a reinsurance payment, within *30 calendar days* of the date of the notification provided under § 153.240(b)(1)(ii); (4) for a default risk adjustment charge, within *30 calendar days* of the date of the notification of such charge; (5) for reconciliation of the cost-sharing reduction portion of the advance payments, within *60 calendar days* of the date of the notification of such payment or charge; and (6) for a risk corridors payment or charge, within *30 calendar days* of the date of the notification of such payment or charge for the purposes of § 153.510(d). In the proposed rule, we proposed to clarify that the last submission of data to which the issuer has attested serves as the notification for purposes of § 153.510(d). We have since issued a public FAQ stating that for the purposes of the 2014 benefit year the public notification of final estimated risk corridors payments and charge amounts served as the notification for purposes of § 153.510(d).[64]

Comment: One commenter agreed with the shortening the deadline to request reconsideration related to risk adjustment to 30 days from 60 days. Other commenters asked that HHS maintain the 60-day deadline. One commenter requested a 90-day timeline to request reconsideration. Some commenters asked that HHS maintain the longer deadline due to new processes surrounding policy based payments and cost-sharing reductions and advance payments of the premium tax credit reconciliation. Another commenter requested that HHS extend the deadline to file a request for reconsideration to 120 days to allow cost-sharing reductions and advance payments of the premium tax credit adjustments due to the 3-month grace period.

Response: We are finalizing our proposal to shorten the timeframe for requesting reconsideration related to the risk adjustment, reinsurance and risk corridors programs to 30 calendar days. Conversely, HHS will maintain a 60-day deadline to request reconsideration for the APTC, CSR and user fee programs. Finalizing a shorter timeline for the premium stabilization programs requests for reconsideration would permit HHS to resolve administrative appeals, calculate final payments and charges, and make payments in a manner consistent with the reporting and payment timelines for those programs. We agree with commenters that there are several benefits to maintaining the longer 60-day timeframe for the APTC, CSR and user fee programs.

Comment: One commenter asked that HHS pay interest to any issuer who pays and then wins a request for reconsideration.

Response: If an appeal is successful, HHS will issue a refund in accordance with the final appeal decision.

Comment: A few commenters suggested HHS allow unresolved discrepancies to be appealed even if the discrepancy does not fit within one of the three reconsideration basis, otherwise discrepancies could be identified and not resolved within the timeframe without an opportunity for resolution.

Response: Issuers cannot appeal data submission errors that resulted from an issuer error because it is the responsibility of the issuer to submit complete and accurate data (with corrections to any errors) prior to the data submission deadline. Throughout the data collection period, HHS maintains a help desk, hosts user group calls and webinars to assist issuers with the identification and resolution of data submission errors and to provide general technical assistance. Issuers are encouraged to review their data and the EDGE server generated reports, as well as to notify HHS of any problems as soon as possible so that, to the extent feasible, assistance can be provided to resolve those problems before the final data submission deadline. Therefore, HHS will only consider requests for reconsideration related to risk adjustment or reinsurance on the basis that HHS made a processing error, incorrectly applied a relevant methodology, or made a mathematical error. Additionally, HHS would continue to require issuers to identify issues through the final formal discrepancy reporting process, if the issue is identifiable at the time, so HHS can work to address such issues prior to the final risk adjustment transfers and reinsurance payment calculations.

Comment: Some commenters asked that HHS provide a timeline for when requests for reconsideration and appeals will be decided.

Response: HHS understands that receiving a reconsideration decision promptly promotes the timely release of funds, however, due to the varying nature, complexity and number of reconsiderations, HHS cannot set forth a specific deadline. HHS is committed to providing a decision as quickly and efficiently as possible.

c. Third Party Payment of Qualified Health Plan Premiums (§ 156.1250)

We proposed to amend § 156.1250 to clarify that a Federal or State government program includes programs of the political subdivisions of the State, namely counties and municipalities, which we referred to as local governments. Including this clarification in regulations will ensure that States have the flexibility to distribute care and Exchange financial assistance to their vulnerable populations through local governments, consistent with their statutory and regulatory authority.

In terms of the distinction between programs sponsored and operated by the government (such as the Ryan White HIV/AIDS programs) and programs that involve Federal grantees that receive considerable public funding, we acknowledged that programs such as the Ryan White HIV/AIDS program operate by working with cities, States, and local, community-based organizations to provide services in line with their statutory authority. Sections 2604(c)(3)(F), 2612(b)(3)(F), and 2651(c)(3)(F) of the PHS Act authorize Ryan White HIV/AIDS program grantees and sub-grantees to use program funds for premium and cost-sharing assistance. These grantees and sub-grantees must provide the assistance through third-party payments as they are prohibited from making payments directly to patients. Though many Ryan White HIV/AIDS program grantees are State and local governments, not all are; similarly, many of the State and local government grantees administer funds through sub-grantees that are not government entities. We proposed to distinguish government programs from government grantees such that the requirement at § 156.1250 would apply to government programs, but not necessarily to entities that are government grantees, unless specifically authorized and funded by the Federal, State, or local government program to make the payments on behalf of the program, consistent with the government programs' statutory and regulatory authority to provide premium and cost-sharing assistance through grants and grantees. In other words, if such Federal, State, and local governments are authorized to administer their premium and cost-

[64] For the 2014 benefit year, we clarified this deadline in FAQ 14470 (Dec. 21, 2015), available at *https://www.regtap.info.*

sharing assistance through grantees or sub-grantees, the payments may not be rejected on the grounds that they did not come directly from the government programs. In such cases, the source of the Exchange financial assistance is the government program, and administration or distribution of that assistance through grants and grantees is authorized under statute or regulation.

We also proposed to require entities that make third party payments of premiums under this section to notify HHS, in a format and timeline specified in guidance. We proposed that the notification must reflect the entity's intent to make payments of premiums under this section and the number of consumers for whom it intends to make payments.

We also proposed to clarify that while issuers offering individual market QHPs, including SADPs, generally do not collect cost-sharing payments, they are required to accept third party cost-sharing payments on behalf of enrollees in circumstances where the issuer or the issuer's downstream entity accepts cost-sharing payments from plan enrollees. We noted that although cost-sharing payments are generally made to providers, rather than to issuers, there are certain contractual circumstances in which an issuer's non-provider downstream entity engages in activities such as the collection of cost-sharing payments. For example, an issuer's pharmacy benefits manager may collect cost-sharing payments from the issuer's plan enrollees for prescription drugs. We proposed to clarify that in such situations, the rules at § 156.1250 regarding the requirement to accept third-party payments would apply to cost sharing payments.

We noted that we are considering whether to expand the list of entities from whom issuers are required to accept payment under § 156.1250 to include not-for-profit charitable organizations in future years, subject to certain guardrails intended to minimize risk pool impacts, such as limiting assistance to individuals not eligible for other minimum essential coverage and requiring assistance until the end of the calendar year.

Comment: Some commenters expressed concern that the language proposed in § 156.1250(a)(3), ''consistent with the program's statutory authority,'' might be read to require explicit statutory authority to make premium and cost-sharing payments. The commenters stated that such a reading could unduly restrict the ability of some programs to assist clients and cause confusion for both programs and issuers.

Response: We are amending § 156.1250(a) to remove the phrase, ''consistent with the program's statutory authority,'' in order to avoid such confusion. We believe that the phrase, ''directed by a government program to make payments on its behalf,'' is sufficiently specific and clear.

Comment: Several commenters asked that we provide a specific list of entities that qualify as government programs from which third party payments must be accepted. Several other commenters urged that we immediately include not-for-profit, charitable organizations as entities from which third party payments for QHP premiums and cost-sharing must be accepted, with certain guardrails intended to minimize adverse selection. Some of these commenters also urged that HHS provide a list of acceptable foundation types as referenced in HHS's February 7, 2014 FAQ,[65] which stated that the concerns addressed in the November 4, 2013 FAQ[66] do not apply to payments from private, not-for-profit foundations if they are made on behalf of QHP enrollees who satisfy defined criteria that are based on financial status and do not consider enrollees' health status. These commenters expressed that the provision of a list of acceptable foundation types is critical to ensure that these foundations meet the criteria noted in the February 7, 2014 FAQ. Some commenters asked that we collect the following information under our proposed information collection: Number of consumers for whom the entity will be making payments (by State or rating area); volume of payments over a specified time period; contact information; tax ID and filing status; governance (for example, leadership, members of Board of Directors, principal shareholders, etc.); funding sources; information on relationships with provider organizations (financial or other); and information on relationships with pharmaceutical companies (financial or other).

Response: We are not providing a specific list of entities that qualify as government programs at this time, as we believe that the parameters established in § 156.1250(a) are sufficiently precise.

We are removing § 156.1250(b), the information collection provision, as we believe it will unduly burden Indian tribes, Ryan White HIV/AIDS programs, and government programs to provide such notification to HHS. Although HRSA collects information regarding premium assistance from its Ryan White HIV AIDS programs and grantees, Indian tribes and other Federal, State, and Local government programs may not currently collect or maintain this information. Further, we believe that payment information from these entities would be unlikely to inform the impacts on the risk pool that may result from expanding the requirement at § 156.1250 to third party payments made by non-profit organizations. The latter may make payments for a different population with different health care needs and conditions. We defer the question of acceptance of third-party payments made by non-profit organizations to future rulemaking. We refer stakeholders to our February 7, 2014, FAQ, which clarified that the concerns addressed in our November 4, 2013 FAQ[67] do not apply to payments from private, not-for-profit foundations if the payments are made on behalf of QHP enrollees who satisfy defined criteria that are based on financial status and do not consider enrollees' health status. In this situation, the FAQ stated that HHS would expect that the premium and any cost-sharing payments cover the entire policy year.

Comment: Some commenters raised concerns that it would be confusing to create a requirement for issuers or their downstream entities such as PBMs to accept cost sharing from third party payers because there is currently no industry infrastructure in place to facilitate third-party payments, including the lack of the following: Secondary payer guidelines; enrollment file sharing requirements; specific guidelines for accumulators; a coordination of benefits entity to collect and share data with issuers; a transaction facilitator; data exchange agreements; the ability of plans to use common identifiers; and an National Council for Prescription Drug Programs transaction process. Other commenters agreed that when an issuer uses an entity, such as a PBM, to provide a benefit such as prescription drugs, that entity is required to accept third party payments of cost-sharing by virtue of being a downstream entity.

[65] Third Party Payments of Premiums for Qualified Health Plans in the Marketplaces (Feb. 7, 2014), available at *http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/third-party-payments-of-premiums-for-qualified-health-plans-in-the-marketplaces-2-7-14.pdf.*

[66] Third Party Payments of Premiums for Qualified Health Plans in the Marketplaces (Nov. 4, 2013), available at *http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/third-party-qa-11-04-2013.pdf.*

[67] Third Party Payments of Premiums for Qualified Health Plans in the Marketplaces (Nov. 4, 2013), available at *http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/third-party-qa-11-04-2013.pdf.*

Response: We are finalizing our proposal, with an additional clarification that while issuers offering individual market QHPs, including SADPs, generally do not collect cost-sharing payments, their downstream entities, or agents of the issuer, are required to accept third party cost-sharing payments made by the entities listed at § 156.1250(a) on behalf of QHP enrollees if the downstream entities or agent routinely accept cost-sharing payments from enrollees. We are also clarifying in response to comments, that an agent of the QHP issuer with a mail order pharmacy, such as a PBM with a mail order pharmacy, must accept the third party cost-sharing payments directly from the entities listed at § 156.1250(a).

d. Other Notices (§ 156.1256)

We proposed to add a new § 156.1256, which would add a requirement for issuers, in the case of a plan or benefit display error included in § 155.420(d)(4), to notify their enrollees within 30 calendar days after the error has been identified, if directed to do so by the FFE. We believe that enrollees should be made aware of any error that may have impacted their QHP selection and enrollment and any associated monthly or annual costs. Therefore, we proposed a requirement that issuers, if directed to do so by the FFE, must notify their enrollees of such error, as well as the availability of a special enrollment period, under § 155.420(d)(4), for the enrollee to select a different QHP, if desired.

We are finalizing the provisions with two modifications. In response to comments received, we are amending the timeframe within which issuers must notify their affected enrollees of a plan or benefit display error and the availability of a special enrollment period, from 30 calendar days after the error is identified to 30 calendar days after the issuer is notified by the FFE that the error has been fixed. By waiting until after the error has been corrected, issuers will be more likely to have a complete list of affected enrollees to notify. In addition, by waiting until the error has been corrected and the plan information is properly displayed, enrollees will be able to compare their current plan to others in the service area when deciding whether or not to change plans under the special enrollment period. In addition, we are clarifying that this rule will apply to issuers on SBE–FPs.

Comment: We received general support from commenters for finalizing this proposal, so that consumers are informed about plan or benefit information that was incorrect when they selected that plan and may have impacted their plan selection. One commenter requested that the proposal be extended to State-based Exchanges. Other commenters supported this requirement, but requested that it be limited to those plan or benefit display errors for which issuers are responsible or in cases when issuers fail to comply with the FFE's correction procedures.

Response: We agree with commenters that issuers should notify affected enrollees of display errors that may have impacted plan selection and of their opportunity to select a different plan through the FFE. While we agree that all affected enrollees, regardless of location, should be notified of such errors, we leave it to States operating SBEs to determine the method and timeframe for which enrollees in their Exchanges should be notified. However, SBE–FPs will be using the FFE eligibility and enrollment platform, and, as we note in the preamble to § 156.350 in this final rule, it is not possible at this time for the FFEs to accommodate State customization in policy or operations, such as State-specific display elements in plan compare. Accordingly, we are modifying the regulation text to specify that this rule would require issuers offering QHPs through SBE–FPs to comply with FFE directions to provide notice under this section.

The plan and benefit display errors included in this noticing requirement includes information submitted by issuers to the FFE to be displayed for consumers on Plan Compare. Many errors falling into this category thus far have been due to errors in plan information provided by issuers and all errors in this category have a specific impact on the information available to consumers about one or more plans provided by a particular issuer.

Comment: Many commenters requested additional clarification of the parameters of plan or benefit display errors under § 155.420(d)(4), including whether errors in provider directories or drug formularies, such as those newly accessible through the premium estimator tool, are included in this new notification requirement.

Response: Plan or benefit display errors under § 155.420(d)(4) refer to misinformation, including errors related to service areas, covered services, and premiums, displayed incorrectly on the Exchange Web site. For the FFEs, this only includes the Plan Compare section of the application where a consumer may enroll in a plan. If the plan information incorrectly displayed does not have a direct bearing on coverage or benefits, such as plan contact information, those errors generally do not enable an enrollee to qualify for a special enrollment period under § 155.420(d)(4). Only those plan or benefit display errors that qualify an enrollee for a special enrollment period under § 155.420(d)(4) would trigger this new noticing requirement.

Errors to provider networks or drug formularies, whether incorrectly displayed on the issuer's Web site or accessible through the premium estimator tool on HealthCare.gov, generally do not qualify an enrollee for a special enrollment period. Therefore, issuers are not required to notify affected enrollees in the manner and timeframe outlined in this provision, although notifying enrollees of important changes is encouraged. HHS notes the importance of issuers providing accurate and complete plan information, including provider network and drug formulary information, so that consumers may make informed choices. QHP issuers are reminded that § 156.225(b) prohibits them from employing marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs. Issuers may also be subject to Federal civil rights laws that prohibit discriminatory marketing practices and benefit designs, such as section 1557 of the Affordable Care Act.

Comment: Some commenters requested that that HHS provide model notices for issuers to send to enrollees in the event of a plan or benefit display error. Other requested that issuers retain the flexibility to draft notices to consumers the best way that they see fit.

Response: HHS recognizes that notifying their enrollees of a plan or benefit display error is already included in the business practices of many issuers offering QHPs through the Exchanges and, therefore, issuers have an established method of communicating such errors to their enrollees. HHS also recognizes the need to communicate accurate and standard information about the availability of a special enrollment period to consumers. Therefore, HHS will provide issuers with suggested special enrollment period language that they could use in their existing consumer notices to satisfy the requirement that they notify enrollees of their eligibility for a special enrollment period.

Comment: Several issuers requested that we amend the amount of time issuers have to notify affected enrollees, either by extending it from 30 to 60 calendar days or by starting the 30 calendar days from the date that the

plan or benefit display error has been fixed, while other commenters wanted to ensure that enrollees are notified of an error in a timely manner.

Response: We believe that 30 calendar days is sufficient time for issuers to notify their enrollees affected by a plan or benefit display error and is soon enough to minimize sustained harm to affected enrollees. However, as discussed above, we agree that the 30 calendar days should begin on the date that the issuer is notified that the error has been fixed, and we are amending this provision accordingly.

Comment: One commenter stated that State regulators, including SBEs and departments of insurance, should be responsible for the identification of plan and benefit display errors.

Response: We agree that, States should play a role in identifying plan or benefit display errors, and we encourage State regulators to notify the applicable Exchange of the error. Nothing in this rule prohibits a State from taking that role. We also note that issuers offering QHPs through an FFE must obtain State authorization to change QHP data after certification.

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

1. Definitions (§ 158.103)

In the proposed rule, we proposed to revise the regulatory definitions of large employer and small employer in § 158.103 to cross-reference the definitions of those terms in § 144.103, in order to ensure consistency in those definitions between the MLR regulation and the market reform requirements, and to reflect the recent amendments made by the Protecting Affordable Coverage for Employees Act (Pub. L. 114–60).

Comment: We received two comments supporting this proposal. One commenter suggested that the amendment not apply until the 2016 and later MLR reporting years.

Response: We appreciate the comments regarding the definitions of large employer and small employer. We also agree that although the Protecting Affordable Coverage for Employees Act was passed in and effective as of October 2015, policies that were in effect in 2015 were issued using the group definitions that existed prior to this Act. Therefore, we are finalizing the proposed definitional changes effective with the 2016 MLR reporting year.

2. Reporting of Incurred Claims (§§ 158.103 and 158.140(a))

The MLR December 1, 2010 interim final rule (75 FR 74864) and the May 16, 2012 technical corrections to that rule (77 FR 28788) direct issuers to report incurred claims with a 3-month run-out period, and define unpaid claim reserves to mean reserves and liabilities established to account for claims that were incurred during the MLR reporting year but had not been paid within 3 months of the end of the MLR reporting year. In the proposed rule, we proposed to amend the definition of unpaid claims reserves in § 158.103 and the requirements for reporting incurred claims in § 158.140(a) to utilize a 6-month, rather than a 3-month run-out period, beginning with the 2015 reporting year. The proposed amendment was intended to improve the accuracy of incurred claims amounts in MLR calculation as well as in the risk corridors calculation under a related proposed amendment to § 153.530.

Comment: We received many comments, split equally between supporting the change and opposing it. Some commenters that opposed our proposal requested that any extension in the run-out period include an extension to the filing deadline. Other commenters were principally concerned that the MLR rebate deadline would also be extended, which they believed would harm consumers. One commenter also noted that a longer run-out period could negatively affect States' timely review of issuers' rate filings. Additionally, many opponents noted that the NAIC had considered a 6-month run-out period in 2010 and determined that it would not result in a materially more accurate MLR. The commenters stated that any increase in accuracy would therefore be outweighed by the administrative burden required to update issuer processes. Further, some of these commenters noted that since two of the three premium stabilization programs are temporary and will expire in the near future, HHS could, at that time, revert back to the June 1 MLR filing deadline, rather than maintain the current July 31 deadline that was adopted to accommodate the premium stabilization programs. Commenters point out that this would allow consumers to receive rebates sooner. Supporters of the 6-month run-out period agreed that a longer run-out period would improve the accuracy of MLRs and rebate amounts by utilizing actual rather than estimated claims amounts.

Response: We appreciate the comments supporting our proposal, but also acknowledge the practical considerations raised by the commenters that opposed our proposal. We agree with those commenters that suggested that it may be more beneficial for all stakeholders if we do not modify the run-out period at this time, but instead explore ways to restore the earlier MLR deadlines after two of the three premium stabilization programs expire. Consequently, we are not finalizing the proposed amendments to §§ 158.103 and 158.140(a) regarding unpaid claims reserves and incurred claims, and are retaining the existing 3-month run-out period.

3. Reporting of Fraud Prevention Expenditures

In the proposed rule, we invited comment on whether we should modify the treatment of a health insurance issuer's investments in fraud prevention activities for MLR reporting purposes, noting that we were considering amending the MLR regulation to permit the counting of a health insurance issuer's investments in fraud prevention activities among those expenses attributable to incurred claims. We asked for comments on this approach, including whether safeguards against potential abuse should be included (such as an upper limit on this allowance); whether we should collect fraud prevention activity expense data as an informational item on the MLR Annual Reporting Form before amending the regulation; as well as on potential alternative treatment of these expenses for MLR reporting or rebate calculation purposes. We also asked for any specific, actual data with respect to the additional incentives that would result for health plan investments of this sort.

Comment: We received numerous comments, with the majority opposing any deviation from the current treatment of fraud prevention in MLR. Opponents stated that our proposal to modify treatment of fraud prevention expenses in MLR directly contradicts the NAIC's previous recommendation that such expenses should not be allowed. These commenters noted that the NAIC had conducted extensive debate and analysis of this issue with input from all stakeholders, and had concluded that allowing any additional fraud-related costs in the MLR calculation would be inappropriate. These commenters further stressed that the current rule is working as intended and that there is no evidence that a change is necessary, that fraud prevention is principally a cost-containment expense that should be part of the cost of doing business, and that any benefit to consumers is indirect, or difficult or impossible to isolate. Several commenters requested that we not proceed without additional data, or that we limit any allowance to

0.5 percent of earned premium. Many commenters requested that HHS not finalize the proposal until the NAIC's recently reconvened MLR Quality Improvement Activities subgroup determines whether to support a change in the treatment of fraud prevention expenses. In contrast, other commenters fully supported the proposal, expressing a view that allowing fraud prevention expenses in the MLR calculation would provide issuers an incentive to invest in preventing fraud, waste and abuse. Some of these commenters did not believe that we should impose any caps, while one commenter suggested a cap of 0.3 percent of earned premium. Many of these commenters additionally did not believe that data collection prior to finalizing the proposal would be useful, arguing that issuers have been underinvesting in fraud prevention. Some supporters stated that fraud prevention has a patient safety component, while others focused on the monetary savings for issuers. Some commenters further suggested that issuers would use the money saved through fraud prevention to lower premiums or cost sharing, or on medical services.

Response: We note that no stakeholder has provided specific data to support the notion that allowing fraud prevention expenses in the MLR calculation would have a positive impact. We agree with the commenters who stated that fraud prevention is principally a cost-containment activity, which generally is not permitted in the MLR calculation. In addition, we appreciate the NAIC's indication in its comment letter that its views regarding inclusion of fraud prevention as an adjustment to incurred claims have not changed since its 2010 recommendation. We also agree that, given the possibility that the treatment of fraud prevention may be addressed during the NAIC's review of quality improvement activities that is currently under way, it would be premature for HHS to modify the MLR regulation at this time. Therefore, we are not adopting any changes to the treatment of fraud prevention activities for MLR purposes.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. This final rule contains information collection requirements (ICRs) that are subject to review by OMB. A description of these provisions is given in the following paragraphs with an estimate of the annual burden, summarized in Table 11. In the December 2, 2015 (80 FR 75487) proposed rule, we requested public comment on each of the following collection of information requirements. The comments and our responses to them are discussed below.

A. ICRs Regarding Student Health Insurance Coverage (§ 147.145)

The final rule requires issuers of student health insurance coverage to specify the AV of the coverage and the metal level (or next lowest metal level) the coverage would otherwise satisfy. This information must be included in any plan materials summarizing the terms of coverage. We estimate that there are 49 student health insurance issuers nationwide that will each need to provide an average of 25,612 notifications annually.[68] We estimate that each student health insurance issuer will require an average of one hour for clerical staff (at a labor cost of $33.18 per hour) to insert the AV and metal level information into plan materials for all plans offered by the issuer, resulting in a total annual burden of 1 hour and an associated cost of $33.18 per issuer. There is no additional burden to determine these values as student health insurance issuers are currently required to calculate a plan's AV using the AV Calculator. For all 49 issuers currently providing student health insurance coverage, the total combined hour burden is estimated to be 49 hours with a total combined cost of $1,625.82 annually. This information will be included in existing plan materials; therefore, we do not estimate any additional distribution costs.

The final rule discontinues the outdated requirement that student health insurance issuers provide notice informing students that the coverage does not meet the annual limits requirements under section 2711 of the PHS Act. This regulatory provision, by its own terms, no longer applies, as student health insurance coverage is subject to the prohibition on annual dollar limits for policy years beginning or after January 1, 2014. Issuers will experience a reduction in burden related to the discontinued notices, which was previously estimated to be 1,071 hours, with an equivalent labor and mailing cost of $43,757.14 for all student health insurance issuer (under OMB Control No. 0938–1157).

[68] Estimate based on data from Medical Loss Ratio submissions for 2014 reporting year.

B. ICRs Regarding Submission of Risk Corridors Data (§ 153.530)

We finalized our amendment to the risk corridors program requirements at § 153.530 to require issuers to true-up claims liabilities and reserves used to determine the allowable costs reported for the preceding benefit year to reflect the actual claims payments made through March 31 of the year following the benefit year. This policy requires issuers to submit data indicating the difference between their incurred liability estimated as of March 31 following the preceding benefit year and March 31 following the current benefit year. While we believe that issuers will be recording these amounts as part of their normal business practices, we estimate that it will take approximately 1 hour for each issuer at $54.44 per hour (according to the wage estimates provided in the MLR notice CMS–10418–OCN 0938–1164) to record these amounts. Therefore, we estimate the overall cost burden of implementing this policy will be $54.44 per issuer, for approximately 320 applicable risk corridors program issuers, for a total cost burden of $17,421.

C. ICRs Regarding Submission of Rate Filing Justification (§ 154.215)

This final rule amends § 154.215 to require health insurance issuers to submit a Unified Rate Review Template (URRT) for all single risk pool coverage regardless of whether there is a plan within a product that experiences a rate increase. The existing information collection requirement is approved under OMB Control Number 0938–1141. This includes the URRT and instructions for rate filing documentation that issuers currently use to submit rate information to HHS for rate increases of any size for single risk pool coverage. We believe most issuers already report this information. However, we estimate the number of URRT submissions may increase by 1 percent due to this requirement. We released information regarding revisions to the information collection template and instructions in accordance with the Paperwork Reduction Act of 1995, in CMS–10379, for a 60-day comment period.[69]

D. ICRs Regarding Election To Operate an Exchange After 2014 (§ 155.106)

This final rule amends the dates for application submission and approval for States seeking to operate an SBE, and have an approved or conditionally

[69] 81 FR 8498 (February 19, 2016). Available at, *https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-03474.pdf.*

approved Exchange Blueprint application and operational readiness assessment. We are not modifying the documents that States already must submit as part of the required Exchange Blueprint application. Therefore, we do not anticipate any additional impact to the administrative burden associated with the regulatory changes to § 155.106. HHS is utilizing the existing PRA package approved under OMB Control Number 0938–1172 for the Exchange Blueprint application.

E. ICRs Regarding Standards for Certified Application Counselors (§ 155.225(b)(1)(iii))

Section 155.225(b)(1)(ii) requires certified application counselor designated organizations to maintain a registration process and method to track the performance of certified application counselors. This final rule adds a new § 155.225(b)(1)(iii) requiring certified application counselor designated organizations to provide the Exchange with information and data regarding the number and performance of the organization's certified application counselors, and the consumer assistance they provide. Although the requirement at § 155.225(b)(1)(ii) does not specify the type of performance information that must be tracked, or require that the information be provided to the Exchange, we expect that certified application counselor designated organizations already have a tracking process in place to collect performance information from individual certified application counselors, and that individual certified application counselors are already recording and submitting this required information to their organization. Therefore, we expect this final rule to have minimal impact on individual certified application counselors and on certified application counselor designated organizations.

Section 155.225(b)(1)(iii) would add a new burden of compiling the performance information and submitting it to the Exchanges. In States with FFEs, HHS anticipates that, beginning for the third quarter of calendar year 2017, it will collect three performance data points each quarter from certified application counselor designated organizations: The number of individuals who have been certified by the organization; the total number of consumers who received application and enrollment assistance from the organization; and of that number, the number of consumers who received assistance applying for and selecting a QHP, enrolling in a QHP, or applying for Medicaid or CHIP. We anticipate that this data will be reported to FFEs electronically, through HIOS or another electronic submission vehicle. For the purpose of estimating costs and burdens, we assume that SBEs will collect the same information with the same frequency, although our rule gives Exchanges the flexibility to determine which data to collect and the form and manner of the collection. We estimate that certified application counselor designated organizations will have a mid-level health policy analyst prepare the reports and a senior manager will review each quarterly report. HHS expects that a mid-level health policy analyst (at an hourly wage rate of $40.64) will spend 2 hours each quarter to provide the required quarterly submissions and a senior manager (at an hourly wage rate of $91.31) will spend ⅜ hour to review the submissions. Therefore, we estimate each quarterly report will require 2.375 hours and a cost burden of $115.52 per quarter per organization, or 9.50 hours with a cost (four quarterly reports) of $462.08 annually per certified application counselor designated organization. Nationwide, we estimate there are 5,000 certified application counselor designated organizations, resulting in an annual cost burden of $2,310,400 and 47,500 hours for certified application counselor designated organizations.

Under § 155.225(b)(1)(iii), if an Exchange requests these certified application counselor reports, the Exchange would also need to review the reports. We assume that all Exchanges will require quarterly reports and will utilize in-house staff to review them. We assume that an employee earning a wage that is equivalent to a mid-level GS–11 employee would review quarterly report submissions from certified application counselor designated organizations.[70] We estimate that a mid-level employee (at an hourly wage rate of $43.13) will spend 10 minutes reviewing each quarterly report for a cost burden of approximately $7.19 per quarterly report per certified application counselor designated organization. For all SBEs, we estimate that there are 1,500 certified application counselor designated organizations resulting in a cost burden of 1,000 hours and approximately $43,130 annually. Costs to the FFEs are estimated separately in the Regulatory Impact Analysis section of this final rule.

[70] Federal wage rates are available at *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2015/GS_h.pdf.*

F. ICRs Regarding Network Adequacy Standards (§ 156.230(d) and (e))

Section 156.230(d) requires that QHP issuers make a good faith effort to provide written notice of discontinuation of a provider 30 days prior to the effective date of the change or otherwise as soon as practicable, to enrollees who are patients seen on a regular basis by the provider or who receive primary care from the provider whose contract is being discontinued, irrespective of whether the contract is being discontinued due to a termination for cause or without cause, or due to a non-renewal. This is a third-party disclosure requirement. The notification requirement under § 156.230(d)(1) is a common practice in the current market as several States, Medicare Advantage, Medicaid Managed Care, and the NAIC Network Adequacy Model Act have standards regarding enrollee notification of a provider leaving a network. As discussed in the preamble, under State laws, many QHP issuers will already be under this obligation, and therefore, our notification requirements will apply in a more limited fashion. Additionally, we incorporated SADPs into our calculations, but we recognize given the notification requirements that SADPs may rarely need to send a notification.

We estimate that a total of 475 issuers participate in the FFE and would be required to comply with the standard. We estimated that 5 percent of providers discontinue contracts per year, and that an issuer in the FFE covers 7,500 National Provider Identifiers, which means that we estimate an issuer would have 375 provider discontinuations in a year. In response to comment to the proposed rule, we are clarifying that our assumption is that the database manager will receive notification from the issuer's contracting team that a provider contract is being discontinued. From that notification, the database manager would aggregate the claims data associated with the provider to develop the list of effected enrollees with associated enrollee information for the notice. This list of affected enrollees and associated enrollee information would be sent to an administrative assistant to aggregate into a notification template to be sent to the enrollee. Assuming 375 notifications per year, we believe that this task would be a routine process for the administrative assistant to undertake that would need little to no oversight to produce. As the issuer has the discretion to define regular basis and that the number of notifications are likely to widely varying between network and type of provider, we did not estimate based on the number of

individual notifications, but rather the number of provider discontinuations. For each provider discontinuation, we estimate that it will take a database administrator 30 minutes for data analysis to produce the list of affected enrollees, at $55.37 an hour, and an administrative assistant 30 minutes to develop the notification and send the notification to the affected enrollees, at $29.93 an hour. In response to comment, we are also clarifying these hourly rates include 35 percent adjustment for fringe benefits and overhead costs. The total costs per issuer would be $15,993.75. The total annual costs estimate would be $7,597,031. Because we are already collecting information regarding network classifications as part of the existing QHP certification process, we do not believe that the network classifications described in the preamble will result in additional information collection requirements for issuers.

In § 156.230(e), we require QHP issuers to provide a notice to enrollees of the possibility of out-of-network charges from an ancillary out-of-network provider in an in-network setting prior to the benefit being provided, to avoid counting the out-of-network costs against the annual limitation on cost sharing. This provision applies to all QHPs, which includes 575 issuers, and would start in 2018. We estimate it would take an issuer's mid-level health policy analyst (at an hourly wage rate of $54.87) approximately 6 minutes to create a notification and send the information. In response comments, we are clarifying the hourly rates include 35 percent adjustment for fringe benefits and overhead costs. We estimate that approximately two notices would be sent for every 100 enrollees. Assuming approximately 24 million enrollees in QHPs for 2018,[71] we estimate QHPs would send approximately 320,000 total notices, for a total 21,334.40 hours, at a total cost of $1,170,619.

G. ICR Regarding Monthly SHOP Enrollment Reconciliation Files Submitted by Issuers (156.285(c)(5))

We are finalizing amendments to § 156.285(c)(5) to specify that issuers in a Federally-facilitated SHOP would send monthly enrollment reconciliation files to the SHOP according to a process, timeline and file format established by the FF–SHOP. We anticipate that this would require FF–SHOP issuers to submit a standard file with specific data elements and submit their files in a process set out by the SHOP, at least monthly. Issuers of QHPs available through the SHOP are already required under the current version of § 156.285(c)(5) to reconcile enrollment files with the SHOP at least monthly. Therefore, we expect this policy to have minimal impact on SHOP issuers.

H. ICR Regarding Patient Safety Standards (§ 156. 1110)

In § 156.1110(a)(2)(i), for plan years beginning on or after January 1, 2017, a QHP issuer that contracts with a hospital with greater than 50 beds must verify that the hospital uses a patient safety evaluation system and implements a mechanism for comprehensive person-centered hospital discharge to improve care coordination and health care quality for each patient. In § 156.1100(a)(2)(ii), we also establish reasonable exceptions to these new QHP issuer patient safety requirements (rather than requiring reporting of such information to a Patient Safety Organization). The burden estimate associated with the information collection, recordkeeping, and disclosure requirements to demonstrate compliance with these standards includes the time and effort required for QHP issuers to maintain and submit to the applicable Exchanges documentation that would include hospital agreements to partner with, or other information demonstrating a partnership with, a Patient Safety Organization, a Hospital Engagement Network, or a Quality Improvement Organization that demonstrate that each of its contracted hospitals with greater than 50 beds meets the patient safety standards required in § 156.1110(a)(2) for plan years beginning on or after January 1, 2017. QHP issuers may not already be collecting such network provider information; therefore, we estimate the cost and burden to collect this administrative information as follows: For a total of 575 QHP issuers, offering 15 plans as potential QHPs, we estimated each issuer would require one senior manager an average of 3 hours to collect and maintain the hospital agreements or other information necessary to demonstrate compliance as required in § 156.1110(a)(2) for their QHPs offered on Exchanges for plan years beginning on or after January 1, 2017. For a senior manager (at an hourly wage rate of $91.31), we estimated the total annual cost for a QHP issuer to be $273.93. Therefore, we estimated a total annual burden of 1,725 hours, resulting in an annual cost of $157,510.

I. ICRs Regarding Other Notices (§ 156.1256)

We are adding a new section at § 156.1256 to require that, in the event of a plan or benefit display error, QHP issuers notify their enrollees within 30 calendar days after the issuer is informed by the FFE that the error has been fixed, if directed to do so by the FFE, both of the plan or benefit display error and of the opportunity to enroll in a new QHP under a special enrollment period at § 155.420(d)(4), if directed to do so by the FFE. This provision would apply to all QHPs in the FFEs, as well as all QHPs in the SBE–FPs, which includes 475 issuers. We anticipate that issuers will need to notify multiple enrollees of the same display error, and therefore estimate that one form notice would cover approximately 100 of the enrollees receiving such a notice. For each group of 100 form notices, we estimate that it would take approximately 30 minutes for an issuer's mid-level health policy analyst (at an hourly wage rate of $54.87) to amend, add SEP language provided by the FFE, and send the information. We estimate that approximately 4 percent of enrollees would receive such a notice. Assuming approximately 19 million FFE and SBE–FP enrollees in 2017,[72] we estimate QHPs in the FFEs and SBE–FPs would send approximately 760,000 total notices (4 percent of the estimated 19 million FFE and SBE–FP enrollees), for a total hours of 3,800, with a total cost of $208,506.

Although this final rule requires issuers to send notices for the specified situation, sending these notices is already part of normal issuer business practices and issuers are already working with the FFE to include language in their notices about special enrollment periods, as applicable and appropriate. Therefore, there will be no additional information required by issuers and no new administrative burden as a result of this final rule. In accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2), we believe the burden associated with this requirement would be exempt as it associated with a usual and customary business practice.

[71] We used the most recent CBO estimates for enrollment from March 2015 available at *https://www.cbo.gov/sites/default/files/cbofiles/attachments/43900-2015-03-ACAtables.pdf.*

[72] We applied the current FFE to total Exchange enrollment ratio to the most recent CBO estimates for total Exchange enrollment from March 2015 available at *https://www.cbo.gov/sites/default/files/cbofiles/attachments/43900-2015-03-ACAtables.pdf.*

TABLE 11—ANNUAL REPORTING, RECORDKEEPING AND DISCLOSURE BURDEN

Regulation Section	OMB Control No.	Number of respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total cost ($)
§ 147.145—AV	0938–1157	49	25,612	1	49	33.18	1,625.82	1,625.82
§ 153.530	0938–1164	320	1	1	320	54.44	17,421	17,421
§ 155.225 (b)(1)(iii)—certified application counselor (CAC) organizations	0938–1172	5,000	4	2.375	47,500	48.64	2,310,400	2,310,400
§ 155.225 (b)(1)(iii)—SBE	0938–1172	1,500	4	0.167	1,000	43.13	43,130	43,130
§ 156.230(d)	0938–NEW	475	375	1	375	85.3	7,597,031	7,597,031
§ 156.230(e)	0938–NEW	575	320,000	0.1	32,000	54.87	1,170,619	1,170,619
§ 156.1110	0938–1249	575	8,625	0.2	1,725	91.31	157,510	157,510
§ 156.1256	0938–NEW	475	760,000	0.5	3,800	54.87	208,506	208,506
Total		5,575			86,769		11,506,243	11,506,243

Note: There are no capital/maintenance costs associated with the information collection requirements contained in this rule; therefore, we have removed the associated column from Table 11.

We have submitted an information collection request to OMB for review and approval of the ICRs contained in this final rule. The requirements are not effective until approved by OMB and assigned a valid OMB control number.

V. Regulatory Impact Analysis

A. Statement of Need

This rule sets forth standards related to the premium stabilization programs (risk adjustment, reinsurance, and risk corridors) for the 2017 benefit year, as well as certain modifications to these programs 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 previous Payment Notices provided detail on the implementation of these programs, including the specific parameters for the 2014, 2015, and 2016 benefit years applicable to these programs. This rule provides additional standards related to essential health benefits, consumer assistance tools and programs of an Exchange, Navigators, non-Navigator assistance personnel, agents and brokers registered with the Federally-facilitated Exchange, certified application counselors, cost-sharing parameters and cost-sharing reduction notices, essential community providers, qualified health plans, network adequacy, stand-alone dental plans, acceptance of third-party payments by QHP issuers, patient safety standards for issuers of qualified health plans participating in Exchanges, the rate review program, 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 final 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 rule.

Although it is difficult to assess the 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 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 2017 and Exchange financial assistance assists 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 the next phase of patient safety standards, and increased plan transparency. Through the reduction in financial uncertainty for issuers and increased affordability for consumers, these provisions are expected to increase access to affordable health coverage.

HHS anticipates that the provisions of this 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 established provisions, including administrative costs related to notices, new patient safety requirements, and training and recertification requirements. In accordance with Executive Order 12866, HHS believes that the benefits of this regulatory action justify the costs.

Comment: A commenter criticized the regulatory analysis for lacking an adequate economic analysis. The

commenter criticized the credibility of the sources of the estimates and assumptions used. Additionally, the commenter noted that in Table 12 the magnitude of cost estimates is not labeled, and the costs associated with the user fee to be assessed on issuers in State-based Exchanges using the Federal platform were not included in the analysis.

Response: We previously estimated the annualized impact on issuers, contributing entities, and States of transfers and other programs in the 2014, 2015 and 2016 Payment Notice rules. Therefore, to avoid double-counting, Table 12 contains only incremental changes incurred as a result of provisions in this rule. The results of HHS's internal analyses were used to assess the impact of the policies of this rule. For this analysis, we continue to believe that the best available estimates of the impact of the Affordable Care Act on the Federal budget, enrollment in health insurance programs, and revenue collection are by the Congressional Budget Office. The CBO's most recent updates are available at *https://www.cbo.gov/sites/default/files/cbofiles/attachments/43900-2015-03-ACAtables.pdf.* We have clarified the units for the cost estimates in Table 12. We also note that the estimate of user fees to be assessed on issuers in State-based Exchanges using the Federal platform has been incorporated in the annual monetized costs described in Table 12.

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

In accordance with OMB Circular A–4, Table 12 depicts an accounting statement summarizing HHS's assessment of the benefits, costs, and transfers associated with this regulatory action.

This final rule implements standards for programs that will have numerous effects, including providing consumers with affordable health insurance coverage, reducing the impact of adverse selection, and stabilizing premiums in the individual and small group health insurance markets and in an Exchange. We are unable to quantify certain benefits of this final rule—such as improved health outcomes and longevity due to continuous quality improvement, improved patient safety and increased insurance enrollment—and certain costs—such as the cost of providing additional medical services to newly-enrolled individuals. The effects in Table 12 reflect qualitative impacts and estimated direct monetary costs and transfers resulting from the provisions of this final rule for health insurance issuers. The annualized monetized costs described in Table 12 reflect direct administrative costs to health insurance issuers as a result of the finalized provisions, and include administrative costs related to student health insurance coverage, rate filing justification, notices, new patient safety requirements, and training and recertification requirements that are estimated in the Collection of Information section of this final rule. The annual monetized transfers described in Table 12 include costs associated with FFE user fees and the risk adjustment user fee paid to HHS by issuers. We estimate that that the total cost for HHS to operate the risk adjustment program on behalf of States for 2017 will be approximately $24 million and that the risk adjustment user fee would be $1.56 per enrollee per year from risk adjustment issuers, which is less than the anticipated $50 million in benefit year 2016 for which we established a $1.75 per-enrollee-per-year risk adjustment user fee amount. We reassessed our contract costs for 2017 and were able to base 2017 risk adjustment eligible plan enrollment projections on actual 2014 risk adjustment enrollment. We revised our user fee rate from the proposed amount to reflect these considerations. Also, the increase in FFE user fee collections is the result of expected growth in enrollment in the FFEs rather than an increase in the user fee rate, which at 3.5 percent remains the same from 2016 to 2017. Beginning in 2017, we are also charging a user fee for State-based Exchanges using the Federal platform for eligibility and enrollment services. This user fee rate would be set at 1.5 percent for benefit year 2017.

TABLE 12—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.
- Continuous quality improvement among QHP issuers to reduce patient harm and improve health outcomes at lower costs.
- More informed Exchange QHP certification decisions.
- Increased coverage options for small businesses and employees with minimal adverse selection.

Costs	Estimate	Year dollar	Discount rate percent	Period covered
Annualized Monetized ($millions/year)	$11.67	2016	7	2016–2020
	$11.67	2016	3	2016–2020

Quantitative:

- Costs reflect administrative costs incurred by issuers and States to comply with provisions in this final rule.

Transfers	Estimate	Year dollar	Discount rate percent	Period covered
Annualized Monetized ($millions/year)	$25.89	2016	7	2016–2020
	$25.86	2016	3	2016–2020

- Transfers reflect a decrease in annual cost of risk adjustment user fees (the total risk adjustment user fee amount for 2016 was $50 million and $24 million for 2017), which are transfers from health insurance issuers to the Federal government. Transfers also reflect an increase of $30 million in 2017 and $65million in future years, in the amount of user fees collected from State-based Exchanges that use the Federal platform for eligibility and enrollment which are transfers from issuers to the Federal government.
- Unquantified: Lower premium rates in the individual market due to the improved risk profile of the insured, competition, and pooling.

This RIA expands upon the impact analyses of previous rules and utilizes the Congressional Budget Office's (CBO) analysis of the Affordable Care Act's impact on Federal spending, revenue collection, and insurance enrollment. The temporary risk corridors program and the transitional reinsurance program end after the 2016 benefit year. Therefore, the costs associated with those programs are not included in Tables 12 or 13 for fiscal years 2019–2020. Table 13 summarizes the effects of the risk adjustment program on the Federal budget from fiscal years 2016 through 2020, with the additional, societal effects of this rule discussed in this RIA. We do not expect the provisions of this final rule to significantly alter CBO's estimates of the budget impact of the premium stabilization programs that are described in Table 13. 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 rule (Table 12).

In addition to utilizing CBO projections, HHS conducted an internal analysis of the effects of its regulations on enrollment and premiums. Based on these internal analyses, we anticipate that the quantitative effects of the provisions in this rule are consistent with our previous estimates in the 2016 Payment Notice for the impacts associated with the advance payments of cost-sharing reductions and premium tax credits, the premium stabilization programs, and FFE user fee requirements.

TABLE 13—ESTIMATED FEDERAL GOVERNMENT OUTLAYS AND RECEIPTS FOR THE RISK ADJUSTMENT, REINSURANCE, AND RISK CORRIDORS PROGRAMS FROM FISCAL YEAR 2016–2020, IN BILLIONS OF DOLLARS

Year	2016	2017	2018	2019	2020	2016–2020
Risk Adjustment, Reinsurance, and Risk Corridors Program Payments	16.5	19.5	13	15	16	80
Risk Adjustment, Reinsurance, and Risk Corridors Program Collections*	15.5	18.5	13	15	16	78

Note 1: Risk adjustment program payments and receipts lag by one quarter. Receipt will fully offset payments over time.
Note 2: The CBO score reflects an additional $2 million in collections in FY 2015 that are outlayed in the FY 2016–FY 2020 timeframe. CBO does not expect a shortfall in these programs.
Source: Congressional Budget Office. Insurance Coverage Provisions of the Affordable Care Act—CBO's March 2015 Baseline Table *https://www.cbo.gov/sites/default/files/cbofiles/attachments/43900-2015-03-ACAtables.pdf.*

1. Fair Health Insurance Premiums

The final rule permits a rating area to be identified for a small employer that is within the service area of an issuer's network plan, for purposes of rating based on geography where the employer's principal business address is not within that service area. This will ensure that the network plan can be appropriately rated for sale to the group policyholder, benefitting both issuers and employers.

2. Student Health Insurance Coverage

The final rule eliminates the requirement that issuers of student health insurance coverage provide coverage comprised of the specific metal levels, and instead requires that student health insurance coverage provide at least 60 percent AV. The final rule also requires issuers of student health insurance coverage to specify in any plan materials summarizing the terms of coverage the AV of the coverage and the metal level (or next lowest metal level) the coverage would otherwise satisfy. This will provide flexibility for institutions of higher education to offer student health insurance plans that are more generous than the standard metal levels, while providing students with information that allows them to compare the generosity of student health insurance coverage with other available coverage options. This will affect an estimated 49 issuers nationwide that offer student health insurance coverage and approximately 1.4 million students and dependents enrolled in such plans.[73]

3. 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, 2015, and 2016 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 2017 benefit year, we estimate that the total cost for HHS to operate the risk adjustment program on behalf of States for 2017 will be approximately $24 million, and that the risk adjustment user fee would be $1.56 per enrollee per year. This user fee reflects our reassessment of both contract costs to support the risk adjustment program in 2017 and the expected member month enrollment in risk adjustment covered QHPs.

4. Risk Corridors

The Federally operated temporary risk corridors program ends in benefit year 2016 as required by statute. Because risk corridors charges are collected in the year following the applicable benefit year, and risk corridors payments lag receipt of collections by one quarter, we estimate that risk corridors transfers will continue through fiscal year 2018. In this rule, we establish that for the 2015 and 2016 benefit years, the issuer must true up claims liabilities and reserves used to determine the allowable costs reported for the preceding benefit year to reflect the actual claims payments made through March 31 of the year following the benefit year. This amendment provides for a more accurate risk corridors calculation by substituting actual experience in place of estimates. Some issuers overestimate their claims and liabilities, while others underestimate them. Based on the 2014 MLR and risk corridors data, we estimate that this amendment will result in a combined total reduction in risk corridors payments or increase in risk corridors charges for some issuers; and a combined total increase in risk corridors payments or decrease in risk corridors charges for other issuers. HHS

[73] Source: Data from Medical Loss Ratio submissions for 2014 reporting year.

continues to implement the risk corridors program in a budget neutral manner such that payments are made from collections that are received. If collections are insufficient to fund payment obligations, HHS will apply a pro rata reduction to risk corridors payments to issuers for the benefit year. Because of uncertainty in the amount of collections that will be received for payment for the 2015 benefit year, we are unable to estimate the magnitude of the net impact of the modification in the final rule, but believe that it will reduce the overall amount of risk corridors transfers for the 2015 benefit year.

5. Rate Review

In § 154.215, we amend the criteria for submission of the Unified Rate Review Template for single risk pool coverage to HHS. We expect URRT submissions may increase by 1 percent. We have revised the information collection currently approved under OMB Control Number 0938–1141 to clarify instructions related to completing the template for single risk pool coverage.

6. Additional Required Benefits

In § 155.170, we amended the requirement for coverage of benefits in addition to the essential health benefits. Specifically, we are rewording § 155.170(a)(2) to make clear that a benefit required by the State through action taking place on or before December 31, 2011 is considered an EHB and one required by the State through action taking place after December 31, 2011 is considered in addition to EHB. As we see this as a clarification, we do not anticipate an additional burden on States or issuers. At § 155.170(a)(3), we currently require the Exchange to identify which additional State-required benefits, if any, are in excess of EHB. We amended paragraph (a)(3) to designate the State, rather than the Exchange, as the entity that identifies which State-required benefits are not EHB. Because Exchanges have been relying upon State departments of insurance in determining what constitutes an essential health benefit, we do not anticipate any additional burden to States because of this modification, but simply a shift in burden from one State agency to another.

7. Standards for Navigators and certain Non-Navigator Assistance Personnel

This final rule amends some of the standards for consumer assistance functions under § 155.205(d) and (e), as well as for the activities of Navigators under § 155.210, and non-Navigator assistance personnel subject to § 155.215. The changes include ensuring consumers have access to skilled assistance with Exchange-related issues beyond applying for and enrolling in coverage. Such post enrollment and other assistance includes assisting consumers with applying for exemptions from the individual shared responsibility payment that are granted through the Exchange, with understanding the process of filing Exchange appeals, and with understanding basic concepts and rights related to health coverage and how to use it. The final rule also requires Navigators to provide targeted assistance to serve underserved or vulnerable populations, as identified by each Exchange. In addition, the final rule specifies that any individual or entity carrying out consumer assistance functions under § 155.205(d) and (e) or § 155.210 must complete training prior to performing any assister duties, including conducting outreach and education activities.

The final rule's amendments to §§ 155.205(d) and 155.215(b)(1)(i) related to completing training for Navigators and non-Navigator assistance personnel apply only to the timing of the training and do not have any impact on the training itself. Therefore, they do not affect the burden or cost for entities already subject to training requirements. Because under existing § 155.215(b)(2), Navigators in FFEs must already be trained on the tax implications of enrollment decisions, the individual responsibility to have health coverage, eligibility appeals, and rights and processes for QHP appeals and grievances, we expect our amendments to § 155.210(b)(2)(v) through (ix) to have minimal impact on FFE training. If any SBEs do not already provide training on these topics, we expect they would incur minimal costs in developing and implementing this training. Our final rule requiring Navigators to provide targeted assistance to underserved or vulnerable populations will have an increased benefit for consumers, especially hard to reach populations. All costs associated with reaching these consumers in FFEs are considered allowable costs that would be covered by the Navigator grants for the FFEs and that may be drawn down as the grantee incurs such costs. Additionally, § 155.210(b)(2)(i) already requires Navigators in all Exchanges to receive training on the needs of underserved and vulnerable populations.

8. Certified Application Counselors

This final rule requires certified application counselor organizations to submit data and information to the Exchanges regarding the number and performance of their certified application counselors and the consumer assistance they provide, upon request, in a form and manner specified by the Exchange. Under § 155.225(b)(1)(iii), if an Exchange requests these certified application counselor reports, the Exchange would also need to review them. We assume that all Exchanges will require quarterly reports and will utilize in-house staff to review them. We assume that an employee earning a wage that is equivalent to a mid-level GS–11 employee would review quarterly report submissions from certified application counselor designated organizations.[74] We estimate that a mid-level employee (at an hourly wage rate of $43.13) will spend 10 minutes reviewing each quarterly report for a cost burden of approximately $7.19 per quarterly report per certified application counselor designated organization. We estimate the costs of this requirement for State Exchanges in the Collection of Information Requirements section of this final rule. For the FFEs, we estimate there are 3,500 certified application counselor designated organizations, resulting in a total annual burden for FFEs of 2,333 hours, at a cost of $100,660.

9. SHOP

The SHOP facilitates the enrollment of eligible employees of eligible small employers into small group health insurance plans. A qualitative analysis of the costs and benefits of establishing a SHOP was included in the RIA published in conjunction with the Exchange Establishment Rule.[75] Section 155.735(d)(2)(iii), added in this rule, requires the FF–SHOPs to send qualified employees a notice notifying them in advance of a child dependent's loss of eligibility for dependent child coverage under their plan because of age. The notice will be sent 90 days in advance of the date when the dependent enrollee would lose eligibility for dependent child coverage. We estimate the FF–SHOPs will spend roughly 35 hours annually, per State, to prepare the notice, for a total cost of $1,775, per State, to design and implement the notices under § 155.735(d)(2)(iii). We estimate that there will be approximately 32 States operating under the FF–SHOPs and all will be subject to this requirement. Therefore, we estimate

[74] Federal wage rates are available at *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2015/GS_h.pdf.*

[75] Available at *http://cciio.cms.gov/resources/files/Files2/03162012/hie3r-ria-032012.pdf.*

a total annual cost of $58,575 for the FF–SHOPs as a result of this requirement.

10. Standardized Options

In assessing the burden associated with implementing standardized options, as described in § 156.20, we assessed the potential impact on premiums established by QHP issuers in the FFEs. We anticipate that an issuer will price a standardized option based on how similar or different the standardized option is to the issuer's current shelf (plan offerings). Because of the large variation across the country, we expect that how standardized options will be priced will vary by issuer and by State. We do not anticipate that it will significantly affect 2017 plan premiums. We expect that issuers will offer standardized options at a given metal level if the standardized options are similar to their existing plans and can be priced competitively.

The premium impact on issuers' non-standard plan offerings is difficult to estimate. Among the six State Exchanges that standardized plans and required standardized options to be offered by QHP issuers in 2014, two (California and New York) that attempted to conduct premium impact analysis found that introduction of the requirement on issuers to offer standardized options was associated with a negligible or downward impact on premiums. However, these SBEs found it was difficult to isolate the effects of plan standardization on premiums given the many changes that occurred in the insurance market in 2014 (including the uptake in individual market enrollment, the movement to narrow networks, and active purchasing and rate negotiation in California).

Again, we note that there is a great deal of uncertainty in how this policy will affect Exchanges due to several considerations:

- While we standardize cost-sharing on key essential health benefits, there are a wide range of other benefit design parameters that we will not standardize. It is not clear how this differentiation will manifest among plans or affect consumer choice.
- There is also wide geographic variation in health care markets, including with respect to prices, plan designs, and provider networks. As such, we anticipate that the take-up of standardized options and their impacts on consumers will vary in different locations across the country.

11. User Fees

To support the operation of FFEs, we require in § 156.50(c) that a participating issuer offering a plan through an FFE must remit a user fee to HHS each month equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year and the monthly premium charged by the issuer for each policy under the plan where enrollment is through an FFE. In this final rule, for the 2017 benefit year, we finalize a monthly FFE user fee rate equal to 3.5 percent of the monthly premium. For a State-based Exchange using the Federal platform, we finalize a user fee rate equal to 1.5 percent of the monthly premium. For the accounting statement of this rule, we have reduced the incremental increase in the user fee collected for the first year by one-half, after which we estimate $30 million in the amount of user fees collected from State-based Exchanges that use the Federal platform for 2017 and $65 million for years after 2017. For the user fee charges assessed on issuers in the FFE, we have previously received a waiver 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. Similarly, for this year, for the user fee charges assessed on issuers in the FFE and State-based Exchanges using the Federal platform, we have sought 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. This exception ensures 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).

12. Actuarial Value

In response to comments, we are clarifying that we take into consideration stakeholder feedback on needed changes. One commenter asked for the basis on which we concluded that the cost sharing changes that might be required by a change to the AV calculator would likely be minor. We note that because of the de minimis range established at § 156.140, many plans do not require significant changes to cost-sharing structure each year beyond those permitted by the statute (such as for changes to the annual limitation on cost sharing). However, where significant changes are required, for example when a plan has reached the permissible de minimis limit and the change in annual limitation on cost sharing does not fully accommodate changed calculations established by an updated AV Calculator, we acknowledge that plans likely engage in significant analysis in order to establish new cost-sharing structures. We do not anticipate that our policy providing us with additional flexibility in updating the AV Calculator will substantially change the number of plans for which new cost-sharing structures must be calculated each year—it is our intent to continue to provide annual updates to the AV Calculator.

13. Network Adequacy

In § 156.230(e), we are finalizing our proposal to require QHPs in the FFEs to count certain out-of-network cost sharing towards the in-network annual limitation on cost sharing for enrollees who receive EHB from an out-of-network *ancillary* provider at an in-network setting, with modifications. The premium impact will vary based on existing State laws. We received no comments on this estimate.

14. 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.[76]

We set forth in this rule the reductions in the maximum annual limitation on cost sharing for silver plan variations. Consistent with our analysis in previous 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 2017 maximum annual limitation on cost sharing for self only coverage ($7,150). We do not believe these changes will result in a significant economic impact. Therefore, we do not believe the provisions related to cost-sharing reductions in this rule will have an impact on the program established by and described in the 2015 and 2016 Payment Notices.

[76] 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.*

We also finalize the premium adjustment percentage for the 2017 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 coverage the Secretary may use to determine eligibility for hardship exemptions under section 5000A of the Code, and the assessable payments under sections 4980H(a) and 4980H(b). We believe that the 2017 premium adjustment percentage of 13.25256291 percent is well within the parameters used in the modeling of the Affordable Care Act, and we do not expect that these provisions will have a substantial, if any, effect on CBO's March 2016 baseline estimates of the budget impact.

15. Stand-Alone Dental Plans

In § 156.150, we are increasing the annual limitation on cost sharing for stand-alone dental plans being certified by the Exchanges. We believe that the benefit of increasing the annual limit on cost sharing is that issuers would be able to offer consumers SADPs that provide preventive care without any cost sharing, similar to what is generally offered by SADPs in the large group market. We received several comments noting that preventive care without any cost sharing would be easier to achieve with a high annual limitation on cost sharing. We have established that increasing the annual limitation on cost sharing over time will decrease the likelihood of premium increases.

16. Meaningful Difference

In § 156.298, we remove the health savings account eligibility and the individual coverage or enrollment group coverage criteria as options for meeting the meaningful difference standard. As we believe the health savings account eligibility criterion to overlap with cost-sharing criterion (that is, we believe that a plan that meets the meaningful difference standard for health savings account eligibility would also meet the standard under the cost-sharing criterion), we do not believe that removing this criterion will have any impact on issuers. Additionally, our records indicate that no other than self-only coverage plans were reviewed for meaningful difference in 2015 and none are offered for 2016 Open Enrollment, meaning that there will be limited impact on removing these criteria. As such, we estimate that the impact of this change is negligible.

17. Patient Safety Standards

The next phase of patient safety standards requires QHP issuers participating in Exchanges to track hospital participation with PSOs or other evidence-based patient safety initiatives. We believe this new requirement to verify that hospitals use a patient safety evaluation tool and implement a comprehensive person-centered hospital discharge program would encourage continuous quality improvement among QHP issuers by strengthening system-wide efforts to reduce patient harm in a measurable way, improve health outcomes at lower costs, allow for flexibility and innovation in patient safety interventions and practices, and encourage meaningful health care quality improvements. We discuss the administrative costs associated with submitting this information in the Collection of Information section of this final rule.

18. Acceptance of Certain Third Party Payments

On March 19, 2014, we published in the **Federal Register** an interim final rule (IFR) with comment period titled, Patient Protection and Affordable Care Act; Third Party Payment of Qualified Health Plan Premiums (79 FR 15240). In § 156.1250, we finalize this rule to require individual market QHPs and SADPs to accept premium payments made by certain third parties. This rule describes the circumstances in which individual market QHPs and SADPs must accept payments made by Ryan White HIV/AIDS program; Federal and State government programs that provide premium and cost sharing support for specific individuals; and Indian tribes, tribal organizations, and urban Indian organizations. We do not believe these actions would impose any significant new costs on issuers because we assume that most issuers already accept such payments under our interim final rule.

19. Medical Loss Ratio

This final rule amends the risk corridors program requirements at § 153.530 to require issuers to true-up the claims liabilities and reserves used to determine the 2014 and 2015 allowable costs to reflect the actual claims payments made through March 31, 2016 and March 31, 2017, respectively. We discuss the impact of this proposal on the risk corridors program elsewhere in this RIA. Because risk corridors payments and charges are a component of the MLR and rebate calculation, the impact of this amendment on risk corridors payments and charges may in turn affect MLR rebates to consumers. While, as noted previously, we are unable to estimate the magnitude of the net impact of this modification on risk corridors transfers, and consequently on MLR rebates, we believe that this amendment would increase rebate payments from issuers to consumers.

D. Regulatory Alternatives Considered

In developing the policies contained in this final rule, we considered numerous alternatives to the presented proposals. Below we discuss the key regulatory alternatives that we considered.

Regarding the open enrollment periods for 2017 and beyond, we considered gradually shifting the end of the open enrollment period earlier. However, we believe keeping the open enrollment period the same for benefit years 2017 and 2018 as it was for 2016 and then moving to a December 15 end date simplifies messaging to consumers, while achieving our ultimate goal of shifting the open enrollment period so that it ends prior to the start of the benefit year.

Regarding the 2017 required contribution percentage, which establishes the threshold for spending on minimum essential coverage required for an affordability exemption from the individual shared responsibility requirement, we considered continuing to use the per capita gross domestic product as the measure of income growth. However, a new measure of income growth, per capita personal income, became available for the first time last year as part of the National Health Expenditure's projections, and includes not only participation in production but also transfer payments. We believe that this broader measure of personal income more accurately reflects individual income than GDP per capita.

For SBE–FP model provisions at § 155.200(f), we considered a number of alternatives. We considered not codifying the SBE–FP model, and winding down use of the Federal platform by SBEs. In this alternative, SBEs currently utilizing these services would have had to find a way to perform all required Exchange eligibility and enrollment functions themselves, including the implementation of an Exchange technology platform, or else convert to FFEs. We finalized the

proposal without significant change because we believe that it is technically feasible and will permit a number of SBEs to access the Federal government's greater economies of scale. We also considered a more customized option, under which an SBE would be permitted to select from a menu of Federal services. While we are considering providing more flexibility to SBE–FPs in the future, at this point we do not have the operational ability to permit that level of customization. Finally, we considered alternatives under which issuers and other delegated and downstream entities in States with SBE–FPs would not be required to meet FFE standards, or HHS would not participate in enforcement against issuers violating those FFE rules. We believe that applying Federal standards to issuers and their downstream entities for SBE–FPs helps promote consistent minimum standards associated with HealthCare.gov.

For employer choice in the FF–SHOPs, we considered offering an additional employer choice option that would permit an employer to select an actuarial value level of coverage, after which employees could choose from plans available at that level and at the level above it. Recognizing that small group market dynamics differ by State, we decided to seek comment on, but not finalize this option at this time. We also considered requiring all SHOPs to offer the additional employer choice options we proposed, but instead generally opted to maintain State-based SHOPs' flexibility under the current regulations, so that States can decide whether implementing additional employer choice options would be in the best interest of small group market consumers in their State.

We considered requiring QHP issuers to offer standardized options as a condition of participation in the FFEs. However, we believe that markets and Exchanges may be at different stages of readiness for standardized options, and that the cost-sharing structure that HHS specifies may not be well tailored for all States. Similarly, we believe that some issuers may have difficulty offering standardized options in the short run because of operational constraints.

Since releasing the proposed rule, the NAIC has adopted the NAIC Network Adequacy Model Act.[77] We applaud NAIC's work on the Model Act and appreciate the extensive efforts of the Network Adequacy Model Review Subgroup members, as well as the participating stakeholders. As a result of the NAIC Network Adequacy Model Act finalization, we made revisions to this rule to give States more opportunity to implement the NAIC Network Adequacy Model Act. For example, we elected not to finalize our policy requiring each State with an FFE to establish a minimum quantitative network adequacy threshold this year, and stated we would closely monitor States' efforts to implement the provisions of the NAIC Network Adequacy Model Act.

In § 156.1110, we considered maintaining the current approach of aligning with Medicare hospital Conditions of Participation standards and not establishing further regulations at this time for QHP issuers to collect information, such as hospital participation agreements with PSOs, to comply with new patient safety standards for plan years beginning on or after January 1, 2017. However, we decided to adopt this next phase in this final rule because we believe that strengthening patient safety standards and aligning with current, effective patient safety interventions will achieve greater impact for consumers, in terms of health care quality improvement and harm reduction, resulting in higher quality QHPs being offered in the Exchanges. Additionally, we considered an approach that did not include establishing reasonable exceptions to the requirements for a QHP issuer that contracts with a hospital with greater than 50 beds to utilize a patient safety evaluation system and implement a mechanism for comprehensive person-centered hospital discharges, as described in section 1311(h)(1) of the Affordable Care Act. However, we determined that it is important to support national patient safety efforts, promote evidence-based patient safety interventions and allow for flexibility, innovation, and minimal burden for issuers and hospitals.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act, (5 U.S.C. 601, *et seq.*), requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of the 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 rule, we set forth 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 rule:

- Health insurance issuers.
- Group health plans.

We believe that health insurance issuers and group health plans would be classified under the North American Industry Classification System code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of $38.5 million or less would be considered small entities for these North American Industry Classification System codes. Issuers could possibly be classified in 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard would be $32.5 million or less.

Based on data from MLR annual report submissions for the 2014 MLR reporting year, approximately 118 out of 525 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 may be affected, since almost 80 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. Based on data from the 2014 MLR and risk corridors annual report submissions, 20 of these 118 potentially small entities had risk corridors payments or charges for the 2014 benefit year. Only one of these entities is estimated to experience a decrease in its risk corridors payment under the provisions in § 153.530(b)(2)(iv), with no impact on its rebate liability. Therefore, we do not expect the provisions of this rule to affect a substantial number of small health insurance issuers or group health plans.

Among the policies established by this rule are policies that could increase the choice of QHPs available to small

[77] *http://www.naic.org/store/free/MDL-74.pdf.*

groups participating in an FF–SHOP, and policies imposing requirements, including information collection requirements, on Navigators, non-Navigator assistance personnel, and certified application counselor organizations. We believe that the effects on small employers participating in an FF–SHOP are difficult to quantify, but will not result in substantial additional burden, since they will simply permit certain small employers greater choice in the QHPs they may make available. The burden estimates for Navigators, non-Navigator assistance personnel, and certified application counselor organizations are described elsewhere in the ICR and RIA sections of this final rule.

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 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. Currently that threshold is approximately $144 million. Although we have not been able to quantify all costs, the combined administrative cost and user fee impact on State, local, or Tribal governments and the private sector may be above the threshold. Earlier portions of this RIA constitute our UMRA analysis.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications. Because States have flexibility in designing their Exchange and Exchange-related programs, State decisions will ultimately influence both administrative expenses and overall premiums. States are not required to establish an Exchange or risk adjustment or reinsurance program. For States electing to operate an Exchange, risk adjustment or reinsurance program, much of the initial cost of creating these programs was 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 may charge user fees to issuers.

In HHS's view, while this 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. For example, in this final rule we have established a number of policies relating to network adequacy and continuity of care for QHPs on FFEs. States have traditionally played a major role in regulating these aspects of health insurance, when offered off the Exchange.

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. Following review of comments from State insurance officials and the NAIC, we have made substantial changes to our network adequacy policies in this final rule.

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

H. Congressional Review Act

This 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 Parts 144 and 147

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 153

Administrative practice and procedure, Health care, Health insurance, Health records, Organization and functions (Government agencies), Reporting and recordkeeping requirements.

45 CFR Part 154

Administrative practice and procedure, Claims, Health care, Health insurance, Penalties, Reporting and recordkeeping requirements.

45 CFR Part 155

Administrative practice and procedure, Health care, Health insurance, Reporting and recordkeeping requirements, State and local governments

45 CFR Part 156

Administrative practice and procedure, Advertising, American Indian/Alaska Natives, Conflict of interest, Consumer protection, Cost-sharing reductions, Grant programs—health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Individuals with disabilities, Loan programs—health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, State and local governments, Sunshine Act, Technical assistance, Women, Youth.

45 CFR Part 158

Administrative practice and procedure, Claims, Health care, Health insurance, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR parts 144, 147, 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 paragraph (1) of the definition of ''Excepted benefits'' and revising the definitions of ''Large employer'' and ''Small employer'' to read as follows:

§ 144.103 Definitions.

* * * * *

Excepted benefits * * *

(1) Group market provisions in 45 CFR part 146, subpart D, is defined in 45 CFR 146.145(b); and

* * * * *

Large employer means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 51 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year. A State may elect to define large employer by substituting ''101 employees'' for ''51 employees.'' In the case of an employer that was not in existence throughout the preceding calendar year, the determination of whether the employer is a large employer is based on the average number of employees that it is reasonably expected the employer will employ on business days in the current calendar year.

* * * * *

Small employer means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 1 but not more than 50 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year. A State may elect to define small employer by substituting ''100 employees'' for ''50 employees.'' In the case of an employer that was not in existence throughout the preceding calendar year, the determination of whether the employer is a small employer is based on the average number of employees that it is reasonably expected the employer will employ on business days in the current calendar year.

* * * * *

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

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

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

■ 4. Section 147.102 is amended by revising paragraph (a)(1)(ii) to read as follows:

§ 147.102 Fair health insurance premiums.

(a) * * *

(1) * * *

(ii) Rating area, as established in accordance with paragraph (b) of this section. For purposes of this paragraph (a), rating area is determined—

(A) In the individual market, using the primary policyholder's address.

(B) In the small group market, using the group policyholder's principal business address. For purposes of this paragraph (a)(1)(ii)(B), principal business address means the principal business address registered with the State or, if a principal business address is not registered with the State, or is registered solely for purposes of service of process and is not a substantial worksite for the policyholder's business, the business address within the State where the greatest number of employees of such policyholder works. If, for a network plan, the group policyholder's principal business address is not within the service area of such plan, and the policyholder has employees who live, reside, or work within the service area, the principal business address for purposes of the network plan is the business address within the plan's service area where the greatest number of employees work as of the beginning of the plan year. If there is no such business address, the rating area for purposes of the network plan is the rating area that reflects where the greatest number of employees within the plan's service area live or reside as of the beginning of the plan year.

* * * * *

■ 5. Section 147.145 is amended by revising paragraphs (b)(2) and (3) and removing paragraphs (d) and (e) to read as follows:

§ 147.145 Student health insurance coverage.

* * * * *

(b) * * *

(2) *Levels of coverage.* The requirement to provide a specific level of coverage described in section 1302(d) of the Affordable Care Act does not apply to student health insurance coverage for policy years beginning on or after July 1, 2016. However, the benefits provided by such coverage must provide at least 60 percent actuarial value, as calculated in accordance with § 156.135 of this subchapter. The issuer must specify in any plan materials summarizing the terms of the coverage the actuarial value and level of coverage (or next lowest level of coverage) the coverage would otherwise satisfy under § 156.140 of this subchapter.

(3) *Single risk pool.* Student health insurance coverage is not subject to the requirements of section 1312(c) of the Affordable Care Act. A health insurance issuer that offers student health insurance coverage may establish one or more separate risk pools for an institution of higher education, if the distinction between or among groups of students (or dependents of students) who form the risk pool is based on a bona fide school-related classification and not based on a health factor (as described in § 146.121 of this subchapter). However, student health insurance rates must reflect the claims experience of individuals who comprise the risk pool, and any adjustments to rates within a risk pool must be actuarially justified.

* * * * *

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

■ 6. The authority citation for part 153 continues to read as follows:

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

■ 7. Section 153.405 is amended by revising paragraph (i) to read as follows:

§ 153.405 Calculation of reinsurance contributions.

* * * * *

(i) *Audits.* HHS or its designee may audit a contributing entity to assess its compliance with the requirements of this subpart. A contributing entity that uses a third party administrator, administrative services-only contractor, or other third party to assist with its obligations under this subpart must ensure that the third party administrator, administrative services-only contractor, or other third party cooperates with any audit under this section.

■ 8. Section 153.510 is amended by adding paragraph (g) to read as follows:

§ 153.510 Risk corridors establishment and payment methodology.

* * * * *

(g) *Adjustment to risk corridors payments and charges.* If an issuer reported a certified estimate of 2014 cost-sharing reductions on its 2014 MLR and Risk Corridors Annual Reporting Form that is lower than the actual value of cost-sharing reductions calculated under § 156.430(c) of this subchapter for the 2014 benefit year, HHS will make an adjustment to the amount of the issuer's 2015 benefit year risk corridors payment or charge measured by the full difference between the certified estimate of 2014 cost-sharing reductions reported and the actual value of cost-sharing reductions provided as calculated under § 156.430(c) for the 2014 benefit year.

■ 9. Section 153.530 is amended by revising paragraphs (b)(2)(ii) and (iii) and adding paragraph (b)(2)(iv) to read as follows:

§ 153.530 Risk corridors data requirements.

* * * * *

(b) * * *

(2) * * *

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

(iii) A cost-sharing reduction amount equal to the amount of cost-sharing reductions for the benefit year as calculated under § 156.430(c) of this subchapter, to the extent not reimbursed to the provider furnishing the item or service.

(iv) For the 2015 and 2016 benefit years, any difference between—

(A) The sum of unpaid claims reserves and claims incurred but not reported, as set forth in §§ 158.103 and 158.140(a)(2) and (3) of this subchapter, that were reported on the MLR and Risk Corridors Annual Reporting Form for the year preceding the benefit year; and

(B) The actual claims incurred during the year preceding the benefit year and paid between March 31 of the benefit year and March 31 of the year following the benefit year.

* * * * *

■ 10. Section 153.710 is amended by—

■ a. Removing paragraph (d).

■ b. Redesignating paragraphs (e) and (f) as paragraphs (d) and (e), respectively.

■ c. Revising newly redesignated paragraph (e).

■ d. Adding paragraph (f).

■ e. Adding paragraph (g) introductory text and revising paragraphs (g)(1) introductory text, (g)(1)(iii) and (iv), and (g)(2).

■ f. Adding paragraph (g)(3).

The revisions and additions read as follows:

§ 153.710 Data requirements.

* * * * *

(e) *Unresolved discrepancies.* If a discrepancy first identified in a final dedicated distributed data environment report in accordance with paragraph (d)(2) of this section remains unresolved after the issuance of the notification of risk adjustment payments and charges or reinsurance payments under § 153.310(e) or § 153.240(b)(1)(ii), respectively, an issuer of a risk adjustment covered plan or reinsurance-eligible plan may make a request for reconsideration regarding such discrepancy under the process set forth in § 156.1220(a) of this subchapter.

(f) *Evaluation of dedicated distributed data.* If an issuer of a risk adjustment covered plan fails to provide sufficient required data, such that HHS cannot apply the applicable methodology to calculate the risk adjustment payment transfer amount for the risk adjustment covered plan in a timely or appropriate fashion, then HHS will assess a default risk adjustment charge under § 153.740(b). If an issuer of a reinsurance eligible plan fails to provide data sufficient for HHS to calculate reinsurance payments, the issuer will forfeit reinsurance payments for claims it fails to submit.

(1) *Data quantity.* An issuer of a risk adjustment covered plan or a reinsurance-eligible plan must provide, in a format and on a timeline specified by HHS, data on its total enrollment and claims counts by market, which HHS may use in evaluating whether the issuer provided access in the dedicated distributed data environment to a sufficient quantity of data to meet reinsurance and risk adjustment data requirements.

(2) *Data quality.* If, following the deadline for submission of data specified in § 153.730, HHS identifies an outlier that would cause the data that a risk adjustment covered plan or a reinsurance-eligible plan made available through a dedicated distributed data environment to fail HHS's data quality thresholds, the issuer may, within 10 calendar days of receiving notification of the outlier, submit an explanation of the outlier for HHS to consider in determining whether the issuer met the reinsurance and risk adjustment data requirements.

(g) *Risk corridors and MLR reporting.* Except as provided in paragraph (g)(3) of this section:

(1) Notwithstanding any discrepancy report made under paragraph (d)(2) of this section, or any request for reconsideration under § 156.1220(a) of this subchapter with respect to any risk adjustment payment or charge, including an assessment of risk adjustment user fees; reinsurance payment; cost-sharing reduction payment or charge; or risk corridors payment or charge, unless the dispute has been resolved, an issuer must report, for purposes of the risk corridors and MLR programs:

* * * * *

(iii) A cost-sharing reduction amount equal to the actual amount of cost-sharing reductions for the benefit year as calculated under § 156.430(c) of this subchapter, to the extent not reimbursed to the provider furnishing the item or service; and

(iv) For medical loss ratio reporting only, the risk corridors payment to be made or charge assessed by HHS under § 153.510.

(2) An issuer must report during the current MLR and risk corridors reporting year any adjustment made or approved by HHS for any risk adjustment payment or charge, including an assessment of risk adjustment user fees; any reinsurance payment; any cost-sharing reduction payment or charge; or any risk corridors payment or charge before August 15, or the next applicable business day, of the current MLR and risk corridors reporting year unless instructed otherwise by HHS. An issuer must report any adjustment made or approved by HHS for any risk adjustment payment or charge, including an assessment of risk adjustment user fees; any reinsurance payment; any cost-sharing reduction payment or charge; or any risk corridors payment or charge where such adjustment has not been accounted for in a prior MLR and Risk Corridor Annual Reporting Form, in the MLR and Risk Corridors Annual Reporting Form for the following reporting year.

(3) In cases where HHS reasonably determines that the reporting instructions in paragraph (g)(1) or (2) of this section would lead to unfair or misleading financial reporting, issuers must correct their data submissions in a form and manner to be specified by HHS.

PART 154—HEALTH INSURANCE ISSUER RATE INCREASES: DISCLOSURE AND REVIEW REQUIREMENTS

■ 11. 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).

■ 12. Section 154.200 is amended by revising paragraph (c)(2) to read as follows:

§ 154.200 Rate increases subject to review.

* * * * *

(c) * * *

(2) For rates filed for single risk pool coverage beginning on or after January 1, 2017, the average increase, including premium rating factors described in § 147.102 of this subchapter, for all enrollees weighted by premium volume for any plan within the product meets or exceeds the applicable threshold.

* * * * *

■ 13. Section 154.215 is amended by revising paragraphs (a) and (b) introductory text and removing and reserving paragraph (c) to read as follows:

§ 154.215 Submission of rate filing justification.

(a) A health insurance issuer must submit to CMS and to the applicable State (if the State accepts such submissions) the information specified below on a form and in a manner prescribed by the Secretary.

(1) For all single risk pool products, including new and discontinuing products, the Unified Rate Review Template, as described in paragraph (d) of this section;

(2) For each single risk pool product that includes a plan that is subject to a rate increase, regardless of the size of the increase, the unified rate review template and actuarial memorandum, as described in paragraph (f) of this section;

(3) For each single risk pool product that includes a plan with a rate increase that is subject to review under § 154.210, all parts of the Rate Filing Justification, as described in paragraph (b) of this section

(b) A Rate Filing Justification includes one or more of the following:

* * * * *

■ 14. Section 154.220 is amended by revising the introductory text and paragraphs (b) introductory text and (b)(1) to read as follows:

§ 154.220 Timing of providing the rate filing justification.

A health insurance issuer must submit applicable sections of the Rate Filing Justification for all single risk pool coverage in the individual or small group market, as follows:

* * * * *

(b) For coverage effective on or after January 1, 2017, by the earlier of the following:

(1) The date by which the State requires submission of a rate filing; or

* * * * *

■ 15. Section 154.230 is amended by revising paragraph (c)(2)(i) to read as follows:

§ 154.230 Submission and posting of Final Justifications for unreasonable rate increases.

* * * * *

(c) * * *

(2) * * *

(i) The information made available to the public by CMS and described in § 154.215(h).

* * * * *

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

■ 16. 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).

■ 17. Section 155.20 is amended by—

■ a. Revising paragraph (2) in the definition of ''Applicant''.

■ b. Adding the definitions of ''Federal platform agreement'' and ''Standardized option'' in alphabetical order.

■ c. Revising the definitions of ''Large employer'' and ''Small employer''.

The addition and revisions read as follows:

§ 155.20 Definitions.

* * * * *

Applicant * * *

(2) For SHOP:

(i) An employer seeking eligibility to purchase coverage through the SHOP; or

(ii) An employer, employee, or a 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.

* * * * *

Federal platform agreement means an agreement between a State Exchange and HHS under which a State Exchange agrees to rely on the Federal platform to carry out select Exchange functions.

* * * * *

Large employer means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 51 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year. In the case of an employer that was not in existence throughout the preceding calendar year, the determination of whether the employer is a large employer is based on the average number of employees that it is reasonably expected the employer will employ on business days in the current calendar year. A State may elect to define large employer by substituting ''101 employees'' for ''51 employees.'' The number of employees must be determined using the method set forth in section 4980H(c)(2) of the Code.

* * * * *

Small employer means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least one but not more than 50 employees on business days during the preceding calendar year and who employs at least one employee on the first day of the plan year. In the case of an employer that was not in existence throughout the preceding calendar year, the determination of whether the employer is a small employer is based on the average number of employees that it is reasonably expected the employer will employ on business days in the current calendar year. A State may elect to define small employer by substituting ''100 employees'' for ''50 employees.'' The number of employees must be determined using the method set forth in section 4980H(c)(2) of the Code.

* * * * *

Standardized option means a QHP with a standardized cost-sharing structure specified by HHS in rulemaking and that is offered for sale through an individual market Exchange.

* * * * *

■ 18. Section 155.106 is amended by—

■ a. Revising paragraphs (a) introductory text, (a)(2) and (3), and (b) introductory text.

■ b. Adding paragraphs (a)(4) and (5) and (c).

The revisions and additions read as follows:

§ 155.106 Election to operate an Exchange after 2014.

(a) *Election to operate an Exchange.* Except as provided in paragraph (c) of this section, a State electing to seek approval of its Exchange must:

* * * * *

(2) Submit an Exchange Blueprint application for HHS approval at least 15 months prior to the date on which the Exchange proposes to begin open enrollment as a State Exchange;

(3) Have in effect an approved, or conditionally approved, Exchange Blueprint and operational readiness assessment at least 14 months prior to the date on which the Exchange proposes to begin open enrollment as a State Exchange;

(4) Develop a plan jointly with HHS to facilitate the transition to a State Exchange; and

(5) If the open enrollment period for the year the State intends to begin operating an SBE has not been established, this deadline must be calculated based on the date open enrollment began or will begin in the year in which the State is submitting the Blueprint application.

(b) *Transition process for State Exchanges that cease operations.* If a State intends to cease operation of its Exchange, HHS will operate the Exchange on behalf of the State. Therefore, a State that intends to cease operations of its Exchange must:

* * * * *

(c) *Process for State Exchanges that seek to utilize the Federal platform for select functions.* A State seeking approval as a State Exchange utilizing the Federal platform to support select functions through a Federal platform agreement under § 155.200(f) must:

(1) If the State Exchange does not have a conditionally approved Exchange Blueprint application, submit one for HHS approval at least 3 months prior to the date on which the Exchange proposes to begin open enrollment as an SBE–FP;

(2) If the State Exchange has a conditionally approved Exchange Blueprint application, submit any significant changes to that application for HHS approval, in accordance with § 155.105(e), at least 3 months prior to the date on which the Exchange proposes to begin open enrollment as an SBE–FP;

(3) Have in effect an approved, or conditionally approved, Exchange Blueprint and operational readiness assessment at least 2 months prior to the date on which the Exchange proposes to begin open enrollment as an SBE–FP, in accordance with HHS rules, as a State Exchange utilizing the Federal platform;

(4) Prior to approval, or conditional approval, of the Exchange Blueprint, execute a Federal platform agreement for utilizing the Federal platform for select functions; and

(5) Coordinate with HHS on a transition plan to be developed jointly between HHS and the State.

■ 19. Section 155.170 is amended by revising paragraphs (a)(2) and (3) and (c)(2)(iii) to read as follows:

§ 155.170 Additional required benefits.

(a) * * *

(2) A benefit required by State action taking place on or before December 31, 2011 is considered an EHB. A benefit required by State action taking place on or after January 1, 2012, other than for purposes of compliance with Federal requirements, is considered in addition to the essential health benefits.

(3) The State will identify which State-required benefits are in addition to the EHB.

* * * * *

(c) * * *

(2) * * *

(iii) Reported to the State.

■ 20. Section 155.200 is amended by revising paragraph (a) and adding paragraph (f) to read as follows:

§ 155.200 Functions of an Exchange.

(a) *General requirements.* An Exchange must perform the functions described in this subpart and in subparts D, E, F, G, H, K, M, and O of this part unless the State is approved to operate only a SHOP by HHS under § 155.100(a)(2), in which case the Exchange operated by the State must perform the functions described in subpart H of this part and all applicable provisions of other subparts referenced in that subpart. In a State that is approved to operate only a SHOP, the individual market Exchange operated by HHS in that State will perform the functions described in this subpart and in subparts D, E, F, G, K, M, and O of this part.

* * * * *

(f) *Requirements for State Exchanges on the Federal platform.* (1) A State that receives approval or conditional approval to operate a State Exchange on the Federal platform under § 155.106(c) may meet its obligations under paragraph (a) of this section by relying on Federal services that the Federal government agrees to provide under a Federal platform agreement.

(2) A State Exchange on the Federal platform must establish and oversee requirements for its issuers that are no less strict than the following requirements that are applied to Federally-facilitated Exchange issuers:

(i) Data submission requirements under § 156.122(d)(2) of this subchapter;

(ii) Network adequacy standards under § 156.230 of this subchapter;

(iii) Essential community providers standards under § 156.235 of this subchapter;

(iv) Meaningful difference standards under § 156.298 of this subchapter;

(v) Changes of ownership of issuers requirements under § 156.330 of this subchapter;

(vi) QHP issuer compliance and compliance of delegated or downstream entities requirements under § 156.340(a)(4) of this subchapter; and

(vii) Casework requirements under § 156.1010 of this subchapter.

(3) If a State is not substantially enforcing any requirement listed under § 155.200(f)(2) with respect to a QHP issuer or plan in a State-based Exchange on the Federal platform, HHS may enforce that requirement directly against the issuer or plan by means of plan suppression under § 156.815 of this subchapter.

■ 21. Section 155.205 is amended by—

■ a. Revising paragraphs (a), (b)(1) introductory text, and (d)(1).

■ b. Adding paragraph (b)(7).

The addition and revisions read as follows:

§ 155.205 Consumer assistance tools and programs of an Exchange.

(a) *Call center.* The Exchange must provide for operation of a toll-free call center that addresses the needs of consumers requesting assistance and meets the requirements outlined in paragraphs (c)(1), (c)(2)(i), and (c)(3) of this section, unless it enters into a Federal platform agreement through which it relies on HHS to carry out call center functions, in which case the Exchange must provide at a minimum a toll-free telephone hotline to respond to requests for assistance and appropriately directs consumers to Federal platform services to apply for, and enroll in, Exchange coverage.

(b) * * *

(1) Provides standardized comparative information on each available QHP, which may include differential display of standardized options on consumer-facing plan comparison and shopping tools, and at a minimum includes:

* * * * *

(7) A State-based Exchange on the Federal platform must at a minimum maintain an informational Internet Web site that includes the capability to direct consumers to Federal platform services to apply for, and enroll in, Exchange coverage.

* * * * *

(d) * * *

(1) The Exchange must have a consumer assistance function that meets the standards in paragraph (c) of this section, including the Navigator program described in § 155.210. Any individual providing such consumer assistance must be trained regarding QHP options, insurance affordability programs, eligibility, and benefits rules and regulations governing all insurance affordability programs operated in the State, as implemented in the State, prior to providing such assistance or the outreach and education activities specified in paragraph (e) of this section.

* * * * *

■ 22. Section 155.210 is amended by—

■ a. Revising paragraphs (b)(2)(iii) and (iv).

■ b. Adding paragraphs (b)(2)(v) through (ix).

■ c. Revising paragraphs (d)(6) and (e)(6)(i).

■ d. In paragraph (e)(7), removing the period at the end of the paragraph and adding a semicolon in its place.

■ e. Adding paragraphs (e)(8) and (9).

The revisions and additions read as follows:

§ 155.210 Navigator program standards.

* * * * *

(b) * * *

(2) * * *

(iii) The range of QHP options and insurance affordability programs;

(iv) The privacy and security standards applicable under § 155.260;

(v) In an Exchange that requires Navigators to provide the assistance specified in paragraph (e)(9)(i) of this section, the process of filing Exchange eligibility appeals;

(vi) In an Exchange that requires Navigators to provide the assistance specified in paragraph (e)(9)(ii) of this section, general concepts regarding exemptions from the requirement to maintain minimum essential coverage and from the individual shared responsibility payment, including the application process for exemptions granted through the Exchange, and IRS resources on exemptions;

(vii) In an Exchange that requires Navigators to provide the assistance specified in paragraph (e)(9)(iii) of this section, the Exchange-related components of the premium tax credit reconciliation process and IRS resources on this process;

(viii) In an Exchange that requires Navigators to provide the assistance specified in paragraph (e)(9)(iv) of this section, basic concepts and rights related to health coverage and how to use it; and

(ix) In an Exchange that requires Navigators to provide the assistance specified in paragraph (e)(9)(v) of this section, providing referrals to licensed tax advisers, tax preparers, or other resources for assistance with tax preparation and tax advice related to consumer questions about the Exchange application and enrollment process, exemptions from the requirement to maintain minimum essential coverage and from the individual shared responsibility payment, and premium tax credit reconciliations.

* * * * *

(d) * * *

(6) Provide to an applicant or potential enrollee gifts of any value as an inducement for enrollment. The value of gifts provided to applicants and potential enrollees for purposes other than as an inducement for enrollment must not exceed nominal value, either individually or in the aggregate, when provided to that individual during a single encounter. For purposes of this paragraph (d)(6), the term gifts includes gift items, gift cards, cash cards, cash, and promotional items that market or promote the products or services of a third party, but does not include the reimbursement of legitimate expenses incurred by a consumer in an effort to receive Exchange application assistance, such as travel or postage expenses.

* * * * *

(e) * * *

(6) * * *

(i) Are informed, prior to receiving assistance, of the functions and responsibilities of Navigators, including that Navigators are not acting as tax advisers or attorneys when providing assistance as Navigators and cannot provide tax or legal advice within their capacity as Navigators;

* * * * *

(8) Provide targeted assistance to serve underserved or vulnerable populations, as identified by the Exchange, within the Exchange service area.

(i) In a Federally-facilitated Exchange, this paragraph (e)(8) will apply beginning with the Navigator grant application process for Navigator grants awarded in 2018. The Federally-facilitated Exchange will identify populations as vulnerable or underserved that are disproportionately without access to coverage or care, or that are at a greater risk for poor health outcomes, in the funding opportunity announcement for its Navigator grants, and applicants for those grants will have an opportunity to propose additional vulnerable or underserved populations in their applications for the Federally-facilitated Exchange's approval.

(ii) [Reserved]

(9) The Exchange may require or authorize Navigators to provide information and assistance with any of the following topics. In Federally-facilitated Exchanges, Navigators are authorized to provide information and assistance with any of the following topics and will be required to provide information and assistance with all of the following topics under Navigator grants awarded in 2018 or any later year.

(i) Understanding the process of filing Exchange eligibility appeals;

(ii) Understanding and applying for exemptions from the individual shared responsibility payment that are granted through the Exchange, understanding the availability of exemptions from the requirement to maintain minimum essential coverage and from the individual shared responsibility payment that are claimed through the tax filing process and how to claim them, and understanding the availability of IRS resources on this topic;

(iii) The Exchange-related components of the premium tax credit reconciliation process, and understanding the availability of IRS resources on this process;

(iv) Understanding basic concepts and rights related to health coverage and how to use it; and

(v) Referrals to licensed tax advisers, tax preparers, or other resources for assistance with tax preparation and tax advice related to consumer questions about the Exchange application and enrollment process, exemptions from the requirement to maintain minimum essential coverage and from the individual shared responsibility payment, and premium tax credit reconciliations.

* * * * *

■ 23. Section 155.215 is amended by revising paragraphs (b)(1)(i) and (g)(1) 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.

* * * * *

(b) * * *

(1) * * *

(i) Obtain certification by the Exchange prior to carrying out any consumer assistance functions or outreach and education activities under § 155.205(d) and (e) or § 155.210;

* * * * *

(g) * * *

(1) Are informed, prior to receiving assistance, of the functions and responsibilities of non-Navigator assistance personnel, including that non-Navigator assistance personnel are not acting as tax advisers or attorneys when providing assistance as non-Navigator assistance personnel and cannot provide tax or legal advice within their capacity as non-Navigator assistance personnel;

* * * * *

■ 24. Section 155.220 is amended by—

■ a. Revising paragraph (c)(1) and (3), (f)(4), (g)(2)(ii), and (g)(3) and (4);

■ b. Adding new paragraphs (c)(4)(i)(F), (c)(5), (g)(5) and (6), (j), (k), and (l).

The revisions and additions read as follows:

§ 155.220 Ability of States to permit agents and brokers to assist qualified individuals, qualified employers, or qualified employees enrolling in QHPs.

* * * * *

(c) * * *

(1) The agent or broker ensures the applicant's completion of an eligibility

verification and enrollment application through the Exchange Internet Web site as described in § 155.405, or ensures that the eligibility application information is submitted for an eligibility determination through the Exchange-approved Web service subject to meeting the requirements in paragraphs (c)(3)(ii) and (c)(4)(i)(F) of this section;

* * * * *

(3)(i) When an Internet Web site of the agent or broker is used to complete the QHP selection, at a minimum the Internet Web site must:

(A) Disclose and display all QHP information provided by the Exchange or directly by QHP issuers consistent with the requirements of § 155.205(b)(1) and (c), and to the extent that not all information required under § 155.205(b)(1) is displayed on the agent or broker's Internet Web site for a QHP, prominently display a standardized disclaimer provided by HHS stating that information required under § 155.205(b)(1) for the QHP is available on the Exchange Web site, and provide a Web link to the Exchange Web site;

(B) Provide consumers the ability to view all QHPs offered through the Exchange;

(C) Not provide financial incentives, such as rebates or giveaways;

(D) Display all QHP data provided by the Exchange;

(E) Maintain audit trails and records in an electronic format for a minimum of ten years;

(F) Provide consumers with the ability to withdraw from the process and use the Exchange Web site described in § 155.205(b) instead at any time; and

(G) For the Federally-facilitated Exchange, prominently display a standardized disclaimer provided by HHS, and provide a Web link to the Exchange Web site.

(ii) When an Internet Web site of an agent or broker is used to complete the Exchange eligibility application, at a minimum, the Internet Web site must:

(A) Comply with the requirements in paragraph (c)(3)(i) of this section;

(B) Use exactly the same eligibility application language as appears in the FFE Single Streamlined Application required in § 155.405, unless HHS approves a deviation;

(C) Ensure that all necessary information for the consumer's applicable eligibility circumstances are submitted through the Exchange-approved web service; and

(D) Ensure that the process used for consumers to complete the eligibility application complies with all applicable Exchange standards, including §§ 155.230 and 155.260(b).

(4) * * *

(i) * * *

(F) When an Internet Web site of an agent or broker is used to complete the Exchange eligibility application, obtain HHS approval verifying that all requirements in this section are met.

* * * * *

(5) HHS or its designee may periodically monitor and audit an agent or broker under this subpart to assess its compliance with the applicable requirements of this section.

* * * * *

(f) * * *

(4) When the agreement between the agent or broker and the Exchange under paragraph (d) of this section is terminated under paragraph (f) of this section, the agent or broker will no longer be registered with the Federally-facilitated Exchanges, or be permitted to assist with or facilitate enrollment of qualified individuals, qualified employers or qualified employees in coverage in a manner that constitutes enrollment through a Federally-facilitated Exchange, or be permitted to assist individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs. The agent's or broker's agreement with the Exchange under § 155.260(b) will also be terminated through the termination without cause process set forth in that agreement. The agent or broker must continue to protect any personally identifiable information accessed during the term of either of these agreements with the Federally-facilitated Exchanges.

(g) * * *

(2) * * *

(ii) Any term or condition of the agreement with the Federally-facilitated Exchanges required under paragraph (d) of this section, or any term or condition of the agreement with the Federally-facilitated Exchange required under § 155.260(b);

* * * * *

(3) HHS will notify the agent or broker of the specific finding of noncompliance or pattern of noncompliance made under paragraph (g)(1) of this section, and after 30 days from the date of the notice, may terminate the agreement for cause if the matter is not resolved to the satisfaction of HHS.

(4) After the period in paragraph (g)(3) of this section has elapsed and the agreement under paragraph (d) of this section is terminated, the agent or broker will no longer be registered with the Federally-facilitated Exchanges, or be permitted to assist with or facilitate enrollment of a qualified individual, qualified employer, or qualified employee in coverage in a manner that constitutes enrollment through a Federally-facilitated Exchange, or be permitted to assist individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs. The agent's or broker's agreement with the Exchange under § 155.260(b)(2) will also be terminated through the process set forth in that agreement. The agent or broker must continue to protect any personally identifiable information accessed during the term of either of these agreements with the Federally-facilitated Exchanges.

(5) Fraud or abusive conduct—

(i)(A) If HHS reasonably suspects that an agent or broker may have may have engaged in fraud, or in abusive conduct that may cause imminent or ongoing consumer harm using personally identifiable information of an Exchange enrollee or applicant or in connection with an Exchange enrollment or application, HHS may temporarily suspend the agent's or broker's agreements required under paragraph (d) of this section and under § 155.260(b) for up to 90 calendar days. Suspension will be effective on the date of the notice that HHS sends to the agent or broker advising of the suspension of the agreements.

(B) The agent or broker may submit evidence in a form and manner to be specified by HHS, to rebut the allegation during this 90-day period. If the agent or broker submits such evidence during the suspension period, HHS will review the evidence and make a determination whether to lift the suspension within 30 days of receipt of such evidence. If the rebuttal evidence does not persuade HHS to lift the suspension, or if the agent or broker fails to submit rebuttal evidence during the suspension period, HHS may terminate the agent's or broker's agreements required under paragraph (d) of this section and under § 155.260(b) for cause under paragraph (g)(5)(ii) of this section.

(ii) If there is a finding or determination by a Federal or State entity that an agent or broker engaged in fraud, or abusive conduct that may result in imminent or ongoing consumer harm, using personally identifiable information of Exchange enrollees or applicants or in connection with an Exchange enrollment or application, HHS will terminate the agent's or broker's agreements required under paragraph (d) of this section and under § 155.260(b) for cause. The termination will be effective starting on the date of the notice that HHS sends to the agent or broker advising of the termination of the agreements.

(iii) During the suspension period under paragraph (g)(5)(i) of this section and following termination of the agreements under paragraph (g)(5)(i)(B) or (g)(5)(ii) of this section, the agent or broker will not be registered with the Federally-facilitated Exchanges, or be permitted to assist with or facilitate enrollment of qualified individuals, qualified employers, or qualified employees in coverage in a manner that constitutes enrollment through a Federally-facilitated Exchange, or be permitted to assist individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs. The agent or broker must continue to protect any personally identifiable information accessed during the term of either of these agreements with a Federally-facilitated Exchange.

(6) The State department of insurance or equivalent State agent or broker licensing authority will be notified by HHS in cases of suspensions or terminations effectuated under this paragraph (g).

* * * * *

(j) *Federally-facilitated Exchange standards of conduct.* (1) An agent or broker that assists with or facilitates enrollment of qualified individuals, qualified employers, or qualified employees, in coverage in a manner that constitutes enrollment through a Federally-facilitated Exchange, or assists individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs sold through a Federally-facilitated Exchange, must—

(i) Have executed the required agreement under paragraph § 155.260(b);

(ii) Be registered with the Federally-facilitated Exchanges under paragraph (d)(1) of this section; and

(iii) Comply with the standards of conduct in paragraph (j)(2) of this section.

(2) Standards of conduct. An individual or entity described in paragraph (j)(1) of this section must—

(i) Provide consumers with correct information, without omission of material fact, regarding the Federally-facilitated Exchanges, QHPs offered through the Federally-facilitated Exchanges, and insurance affordability programs, and refrain from marketing or conduct that is misleading or coercive, or discriminates based on race, color, national origin, disability, age, sex, gender identity, or sexual orientation;

(ii) Provide the Federally-facilitated Exchanges with correct information under section 1411(b) of the Affordable Care Act;

(iii) Obtain the consent of the individual, employer, or employee prior to assisting with or facilitating enrollment through a Federally-facilitated Exchange, or assisting the individual in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs;

(iv) Protect consumer personally identifiable information according to § 155.260(b)(3) and the agreement described in § 155.260(b)(2); and

(v) Comply with all applicable Federal and State laws and regulations.

(3) If an agent or broker fails to provide correct information, he or she will nonetheless be deemed in compliance with paragraphs (j)(2)(i) and (ii) of this section if HHS determines that there was a reasonable cause for the failure to provide correct information and that the agent or broker acted in good faith.

(k) *Penalties other than termination of the agreement with the Federally-facilitated Exchanges.* (1) If HHS determines that an agent or broker has failed to comply with the requirements of this section, in addition to any other available remedies, that agent or broker—

(i) May be denied the right to enter into agreements with the Federally-facilitated Exchanges in future years; and

(ii) May be subject to civil money penalties as described in § 155.285.

(2) HHS will notify the agent or broker of the proposed imposition of penalties under paragraph (k)(1)(i) of this section and, after 30 calendar days from the date of the notice, may impose the penalty if the agent or broker has not requested a reconsideration under paragraph (h) of this section. The proposed imposition of penalties under paragraph (k)(1)(ii) of this section will follow the process outlined under § 155.285.

(l) *Application to State-Based Exchanges using a Federal platform.* An agent or broker who enrolls qualified individuals, qualified employers, or qualified employees in coverage in a manner that constitutes enrollment through an State-Based Exchange using a Federal platform, or assists individual market consumers with submission of applications for advance payments of the premium tax credit and cost-sharing reductions through an State-Based Exchange using a Federal platform must comply with all applicable Federally-facilitated Exchange standards in this section.

■ 25. Section 155.222 is amended by—

■ a. Revising the section heading.

■ b. Revising paragraphs (a)(1) and (2), (b)(1) through (5), and (d).

■ c. Adding new paragraph (b)(6).

The revisions and addition read as follows:

§ 155.222 Standards for HHS-approved vendors of Federally-facilitated Exchange training for agents and brokers.

(a) * * *

(1) A vendor must be approved by HHS, in a form and manner to be determined by HHS, to have its training program recognized for agents and brokers assisting with or facilitating enrollment in individual market or SHOP coverage through the Federally-facilitated Exchanges consistent with § 155.220.

(2) As part of the training program, the vendor must require agents and brokers to provide identifying information and successfully complete the required curriculum.

* * * * *

(b) * * *

(1) Submit a complete and accurate application by the deadline established by HHS, which includes demonstration of prior experience with successfully conducting online training, as well as providing technical support to a large customer base.

(2) Adhere to HHS specifications for content, format, and delivery of training, which includes offering continuing education units (CEUs) for at least five States in which a Federally-facilitated Exchange or State-Based Exchange using a Federal platform is operating.

(3) Collect, store, and share with HHS training completion data from agent and broker users of the vendor's training in a manner, format, and frequency specified by HHS, and protect all data from agent and broker users of the vendor's training in accordance with applicable privacy and security requirements.

(4) Execute an agreement with HHS, in a form and manner to be determined by HHS, which requires the vendor to comply with applicable HHS guidelines for implementing the training and interfacing with HHS data systems, 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.

(6) Provide technical support to agent and broker users of the vendor's training as specified by HHS.

* * * * *

(d) *Monitoring.* HHS may periodically monitor and audit vendors approved under this subpart, and their records related to the training 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 functions described under this subpart.

* * * * *

■ 26. Section 155.225 is amended by adding paragraph (b)(1)(iii) and revising paragraphs (f)(1) and (g)(4) to read as follows:

§ 155.225 Certified application counselors.

* * * * *

(b) * * *

(1) * * *

(iii) Provides data and information to the Exchange regarding the number and performance of its certified application counselors and regarding the consumer assistance provided by its certified application counselors, upon request, in the form and manner specified by the Exchange. Beginning for the third quarter of calendar year 2017, in a Federally-facilitated Exchange, organizations designated by the Exchange must submit quarterly reports that include, at a minimum, data regarding the number of individuals who have been certified by the organization; the total number of consumers who received application and enrollment assistance from the organization; and of that number, the number of consumers who received assistance in applying for and selecting a QHP, enrolling in a QHP, or applying for Medicaid or CHIP.

* * * * *

(f) * * *

(1) Are informed, prior to receiving assistance, of the functions and responsibilities of certified application counselors, including that certified application counselors are not acting as tax advisers or attorneys when providing assistance as certified application counselors and cannot provide tax or legal advice within their capacity as certified application counselors;

* * * * *

(g) * * *

(4) Provide to an applicant or potential enrollee gifts of any value as an inducement for enrollment. The value of gifts provided to applicants and potential enrollees for purposes other than as an inducement for enrollment must not exceed nominal value, either individually or in the aggregate, when provided to that individual during a single encounter. For purposes of this paragraph (g)(4), the term gifts includes gift items, gift cards, cash cards, cash, and promotional items that market or promote the products or services of a third party, but does not include the reimbursement of legitimate expenses incurred by a consumer in an effort to receive Exchange application assistance, such as travel or postage expenses;

* * * * *

■ 27. Section 155.260 is amended by revising paragraph (a)(1) introductory text to read as follows:

§ 155.260 Privacy and security of personally identifiable information.

(a) * * *

(1) Where the Exchange creates or collects personally identifiable information for the purposes of determining eligibility for enrollment in a qualified health plan; determining eligibility for other insurance affordability programs, as defined in § 155.300; or determining eligibility for exemptions from the individual shared responsibility provisions in section 5000A of the Code, the Exchange may only use or disclose such personally identifiable information to the extent such information is necessary:

* * * * *

■ 28. Section 155.280 is amended by revising paragraph (a) to read as follows:

§ 155.280 Oversight and monitoring of privacy and security requirements.

(a) *General.* HHS will oversee and monitor the Federally-facilitated Exchanges, State-based Exchanges on the Federal platform, and non-Exchange entities required to comply with the privacy and security standards established and implemented by a Federally-facilitated Exchange pursuant to § 155.260 for compliance with those standards. HHS will oversee and monitor State Exchanges for compliance with the standards State Exchanges establish and implement pursuant to § 155.260. State Exchanges will oversee and monitor non-Exchange entities required to comply with the privacy and security standards established and implemented by a State Exchange in accordance to § 155.260.

* * * * *

■ 29. Section 155.302 is amended by revising paragraph (a)(1) to read as follows:

§ 155.302 Options for conducting eligibility determinations.

(a) * * *

(1) Directly, through contracting arrangements in accordance with § 155.110(a), or as a State-based Exchange on the Federal platform through a Federal platform agreement under which HHS carries out eligibility determinations and other requirements contained within this subpart; or

* * * * *

■ 30. Section 155.310 is amended by revising paragraphs (h) introductory text and (h)(2) to read as follows:

§ 155.310 Eligibility process.

* * * * *

(h) *Notice of an employee's receipt of advance payments of the premium tax credit and cost-sharing reductions to an employer.* The Exchange must notify an employer that an employee has been determined eligible for advance payments of the premium tax credit and cost-sharing reductions and has enrolled in a qualified health plan through the Exchange within a reasonable timeframe following a determination that the employee is eligible for advance payments of the premium tax credit and cost-sharing reductions in accordance with § 155.305(g) or § 155.350(a) and enrollment by the employee in a qualified health plan through the Exchange. Such notice must:

* * * * *

(2) Indicate that the employee has been determined eligible advance payments of the premium tax credit and cost-sharing reductions and has enrolled in a qualified health plan through the Exchange;

* * * * *

■ 31. Section 155.320 is amended by revising paragraphs (c)(3)(vi) introductory text and (d)(3) and adding paragraph (d)(4) to read as follows:

§ 155.320 Verification process related to eligibility for insurance affordability programs.

* * * * *

(c) * * *

(3) * * *

(vi) *Alternate verification process for decreases in annual household income estimates and for situations in which tax return data is unavailable.* If a tax filer qualifies for an alternate verification process based on the requirements specified in paragraph (c)(3)(iv) of this section and the applicant's attestation to projected annual household income, as described in paragraph (c)(3)(ii)(B) of this section, is more than a reasonable threshold below the annual household income computed in accordance with paragraph (c)(3)(ii)(A) of this section, or if data described in paragraph (c)(1)(i) of this section is unavailable, the Exchange must attempt to verify the applicant's attestation of the tax filer's projected annual household income by following the procedures specified in paragraph

(c)(3)(vi)(A) through (G) of this section. For the purposes of this paragraph (c)(3)(vi), a reasonable threshold is established by the Exchange in guidance and approved by HHS, but must not be less than 10 percent, and can also include a threshold dollar amount. The Exchange's threshold is subject to approval by HHS.

* * * * *

(d) * * *

(3) *Verification procedures.* (i) If an applicant's attestation is not reasonably compatible with the information obtained by the Exchange as specified in paragraphs (d)(2)(i) through (iii) of this section, other information provided by the application filer, or other information in the records of the Exchange, the Exchange must follow the procedures specified in § 155.315(f).

(ii) Except as specified in paragraph (d)(3)(i) or (d)(4)(i) of this section, the Exchange must accept an applicant's attestation regarding the verification specified in paragraph (d) of this section without further verification.

(4) *Alternate procedures.* For any benefit year for which it does not reasonably expect to obtain sufficient verification data as described in paragraphs (d)(2)(i) through (iii) of this section, the Exchange must follow the procedures specified in paragraph (d)(4)(i) of this section or, for benefit years 2016 and 2017, the Exchange may follow the procedures specified in paragraph (d)(4)(ii) of this section. For purposes of this paragraph (d)(4), the Exchange reasonably expects to obtain sufficient verification data for any benefit year when, for the benefit year, the Exchange is able to obtain data about enrollment in and eligibility for qualifying coverage in an eligible employer-sponsored plan from at least one electronic data source that is available to the Exchange and that has been approved by HHS, based on evidence showing that the data source is sufficiently current, accurate, and minimizes administrative burden, as described under paragraph (d)(2)(i) of this section.

(i) Select a statistically significant random sample of applicants for whom the Exchange does not have any of the information specified in paragraphs (d)(2)(i) through (iii) of this section and—

(A) Provide notice to the applicant indicating that the Exchange will be contacting any employer identified on the application for the applicant and the members of his or her household, as defined in 26 CFR 1.36B–1(d), to verify whether the applicant is enrolled in an eligible employer-sponsored plan or is eligible for qualifying coverage in an eligible employer-sponsored plan for the benefit year for which coverage is requested;

(B) Proceed with all other elements of the eligibility determination using the applicant's attestation, and provide eligibility for enrollment in a QHP to the extent that an applicant is otherwise qualified;

(C) Ensure that advance payments of the premium tax credit and cost-sharing reductions are provided on behalf of an applicant who is otherwise qualified for such payments and reductions, as described in § 155.305, if the tax filer attests to the Exchange that he or she understands that any advance payments of the premium tax credit paid on his or her behalf are subject to reconciliation;

(D) Make reasonable attempts to contact any employer identified on the application for the applicant and the members of his or her household, as defined in 26 CFR 1.36B–1(d), to verify whether the applicant is enrolled in an eligible employer-sponsored plan or is eligible for qualifying coverage in an eligible employer-sponsored plan for the benefit year for which coverage is requested;

(E) If the Exchange receives any information from an employer relevant to the applicant's enrollment in an eligible employer-sponsored plan or eligibility for qualifying coverage in an eligible employer-sponsored plan, the Exchange must determine the applicant's eligibility based on such information and in accordance with the effective dates specified in § 155.330(f), and if such information changes his or her eligibility determination, notify the applicant and his or her employer or employers of such determination in accordance with the notice requirements specified in § 155.310(g) and (h);

(F) If, after a period of 90 days from the date on which the notice described in paragraph (d)(4)(i)(A) of this section is sent to the applicant, the Exchange is unable to obtain the necessary information from an employer, the Exchange must determine the applicant's eligibility based on his or her attestation regarding coverage provided by that employer.

(G) To carry out the process described in paragraph (d)(4)(i) of this section, the Exchange must only disclose an individual's information to an employer to the extent necessary for the employer to identify the employee.

(ii) Establish an alternative process approved by HHS.

* * * * *

■ 32. Section 155.335 is amended by revising paragraph (j) to read as follows:

§ 155.335 Annual eligibility redetermination.

* * * * *

(j) *Re-enrollment.* If an enrollee remains eligible for enrollment in a QHP through the Exchange upon annual redetermination and—

(1) The product under which the QHP in which he or she is enrolled remains available through the Exchange for renewal, consistent with § 147.106 of this subchapter, such enrollee will have his or her enrollment through the Exchange in a QHP under that product renewed, unless he or she terminates coverage, including termination of coverage in connection with voluntarily selecting a different QHP, in accordance with § 155.430. The Exchange will ensure that re-enrollment in coverage under this paragraph (j)(1) occurs under the same product (except as provided in paragraph (j)(1)(iii)(A) of this section) in which the enrollee was enrolled, as follows:

(i) The enrollee's coverage will be renewed in the same plan as the enrollee's current QHP, unless the current QHP is not available through the Exchange.

(ii) If the enrollee's current QHP is not available through the Exchange, the enrollee's coverage will be renewed in a QHP at the same metal level as the enrollee's current QHP within the same product.

(iii) If the enrollee's current QHP is not available through the Exchange and the enrollee's product no longer includes a QHP at the same metal level as the enrollee's current QHP and—

(A) The enrollee's current QHP is a silver level plan, the enrollee will be re-enrolled in a silver level QHP under a different product offered by the same QHP issuer that is most similar to the enrollee's current product. If no such silver level QHP is available for enrollment through the Exchange, the enrollee's coverage will be renewed in a QHP that is one metal level higher or lower than the enrollee's current QHP under the same product;

(B) The enrollee's current QHP is not a silver level plan, the enrollee's coverage will be renewed in a QHP that is one metal level higher or lower than the enrollee's current QHP under the same product; or

(iv) If the enrollee's current QHP is not available through the Exchange and the enrollee's product no longer includes a QHP that is at the same metal level as, or one metal level higher or lower than the enrollee's current QHP, the enrollee's coverage will be renewed in any other QHP offered under the product in which the enrollee's current

QHP is offered in which the enrollee is eligible to enroll.

(2) No plans under the product under which the QHP in which he or she is enrolled are available through the Exchange for renewal, consistent with § 147.106 of this subchapter, such enrollee may be enrolled in a QHP under a different product offered by the same QHP issuer, to the extent permitted by applicable State law, unless he or she terminates coverage, including termination of coverage in connection with voluntarily selecting a different QHP, in accordance with § 155.430. The Exchange will ensure that re-enrollment in coverage under this paragraph (j)(2) occurs as follows:

(i) The enrollee will be re-enrolled in a QHP at the same metal level as the enrollee's current QHP in the product offered by the same issuer that is the most similar to the enrollee's current product;

(ii) If the issuer does not offer another QHP at the same metal level as the enrollee's current QHP, the enrollee will be re-enrolled in a QHP that is one metal level higher or lower than the enrollee's current QHP in the product offered by the same issuer through the Exchange that is the most similar to the enrollee's current product; or

(iii) If the issuer does not offer another QHP through the Exchange at the same metal level as, or one metal level higher or lower than the enrollee's current QHP, the enrollee will be re-enrolled in any other QHP offered by the same issuer in which the enrollee is eligible to enroll.

(3) No QHPs from the same issuer are available through the Exchange, the enrollee may be enrolled through the Exchange in a QHP issued by a different issuer, to the extent permitted by applicable State law, unless he or she terminates coverage, including termination of coverage in connection with voluntarily selecting a different QHP, in accordance with § 155.430. The Exchange will ensure that re-enrollment in coverage under this paragraph (j)(3) occurs as follows:

(i) As directed by the applicable State regulatory authority; or

(ii) If the applicable State regulatory authority declines to provide direction, in a similar QHP from a different issuer, as determined by the Exchange.

* * * * *

■ 33. Section 155.400 is amended by revising paragraph (e) and adding paragraphs (g) and (h) 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 a binder payment to effectuate an enrollment or to add coverage retroactively to an already effectuated enrollment. Exchanges may, and the Federally-facilitated Exchange will, establish a standard policy for setting premium payment deadlines:

(1) In a Federally-facilitated Exchange:

(i) For prospective coverage to be effectuated under regular coverage effective dates, as provided for in §§ 155.410(f) and 155.420(b)(1), the binder payment must consist of the first month's premium, and the deadline for making the binder payment must be no earlier than the coverage effective date, and no later than 30 calendar days from the coverage effective date.

(ii) For prospective coverage to be effectuated under special effective dates, as provided for in § 155.420(b)(2), the binder payment must consist of the first month's premium, and the deadline for making the binder payment must be no earlier than the coverage effective date and no later than 30 calendar days from the date the issuer receives the enrollment transaction or the coverage effective date, whichever is later.

(iii) For coverage to be effectuated under retroactive effective dates, as provided for in § 155.420(b)(2), the binder payment must consist of the premium due for all months of retroactive coverage through the first prospective month of coverage, and the deadline for making the binder payment must be no earlier than 30 calendar days from the date the issuer receives the enrollment transaction. If only the premium for one month of coverage is paid, only prospective coverage should be effectuated, in accordance with regular effective dates.

(2) [Reserved]

* * * * *

(g) *Premium payment threshold.* Exchanges may, and the Federally-facilitated Exchange will, allow issuers to implement, a premium payment threshold policy under which issuers can consider enrollees to have paid all amounts due if the enrollees pay an amount sufficient to maintain a percentage of total premium paid out of the total premium owed equal to or greater than a level prescribed by the issuer, provided that the level is reasonable and that the level and the policy are applied in a uniform manner to all enrollees. If an applicant or enrollee satisfies the premium payment threshold policy, the issuer may:

(1) Effectuate an enrollment based on payment of the binder payment under paragraph (e) of this section.

(2) Avoid triggering a grace period for non-payment of premium, as described by § 156.270(d) of this subchapter or a grace period governed by State rules.

(3) Avoid terminating the enrollment for non-payment of premium as, described by §§ 156.270(g) of this subchapter and 155.430(b)(2)(ii)(A) and (B).

(h) *Requirements.* A State Exchange may rely on HHS to carry out the requirements of this section and other requirements contained within this subpart through a Federal platform agreement.

■ 34. Section 155.410 is amended by revising paragraphs (e)(2) and (f)(2) and adding paragraphs (e)(3) to read as follows:

§ 155.410 Initial and annual open enrollment periods.

* * * * *

(e) * * *

(2) For the benefit years beginning on January 1, 2016, on January 1, 2017, and on January 1, 2018, the annual open enrollment period begins on November 1 of the calendar year preceding the benefit year, and extends through January 31 of the benefit year.

(3) For the benefit years beginning on January 1, 2019 and beyond, the annual open enrollment period begins on November 1 and extends through December 15 of the calendar year preceding the benefit year.

(f) * * *

(2) For benefit years beginning on or after January 1, 2016, the Exchange must ensure that coverage is effective—

(i) January 1, for QHP selections received by the Exchange on or before December 15 of the calendar year preceding the benefit year.

(ii) February 1, for QHP selections received by the Exchange from December 16 of the calendar year preceding the benefit year through January 15 of the benefit year.

(iii) March 1, for QHP selections received by the Exchange from January 16 through January 31 of the benefit year.

* * * * *

■ 35. Section 155.430 is amended by—

■ a. Adding paragraph (b)(1)(iv).

■ b. Revising paragraphs (b)(2)(ii)(A).

■ c. Redesignating paragraph (b)(2)(vi) as paragraph (b)(2)(vii).

■ d. Adding paragraphs (b)(2)(vi) and (d)(9), (10), (11), and (12).

The additions and revision read as follows:

§ 155.430 Termination of Exchange enrollment or coverage.

* * * * *

(b) * * *

(1) * * *

(iv) The Exchange must permit an enrollee to retroactively terminate or cancel his or her coverage or enrollment in a QHP in the following circumstances:

(A) The enrollee demonstrates to the Exchange that he or she attempted to terminate his or her coverage or enrollment in a QHP and experienced a technical error that did not allow the enrollee to terminate his or her coverage or enrollment through the Exchange, and requests retroactive termination within 60 days after he or she discovered the technical error.

(B) The enrollee demonstrates to the Exchange that his or her enrollment in a QHP through the Exchange was unintentional, inadvertent, or erroneous and was the result of the error or misconduct 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. Such enrollee must request cancellation within 60 days of discovering the unintentional, inadvertent, or erroneous enrollment. For purposes of this paragraph (b)(1)(iv)(B), misconduct includes the failure to comply with applicable standards under this part, part 156 of this subchapter, or other applicable Federal or State requirements as determined by the Exchange.

(C) The enrollee demonstrates to the Exchange that he or she was enrolled in a QHP without his or her knowledge or consent by any third party, including third parties who have no connection with the Exchange, and requests cancellation within 60 days of discovering of the enrollment.

(2) * * *

(ii) * * *

(A) The exhaustion of the 3-month grace period, as described in § 156.270(d) and (g) of this subchapter, required for enrollees, who when first failing to timely pay premiums, are receiving advance payments of the premium tax credit.

* * * * *

(vi) The enrollee was enrolled in a QHP without his or her knowledge or consent by a third party, including by a third party with no connection with the Exchange.

* * * * *

(d) * * *

(9) In case of a retroactive termination in accordance with paragraph (b)(1)(iv)(A) of this section, the termination date will be no sooner than 14 days after the date that the enrollee can demonstrate he or she contacted the Exchange to terminate his or her coverage or enrollment through the Exchange, unless the issuer agrees to an earlier effective date as set forth in paragraph (d)(2)(iii) of this section.

(10) In case of a retroactive cancellation or termination in accordance with paragraph (b)(1)(iv)(B) or (C) of this section, the cancellation date or termination date will be the original coverage effective date or a later date, as determined appropriate by the Exchange, based on the circumstances of the cancellation or termination.

(11) In the case of cancellation in accordance with paragraph (b)(2)(vi) of this section, the Exchange may cancel the enrollee's enrollment upon its determination that the enrollment was performed without the enrollee's knowledge or consent and following reasonable notice to the enrollee (where possible). The termination date will be the original coverage effective date.

(12) In the case of retroactive cancellations or terminations in accordance with paragraphs (b)(1)(iv)(A), (B) and (C) of this section, such terminations or cancellations for the preceding coverage year must be initiated within a timeframe established by the Exchange based on a balance of operational needs and consumer protection. This timeframe will not apply to cases adjudicated through the appeals process.

* * * * *

■ 36. Section 155.505 is amended by adding paragraphs (b)(1)(iii) and (b)(5) and revising paragraph (b)(4) to read as follows:

§ 155.505 General eligibility appeals requirements.

* * * * *

(b) * * *

(1) * * *

(iii) A determination of eligibility for an enrollment period, made in accordance with § 155.305(b);

* * * * *

(4) A denial of a request to vacate dismissal made by a State Exchange appeals entity in accordance with § 155.530(d)(2), made under paragraph (c)(2)(i) of this section; and

(5) An appeal decision issued by a State Exchange appeals entity in accordance with § 155.545(b), consistent with § 155.520(c).

* * * * *

■ 37. Section 155.510 is amended by revising paragraph (a)(1) to read as follows:

§ 155.510 Appeals coordination.

(a) * * *

(1) Minimize burden on appellants, including not asking the appellant to provide duplicative information or documentation that he or she already provided to an agency administering an insurance affordability program or eligibility appeals process, unless the appeals entity, Exchange, or agency does not have access to the information or documentation and cannot reasonably obtain it, and such information is necessary to properly adjudicate an appeal;

* * * * *

■ 38. Section 155.520 is amended by adding paragraph (d)(2)(i)(D) to read as follows:

§ 155.520 Appeal requests.

* * * * *

(d) * * *

(2) * * *

(i) * * *

(D) That, in the event the appeal request is not valid due to failure to submit by the date determined under paragraph (b) or (c) of this section, as applicable, the appeal request may be considered valid if the applicant or enrollee sufficiently demonstrates within a reasonable timeframe determined by the appeals entity that failure to timely submit was due to exceptional circumstances and should not preclude the appeal.

* * * * *

■ 39. Section 155.530 is amended by revising paragraph (a)(4) to read as follows:

§ 155.530 Dismissals.

(a) * * *

(4) Dies while the appeal is pending, except if the executor, administrator, or other duly authorized representative of the estate requests to continue the appeal.

* * * * *

■ 40. Section 155.535 is amended by revising paragraphs (a) introductory text and (b) to read as follows:

§ 155.535 Informal resolution and hearing requirements.

(a) *Informal resolution.* The HHS appeals process will provide an opportunity for informal resolution and a hearing in accordance with the requirements of this section. A State Exchange appeals entity may also provide an informal resolution process prior to a hearing. Any information resolution process must meet the following requirements:

* * * * *

(b) *Notice of hearing.* When a hearing is scheduled, the appeals entity must

send written notice to the appellant and the appellant's authorized representative, if any, of the date, time, and location or format of the hearing no later than 15 days prior to the hearing date unless—

(1) The appellant requests an earlier hearing date; or

(2) A hearing date sooner than 15 days is necessary to process an expedited appeal, as described in § 155.540(a), and the appeals entity has contacted the appellant to schedule a hearing on a mutually agreed upon date, time, and location or format.

* * * * *

■ 41. Section 155.545 is amended by revising paragraphs (b)(1) and (c)(1)(i) and (ii) to read as follows:

§ 155.545 Appeal decisions.

* * * * *

(b) * * *

(1) Must issue written notice of the appeal decision to the appellant within 90 days of the date an appeal request under § 155.520(b) or (c) is received, as administratively feasible.

* * * * *

(c) * * *

(1) * * *

(i) Prospectively, on the first day of the month following the date of the notice of appeal decision, or consistent with § 155.330(f)(2), (3), (4), or (5), if applicable; or

(ii) Retroactively, to the coverage effective date the appellant did receive or would have received if the appellant had enrolled in coverage under the incorrect eligibility determination that is the subject of the appeal, at the option of the appellant.

* * * * *

■ 42. Section 155.555 is amended by revising paragraphs (e)(1) introductory text and (l) to read as follows:

§ 155.555 Employer appeals process.

* * * * *

(e) * * *

(1) Upon receipt of a valid appeal request under this section, or upon receipt of the notice under paragraph (d)(1)(iii) of this section, the Exchange must promptly transmit via secure electronic interface to the appeals entity—

* * * * *

(l) *Implementation of the appeal decision.* After receipt of the notice under paragraph (k)(3) of this section, if the appeal decision affects the employee's eligibility, the Exchange must promptly:

(1) Redetermine the employee's eligibility and the eligibility of the employee's household members, if applicable, in accordance with the standards specified in § 155.305; or

(2) Notify the employee of the requirement to report changes in eligibility as described in § 155.330(b)(1).

* * * * *

■ 43. Section 155.605 is amended by—

■ a. In paragraph (b), removing the reference ''paragraphs (c)(2), (f)(2), and (g) of this section'' and adding in its place the reference ''paragraphs (c)(2) and (d) of this section'';

■ b. Removing paragraphs (d), (e), and (f);

■ c. Redesignating paragraph (g) as paragraph (d);

■ d. Revising newly redesignated paragraph (d); and

■ e. Adding paragraph (e).

The revision and addition read as follows:

§ 155.605 Eligibility standards for exemptions.

* * * * *

(d) *Hardship*—(1) *General.* The Exchange must grant a hardship exemption to an applicant eligible for an exemption for at least the month before, the month or months during which, and the month after a specific event or circumstance, if the Exchange determines that:

(i) He or she experienced financial or domestic circumstances, including an unexpected natural or human-caused event, such that he or she had a significant, unexpected increase in essential expenses that prevented him or her from obtaining coverage under a qualified health plan;

(ii) The expense of purchasing a qualified health plan would have caused him or her to experience serious deprivation of food, shelter, clothing or other necessities; or

(iii) He or she has experienced other circumstances that prevented him or her from obtaining coverage under a qualified health plan.

(2) *Lack of affordable coverage based on projected income.* The Exchange must determine an applicant eligible for an exemption for a month or months during which he or she, or another individual the applicant attests will be included in the applicant's family, as defined in 26 CFR 1.36B–1(d), is unable to afford coverage in accordance with the standards specified in section 5000A(e)(1) of the Code, provided that—

(i) Eligibility for this exemption is based on projected annual household income;

(ii) An eligible employer-sponsored plan is only considered under paragraphs (d)(4)(iii) and (iv) of this section if it meets the minimum value standard described in § 156.145 of this subchapter.

(iii) For an individual who is eligible to purchase coverage under an eligible employer-sponsored plan, the Exchange determines the required contribution for coverage such that—

(A) An individual who uses tobacco is treated as not earning any premium incentive related to participation in a wellness program designed to prevent or reduce tobacco use that is offered by an eligible employer-sponsored plan;

(B) Wellness incentives offered by an eligible employer-sponsored plan that do not relate to tobacco use are treated as not earned;

(C) In the case of an employee who is eligible to purchase coverage under an eligible employer-sponsored plan sponsored by the employee's employer, the required contribution is the portion of the annual premium that the employee would pay (whether through salary reduction or otherwise) for the lowest cost self-only coverage.

(D) In the case of an individual who is eligible to purchase coverage under an eligible employer-sponsored plan as a member of the employee's family, as defined in 26 CFR 1.36B–1(d), the required contribution is the portion of the annual premium that the employee would pay (whether through salary reduction or otherwise) for the lowest cost family coverage that would cover the employee and all other individuals who are included in the employee's family who have not otherwise been granted an exemption through the Exchange.

(iv) For an individual who is ineligible to purchase coverage under an eligible employer-sponsored plan, the Exchange determines the required contribution for coverage in accordance with section 5000A(e)(1)(B)(ii) of the Code, inclusive of all members of the family, as defined in 26 CFR 1.36B–1(d), who have not otherwise been granted an exemption through the Exchange and who are not treated as eligible to purchase coverage under an eligible employer-sponsored plan, in accordance with paragraph (d)(4)(ii) of this section; and

(v) The applicant applies for this exemption prior to the last date on which he or she could enroll in a QHP through the Exchange for the month or months of a calendar year for which the exemption is requested.

(vi) The Exchange must make an exemption in this category available prospectively, and provide it for all remaining months in a coverage year, notwithstanding any change in an individual's circumstances.

(3) *Ineligible for Medicaid based on a State's decision not to expand.* The Exchange must determine an applicant eligible for an exemption for a calendar year if he or she would be determined ineligible for Medicaid for one or more months during the benefit year solely as a result of a State not implementing section 2001(a) of the Affordable Care Act.

(e) *Eligibility for an exemption through the IRS.* Hardship exemptions in this paragraph (e) can be claimed on a Federal income tax return without obtaining an exemption certificate number. The IRS may allow an individual to claim the hardship exemptions described in this paragraph (e) without requiring an exemption certificate number from the Exchange.

(1) *Filing threshold.* The IRS may allow an applicant to claim an exemption specified in HHS Guidance published September 18, 2014, entitled, ''Shared Responsibility Guidance—Filing Threshold Hardship Exemption,'' and in IRS Notice 2014–76, section B (see *https://www.cms.gov/cciio/*).

(2) *Self-only coverage in an eligible employer-sponsored plan.* The IRS may allow an applicant to claim an exemption specified in HHS Guidance published November 21, 2014, entitled, ''Guidance on Hardship Exemptions for Persons Meeting Certain Criteria,'' and in IRS Notice 2014–76, section A (see *https://www.cms.gov/cciio/*).

(3) *Eligible for services through an Indian health care provider.* The IRS may allow an applicant to claim the exemption specified in HHS Guidance published September 18, 2014, entitled, ''Shared Responsibility Guidance—Exemption for Individuals Eligible for Services through an Indian Health Care Provider,'' and in IRS Notice 2014–76, section E (see *https://www.cms.gov/cciio/*).

(4) *Ineligible for Medicaid based on a State's decision not to expand.* The IRS may allow an applicant to claim the exemption specified in HHS Guidance published November 21, 2014, entitled, ''Guidance on Hardship Exemptions for Persons Meeting Certain Criteria,'' and in IRS Notice 2014–76, section F (see *https://www.cms.gov/cciio/*).

■ 44. Section 155.610 is amended by revising paragraph (h)(1) and adding paragraph (k) to read as follows:

§ 155.610 Eligibility process for exemptions.

* * * * *

(h) * * *

(1) Except for the exemptions described in § 155.605(c) and (d), after December 31 of a given calendar year, the Exchange may decline to accept an application for an exemption that is available retrospectively for months for such calendar year, and must provide information to individuals regarding how to claim an exemption through the tax filing process.

* * * * *

(k) *Incomplete application.* (1) If an applicant submits an application that does not include sufficient information for the Exchange to conduct a determination for eligibility of an exemption the Exchange must—

(i) Provide notice to the applicant indicating that information necessary to complete an eligibility determination is missing, specifying the missing information, and providing instructions on how to provide the missing information; and

(ii) Provide the applicant with a period of no less than 30 and no more than 90 days, in the reasonable discretion of the Exchange, from the date on which the notice described in paragraph (k)(1) of this section is sent to the applicant to provide the information needed to complete the application to the Exchange; and

(iii) Not proceed with the applicant's eligibility determination during the period described in paragraph (k)(2) of this section.

(2) If the Exchange does not receive the requested information within the time allotted in paragraph (k)(1)(ii) of this section, the Exchange must notify the applicant in writing that the Exchange cannot process the application and provide appeal rights to the applicant.

■ 45. Section 155.615 is amended by—

■ a. Removing paragraphs (c), (d), and (e).

■ b. Redesignating paragraphs (f), (g), (h), (i), (j), and (k) as paragraphs (c), (d), (e), (f), (g), and (h), respectively.

■ c. Revising the paragraph heading for newly redesignated paragraph (c) and paragraph (c)(1).

■ d. Removing and reserving newly redesignated paragraph (c)(3).

The revision and addition read as follows:

§ 155.615 Verification process related to eligibility for exemptions.

* * * * *

(c) *Verification related to exemption for hardship*—(1) *In general.* For any applicant who requests an exemption based on hardship, except for the hardship exemptions described in § 155.605(d)(1)(i) and (iv), the Exchange must verify whether he or she has experienced the hardship to which he or she is attesting.

* * * * *

■ 46. Section 155.625 is amended by revising paragraphs (a)(2) and (b) and adding paragraph (c) to read as follows:

§ 155.625 Options for conducting eligibility determinations for exemptions.

(a) * * *

(2) By use of the HHS service under paragraph (b) of this section.

(b) *Use of HHS service.* Notwithstanding the requirements of this subpart, the Exchange may adopt an exemption eligibility determination made by HHS.

(c) *Administration of hardship exemption based on affordability.* States may choose to administer the hardship exemption under § 155.605(d)(2) only and delegate to HHS all other exemption determinations generally administered by HHS.

■ 47. Section 155.705 is amended by—

■ a. Adding paragraphs (b)(3)(viii), (ix), and (x).

■ b. In paragraph (b)(4)(ii)(B), removing the semicolon and adding a colon in its place.

■ c. Adding paragraphs (b)(4)(ii)(B)(*1*) and (*2*).

■ d. Revising paragraphs (b)(4)(ii)(C)(*2*) and (b)(11)(ii)(A), (B), (C), and (D).

■ e. Removing paragraph (b)(11)(ii)(E).

The revisions and additions read as follows:

§ 155.705 Functions of a SHOP.

* * * * *

(b) * * *

(3) * * *

(viii) For plan years beginning on or after January 1, 2017, a Federally-facilitated SHOP will provide a qualified employer a choice of at least the two methods to make QHPs available to qualified employees and their dependents described in paragraphs (b)(3)(viii)(A) and (B) of this section, and may also provide a qualified employer with a choice of a third method to make QHPs available to qualified employees and their dependents as described in paragraph (b)(3)(viii)(C) of this section.

(A) The employer may choose a level of coverage as described in paragraph (b)(2) of this section;

(B) The employer may choose a single QHP; or

(C) The employer may offer its qualified employees a choice of all QHPs offered through a Federally-facilitated SHOP by a single issuer across all available levels of coverage, as described in section 1302(d)(1) of the Affordable Care Act and implemented in § 156.140(b) of this subchapter. A State with a Federally-facilitated SHOP may recommend that the Federally-facilitated SHOP not make this

additional option available in that State, by submitting a letter to HHS in advance of the annual QHP certification application deadline, by a date to be established by HHS. The State's letter must describe and justify the State's recommendation, based on the anticipated impact this additional option would have on the small group market and consumers.

(ix) For plan years beginning on or after January 1, 2017, a Federally-facilitated SHOP will provide a qualified employer a choice of at least the two methods to make stand-alone dental plans available to qualified employees and their dependents described in paragraphs (b)(3)(ix)(A) and (B) of this section, and may also provide a qualified employer with a choice of a third method to make stand-alone dental plans available to qualified employees and their dependents as described in paragraph (b)(3)(ix)(C) of this section.

(A) The employer may choose to make available a single stand-alone dental plan;

(B) The employer may choose to make available all stand-alone dental plans offered through a Federally-facilitated SHOP at a level of coverage as described in § 156.150(b)(2) of this subchapter; or

(C) The employer may offer its qualified employees a choice of all stand-alone dental plans offered through a Federally-facilitated SHOP by a single issuer across all available levels of coverage, as described in § 156.150(b)(2) of this subchapter. A State with a Federally-facilitated SHOP may recommend that the Federally-facilitated SHOP not make this additional option available in that State, by submitting a letter to HHS in advance of the annual QHP certification application deadline, by a date to be established by HHS. The State's letter must describe and justify the State's recommendation, based on the anticipated impact this additional option would have on the small group market and consumers.

(x) States operating a State-based Exchange utilizing the Federal platform for SHOP enrollment functions will have the same employer choice models available as States with a Federally-facilitated SHOP, except that a State with a State-based Exchange utilizing the Federal platform for SHOP enrollment functions may decide against offering the employer choice models specified in paragraphs (b)(3)(viii)(C) and (b)(3)(ix)(C) of this section in that State, provided that the State notifies HHS of that decision in advance of the annual QHP certification application deadline, by a date to be established by HHS.

(4) * * *

(ii) * * *

(B) * * *

(*1*) In a Federally-facilitated SHOP, payment for the group's first month of coverage must be received by the premium aggregation services vendor on or before the 20th day of the month prior to the month that coverage begins.

(*2*) In a Federally-facilitated SHOP, when coverage is effectuated retroactively, payment for the first month's coverage and all months of the retroactive coverage must be received and processed no later than 30 days after the event that triggers the eligibility for retroactive coverage. If payment is received on or before the 20th day of a month, coverage will be effectuated upon the first day of the following month retroactive to the effective date of coverage. If payment is received after the 20th day of a month, coverage will be effectuated upon the first day of the second following month retroactive to the effective date of coverage, provided that the payment includes the premium for the intervening month.

(C) * * *

(*2*) The number of days for which coverage is being provided in the month described in paragraph (b)(4)(ii)(C)(*1*) of this section.

* * * * *

(11) * * *

(ii) * * *

(A) When the employer offers a single plan to qualified employees, the employer must use a fixed contribution methodology under which the employer contributes a fixed percentage of the plan's premium for each qualified employee and, if applicable, for each dependent of a qualified employee. The employer's contribution is calculated based on an enrollee's premium before any applicable tobacco surcharge, based on the total premium owed for the enrollee, is applied.

(B) When the employer offers a choice of plans to qualified employees, the employer may use a fixed contribution methodology or a reference plan contribution methodology. Under the fixed contribution methodology, the employer contributes a fixed percentage of the premiums for each qualified employee and, if applicable, for each dependent of a qualified employee, across all plans in which any qualified employee, and, if applicable, any dependent of a qualified employee, is enrolled. Under the reference plan contribution methodology, the employer will select a plan from among the plans offered by the employer as described in paragraphs (b)(2) and (3) of this section to serve as a reference plan on which contributions will be based, and then will define a percentage contribution toward premiums under the reference plan; the resulting contribution amounts under the reference plan will be applied toward any plan in which a qualified employee or, if applicable, any dependent of a qualified employee, is enrolled, up to the lesser of the contribution amount or the total amount of any premium for the selected plan before application of a tobacco surcharge, if applicable. The employer's contribution is calculated based on an enrollee's premium before any applicable tobacco surcharge, based on the total premium owed for the enrollee, is applied.

(C) The employer will define a percentage contribution toward premiums for employee-only coverage and, if dependent coverage is offered, a percentage contribution toward premiums for dependent coverage. To the extent permitted by other applicable law, for plan years beginning on or after January 1, 2015, a Federally-facilitated SHOP may permit an employer to define a different percentage contribution for full-time employees from the percentage contribution it defines for non-full-time employees, and it may permit an employer to define a different percentage contribution for dependent coverage for full-time employees from the percentage contribution it defines for dependent coverage for non-full-time employees.

(D) A Federally-facilitated SHOP may permit employers to base contributions on a calculated composite premium for employees, for adult dependents, and for dependents below age 21.

* * * * *

■ 48. Section 155.715 is amended by revising paragraph (g)(1) to read as follows:

§ 155.715 Eligibility determination process for SHOP.

* * * * *

(g) * * *

(1) Each QHP terminates the enrollment through the SHOP of the employer's enrollees enrolled in a QHP through the SHOP; and

* * * * *

■ 49. Section 155.725 is amended by revising paragraphs (c), (e), (h)(2), (i)(1) introductory text, and (j)(2)(i) to read as follows:

§ 155.725 Enrollment periods under SHOP.

* * * * *

(c) *Annual employer election period.* The SHOP must provide qualified

employers with a standard election period prior to the completion of the employer's plan year and before the annual employee open enrollment period, in which the qualified employer may change its participation in the SHOP for the next plan year, including—

(1) The method by which the qualified employer makes QHPs available to qualified employees pursuant to § 155.705(b)(2) and (3);

(2) The employer contribution towards the premium cost of coverage;

(3) The level of coverage offered to qualified employees as described in § 155.705(b)(2) and (3); and

(4) The QHP or QHPs offered to qualified employees in accordance with § 155.705.

* * * * *

(e) *Annual employee open enrollment period.* (1) The SHOP must establish a standardized annual open enrollment period for qualified employees prior to the completion of the applicable qualified employer's plan year and after that employer's annual election period.

(2) Qualified employers in a Federally-facilitated SHOP must provide qualified employees with an annual open enrollment period of at least one week.

* * * * *

(h) * * *

(2) For a group enrollment received by the Federally-facilitated SHOP from a qualified employer at the time of an initial group enrollment or renewal:

(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 unless the employer opts for a later effective date within a quarter for which small group market rates are available.

(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 unless the employer opts for a later effective date within a quarter for which small group market rates are available.

(i) * * *

(1) If a qualified employee enrolled in a QHP through the SHOP remains eligible for enrollment through the SHOP in coverage offered by the same qualified employer, the SHOP may provide for a process under which the employee will remain in the QHP selected the previous year, unless—

* * * * *

(j) * * *

(2) * * *

(i) Experiences an event described in § 155.420(d)(1) (other than paragraph (d)(1)(ii)), or experiences an event described in § 155.420(d)(2), (4), (5), (7), (8), or (9);

* * * * *

■ 50. Section 155.735 is amended by revising paragraph (c)(2) introductory text and paragraph (d)(2) to read as follows:

§ 155.735 Termination of SHOP enrollment or coverage.

* * * * *

(c) * * *

(2) In an FF–SHOP, for premium payments other than payments for the first month of coverage—

* * * * *

(d) * * *

(2) In the FF–SHOP, termination is effective:

(i) In the case of a termination in accordance with paragraphs (d)(1)(i), (ii), (iii), and (v) of this section, termination is effective on the last day of the month in which the Federally-facilitated SHOP receives notice of the event described in paragraph (d)(1)(i), (ii), (iii), or (v) of this section.

(ii) In the case of a termination in accordance with paragraph (d)(1)(iv) 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 for any retroactive enrollments effectuated under § 155.725(j)(5).

(iii) The FF–SHOP will send qualified employees a notice notifying them in advance of a child dependent's loss of eligibility for dependent child coverage under their plan because of age. The notice will be sent 90 days in advance of the date when the dependent enrollee would lose eligibility for dependent child coverage. The enrollee will also receive a separate termination notice when coverage is terminated, under § 155.735(g).

* * * * *

■ 51. Section 155.740 is amended by revising paragraphs (c)(2), (d)(2), and (l)(3) to read as follows:

§ 155.740 SHOP employer and employee eligibility appeals requirements.

* * * * *

(c) * * *

(2) A failure by the SHOP to provide a timely eligibility determination or a timely notice of an eligibility determination in accordance with § 155.715(e).

(d) * * *

(2) A failure by the SHOP to provide a timely eligibility determination or a timely notice of an eligibility determination in accordance with § 155.715(f).

* * * * *

(l) * * *

(3) Be effective as follows:

(i) If an employer is found eligible under the decision, then at the employer's option, the effective date of coverage or enrollment through the SHOP under the decision can either be made retroactive to the effective date of coverage or enrollment through the SHOP that the employer would have had if the employer had been correctly determined eligible, or prospective to the first day of the month following the date of the notice of the appeal decision.

(ii) For employee appeal decisions only, if an employee is found eligible under the decision, then at the employee's option, the effective date of coverage or enrollment through the SHOP under the decision can either be made effective retroactive to the effective date of coverage or enrollment through the SHOP that the employee would have had if the employee had been correctly determined eligible, or prospective to the first day of the month following the date of the notice of the appeal decision.

(iii) If the employer or employee is found ineligible under the decision, then the appeal decision is effective as of the date of the notice of the appeal decision.

* * * * *

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

■ 52. 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).

■ 53. Section 156.50 amended by revising paragraph (c) to read as follows:

§ 156.50 Financial support.

* * * * *

(c) *Requirement for Federally-facilitated Exchange user fee.* (1) To support the functions of Federally-facilitated Exchanges, a participating issuer offering a plan through a Federally-facilitated Exchange must remit a user fee to HHS each month, in the timeframe and manner established by HHS, equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for Federally-facilitated Exchanges for the applicable benefit year and the monthly premium

charged by the issuer for each policy under the plan where enrollment is through a Federally-facilitated Exchange.

(2) To support the functions of State-based Exchanges on the Federal platform, unless the State-based Exchange and HHS agree on an alternative mechanism to collect the funds, a participating issuer offering a plan through a State-based Exchange that elects to utilize the Federal Exchange platform for certain Exchange functions described in § 155.200 of this subchapter, as specified in a Federal platform agreement, must remit a user fee to HHS, in the timeframe and manner established by HHS, equal to the product of the sum of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for State-based Exchanges that use the Federal platform for the applicable benefit year plus, if a written request is made by a State, any additional user fee rate that HHS will collect on behalf of the State-based Exchange, multiplied by the monthly premium charged by the issuer for each policy under the plan where enrollment is through the State-based Exchange on the Federal platform.

* * * * *

■ 54. Section 156.80 is amended by revising paragraph (d)(3)(ii) to read as follows:

§ 156.80 Single risk pool.

* * * * *

(d) * * *

(3) * * *

(ii) A health insurance issuer in the small group market (not including a merged market) may establish index rates and make the marketwide adjustments under paragraph (d)(1) of this section, and make the plan-level adjustments under paragraph (d)(2) of this section, no more frequently than quarterly. Any changes to rates must have effective dates of January 1, April 1, July 1, or October 1. Such rates may only apply to coverage issued or renewed on or after the rate effective date and will apply for the entire plan year of the group health plan.

* * * * *

■ 55. Section 156.115 is amended by revising paragraph (a)(5) introductory text to read as follows:

§ 156.115 Provision of EHB.

(a) * * *

(5) With respect to habilitative services and devices—

* * * * *

■ 56. Section 156.122 is amended by adding paragraph (c)(4) to read as follows:

§ 156.122 Prescription drug benefit.

* * * * *

(c) * * *

(4) *Application of coverage appeals laws.* (i) A State may determine that a health plan in the State satisfies the requirements of this paragraph (c) if the health plan has a process to allow an enrollee to request and gain access to clinically appropriate drugs not otherwise covered by the health plan that is compliant with the State's applicable coverage appeals laws and regulations that are at least as stringent as the requirements of this paragraph (c) and include:

(A) An internal review;

(B) An external review;

(C) The ability to expedite the reviews; and

(D) Timeframes that are the same or shorter than the timeframes under paragraphs (c)(1)(ii) and (c)(2)(iii) of this section.

* * * * *

■ 57. Section 156.135 is amended by revising paragraph (g) to read as follows:

§ 156.135 AV calculation for determining level of coverage.

* * * * *

(g) *Updates to the AV Calculator.* HHS will update the AV Calculator annually for material changes that may include costs, plan designs, the standard population, developments in the function and operation of the AV Calculator and other actuarially relevant factors.

■ 58. Section 156.150 is amended by adding paragraphs (a)(1) and (2), (c), and (d) to read as follows:

§ 156.150 Application to stand-alone dental plans inside the Exchange.

(a) * * *

(1) For plan years beginning after 2017, for one covered child—the dollar limit applicable to a stand-alone dental plan for one covered child specified in this paragraph (a) increased by the percent increase of the consumer price index for dental services for the year 2 years prior to the applicable plan year over the consumer price index for dental services for 2016.

(2) For plan years after 2017, for two or more covered children—twice the dollar limit for one child described in paragraph (a)(1) of this section.

* * * * *

(c) *Consumer price index for dental services defined.* The consumer price index for dental services is a sub-component of the U.S. Department of Labor's Bureau of Labor Statistics Consumer Price Index specific to dental services.

(d) *Increments of cost sharing increases.* Any increase in the annual dollar limits described in paragraph (a)(1) of this section that does not result in a multiple of 25 dollars will be rounded down, to the next lowest multiple of 25 dollars.

■ 59. Section 156.230 is amended by adding paragraphs (d) and (e) to read as follows:

§ 156.230 Network adequacy standards.

* * * * *

(d) *Provider transitions.* A QHP issuer in a Federally-facilitated Exchange must—

(1) Make a good faith effort to provide written notice of discontinuation of a provider 30 days prior to the effective date of the change or otherwise as soon as practicable, to enrollees who are patients seen on a regular basis by the provider or who receive primary care from the provider whose contract is being discontinued, irrespective of whether the contract is being discontinued due to a termination for cause or without cause, or due to a non-renewal;

(2) In cases where a provider is terminated without cause, allow an enrollee in an active course of treatment to continue treatment until the treatment is complete or for 90 days, whichever is shorter, at in-network cost-sharing rates.

(i) For the purposes of paragraph (d)(2) of this section, active course of treatment means:

(A) An ongoing course of treatment for a life-threatening condition, defined as a disease or condition for which likelihood of death is probable unless the course of the disease or condition is interrupted;

(B) An ongoing course of treatment for a serious acute condition, defined as a disease or condition requiring complex ongoing care which the covered person is currently receiving, such as chemotherapy, radiation therapy, or post-operative visits;

(C) The second or third trimester of pregnancy, through the postpartum period; or

(D) An ongoing course of treatment for a health condition for which a treating physician or health care provider attests that discontinuing care by that physician or health care provider would worsen the condition or interfere with anticipated outcomes.

(ii) Any QHP issuer decision made for a request for continuity of care under paragraph (d)(2) of this section must be subject to the health benefit plan's

internal and external grievance and appeal processes in accordance with applicable State or Federal law or regulations.

(e) *Out-of-network cost sharing.* Beginning for the 2018 and later benefit years, for a network to be deemed adequate, each QHP that uses a provider network must:

(1) Notwithstanding § 156.130(c), count the cost sharing paid by an enrollee for an essential health benefit provided by an out-of-network ancillary provider in an in-network setting towards the enrollee's annual limitation on cost sharing; or

(2) Provide a written notice to the enrollee by the longer of when the issuer would typically respond to a prior authorization request timely submitted, or 48 hours before the provision of the benefit, that additional costs may be incurred for an essential health benefit provided by an out-of-network ancillary provider in an in-network setting, including balance billing charges, unless such costs are prohibited under State law, and that any additional charges may not count toward the in-network annual limitation on cost sharing.

■ 60. Section 156.235 is amended by revising paragraphs (a)(2)(i) and (b)(2)(i) to read as follows:

§ 156.235 Essential community providers.

(a) * * *

(2) * * *

(i) The network includes as participating practitioners at least a minimum percentage, as specified by HHS, of available essential community providers in each plan's service area. For plan years beginning prior to January 1, 2018, multiple providers at a single location will count as a single essential community provider toward both the available essential community providers in the plan's service area and the issuer's satisfaction of the essential community provider participation standard. For plan years beginning on or after January 1, 2018, multiple contracted or employed full-time equivalent practitioners at a single location will count toward both the available essential community providers in the plan's service area and the issuer's satisfaction of the essential community provider participation standard; and

* * * * *

(b) * * *

(2) * * *

(i) The number of its providers that are located in Health Professional Shortage Areas or five-digit zip codes in which 30 percent or more of the population falls below 200 percent of the Federal Poverty Line satisfies a minimum percentage, specified by HHS, of available essential community provider in the plan's service area. For plan years beginning prior to January 1, 2018, multiple providers at a single location will count as a single essential community provider toward both the available essential community providers in the plan's service area and the issuer's satisfaction of the essential community provider participation standard. For plan years beginning on or after January 1, 2018, multiple contracted or employed full-time equivalent practitioners at a single location will count toward both the available essential community providers in the plan's service area and the satisfaction of the essential community provider participation standard; and

* * * * *

■ 61. Section 156.265 is amended by revising paragraph (b)(2)(ii) and adding paragraphs (b)(3) through (5) to read as follows:

§ 156.265 Enrollment process for qualified individuals.

* * * * *

(b) * * *

(2) * * *

(ii) Ensure the applicant's completion of an eligibility verification and enrollment application through the Exchange Internet Web site as described in § 155.405, or ensure that the eligibility application information is submitted for an eligibility determination through the Exchange-approved Web service subject to meeting the requirements in paragraph (b)(3) through (5) of this section;

(3) When an Internet Web site of an issuer is used to complete the Exchange eligibility application outlined in this section, at a minimum, the Internet Web site must:

(i) Use exactly the same eligibility application language as appears in the FFE Single Streamlined Application required in § 155.405 of this subchapter, unless HHS approves a deviation;

(ii) Ensure that all necessary information for the consumer's applicable eligibility circumstances are submitted through the Exchange-approved Web service; and

(iii) Ensure that the process used for consumers to complete the eligibility application complies with all applicable Exchange standards, including §§ 155.230 and 155.260(b) of this subchapter.

(4) An issuer must obtain HHS approval that the requirements of this section have been met prior to completing an applicant's eligibility application through the issuer's Internet Web site.

(5) HHS or its designee may periodically monitor and audit an agent, broker, or issuer to assess its compliance with the applicable requirements of this section.

* * * * *

■ 62. Section 156.270 is amended by revising paragraphs (d) introductory text and (g) to read as follows:

§ 156.270 Termination of coverage or enrollment for qualified individuals.

* * * * *

(d) *Grace period for recipients of advance payments of the premium tax credit.* A QHP issuer must provide a grace period of 3 months for an enrollee, who when failing to timely pay premiums, is receiving advance payments of the premium tax credit. During the grace period, the QHP issuer must:

* * * * *

(g) *Exhaustion of grace period.* If an enrollee receiving advance payments of the premium tax credit exhausts the 3-month grace period in paragraph (d) of this section without paying all outstanding premiums, subject to a premium payment threshold implemented under § 155.400(g) of this subchapter, if applicable, the QHP issuer must terminate the enrollee's enrollment through the Exchange on the effective date described in § 155.430(d)(4) of this subchapter, provided that the QHP issuer meets the notice requirement specified in paragraph (b) of this section.

* * * * *

■ 63. Section 156.285 is amended by revising paragraph (c)(5) and removing and reserving paragraph (d)(2) to read as follows:

§ 156.285 Additional standards specific to SHOP.

* * * * *

(c) * * *

(5) Send enrollment reconciliation files on at least a monthly basis, and, in a Federally-facilitated SHOP, according to a process, timeline, and file format established by the Federally-facilitated SHOP;

* * * * *

■ 64. Section 156.298 is amended by—

■ a. Revising paragraph (b)(4).

■ b. Removing paragraph (b)(5).

■ c. Redesignating paragraph (b)(6) as paragraph (b)(5).

■ d. Revising newly redesignated paragraph (b)(5).

The revisions read as follows:

§ 156.298 Meaningful difference standard for Qualified Health Plans in the Federally-facilitated Exchanges.

* * * * *

(b) * * *

(4) Plan type; or

(5) Child-only versus non Child-only plan offerings.

* * * * *

■ 65. The heading of subpart D is revised to read as follows:

Subpart D—Standards for Qualified Health Plan Issuers on Federally-Facilitated Exchanges and State-Based Exchanges on the Federal Platform

■ 66. Section 156.350 is added to read as follows:

§ 156.350 Eligibility and enrollment standards for Qualified Health Plan issuers on State-based Exchanges on the Federal platform.

(a) In order to participate in a State-based Exchange on the Federal platform, a QHP issuer must comply with HHS regulations, and guidance pertaining to issuer eligibility and enrollment functions as if the issuer were an issuer of a QHP on a Federally-facilitated Exchange. These requirements include—

(1) Section 156.285(a)(4)(ii) regarding the premiums for plans offered on the SHOP;

(2) Section 156.285(c)(8)(iii) regarding enrollment process for SHOP; and

(3) Section 156.715 regarding compliance reviews of QHP issuers, to the extent relating directly to applicable eligibility and enrollment functions.

(b) HHS will permit issuers of QHPs in each State-based Exchange on the Federal platform to directly enroll applicants in a manner that is considered to be through the Exchange, as if the issuers were issuers of QHPs on Federally-facilitated Exchanges under § 156.1230(a), to the extent permitted by applicable State law.

(c) If the State-based Exchange on the Federal platform does not substantially enforce a requirement in paragraph (a) of this section against the issuer or plan, then HHS may do so, in accordance with the enforcement remedies in subpart I of this part, subject to the administrative review process in subpart J of this part.

■ 67. Section 156.805 is amended by revising paragraph (d) to read as follows:

§ 156.805 Bases and process for imposing civil money penalties in Federally-facilitated Exchanges.

* * * * *

(d) *Request for hearing.* (1) An issuer may appeal the assessment of a civil money penalty under this section by filing a request for hearing under an applicable administrative hearing process.

(2) If an issuer files a request for hearing under this paragraph (d), the assessment of a civil money penalty will not occur prior to the issuance of the final administrative decision in the appeal.

* * * * *

■ 68. Section 156.810 is amended by revising paragraphs (a)(12) and (13) and (e) and adding paragraphs (a)(14) and (15) to read as follows:

§ 156.810 Bases and process for decertification of a QHP offered by an issuer through a Federally-facilitated Exchange.

(a) * * *

(12) The QHP issuer substantially fails to meet the requirements related to the cases forwarded to QHP issuers under subpart K of this part;

(13) The QHP issuer substantially fails to meet the requirements related to the offering of a QHP under subpart M of this part;

(14) The QHP issuer offering the QHP is the subject of a pending, ongoing, or final State regulatory or enforcement action or determination that relates to the issuer offering QHPs in the Federally-facilitated Exchanges; or

(15) HHS reasonably believes that the QHP issuer lacks the financial viability to provide coverage under its QHPs until the end of the plan year.

* * * * *

(e) *Request for hearing.* An issuer may appeal the decertification of a QHP offered by that issuer under paragraph (c) or (d) of this section by filing a request for hearing under an applicable administrative hearing process.

(1) If an issuer files a request for hearing under this paragraph (e):

(i) If the decertification is under paragraph (b)(1) of this section, the decertification will not take effect prior to the issuance of the final administrative decision in the appeal, notwithstanding the effective date specified in paragraph (b)(1) of this section.

(ii) If the decertification is under paragraph (b)(2) of this section, the decertification will be effective on the date specified in the notice of decertification, but the certification of the QHP may be reinstated immediately upon issuance of a final administrative decision that the QHP should not be decertified.

(2) [Reserved]

■ 69. Section 156.1110 is amended by revising paragraphs (a) and (b) and removing paragraph (d) to read as follows:

§ 156.1110 Establishment of patient safety standards for QHP issuers.

(a) *Patient safety standards.* A QHP issuer that contracts with a hospital with greater than 50 beds must verify that the hospital, as defined in section 1861(e) of the Act:

(1) For plan years beginning before January 1, 2017, is Medicare-certified or has been issued a Medicaid-only CMS Certification Number (CCN) and is subject to the Medicare Hospital Conditions of Participation requirements for—

(i) A quality assessment and performance improvement program as specified in 42 CFR 482.21; and

(ii) Discharge planning as specified in 42 CFR 482.43.

(2) For plan years beginning on or after January 1, 2017—

(i)(A) Utilizes a patient safety evaluation system as defined in 42 CFR 3.20; and

(B) Implements a mechanism for comprehensive person-centered hospital discharge to improve care coordination and health care quality for each patient; or

(ii) Implements an evidence-based initiative, to improve health care quality through the collection, management and analysis of patient safety events that reduces all cause preventable harm, prevents hospital readmission, or improves care coordination.

(3) A QHP issuer must ensure that each of its QHPs meets the patient safety standards in accordance with this section.

(b) *Documentation.* A QHP issuer must collect:

(1) For plan years beginning before January 1, 2017, the CCN from each of its contracted hospitals with greater than 50 beds, to demonstrate that those hospitals meet patient safety standards required in paragraph (a)(1) of this section; and

(2) For plan years beginning on or after January 1, 2017, information, from each of its contracted hospitals with greater than 50 beds, to demonstrate that those hospitals meet patient safety standards required in paragraph (a)(2) of this section.

* * * * *

■ 70. Section 156.1215 is amended by revising paragraphs (b) and (c) to read as follows:

§ 156.1215 Payment and collections processes.

* * * * *

(b) *Netting of payments and charges for later years.* As part of its payment

and collections process, HHS may net payments owed to issuers and their affiliates operating under the same tax identification number against amounts due to the Federal or State governments from the issuers and their affiliates under the same taxpayer identification number for advance payments of the premium tax credit, advance payments of and reconciliation of cost-sharing reductions, payment of Federally-facilitated Exchange user fees, payment of any fees for State-based Exchanges utilizing the Federal platform, and risk adjustment, reinsurance, and risk corridors payments and charges.

(c) *Determination of debt.* Any amount owed to the Federal government by an issuer and its affiliates for advance payments of the premium tax credit, advance payments of and reconciliation of cost-sharing reductions, Federally-facilitated Exchange user fees, including any fees for State-based Exchanges utilizing the Federal platform, risk adjustment, reinsurance, and risk corridors, after HHS nets amounts owed by the Federal government under these programs, is a determination of a debt.

■ 71. Section 156.1220 is amended by revising paragraphs (a)(3) and (a)(4)(ii) to read as follows:

§ 156.1220 Administrative appeals.

(a) * * *

(3) *Time for filing a request for reconsideration.* The request for reconsideration must be filed in accordance with the following timeframes:

(i) For advance payments of the premium tax credit, advance payments of cost-sharing reductions, Federally-facilitated Exchange user fee charges, or State-based Exchanges utilizing the Federal platform fees, within 60 calendar days after the date of the final reconsideration notification specifying the aggregate amount of advance payments of the premium tax credit, advance payments of cost-sharing reductions, Federally-facilitated Exchange user fees, and State-based Exchanges utilizing the Federal platform fees for the applicable benefit year;

(ii) For a risk adjustment payment or charge, including an assessment of risk adjustment user fees, within 30 calendar days of the date of the notification under § 153.310(e) of this subchapter;

(iii) For a reinsurance payment, within 30 calendar days of the date of the notification under § 153.240(b)(1)(ii) of this subchapter;

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

(v) For reconciliation of cost-sharing reductions, within 60 calendar days of the date of the notification of the cost-sharing reduction reconciliation payment or charge; and

(vi) For a risk corridors payment or charge, within 30 calendar days of the date of the notification under § 153.510(d) of this subchapter.

(4) * * *

(ii) Notwithstanding paragraph (a)(1) of this section, a reconsideration with respect to a processing error by HHS, HHS's incorrect application of the relevant methodology, or HHS's mathematical error may be requested only if, to the extent the issue could have been previously identified by the issuer to HHS under § 153.710(d)(2) of this subchapter, it was so identified and remains unresolved.

* * * * *

■ 72. Section 156.1250 is revised to read as follows:

§ 156.1250 Acceptance of certain third party payments.

Issuers offering individual market QHPs, including stand-alone dental plans, and their downstream entities, must accept premium and cost-sharing payments for the QHPs from the following third-party entities from plan enrollees (in the case of a downstream entity, to the extent the entity routinely collects premiums or cost sharing):

(a) A Ryan White HIV/AIDS Program under title XXVI of the Public Health Service Act;

(b) An Indian tribe, tribal organization, or urban Indian organization; and

(c) A local, State, or Federal government program, including a grantee directed by a government program to make payments on its behalf.

■ 73. Section 156.1256 is added to read as follows:

§ 156.1256 Other notices.

As directed by the FFE, a health insurance issuer that is offering QHP coverage through an FFE or an SBE–FP must notify its enrollees of material plan or benefit display errors and the enrollees' eligibility for a special enrollment period, included in § 155.420(d)(4) of this subchapter, within 30 calendar days after being notified by the FFE that the error has been fixed, if directed to do so by the FFE.

PART 158—ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS

■ 74. 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.

■ 75. Section 158.103 is amended by revising the definitions of ''Large Employer'' and ''Small Employer'' to read as follows:

§ 158.103 Definitions.

* * * * *

Large Employer has the meaning given the term in § 144.103 of this subchapter.

* * * * *

Small Employer has the meaning given the term in § 144.103 of this subchapter.

* * * * *

Dated: February 22, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: February 23, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2016–04439 Filed 2–29–16; 4:15 pm]

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