

DEPARTMENT OF HEALTH AND HUMAN SERVICES**45 CFR Parts 144, 146, 147, 148, 153, 154, 155, 156, 157, and 158****[CMS-9934-F; CMS-9933-F]****RIN 0938-AS95, RIN 0938-AS87****Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2018; Amendments to Special Enrollment Periods and the Consumer Operated and Oriented Plan Program****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 program; cost-sharing parameters and cost-sharing reductions; and user fees for Federally-facilitated Exchanges and State-based Exchanges on the Federal platform. It also provides additional guidance relating to standardized options; qualified health plans; consumer assistance tools; network adequacy; the Small Business Health Options Programs; stand-alone dental plans; fair health insurance premiums; guaranteed availability and guaranteed renewability; the medical loss ratio program; eligibility and enrollment; appeals; consumer-operated and oriented plans; special enrollment periods; and other related topics.

DATES: These regulations are effective January 17, 2017.

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Acronyms and Abbreviations

The Act Social Security Act
 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

APTC Advance payments of the premium tax credit
 AV Actuarial value
 CBO Congressional Budget Office
 CFR Code of Federal Regulations
 CHIP Children's Health Insurance Program
 CMP Civil money penalties
 CMS Centers for Medicare & Medicaid Services
 Code Internal Revenue Code of 1986 (26 U.S.C. 1, *et seq.*)
 CO-OPs Consumer Operated and Oriented Plans
 CPI Consumer price index
 ECP Essential community provider
 EDGE External data gathering environment
 EHB Essential health benefits
 ESRD End Stage Renal Disease
 FDA Food and Drug Administration
 FFE Federally-facilitated Exchange
 FF-SHOP Federally-facilitated Small Business Health Options Program
 FPL Federal poverty level
 FR Federal Register
 FTE Full-time equivalent
 HCC Hierarchical condition category
 HDHP High deductible health plan
 HHS United States Department of Health and Human Services
 HIPAA Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191)
 HMO Health maintenance organization
 IRS Internal Revenue Service
 LEP Limited English proficient/proficiency
 MLR Medical loss ratio
 NAIC National Association of Insurance Commissioners
 NDC National Drug Code
 NHEA National Health Expenditure Accounts
 OCR Office for Civil Rights
 OMB Office of Management and Budget
 PCIP Pre-Existing Condition Insurance Plan
 PHI Protected health information
 PHS Act Public Health Service Act
 PI Personal income
 PII Personally identifiable information
 PMPM Per member per month
 PPO Preferred provider organization
 QHP Qualified health plan
 RXC Prescription Drug Categories
 SADP Stand-alone dental plan
 SBC Summary of benefits and coverage
 SBE-FP State-based Exchange on the Federal platform
 SHOP Small Business Health Options Program
 USP United States Pharmacopeia

I. Executive Summary

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^{SM,1} or MarketplaceSM),

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 claim a premium tax credit to make health insurance premiums 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 risk adjustment program and rules that are intended to 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 final rule, to further promote stable premiums in the individual and small group markets, we finalize several updates to the risk adjustment methodology based on our experience with the program to date that are intended to refine the methodology's ability to estimate risk. In particular, beginning for the 2017 benefit year, we finalize an update to better estimate the actuarial risk associated with enrollees who are not enrolled for a full 12 months, and beginning for the 2018 benefit year, we finalize updates to use prescription drug data to update the predictive ability of our risk adjustment models, to establish transfers that will better account for the risk of high-cost enrollees, and to reduce the Statewide average premium in the transfer formula by a portion of administrative costs. We also finalize several amendments to the risk adjustment data validation process, including amendments relating to the review of prescription drug data and the establishment of a discrepancy identification and administrative appeals process.

We finalize several provisions related to cost-sharing parameters. First, we finalize the premium adjustment percentage for 2018, 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 2018. We also finalize the maximum annual limitations on cost sharing for the 2018 benefit year for cost-sharing reduction plan variations. This final rule also finalizes standards for stand-alone dental plans (SADPs) related to the annual limitation on cost sharing.

We are also finalizing a number of amendments that we believe will help promote consumer choice in health plans. These include a requirement that at least one QHP at the silver coverage

level and at least one QHP at the gold coverage level must be offered throughout the service area in which a QHP issuer offers coverage through the Exchange; and amendments that would permit a broader de minimis range for the actuarial value of bronze plans to permit greater flexibility in benefit design and to accommodate updates to the 2018 Actuarial Value (AV) Calculator.

We also require QHP issuers on an Exchange to make their QHPs available through the Exchange for a full plan year (unless a basis for suppression applies) as a QHP certification requirement, which would help ensure that individuals enrolling through special enrollment periods and newly qualified employees have access to a range of plans that is generally comparable to the range of plans that can be accessed by those who enroll during an open enrollment period. We also remove a requirement tying participation in the individual market Federally-facilitated Exchanges (FHEs) to participation in the Federally-facilitated Small Business Health Options Programs.

We are finalizing a provision to expand the medical loss ratio (MLR) provision allowing issuers to defer reporting of policies newly issued with a full 12 months of experience (rather than policies newly issued and with less than 12 months of experience) in that MLR reporting year, and to provide the option to limit the total rebate liability payable with respect to a given calendar year to mitigate the impact of the 3-year averaging requirement on new and growing issuers. We finalize several changes to the guaranteed renewability regulations that would address instances where issuers may inadvertently trigger a market withdrawal and 5-year prohibition on market re-entry. We also finalize a change to the age rating rules for children.

In this final rule, we finalize several provisions regarding when and how consumers may choose and enroll in plans. This rule includes provisions relating to: Codifying several special enrollment periods that are already available to consumers in order to ensure the rules are clear and to limit potential abuse; the enrollment processes in the Small Business Health Options Programs (SHOPs); and binder payment deadlines. We also finalize several amendments related to insurance affordability programs, including regarding eligibility determinations, and periodic data matching.

¹ Health Insurance MarketplaceSM and MarketplaceSM are service marks of the U.S. Department of Health & Human Services.

We are finalizing a number of amendments to assist consumers in selecting and enrolling in QHPs and insurance affordability programs. In the HHS Notice of Benefit and Payment Parameters for 2017 Final Rule (2017 Payment Notice), we established standardized options, which we will display on *HealthCare.gov* in a manner that distinguishes them from other QHPs, and a categorization of network breadth. We believe both policies will make it easier for consumers to select health plans through *HealthCare.gov*. For standardized options, we are finalizing the selection of three bronze standardized options (in addition to one high deductible health plan (HDHP), within the meaning of section 223(c)(2) of the Internal Revenue Code of 1986 (26 U.S.C. 1, *et seq.*) (the Code), at the bronze level of coverage), and three standardized options at each of the silver, silver cost-sharing reduction variations, and gold metal levels. We have identified one standardized option at each metal level and one at each cost-sharing reduction plan variation level for use in each State. By increasing the scope of potential standardized designs, we will better accommodate State cost-sharing laws. We are finalizing a provision to make differential display of standardized options available in State-based Exchanges on the Federal platform (SBE-FPs) at the State's option, as well as to require differential display of standardized options by QHP issuers and Web-brokers² using a direct enrollment pathway to facilitate enrollment through a FFE or SBE-FP. Additionally, we are finalizing a number of standards and consumer protections that would apply to a Web-broker or issuer using the direct enrollment pathway. We are augmenting our network adequacy network breadth display policy to account for QHPs that are part of an integrated delivery system. We are also finalizing standards relating to the essential community provider (ECP) requirements and amending the standards regarding providing taglines in non-English languages indicating the availability of language services.

We also finalize several amendments that would strengthen Exchanges' oversight capabilities. These include provisions requiring issuers seeking to rescind coverage purchased through the Exchange to show that the rescission is

appropriate and making explicit HHS's authority to impose civil money penalties (CMPs) in situations where QHP issuers are non-responsive or uncooperative with compliance reviews. We also finalize an avenue through which issuers can appeal a non-certification or decertification.

Finally, in this final rule, we make minor adjustments to our rules governing the single risk pool, SHOP, user fees, notices, decertification, and appeals.

This final rule also finalizes the "Patient Protection and Affordable Care Act; Amendments to Special Enrollment Periods and the Consumer Operated and Oriented Plan Program" interim final rule with comment published in the May 11, 2016 **Federal Register** (81 FR 29146). In this final rule, we finalize a number of amendments to special enrollment periods for individuals who gain access to new QHPs as a result of a permanent move so that this special enrollment period is generally available only to those individuals who had minimum essential coverage prior to their permanent move. We are also finalizing amendments to the CO-OP governance requirements to provide greater flexibility and facilitate private market transactions that can provide access to needed capital.

II. HHS Notice of Benefit and Payment Parameters for 2018

A. Background

1. 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."

The Affordable Care Act reorganizes, amends, and adds to the provisions 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, geographic 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 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 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.³

Section 2703 of the PHS Act, as added by the Affordable Care Act, and former section 2712 and section 2742 of the PHS Act, as added by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), require health insurance issuers that offer health insurance coverage in the group or individual market to renew or continue in force such coverage at the option of the plan sponsor or individual, unless an exception applies.

Section 2718 of the PHS Act, as added by the Affordable Care Act, generally requires health insurance issuers to submit an annual medical loss ratio 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.⁴ 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 1101 of the Affordable Care Act required the Secretary to establish a

³ 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.

⁴ 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.

² CMS uses the term "Web-broker" to describe an individual agent or broker, group of agents and brokers, or company registered with the FFEs that provides a non-Exchange Web site to assist consumers in the selection and enrollment in qualified health plans (QHPs) offered through the Exchanges as described in 45 CFR 155.220(c)(3).

temporary high-risk health insurance pool program to provide health insurance coverage from the establishment of the program until January 1, 2014 for eligible individuals, namely U.S. residents who are U.S. citizens or lawfully present in the U.S.; did not have other health insurance coverage in the 6 months preceding enactment; and have a pre-existing condition. Section 1101 also requires that the Secretary develop procedures to provide for the transition of eligible individuals enrolled in this health insurance coverage into qualified health plans offered through an Exchange to avoid a lapse in coverage.

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

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 market 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 section 1302(c)(1) of the Affordable Care Act.

Section 1302(d) of the Affordable Care Act describes the various levels of coverage based on AV. Consistent with section 1302(d)(2)(A) of the Affordable

Care Act, AV is calculated based on the provision of EHB to a standard population. Section 1302(d)(3) of the Affordable Care Act directs the Secretary to develop guidelines that allow for de minimis variation in AV calculations.

Section 1311(b)(1)(B) of the Affordable Care Act directs that the 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.⁵

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)(C) of the Affordable Care Act states that the Secretary is to provide for special enrollment periods specified in section 9801 of the Code and other special enrollment periods under circumstances similar to such periods under part D of title XVIII of the Social Security Act (the Act).

Section 1312(e) of the Affordable Care Act directs the Secretary to establish procedures under which a State may permit agents and brokers to enroll qualified individuals and qualified employers in QHPs through an Exchange, and to assist individuals in applying for financial assistance for QHPs sold through an Exchange.

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

⁵ If a State elects this option, the rating rules in section 2701 of the PHS Act and its implementing regulations at 45 CFR 147.102 will apply to all coverage offered in such State's large group market under section 2701(a)(5) of the PHS Act.

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 a Federally-facilitated Exchange (FFE) under section 1321(c)(1) of the Affordable Care Act, HHS has the authority under sections 1321(c)(1) and 1311(d)(5)(A) of the Affordable Care Act to collect and spend user fees. In addition, 31 U.S.C. 9701 permits a Federal agency to establish a charge for a service provided by the agency. These user fees are appropriated to CMS in the CMS Program Management appropriation.

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 with respect to health insurance issuers 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 1343 of the Affordable Care Act establishes a risk adjustment program in which States, or HHS on behalf of States, collect charges from health insurance issuers that attract lower-risk populations in order to use those funds to provide payments to health insurance issuers that attract higher-risk populations, such as those with chronic conditions, 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. These sections also provide for reductions in cost sharing for Indians enrolled in QHPs at any metal level.

a. 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) (2014 Payment Notice).

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) (2015 Payment Notice).

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) (2016 Payment Notice).

In the December 2, 2015 **Federal Register** (80 FR 75487), we published a proposed rule outlining the benefit and payment parameters for the 2017 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 2017 Payment Notice). We published the 2017 Payment Notice final rule in the March 8, 2016 **Federal Register** (81 FR 12203) (2017 Payment Notice).

b. 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).

c. 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 (78 FR 15409) and in a proposed rule published in the March 11, 2013 **Federal Register** (78 FR 15553) and finalized in the June 4, 2013 **Federal Register** (78 FR 33233). We also set forth standards related to Exchange user fees in the 2014 Payment Notice.

In the 2017 Payment Notice we established additional Exchange standards, including requirements for State Exchanges using the Federal platform and standardized options.

In an interim final rule with comment published in the May 11, 2016 **Federal Register** (81 FR 29146) we amended the parameters of certain special enrollment periods.

d. Essential Health Benefits and Actuarial Value

On December 16, 2011, HHS released a bulletin⁶ (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

⁶ Essential Health Benefits Bulletin. Dec. 16, 2011. Available at https://www.cms.gov/CCIIO/Resources/Files/Downloads/essential_health_benefits_bulletin.pdf.

calculations of AV on February 24, 2012.⁷ 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).

e. 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 30240) (2015 Market Standards Rule).

f. 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).

g. 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 relating to the MLR program on December 1, 2010 (75 FR 74863). A final rule was published in the December 7, 2011 **Federal Register** (76 FR 76573). An interim final rule was published in the December 7, 2011 **Federal Register** (76 FR 76595). A final rule was published in the **Federal Register** on

⁷ Actuarial Value and Cost-Sharing Reductions Bulletin. Feb. 24, 2012. Available at <https://www.cms.gov/CCIIO/Resources/Files/Downloads/Av-csr-bulletin.pdf>.

May 16, 2012 (77 FR 28790). The Medical Loss Ratio (MLR) program requirements were amended in final rules published in the March 11, 2014 **Federal Register** (79 FR 13743), the May 27, 2014 **Federal Register** (79 FR 30339), the February 27, 2015 **Federal Register** (80 FR 10749), and the March 8, 2016 **Federal Register** (81 FR 12203).

h. Pre-Existing Condition Insurance Plan Program

We published an interim final rule in the July 30, 2010 **Federal Register** (75 FR 45013) setting forth implementing regulations for the Pre-Existing Condition Insurance Plan Program. An amendment to this interim final rule was published in the August 30, 2012 **Federal Register** (77 FR 52614). We published an interim final rule in the May 22, 2013 **Federal Register** (78 FR 30218).

2. Stakeholder Consultation and Input

HHS has consulted with stakeholders on policies related to the operation of Exchanges, including the SHOPs, 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 (NAIC), regular contact with States, and meetings with Tribal leaders and representatives, health insurance issuers, trade groups, consumer advocates, employers, and other interested parties.

On March 31, 2016, we hosted a public conference to discuss the potential improvements to the Federally certified HHS-operated risk adjustment methodology. Prior to the conference, we published the “March 31, 2016, HHS-Operated Risk Adjustment Methodology Meeting: Discussion Paper” (“White Paper”),⁸ on which we received public comment. These comments are available at https://www.regtap.info/uploads/library/RA_Onsite_Discussion_Paper_Comments_5CR_080916.pdf.

We considered all public input we received as we developed the policies in this final rule.

3. Structure of Final Rule

The regulations outlined in this final rule will be codified in 45 CFR parts

144, 146, 147, 148, 153, 154, 155, 156, 157 and 158.

The regulations in parts 144 and 154 make conforming revisions to the regulatory definitions of “plan” and “product” with respect to the transfer of coverage to a related issuer within the same controlled group.

The regulations in parts 146, 147 and 148 address two scenarios in which the discontinuation of all coverage currently offered by an issuer within a market and State will not be treated as a market withdrawal for purposes of the guaranteed renewability requirements. The regulations in part 147 create multiple child age bands for rating purposes, and amend the provision regarding limited open enrollment periods (also known as special enrollment periods) in the individual market to provide greater clarity and to reflect the amendments regarding special enrollment periods in the Exchanges.

Discussion in part 152 responds to comments on potential approaches to ensure the successful transition of former Pre-Existing Condition Insurance Plan (PCIP) Program enrollees to the Exchange without a lapse in coverage, under the PCIP statute.

The regulations in part 153 include the risk adjustment user fee for 2018 and outline a number of modifications to the HHS risk adjustment methodology, including modifications to: (1) Address partial year enrollment; (2) use prescription drug data to predict actuarial risk; and (3) alter the methodology to better account for high-cost enrollees. We also provide for the use of External data gathering environment (EDGE) server data to recalibrate the risk adjustment models.

The regulations in part 155 include several amendments regarding standardized options, including the 2018 cost-sharing structures for standardized options. Other requirements in part 155 are related to the eligibility and verification processes for insurance affordability programs. We amend rules related to enrollment of qualified individuals into QHPs and make various amendments related to the SHOPs. We amend the regulations requiring Exchanges, QHP issuers, and Web-brokers to provide taglines in non-English languages. We also amend existing requirements, as well as establish new ones, for agents and brokers that use the current direct enrollment process to strengthen the consumer protections when a Web-broker is facilitating enrollment through an FFE or SBE-FP. We finalize the required contribution percentage for 2018. We finalize a new policy

regarding appealing denials of QHP certification. We also amend the standards applicable in State Exchanges using the Federal platform for SHOP functions in parts 155 and 156. We also amend the regulations applicable to qualified employers in the SHOPs in part 157.

The regulations in part 156 include amendments related to cost-sharing parameters, 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 2018. We also finalize the user fee rate applicable in the FFEs and SBE-FPs. We also finalize changes regarding AV, levels of coverage, and ECP requirements, and provide for calibration of the single risk pool index rate. Additionally, we amend the regulation requiring issuers to adhere to the SHOP participation provision.

The amendments to the regulations in part 158 revise the provisions related to deferral of reporting of experience for newer business, as well as add provisions related to limiting the total rebate liability payable with respect to a given calendar year.

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

In the September 6, 2016 **Federal Register** (81 FR 61456), we published the Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2018 proposed rule (proposed 2018 Payment Notice). We received 662 comments, including 456 substantially similar letters regarding our cost-sharing proposal related to speech therapy services for the proposed 2018 standardized options. Comments were received from the National Association of Insurance Commissioners, State departments of insurance, State Exchanges, 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 the proposals, our responses to them, and a description of the provisions we are finalizing.

⁸ March 31, 2016, HHS-Operated Risk Adjustment Methodology Meeting: Discussion Paper. March 24, 2016. Available at <https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/RA-March-31-White-Paper-032416.pdf>.

Comment: We received comments stating that the comment period was unreasonably short, making it difficult for stakeholders to provide in-depth analysis and input. Commenters suggested that HHS 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: We published the proposed 2018 Payment Notice earlier this year in order to better assist issuers in planning for the upcoming benefit year. In previous years, we received issuer feedback requesting that the rule be released and finalized earlier in order to facilitate their actuarial work estimating rates and developing benefit packages. We continue to try to expand the comment period while also providing industry stakeholders with more time to implement the final rule.

Comment: We received a number of comments requesting that HHS propose further rules around essential health benefits (EHB) and network adequacy. Commenters encouraged HHS to strengthen Federal oversight of the EHB plans' compliance with nondiscrimination requirements. Some commenters emphasized the importance of ensuring coverage is affordable to consumers.

Response: We recognize the importance of patient protections and non-discrimination in benefit design. As stated in § 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, as stated in § 156.125(b), an issuer providing EHB must also comply with § 156.200(e), which prohibits discrimination on the basis of race, color, national origin, disability, age, sex, gender identity, and sexual orientation. As in previous years, HHS will continue to outline its review of health plans applying to be qualified health plans (QHPs) or stand-alone dental plan (SADPs) in the FFEs for compliance with nondiscrimination standards in the Letter to Issuers in the Federally-facilitated Marketplaces. Because nondiscrimination provisions applicable to plans required to offer EHB also are related to many requirements under the joint interpretive jurisdiction of HHS and the Departments of Labor and the Treasury, HHS will consult with relevant Federal agencies, such as the Departments of Labor and the Treasury, as necessary in developing new guidance related to

discriminatory benefit designs. As noted previously, we remind issuers that certain other Federal civil rights laws also impose nondiscrimination requirements. We will consider the comments we have received with respect to network adequacy as we monitor the work of States and the National Association of Insurance Commissioners (NAIC) in this area. Finally, we appreciate the comments regarding affordability of coverage, and agree that affordability is critical to the success of the Exchanges.

1. Part 144—Requirements Relating to Health Insurance Coverage

a. Definitions (§ 144.103)

In the proposed rule, consistent with our proposal regarding the transfer of products within a group of related issuers, we proposed to revise the definitions of “plan” and “product” in 45 CFR 144.103 by removing language that would restrict a plan or product from being considered the same plan or product when it is no longer offered by the same issuer, but is still offered by a different issuer in the same controlled group.

We also proposed that, in the case of a product that has been modified, transferred, or replaced, the product will be considered to be the “same product” when it meets the standards for uniform modification of coverage at §§ 146.152(f), 147.106(e), or 148.122(g), as applicable. For clarity, we also proposed to include in the definition of “product” examples of product network types including health maintenance organization (HMO), preferred provider organization (PPO), exclusive provider organization, point of service, and indemnity.

We are finalizing these provisions as proposed, with minor non-substantive modifications to the definition of “product” for clarity.

Comment: One commenter requested that HHS clarify whether claims reporting for risk adjustment or medical loss ratio (MLR) would change based on these different definitions.

Response: This change will not alter the claims reporting process for risk adjustment or MLR. We note that when business subject to MLR is transferred between related issuers within the same controlled group, the acquiring issuer must include the ceding issuer's prior year experience in calculating the 3-year average MLR. We also note that if an issuer of a QHP, a plan otherwise subject to risk corridors, a risk adjustment covered plan, or a reinsurance-eligible plan experiences a change of ownership, as recognized by

the State in which the plan is offered, the issuer must notify HHS in accordance with 45 CFR 147.106(g).

Comment: Some commenters requested that HHS expand the definitions, so that any transaction that results in a product with the same provider network and same benefit structure as the prior product would be considered to be the same product regardless of whether the acquiring issuer is part of the same controlled group as the ceding issuer.

Response: We are not expanding the proposed definitions at this time. As discussed in the preamble to § 147.106, below, in the case of a transaction that results in a product being offered by a different issuer, the resulting new product will be considered the same as the prior product only if the acquiring issuer is part of the same controlled group as the ceding issuer and any changes to the product are within the scope of a uniform modification of coverage.

Comment: We have been requested by stakeholders to clarify whether a visit limit is considered a “benefit” in the definition of product or a “cost-sharing structure” in the definition of plan under § 144.103.

Response: At § 155.20, we defined “cost sharing” based on the definition in section 1302(c) of the Affordable Care Act, which applies to title I of the Affordable Care Act, to mean any expenditure required by or on behalf of an enrollee with respect to essential health benefits; such term includes deductibles, coinsurance, copayments, or similar charges, but excludes premiums, balance billing amounts for non-network providers, and spending for non-covered services. For purposes of consistency, we interpret “cost-sharing structure” in the definition of “plan” under § 144.103 as being based on the same concept of “cost sharing.” This definition does not include limits on benefits based on the frequency of treatment, number of visits, days of coverage, or other similar limits on the amount, scope or duration of treatment. We interpret such types of limitations, which specify the scope of benefits covered rather than the portion of the payment made to the health care provider owed by the consumer, to be features of a product's “discrete package of health insurance coverage benefits.” Accordingly, each plan within a product must have the same visit or other frequency limits (if any) on the same covered benefits.

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

a. Guaranteed Renewability of Coverage for Employers in the Group Market (§ 146.152)

For a discussion of the provisions of this final rule related to part 146, please see the preamble to § 147.106.

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

a. Fair Health Insurance Premiums (§ 147.102)

In the proposed rule, we proposed to replace the age band for individuals age 0 through 20 with multiple child age bands to better reflect the actuarial risk of children and to provide a more gradual transition from child to adult age rating. We specifically proposed one age band for individuals age 0 through 14, and then single-year age bands for individuals age 15 through 20, effective for plan years or policy years beginning on or after January 1, 2018. We proposed age rating factors for the default Federal standard child curve to correspond to the proposed child age bands. We sought comments on this proposal and whether the age factors should be implemented at one time or phased in over a 3-year period.

We are finalizing this proposal with a modification to specify that the new child age bands will apply for plan years or policy years beginning on or after January 1, 2018; until that time the single age band for children will continue to apply.

Comment: Some commenters requested that HHS establish multiple age bands between ages 0 and 14.

Response: We proposed one age band for ages 0 through 14 because, in general, claims costs are highest for children age 0 through 4 and then lower for children age 4 through 14. Having one age band for individuals age 0 through 14 spreads the cost of newborns, avoiding significant premium increases for families with young children.

Comment: Some commenters recommended that there be a child rating factor added to recognize when a plan includes embedded pediatric dental coverage.

Response: Under the single risk pool provision at § 156.80, claims costs for providing EHB—including the pediatric dental EHB—are incorporated into the marketwide index rate and spread across all of an issuer's plans in the single risk pool, regardless of whether any particular plan includes the pediatric dental EHB. Because these costs are reflected in the plan-adjusted

index rate for each plan, it would not be appropriate to further vary premium rates at the consumer level based on whether a plan includes the pediatric dental EHB.

Comment: Although some commenters recommended phasing in the child age rating factors, the majority of commenters expressed a preference for a one-time implementation of the change to minimize market disruption.

Response: We are finalizing the proposed changes to the default Federal standard child age curve as proposed. In guidance being released with this final rule, we provide a complete, updated version of the default Federal standard age curve, and provide guidance for States on reporting State-specific rating requirements to HHS in accordance with §§ 147.103 and 156.80(c). We note that States may, but are not required to, modify existing State-specific age curves as a result of this final rule; State-specific age curves that utilize the same factor for ages 0 through 20 are not inconsistent with the multiple child age bands established by this final rule. We are also adding regulation text to reflect that the changes to the age curve and rating factors will occur all at once, and will be effective for the 2018 plan year.⁹

b. Guaranteed Availability of Coverage (§ 147.104)

(1) Limited Open Enrollment Periods

For a discussion of the provisions of this final rule related to limited open enrollment periods (also known as special enrollment periods) in § 147.104, please see the preamble to § 155.420 in sections II.B and III.B of this final rule.

(2) Network Sharing Arrangements Between Affiliated Issuers

Under section 2702 of the PHS Act, as added by the Affordable Care Act, a health insurance issuer that offers health insurance coverage in the group market generally must accept every employer in the State that applies for such coverage, but may limit its offer of coverage to employers in the small group and large group market that have eligible individuals who live, work, or reside in the service area of the issuer's network plan. In the proposed rule (81 FR at 61462 through 61463), we explained that Federal law does not require that the employer itself have a place of business within the issuer's

service area to be entitled to guaranteed availability for its employees.¹⁰

Some affiliated issuers have contractual arrangements that do not allow them to offer coverage to an employer whose business headquarters is outside their service area, but will allow the employer's employees who live, work, or reside in the service area of an affiliate issuer to access in-network coverage under the employer's plan through network sharing arrangements between the affiliated issuers. For example, affiliated issuers A and B have service areas A and B, respectively. Under the terms of the agreements, an employer with business headquarters in service area A could purchase coverage from issuer A to cover its employees in both service areas A and B using the provider networks of both issuer A and B, but that employer could not purchase coverage from issuer B. These issuers believe that issuer B satisfies the guaranteed availability requirements because the employer can purchase coverage from issuer A, and its employees in service area B can have access to the coverage under the plan issued by issuer A using issuer B's provider network. We sought comment on whether or how these arrangements could be structured, consistent with State licensure requirements, to satisfy guaranteed availability requirements.

Comment: Several commenters expressed support for the use of network sharing arrangements, though they did not explain how the restrictions on the sale of coverage were consistent with the requirements of section 2702 of the PHS Act. Other commenters were concerned about allowing issuers to deny coverage under these arrangements, suggesting it would create an uneven playing field for non-affiliated issuers, reduce employers' and employees' coverage options, and violate the guaranteed availability requirements.

Response: We agree with commenters who suggested that there is no exception to the guaranteed availability requirements for issuers who are members of a group of affiliated issuers. Under the statute, "each" issuer must guarantee availability of all of its products that are approved for sale in the market in the State, and the statute does not allow an issuer to satisfy its

⁹ CMS Insurance Standards Bulletin: Guidance Regarding Age Curves and State Reporting, Dec. 16, 2016. Available at [https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/index.html#Health Insurance Market Reforms](https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/index.html#Health%20Insurance%20Market%20Reforms).

¹⁰ Nothing in section 2702 of the PHS Act requires an issuer to offer coverage to an employer where the situs of the contract is outside the State in which the issuer is licensed to engage in the business of insurance, or requires an issuer to offer coverage to an employer if doing so would exceed the scope of that issuer's license from the applicable State authority.

obligations by ensuring that a plan is available from one or more separately licensed issuers. While issuers, therefore, may not deny an application for coverage of an employer with eligible employees who live, work, or reside within the issuer's service area absent an applicable exception, we note that nothing in section 2702 of the PHS Act prohibits an issuer from entering into a network sharing arrangement or from referring employers that apply for coverage to an affiliate issuer, and we agree with commenters that network sharing arrangements can be an attractive coverage arrangement for many employers.

We recognize that issuers with these types of arrangements may need time to modify their contractual agreements, and that this process may not be completed when issuers will be completing their plan designs in early 2017 for plan years beginning in 2018. Accordingly, HHS will not take enforcement action for plan years beginning before January 1, 2019, with respect to an issuer with a contractual arrangement in effect as of the publication date of this final rule that prevents it from offering coverage to an employer that is located outside the issuer's service area as required under section 2702 of the PHS Act, if the following conditions are met: (1) An affiliate issuer makes coverage available to the employer on a guaranteed availability basis, and (2) the employer's employees can access in-network coverage under the same plan through the affiliated issuers' provider networks. States, as primary enforcers of the guaranteed availability requirements, may exercise similar enforcement discretion, and will not be considered by HHS to be failing to substantially enforce the guaranteed availability provision for this reason.

c. Guaranteed Renewability of Coverage (§ 147.106)

(1) Market Withdrawal Exception to Guaranteed Renewability Requirements

Section 147.106(d)(2) provides that a health insurance issuer that elects to discontinue all health insurance coverage in the individual, small group, or large group market in a State is prohibited from re-entering the applicable market for at least 5 years. The following amendments will become effective with the effective date of this final rule.

i. Transfer of Products to a Related Issuer

To align with State approaches to corporate structuring or other

transactions within a controlled group of issuers, and to avoid unintended market bans where continuity of coverage is effectively provided, we proposed to add new § 147.106(d)(3) to provide that an issuer has not discontinued offering all health insurance coverage in a market if the issuer or a member of the issuer's controlled group continues to offer and make available for enrollment at least one product of the original issuer that is considered to be the same product (as amended in § 144.103 of this final rule), meaning that any change to the product is within the scope of a uniform modification of coverage under § 147.106(e). We also proposed to amend § 147.106(e)(3)(i) to provide that, for purposes of guaranteed renewability, a product will be considered to be the same product when offered by a different issuer within an issuer's controlled group, provided it otherwise meets the standards for uniform modification of coverage.¹¹ We are finalizing the amendments to § 147.106(d)(3), (d)(3)(i), and (e)(3)(i) and finalizing conforming amendments at §§ 146.152(d)(3), (d)(3)(i), and (f)(3)(i) and 148.122(e)(4), (e)(4)(i) and (g)(3)(i), with non-substantive clarifying modifications to the text of the regulation, including the addition of §§ 146.152(d)(4), 147.106(d)(4), and § 148.122(e)(5).

For purposes of guaranteed renewability, we proposed to use a definition based on the Code definition of controlled group that applies for purposes of determining whether a group of two or more persons is treated as a single covered entity under the health insurance providers fee under section 9010 of the Affordable Care Act and 26 CFR 57.2(c). Specifically, for purposes of guaranteed renewability, we proposed that "controlled group" means a group of two or more persons that is treated as a single employer under sections 52(a), 52(b), 414(m), or 414(o) of the Code. We proposed that definition for consistency with other Affordable Care Act provisions, including sections 9008 and 9010, which pertain to the branded prescription drug fee and health insurance provider's fee, respectively, and are familiar to health insurance

issuers. We also noted that the definition of issuer group under § 156.20 is familiar to issuers and sought comment on whether to use a similar definition or another definition for purposes of these regulations. We are finalizing the definition of "controlled group" as proposed, including by explicitly providing additional flexibility for States as described below for purposes of guaranteed renewability (as discussed in the proposed rule).

As we discussed in the proposed rule, issuers transferring products to another issuer in their controlled group that otherwise remain within the scope of a uniform modification are not required to send discontinuation notices under paragraph (c)(1) or (d)(1), as applicable. However, the issuer of the coverage (whether the current issuer or the acquiring issuer) must provide a renewal notice under §§ 146.152(h), 147.106(f) or 148.122(i), as applicable, at the time the renewal notice is otherwise required to be provided.

We also proposed that States that interpret or apply market withdrawal provisions differently under State law would not be prohibited from considering products transferred to a different issuer within a controlled group to be a new product and the scenario a market withdrawal. We are finalizing this proposal with a modification to specify that a controlled group may be defined more narrowly under State law—that is, a controlled group may be defined to not include all of the entities that would be included under the definition established in this final rule.

Because the products would be considered under these regulations the same products for purposes of continuity of coverage for the enrollees, we also proposed that the products be considered the same products for purposes of the Federal rate review requirements, to the extent applicable, and therefore we proposed conforming amendments as described in the preamble to § 154.102. For further discussion of the amendment to § 154.102, see that section of the preamble in this rule.

Comment: One commenter noted that each State has its own definition of related business entities, and therefore recommended that HHS defer to the States as to which entities are included instead of using "controlled group" as defined by the Code.

Response: States may continue to interpret and apply market withdrawal provisions differently under State law, provided the State law interpretation does not prevent the application of the market withdrawal provision under the

¹¹ As we explained in an FAQ related to Market Reforms, https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/qa_hmr.html, enrollees in a grandfathered product can maintain that coverage if that coverage continues to be offered and the coverage does not make a change that would cause the product to cease to be grandfathered as provided for in regulations. See 26 CFR 54.9815–1251(g)(1); 29 CFR 2590.715–1251(g)(1); and 45 CFR 147.140(g)(1).

Federal standard. In other words, States may use a definition of “controlled group” that is narrower than the Code definition, but may not use a broader definition, because a broader definition would at least in some instances prevent the application of the Federal provision. We codify this State flexibility in the text of the regulation. HHS will use the definition of “controlled group” finalized in this rule for States where HHS is responsible for enforcement of the guaranteed renewability provisions of the PHS Act.

Comment: One commenter recommended that HHS maintain the current requirements that enrollees be notified within a given timeframe that an issuer is undergoing a corporate change, which may result in changes to the enrollee’s benefits and other issuer policies.

Response: All notice requirements continue to apply. Issuers should refer to section XI of the Bulletin regarding Updated Federal Standard Renewal and Product Discontinuation Notices that HHS released on September 2, 2016.¹² We note that a renewal notice, rather than a discontinuation notice, is appropriate in the case of a product transfer within an issuer controlled group where any changes to the transferred product are within the scope of a uniform modification.

Comment: Several commenters encouraged HHS to provide additional technical guidance and clarification as part of the Uniform Rate Review (URR) Instructions on how product transfers to a different issuer within a controlled group would be handled for purposes of rate review.

Response: We intend to provide technical guidance as part of the 2018 URR Instructions.

ii. Replacement of Entire Product Portfolio

We proposed that it may not be appropriate to interpret an issuer’s actions to constitute a market withdrawal resulting in a 5-year ban on market re-entry when an issuer discontinues offering all of its products and seeks to offer new products within the same market, even if the changes made to the new products exceed the scope of a uniform modification of coverage.¹³ State regulators and other

interested parties indicated that this scenario is not viewed by some States as a market withdrawal under State law, as long as the issuer continues to provide a product in the same market in which it previously offered the discontinued products.¹⁴

To prevent issuers from avoiding Federal rate review requirements by altering all of their existing products, we proposed to permit an issuer to replace its entire portfolio of products without triggering the 5-year ban under the market withdrawal provision, provided the issuer: (1) Reasonably identifies which newly offered product (or products) replace which discontinued product (or products); and (2) subjects the new product (or products) to the Federal rate review process under part 154 (to the extent otherwise applicable to coverage of the same type and in the same market (for example, the Federal rate review process does not apply in the U.S. territories)) as if it were the same product as the discontinued product it replaces.¹⁵ An issuer’s identification of which new product replaces which discontinued product will be considered reasonable if it reflects the issuer’s expectations regarding significant transfer of enrollment from one product to the other (for example, because the products have been cross-walked for that purpose).

To reflect these exceptions to market withdrawal requirements, we proposed to add new paragraph (d)(3) to § 147.106 to provide that an issuer has not discontinued offering all health insurance coverage in a market if the issuer continues to offer and make available a product in the applicable market in a State and subjects the new product to the rate review requirements under part 154 of this title (to the extent otherwise applicable to coverage of the same type and in the same market) as if that part applied to that product, and reasonably identifies a discontinued product that corresponds to the new product for purposes of such rate review. We are finalizing the proposal as proposed by adding § 147.106(d)(3)

and-FAQs/Downloads/uniform-mod-and-plan-wd-FAQ-06-15-2015.pdf.

¹⁴ We also note that, in the context of reenrollment through an Exchange in coverage under a different product, we stated that, under certain limited circumstances, enrollments completed under the hierarchy specified in § 155.335(j) will be considered to be a renewal of the enrollee’s coverage.

¹⁵ Under this interpretation, issuers of health insurance products offered in the U.S. territories would be able to replace their products in those markets without subjecting the new products to the Federal rate review process and without triggering the 5-year ban.

with minor non-substantive modifications to the structure and text of the regulation, and also making conforming amendments to §§ 146.152(d)(3) and 148.122(e)(4).

Comment: Some commenters suggested that the Federal rate review process should be required when an issuer replaces only a few products (as opposed to when they replace all products). Most commenters supported subjecting new products to rate review when those products are replacing discontinued products, noting that rate review is an important consumer protection.

Response: When an issuer replaces all products in a market, we are requiring the issuer to subject the new products to the Federal rate review process as a condition for not triggering a market withdrawal and the 5-year ban on market re-entry. States may impose rate review requirements in more instances.

(2) Guaranteed Renewability in the Individual Market and Medicare Eligibility

Section 1882(d)(3) of the Act prohibits the sale or issuance of an individual health insurance policy to an individual entitled to benefits under Part A or enrolled under Part B of Medicare¹⁶ with knowledge that the policy duplicates health benefits to which the individual is otherwise entitled under Medicare or Medicaid (the anti-duplication provision). Sections 2703 and 2742 of the PHS Act generally require guaranteed renewability of coverage for employers and individuals in the group and individual health insurance markets. Under existing regulations at §§ 147.106(h)(2) and 148.122(b)(2) implementing the guaranteed renewability requirement, Medicare eligibility or entitlement is not a basis for nonrenewal or termination of an individual’s health insurance coverage in the individual market.

We sought comments on whether the guaranteed renewability statute and the anti-duplication provision should together be interpreted to require or prohibit renewal of a Medicare beneficiary’s individual market coverage, if the issuer has knowledge that the renewed coverage would duplicate the Medicare beneficiary’s benefits: (1) In a plan under the same contract of insurance; (2) under a plan that was modified but is considered under the guaranteed renewability provisions to be the same plan but that

¹² Updated Federal Standard Renewal and Product Discontinuation Notices. Sept 2, 2016. Available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-Updated-Federal-Standard-Renewal-and-Product-Discontinuation-Notices-090216.pdf>.

¹³ Uniform Modification and Plan/Product Withdrawal FAQ. Jun. 15, 2015. Available at <https://www.cms.gov/CCIIO/Resources/Fact-Sheets->

¹⁶ For information on when individuals are entitled to, eligible for, or able to enroll in Medicare, see <https://www.cms.gov/medicare/eligibility-and-enrollment/origmicarepartabeligenrol/index.html>.

would require a new contract; (3) under a different plan within the same product; (4) under a different product with the same issuer; or, as discussed earlier in this preamble; (5) under the same product offered by a different issuer within the issuer's controlled group.

We are finalizing an interpretation of the anti-duplication provision that prohibits issuers that have knowledge that an enrollee in individual market coverage is entitled to Medicare Part A or enrolled in Medicare Part B from renewing the individual market coverage if it would duplicate benefits to which the enrollee is entitled, unless the renewal is effectuated under the same policy or contract of insurance. This policy will become effective with the effective date of this final rule.

Comment: A number of commenters agreed that Medicare eligible individuals should not be allowed to enroll in or renew coverage under individual market policies; that requiring re-enrollment of Medicare beneficiaries into individual health insurance coverage violated the anti-duplication provisions of the statute and placed the health insurance issuers in an untenable situation of having to choose between complying with the guaranteed renewability provision or the anti-duplication provision. Several commenters expressed concerns that individuals enrolled in Medicare and those who are eligible for but not yet covered by Medicare present a significant burden to the single risk pool. Other commenters, however, indicated that Medicare beneficiaries should not be denied the option to remain in individual health insurance coverage, since there are situations in which individual health insurance coverage may be the better option for an individual than Medicare Parts A or B. Another commenter stated that if "renewal" and "sale or issuance" meant the same thing for purposes of interpreting the anti-duplication provision, the law which provides for "guaranteed issuance of coverage in the individual and group market" would either have no meaning or would be redundant to, and contradict the provisions that address renewability.

Response: We agree that the anti-duplication provision should be interpreted to prohibit the re-enrollment in individual health insurance coverage of an individual who is entitled to Medicare Part A or enrolled in Part B when the requisite knowledge standard about duplication is met, provided the re-enrollment is into a policy or contract of insurance other than the same policy or contract that the enrollee currently

holds. The phrase "to sell or issue" in section 1882(d)(3) of the Act is broad, and interpreting it to include re-enrollments other than renewals under the same contract of insurance is supported by the anti-duplication provision's purpose and statutory context. A renewal under the Act need not be the same as a renewal for purposes of an issuer's satisfying its guaranteed renewability obligations under the PHS Act. The latter meaning has been broadened since we last addressed this issue in rulemaking, and we now have additional years of experience with respect to that meaning. Adopting this interpretation does not equate the phrase "to sell or issue" with "renewal." As explained, we do not understand the phrase to apply to renewals under the same contract of insurance. We note further that the meaning of the phrase "to sell or issue" in the context of section 1882(d)(3) of the Act is distinct from the meaning of the particular terms of sections 2702 and 2703 of the PHS Act. The guaranteed availability provision of section 2702 of the PHS Act states that issuers must "accept" individuals who apply for coverage that is offered in a market in a State, and the guaranteed renewability provision (section 2703(a) of the PHS Act) states that issuers must generally "renew or continue in force" coverage at the option of the individual.

Under our interpretation, issuers of individual market coverage must not re-enroll enrollees who become entitled to Medicare Part A or enrolled in Medicare Part B in coverage, if the issuer has knowledge that the coverage would duplicate benefits to which the enrollee is entitled, unless the coverage can be renewed under the same policy or contract of insurance. Whether any changes in the terms of coverage would require the issuance of a new policy or insurance contract would be determined under applicable State law.

For the reasons stated above, we are amending §§ 147.106(h)(2) and 148.122(b)(2) to finalize an interpretation of the anti-duplication provision that prohibits issuers from re-enrolling in individual market coverage an enrollee who is entitled to Medicare Part A or enrolled in Medicare Part B if the issuer has knowledge that the coverage would duplicate benefits under title XVIII or title XIX of the Act to which the enrollee is entitled, unless the renewal is effectuated under the same policy or contract of insurance.

Comment: Some commenters recommended that we create a more robust screening process in the Federally-facilitated Exchanges (FFE) for individuals nearing their Medicare

eligibility. One commenter recommended that we should require SBEs also to screen for Medicare eligibility and enrollment.

Response: The FFEs have begun conducting periodic data matching, as described in § 155.330(d), to identify Exchange enrollees on whose behalf advance payments of the premium tax credit (APTC) is being paid who may be enrolled in Medicare that is considered minimum essential coverage. We are working toward a more robust process for screening for Medicare eligibility and enrollment for individuals who are applying for individual health insurance coverage in the FFEs and State-based Exchanges on the Federal platform (SBE-FPs), and encourage SBEs to do the same.

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

a. Guaranteed Renewability of Individual Health Insurance Coverage (§ 148.122)

For a discussion of the provisions related to part 148, please see the preamble to § 147.106.

5. Part 152—Pre-Existing Condition Insurance Plan Program

a. Pre-Existing Condition Insurance Plan Program (§ 152.45)

Section 1101 of the Affordable Care Act directed HHS to establish a temporary Federal high risk pool program in 2010 to provide health insurance coverage to individuals who were U.S. citizens or nationals or lawfully present in the United States, did not have other health insurance coverage in the 6 months preceding enactment, and had a pre-existing condition. Section 1101(g)(3)(B) directed HHS to develop procedures to provide for the transition of eligible individuals enrolled in health insurance coverage offered through the high risk pool HHS established into QHPs offered through an Exchange. Those procedures should, in particular, ensure that there is no lapse in coverage with respect to the individual and may extend coverage after the termination of the risk pool involved, if the Secretary determines necessary to avoid such a lapse.

Starting in 2010, shortly after the Affordable Care Act was enacted, HHS established and began operating the PCIP Program required under section 1101, to provide health insurance coverage to eligible individuals, as defined in the Affordable Care Act. Beginning in 2013, HHS worked to enroll these individuals in QHPs through the Exchanges. For a variety of reasons, however, individuals from the

high-risk pool established under section 1101 may find it difficult to obtain and maintain coverage in QHPs without a lapse in coverage.

In the proposed rule, we sought information regarding whether and how the remaining funds provided under section 1101 might be used to ensure the successful transition of former Pre-Existing Condition Insurance Plan (PCIP) enrollees to the Exchange without a lapse in coverage, consistent with section 1101(g)(3)(B) and its objective of ensuring that high-risk individuals with preexisting conditions are able to transition successfully into the new Exchanges without a lapse in coverage. We sought information, in particular, on the best ways to identify former PCIP enrollees in a QHP of an issuer that has participated in the Exchange from 2014 to 2017, available methods for determining their claims costs, and the necessity of taking steps to ensure that they do not experience a lapse in coverage. If it is not possible to identify former PCIP enrollees, HHS also sought information about other appropriate measures to assess the size and impact of former PCIP enrollment on existing issuers.

Comments: Commenters agreed with HHS's continued focus on ensuring coverage for high-risk individuals in the Exchanges. One commenter noted that although they support focusing on this patient population, they would not support efforts to revert to PCIP coverage. Several commenters provided suggestions on ensuring a patient's transition is a smooth, transparent process and that enrollees do not experience lapses in coverage, especially with respect to medications and benefits formerly provided by PCIP. One commenter recommended using the remaining funds to help ensure continuity of care by subsidizing deductibles or out-of-pocket costs under QHPs or supporting case managers working with former PCIP enrollees. Another suggestion was to use remaining PCIP funds to offset issuer costs for high-cost enrollees. We received suggestions on how to best identify former PCIP enrollees, such as working with AIDS Drug Assistance Programs and prior PCIP administrators (both at the State and Federal level). Commenters noted that current QHP issuers are unlikely to be able to identify individuals as prior PCIP enrollees.

Response: We thank commenters for their input. We continue to examine this issue, and will not take action on it in this final rule.

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

a. Sequestration

In accordance with the Office of Management and Budget (OMB) Report to Congress on the Joint Committee Reductions for Fiscal Year 2017,¹⁷ both the transitional reinsurance program and permanent risk adjustment program are subject to the fiscal year 2017 sequestration. The Federal government's 2017 fiscal year began on October 1, 2016. The reinsurance program is sequestered at a rate of 6.9 percent for payments made from fiscal year 2017 resources (that is, funds collected during the 2017 fiscal year). To meet the 6.9 percent sequestration requirement for the risk adjustment program for fiscal year 2017 noted in the OMB Report to Congress, risk adjustment payments made using fiscal year 2017 resources in all States where HHS operates risk adjustment, will be sequestered at a rate of 7.1 percent.

HHS, in coordination with OMB, has determined that, under section 256(k)(6) of the Balanced Budget and Emergency Deficit Control Act of 1985, as amended, and the underlying authority for these programs, the funds that are sequestered in fiscal year 2017 from the reinsurance and risk adjustment programs will become available for payment to issuers in fiscal year 2018 without further Congressional action. If Congress does not enact deficit reduction provisions that replace the Joint Committee reductions, these programs would be sequestered in future fiscal years, and any sequestered funding would become available in the fiscal year following that in which it was sequestered.

Comment: One commenter noted that any reduction in funds that support risk adjustment or reinsurance functions will reduce the ability for these programs to fulfill their purpose.

Response: The sequestering of reinsurance and risk adjustment payments will not affect the overall funding of the reinsurance or risk adjustment programs. Funds that are sequestered in fiscal year 2017 from the reinsurance and risk adjustment programs will become available for payment to issuers in fiscal year 2018.

¹⁷ OMB Report to the Congress on the Joint Committee Reductions for Fiscal Year 2017. Feb. 9, 2016. Available at https://www.whitehouse.gov/sites/default/files/omb/assets/legislative_reports/sequestration/jc_sequestration_report_2017_house.pdf.

b. Definition of Large Employer for the Risk Adjustment and Risk Corridors Programs (§ 153.20)

We proposed deleting the definition of “large employer” set forth in § 153.20, which defines a large employer as having the meaning given to the term at § 155.20.¹⁸ In addition to the proposed rule, HHS provided notice of our intent to make this change in an FAQ¹⁹ that clarified how an issuer should count an employer's employees to determine whether an employer is a small employer or large employer for purposes of the risk adjustment and risk corridors programs.

In that FAQ, we clarified that for the risk adjustment program, the issuer should use the employee counting method used to determine group size under State law, unless that counting method does not account for employees who are not full-time. If the State counting method does not take non-full-time employees into account, then the issuer should use the counting method under section 4980H(c)(2) of the Code.²⁰ The FAQ also noted that under section 1304(b)(4)(D) of the Affordable Care Act and § 155.710(d), when a small employer participating in a Small Business Health Options Program (SHOP) ceases to be a small employer solely by reason of an increase in the number of its employees, it will continue to be treated as a small employer for purposes of SHOP participation for as long as it continues to purchase coverage through the SHOP, and the issuer should treat such an employer as a small employer for purposes of risk adjustment. We note that nothing in this final rule supersedes or conflicts with the option under section 1312(f)(2)(B)(i) of the Affordable Care Act, which will allow large employers to participate in a SHOP, at the option of a State.

In the FAQ, HHS also clarified that for the risk corridors program, the issuer

¹⁸ Section 155.20 defines a large employer, in connection with a group health plan with respect to a calendar year and a plan year, as an employer that employed an average of at least 51 employees on business days during the preceding calendar year and that 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.

¹⁹ FAQs #15450 and #15449. April 12, 2016. Available at https://www.regtp.info/faq_viewu.php?id=15450 and https://www.regtp.info/faq_viewu.php?id=15449.

²⁰ See 79 FR 8544.

should use the employee counting method used to determine group size under State law (see § 153.510(f)). However, under section 1304(b)(4)(D) of the Affordable Care Act and § 155.710(d), when a small employer participating in a SHOP ceases to be a small employer solely by reason of an increase in the number of its employees, it will continue to be treated as a small employer for purposes of SHOP participation for as long as it continues to purchase coverage through the SHOP, and the issuer should treat such an employer as a small employer for purposes of risk corridors. We are finalizing the deletion of the definition of “large employer” set forth in § 153.20 as proposed.

Comment: Some commenters supported this proposal, noting that it would allow employers participating in the SHOP to have their experience included in risk adjustment and risk corridors if the company was considered a “small employer” but grew beyond the definition of small employer while maintaining SHOP coverage. Another commenter supported the proposal stating that HHS should treat an employer as small or large for risk adjustment purposes based on the rules for determining the employer’s status for pricing purposes.

Response: We agree with the commenters and are finalizing the deletion of the definition of “large employer” set forth in § 153.20 as proposed.

Comment: One commenter requested that HHS propose through notice and comment rulemaking the adoption of a consistent counting methodology to align the methods used to count employees for purposes of determining group sizes across all applicable Affordable Care Act provisions, and requested that State and Federal regulators use the same counting methodology.

Response: We appreciate the suggestion for consistency and uniformity; however, the comment is outside the scope of this rulemaking. HHS believes that the deletion of the definition of “large employer” set forth in § 153.20 helps to achieve greater consistency across Federal programs.

c. Provisions and Parameters for the 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 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 March 31, 2016, HHS convened a public conference to discuss potential updates to the HHS risk adjustment methodology for the 2018 benefit year and beyond. Prior to the conference, we also issued a White Paper that was available for public comment.²¹ The conference and White Paper focused 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 modeling, addressing issues resulting from partial year enrollment, future recalibrations using risk adjustment data, and options for the risk adjustment transfer formula. We received numerous thoughtful and substantive comments to the White Paper and at the conference, which directly informed the policies in this Payment Notice. In addition, we received numerous thoughtful and substantive comments to the risk adjustment provisions of the proposed rule, which we discuss in detail below.

(1) Risk Adjustment Applied to Plans in the Individual and Small Group Markets (§ 153.20)

Section 1312(c) of the Affordable Care Act directs issuers to use a single risk pool for a market—the individual or small group market—when developing rates and premiums. Section 1312(c)(3) of the Affordable Care Act gives States the option to merge the individual and small group market into a single risk pool. To align risk pools for the risk adjustment program and rate development, we stated in the 2014 Payment Notice that we would merge markets when operating risk adjustment on behalf of a State if the State elects to do the same for single risk pool purposes.²² When the individual and small group markets are merged, we stated that the State average premium would be the average premium of all applicable individual and small group market plans in the applicable risk pool, and calculations under the risk adjustment transfer equation would

occur across all plans in the applicable risk pool in the individual and small group markets.

Under the section 1312(c)(3) definition of a merged market and its implementing regulations at §§ 156.80 and 147.104, issuers in a merged individual and small group market must offer the same plans at the same rates to all applicants in the merged market, must offer coverage on a calendar year basis, and may not make quarterly rate adjustments to rates for small group market plans. Some States with markets that are not merged under the Federal merged market provisions require issuers to use a combined individual and small group experience to establish a market-adjusted index rate, but separate the markets for applying plan adjustment factors and for other purposes. This allows small group issuers to make quarterly rate changes that would not otherwise be allowable under the definition at section 1312(c)(3).

Because States that use a combined individual and small group experience to establish a market-adjusted index rate operate in large part as a merged market for purposes of rate setting, we believe they should be risk adjusted as merged markets if the State so elects. Risk adjustment directly impacts rate setting, and as such, should reflect the markets in which States allow issuers to set premiums. Therefore, we proposed to expand our interpretation of merged market for purposes of HHS risk adjustment as described in the 2014 Payment Notice to include States that meet the definition of merged market at section 1312(c)(3), as well as, at State election, States that use a combined individual and small group experience to establish a market-adjusted index rate, beginning with risk adjustment for the 2017 benefit year. We are finalizing this provision as proposed.

Comment: One commenter supported this proposal but requested that HHS make this policy effective beginning with the 2018 benefit year. Another commenter supported the proposal but only if the applicable State agreed. This commenter also requested that HHS consider a different solution that would allow merged market States to have quarterly increases in their small group market.

Response: In light of State input and interest in this proposal, HHS, beginning with the 2017 benefit year risk adjustment, will expand the interpretation of merged market for purposes of HHS risk adjustment as described in the 2014 Payment Notice to include States that meet the definition of merged market at section 1312(c)(3),

²¹ March 31, 2016, HHS-Operated Risk Adjustment Methodology Meeting: Discussion Paper. March 24, 2016. Available at <https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/RA-March-31-White-Paper-032416.pdf>.

²² See 78 FR at 15419.

as well as, at State election, States that use a combined individual and small group experience to establish a market-adjusted index rate. As stated in the proposed rule, HHS intends to work closely with States that use a combined individual and small group experience to establish a market-adjusted index rate to determine whether they elect to be treated as a merged market for purposes of HHS risk adjustment.

(2) 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 enrollee'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 for adults, children, or infants is multiplied by a cost-sharing reductions adjustment.

The enrollment-weighted average risk score of all enrollees in a particular risk adjustment covered plan, also referred to as 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 accords with the Actuarial Standards Board's Actuarial Standards of Practice for risk classification.

(3) Proposed Updates to the Risk Adjustment Model (§ 153.320)

For the 2018 benefit year risk adjustment model, HHS will continue to incorporate the methodological improvements finalized in the 2017 Payment Notice, such as incorporating preventive services in our simulation of plan liability and using more granular trend rates that better reflect the growth in specialty drug expenditures and drugs generally, as compared to medical and surgical expenditures. Consistent with our discussion in the White Paper, we are finalizing a number of updates to the risk adjustment model, including: (1) Adjustment factors for partial year enrollment; (2) prescription drug utilization factors; and (3) modifying

transfers to account for high-cost enrollees. We will also recalibrate our risk adjustment models using 2015 MarketScan® data blended with 2013 and 2014 MarketScan® data following the publication of the final Payment Notice for the 2018 benefit year. Additionally, we note that the HHS risk adjustment methodology will remain in effect for future benefit years until updated through rulemaking, or, in the case of updates of coefficients for the risk adjustment model, through guidance.

Comment: We received several comments in support of HHS engaging the public and seeking feedback through the White Paper and conference based on the experience from the first year of the risk adjustment program operation, and requesting HHS to continue to seek feedback on updating the risk adjustment model. We received a request for HHS to perform a comprehensive study of risk adjustment across Exchanges, Medicare Advantage, Medicaid, Accountable Care Organizations, and Medicare Shared Savings Program participants to better understand the limitations and success of each program and then apply lessons learned to improve risk adjustment for each program.

Response: We appreciate public feedback on HHS's analysis of the risk adjustment program and ways to improve and update the program. The HHS-operated risk adjustment methodology serves different program goals and operates under different conditions, compared to the risk adjustment programs used by other CMS programs. As we noted in our White Paper and conference in March 2016, we remain committed to evaluating the program and engaging stakeholders in the program's policy development. We will continue to evaluate how our experience with other CMS risk adjustment programs may inform the HHS-operated risk adjustment program.

Comment: One commenter noted that HHS should consider including in the risk adjustment risk score calculation data from lower-intensity care settings, such as skilled nursing facilities, home health, and End Stage Renal Disease (ESRD) facilities. The commenter also noted that HHS should also reconsider its International Classification of Diseases (ICD)-10 mapping, specifically for HCC 88 Major Depressive and Bipolar Disorder.

Response: We do not use data from lower intensity care settings due to the potential for significant coding variation. We sought comment on the ICD-10 crosswalk prior to implementation, and will continue to

review all ICD-10 updates and mappings annually, as code updates are released.

Comment: One commenter noted that HHS should create a prospective risk adjustment model for the individual and small group markets instead of the current concurrent model. At the same time, this commenter recommended that HHS not allow issuers to report prior enrollee data for risk adjustment, to establish a level playing field for new entrants. The commenter suggested use of a "credibility-based" adjustment to risk adjustment to compensate for the information imbalance between new and existing issuers.

Response: We believe that a concurrent risk adjustment model continues to be more appropriate for the individual and small group markets. Concurrent models tend to emphasize the prediction of costs associated with current year acute health events. A considerable amount of the costs of chronic conditions are associated with acute exacerbations, which a concurrent model will better capture. Concurrent models can also capture the very high costs of conditions such as organ transplants, metastatic cancer, and low-birthweight babies that reduce or eliminate the disincentive for plans to contract with providers that treat these conditions. Prospective models tend to emphasize the impact of ongoing chronic conditions on costs (as opposed to random current year costs that can be pooled as "insurance risk"). No previous year information on health status existed for the first year of the Affordable Care Act-established individual and small group markets in 2014. Additionally, unlike with Medicare, enrollees move in and out of enrollment in the individual and small group markets and move across issuers. A prospective model was, therefore, infeasible for the first year of the Affordable Care Act risk adjustment program, and we believe could be inaccurate today. Shifting to a prospective model would also require us to increase the lag between modeling and announcement of the risk adjustment model, on the one hand, and rate-setting, on the other. Additionally, in response to the comment regarding not allowing issuers to report prior year enrollee data, we clarify that HHS does not track enrollees across benefit years, and that issuers are only required to report claims data for enrollees for the applicable benefit year.

i. Partial Year Enrollment

After the 2014 benefit year of risk adjustment, we received feedback indicating that some issuers

experienced higher than expected claims costs for partial year enrollees. We sought comment in the 2017 Payment Notice on how the risk adjustment methodology could be adjusted to more directly reflect the experience of partial year enrollees, and we received comments generally supporting an adjustment addressing partial year enrollees in the risk adjustment model. We also received feedback to the White Paper that some believe the methodology does not fully capture the risk associated with enrollees with chronic conditions who may not have accumulated diagnoses in their partial year of enrollment.

In general, we believe that individual and small group health plans are risk adjusted accurately under the HHS risk adjustment methodology. In light of our experience with the 2014 benefit year, we have observed that risk adjustment may not fully account for when a plan's enrollees differ substantially from the market average with respect to characteristics that are not adjusted for in the risk adjustment model. For example, if a plan has an enrollee population with enrollment duration that differs from the market average, and the risk associated with the enrollment duration is not fully captured through other aspects of the methodology, then for that plan, partial year enrollment may not be fully accounted for in the HHS risk adjustment methodology. As we noted in the White Paper, if the risk adjustment methodology does not fully capture risk for partial year enrollment, and if the plan had lower than average enrollment duration, the plan's risk score relative to other plans might be lower than it might have been otherwise.²³

As we discussed in the White Paper, we reviewed the predicted expenditures, actual expenditures, and predictive ratios (that is, the ratios of predicted to actual weighted mean plan liability expenditures) by enrollment duration groups (for each: 1 month, 2 months, and so on up to 12 months) annualized for 2014 MarketScan® adults in our risk adjustment concurrent modeling sample. We found that actuarial risk for all adult enrollees with short enrollment periods tends to be slightly under-predicted, and for adult enrollees with full enrollment periods (12 months) tends to be over-predicted in our methodology. One potential explanation for these results is that

because risk adjustment is calculated on a per member per month basis, the model predicts costs for chronic conditions, which are often spread more evenly over time, better than costs for sudden acute events, which are often concentrated in a small number of months, when the enrollment is only for part of the year.

We discussed various approaches to address this issue in the White Paper, including the use of additional factors and the use of wholly separate models that account for duration of enrollment and metal level.

There was a broadly held preference among commenters to the White Paper for adding enrollment duration binary indicator variables (indicating enrollment duration of: 1 month, 2 months, and so on up to 11 months²⁴) as additional risk factors, as opposed to separate models based on enrollment duration. After reviewing this feedback, we announced on June 8, 2016, that we intended to propose that, beginning for the 2017 benefit year, the risk adjustment model include adjustment factors for partial year enrollees in risk adjustment covered plans.²⁵

Based on analysis we performed on the MarketScan® data, the use of additional risk factors by number of enrollment months that decrease monotonically as the number of months of enrollment increases (with 12 months being the reference group) appears to best address partial year enrollment in the risk adjustment model in the short term, starting in 2017. We also believe that our proposal to add prescription drug utilization in the risk adjustment model will capture additional costs for partial year enrollees beginning in the 2018 benefit year (see discussion below).

We are recalibrating the 2017 risk adjustment adult model to reflect the incorporation of partial year enrollment duration factors. Those factors are labeled "one month of enrollment . . . eleven months of enrollment" in the list of factors for the final 2017 risk adjustment adult model at the bottom of Table 2.²⁶ We are finalizing the incorporation of partial year enrollment duration factors in the risk adjustment model methodology for the reasons discussed above, starting with the 2017

benefit year. We are finalizing our proposal to amend our regulations at § 153.320(a)(1) to allow for HHS to make this update for the 2017 benefit year risk adjustment. Currently, this provision states that a risk adjustment methodology must be Federally certified, and one way a risk adjustment methodology may become Federally certified is to be developed by HHS and published in the applicable annual payment notice. We are amending this provision to state that the methodology will be developed by HHS and published in rulemaking in advance of the benefit year. While HHS would generally make changes to the risk adjustment methodology in the applicable annual payment notice, under this rule, in cases where we have identified a change that we can implement in other rulemaking prior to the benefit year, and where we can provide issuers with sufficient notice and detail on the proposed change so that issuers may reasonably account for the change, HHS will have the authority to implement the change prior to the beginning of the applicable benefit year. We notified issuers of our intent to propose the change regarding partial year enrollment in prior guidance, and provided significant detail on the incorporation of an adjustment factor to account for partial year enrollment beginning with the 2017 benefit year.²⁷ We are finalizing this incorporation to the 2017 adult risk adjustment models as proposed.

Comment: Commenters generally supported the partial year adjustment and recommended implementing the policy for the 2017 benefit year risk adjustment, noting that this adjustment will alleviate some uncertainty around health risk of partial year enrollees. A few commenters recommended that changes to the methodology be limited to the applicable annual payment notice, and did not support the adjustment to the 2017 benefit year methodology, noting that they would have liked the coefficients for the 2017 benefit year risk adjustment model prior to rate setting. Other commenters supported addressing partial year enrollment in the 2017 benefit year risk adjustment methodology because issuers had adequate time to incorporate this change with substantial issuer engagement and warning during rate setting. Commenters stated that without the level of issuer warning and

²⁴ Twelve months is the reference group and therefore is not included.

²⁵ March 31, 2016, HHS-Operated Risk Adjustment Methodology Meeting Questions & Answers. June 8, 2016. Available at <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/RA-OnsiteQA-060816.pdf>.

²⁶ This table replaces Table 1 published at 81 FR 12220 through 12223 as the final adult model for the 2017 benefit year.

²³ March 31, 2016, HHS-Operated Risk Adjustment Methodology Meeting: Discussion Paper, at page 36. March 24, 2016. Available at <https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/RA-March-31-White-Paper-032416.pdf>.

²⁷ March 31, 2016, HHS-Operated Risk Adjustment Methodology Meeting Questions & Answers. June 8, 2016. Available at <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/RA-OnsiteQA-060816.pdf>.

engagement that HHS provided for the 2017 benefit year methodology adjustment, making any changes to the methodology after rate setting and close to the beginning of the benefit year could create uncertainty, and the commenters would not support other changes in those types of instances. Some commenters were concerned about this precedent and recommended that this adjustment to the risk adjustment methodology after the applicable annual payment notice be an exception to the policy to publish changes in the applicable annual payment notice, and not a regular occurrence. Other commenters requested that HHS continue to make any changes to the risk adjustment methodology through a regulatory or subregulatory process with at least a 30-day comment period, and HHS publish clear guidelines as to future changes that could be made after the benefit year's Payment Notice. One commenter suggested that HHS implement the partial year enrollee adjustment changes beginning for the 2016 benefit year, stating that issuers would have sufficient time for this change to be implemented; another supported implementing partial year adjustment factors retroactively, for as early as the 2014 benefit year risk adjustment model.

Response: We are finalizing our proposal to adjust for partial year enrollment beginning with the 2017 benefit year. We recognize that issuers incorporate the applicable benefit year's risk adjustment methodology in their rate setting. Following the Risk Adjustment Conference, we announced our intent to propose to update the risk adjustment methodology for the 2017 benefit year with the partial year adjustment factors in our June 8, 2016, press release. We intend to continue updating the risk adjustment methodology for future years through notice and comment rulemaking, with adequate notice to the issuers prior to rate setting. We did not propose to, and are not changing, the risk adjustment methodology for the 2014, 2015, and 2016 benefit years. As these benefit years have already begun, we could not implement such a change prior to the applicable benefit year or provide advance notice to permit issuers to incorporate the applicable benefit year's risk adjustment methodology in their rate setting. However, for the 2017 benefit year, we provided advance notice to issuers prior to rate setting, and believe an adjustment for partial year enrollees will better compensate

issuers with higher than average partial year enrollees.

Comment: Most commenters supported our proposal to amend our regulations at § 153.320(a)(1) to allow for instances such as for the partial year adjustment for the 2017 benefit year, when HHS can provide sufficient notice. A few commenters suggested that HHS state in the regulation that it may make such changes outside the applicable payment notice with sufficient notice and prior to rate setting. Most commenters supported any adjustments as long as they are in advance of rate setting. A few commenters did not support the amendment to the regulation, and requested that HHS make all changes to the methodology in the applicable payment notice.

Response: Our amendment to our regulation at § 153.320(a)(1) would continue to require that HHS make any changes to the risk adjustment methodology in advance of the benefit year in rulemaking. We are finalizing our proposal to amend our regulation at § 153.320(a)(1) to allow for changes to the methodology in advance of the benefit year where we can provide adequate notice to issuers prior to rate setting.

We also proposed to incorporate partial year enrollment duration factors in the 2018 risk adjustment adult model in the same manner that we proposed for the 2017 benefit year. Those factors are labeled "one month of enrollment . . . eleven months of enrollment" in the list of factors for the 2018 risk adjustment adult model near the bottom of Table 3. We are finalizing partial year enrollment duration factors for the 2018 adult risk adjustment models.

We did not propose to include the partial year enrollment adjustment factor in the child and infant models as those models are based on a smaller dataset that does not provide adequate representation of partial year enrollment in these populations. We will reassess both the partial year enrollment adjustment, and whether we can make this adjustment in the child and infant models in the future. We will also continue to explore approaches under which we would use separate models for enrollees with different enrollment durations, rather than including partial year enrollment factors in the risk adjustment model, and may implement such an approach in future years. While we do not believe, based on the current data available and the analyses we have been able to perform, that using separate models for each enrollment duration is currently feasible, we believe that using separate models may better capture how

the pattern of costs associated with particular diagnoses varies across enrollees with different enrollment duration, particularly for sudden acute events.

Comment: Commenters supported incorporating partial year adjustment duration factors for the 2018 benefit year. One commenter supported the adjustment but noted that MarketScan® data is inadequate for this adjustment and suggested that HHS use enrollee-level External data gathering environment (EDGE) data for further analyses on partial year adjustment. Another commenter noted that the proposed partial year adjustment factors would still undercompensate for special enrollment period enrollees but are adequate for partial year enrollees who began enrollment during the open enrollment period.

Other commenters recommended that HHS use partial year duration factors combined with HCCs. One commenter expressed concern that the proposed adjustment treats partial year enrollees with acute and chronic conditions equally, and that this would excessively favor issuers with partial year enrollees.

One commenter disagreed with this adjustment for the 2018 benefit year as well, and suggested changing special enrollment period regulations instead; a few other commenters suggested HHS to do so in conjunction with this adjustment. Another commenter was concerned that the duration factors may reward plans that prompt consumers to switch plans and may create solvency issues for issuers with longer-term steady enrollments. Additionally, a commenter noted that HHS should analyze EDGE data to assess the variance in partial year enrollment for issuers, and if this variance is consistent across issuers, on average, risk adjustment would not need to be adjusted for partial year enrollment. Another commenter noted that HHS should track enrollees across issuers so that full risk adjustment factors can be applied for individuals that switch plans mid-year.

The commenters also recommended adding the partial year adjustment to child and infant models.

Response: We are finalizing the incorporation of partial year adjustment factors to the 2018 risk adjustment adult models as proposed. We will continue to evaluate this approach. In particular, we anticipate using EDGE data to evaluate whether model accuracy could be improved by estimating separate duration factors for special enrollment period enrollees versus partial year enrollees who began enrollment during the open enrollment period, an issue

that cannot be addressed using MarketScan® data. We clarify that risk scores are calculated including enrollees' enrollments across all of an issuer's risk adjustment covered plans, and so we do not believe the adjustment would encourage issuers to shift consumers to other plans. Because we are unable to track enrollees across issuers, the partial year adjustment factor would adjust for disproportional partial year enrollment by issuer. At this time, we are not adding the partial year adjustment factors for the child and infant models due to limitations on using the MarketScan® data, as a few commenters pointed out. However, we intend to further study the issue.

Comment: Commenters noted HHS should further analyze the partial year enrollees' risk differences. Most commenters supported using a hybrid model in the future that identifies HCCs most likely affected by partial year adjustment, separately for individual and small group market plans, and make partial year adjustments accordingly. One commenter supported separate models by duration cohorts (1–4 months, 5–8 months, 9–12 months), which would provide a sufficient level of accuracy when coupled with the administrative complexity of incorporating this into the model. A few commenters noted that HHS should not change the model type until a detailed analysis of results from the partial year adjustment incorporation is conducted, and that issuers should be provided adequate time to understand the effect of this and other adjustments proposed prior to making additional changes.

Response: We will continue to assess different techniques for estimating the risk of partial year enrollees in the future. We are moving forward with the adjustment as proposed, and may propose different approaches once better data becomes available.

ii. Prescription Drug Hybrid Model

As discussed in the White Paper, HHS has been considering whether to incorporate prescription drug utilization indicators into the HHS risk adjustment model, beginning for the 2018 benefit year, to create a “hybrid” drug-diagnosis risk adjustment model. We are aware that there are advantages and disadvantages to including prescription drug utilization indicators in the HHS risk adjustment model, and sought comments on our proposal.

Many comments to the White Paper stated that drug information can effectively indicate health risk in cases where diagnoses may be missing. For example, diagnoses may be missing if clinicians fail to enter the condition on

a patient's chart, or if there is stigma associated with certain health conditions that leads providers not to record these diagnoses on claims, or if the enrollee simply does not visit a physician during the term of his or her enrollment. However, even in these cases, prescriptions may be filled, providing information on health status.

Drug utilization patterns can also provide information on the severity of the illness. The hierarchical condition categories (HCCs) already capture information about illness severity from diagnoses, but drugs can potentially measure the severity of illness within a given HCC. A patient may receive first, second, or third lines of treatment involving different medications that indicate increasing levels of severity.

Additionally, commenters have noted that drug data can be available sooner and more easily than diagnoses from medical claims. In addition, commenters have noted that because prescription drug data is standardized, it is particularly useful for calibrating and measuring health risk because the prescription drug data will have less variability in coding.

Incorporating prescription drug utilization into the risk adjustment model will help reflect costs incurred by plans for medications for their enrollees in plans' risk scores.

Adding drug data to a diagnosis-based model also introduces operational complexities. Clinical indications for drugs can change quickly, which requires frequent updates to the model calibration and possibly to the therapeutic classification groupings as well. Because the model is calibrated before the start of the benefit year, it may be difficult to assess all updates or upcoming utilization pattern changes. Additional data requirements increase the administrative burden associated with calibrating and applying the model. Issuers of risk adjustment covered plans would be required to report prescription drug utilization as well as diagnoses, and audit and verification of the reported data would be necessary.

We have also indicated our concern that incorporating prescription drug utilization in the model may provide an incentive to overprescribe medications. Drug models may be particularly susceptible to this sort of behavior when there are inexpensive drugs included in therapeutic classes that are statistically linked to high total medical expenditures; in these situations, a small cost to the insurance plan (reimbursement for the drug) can bring a relatively large increase in revenue through the risk adjustment program.

In analyzing our proposal to use drug data in the risk adjustment model, we sought to strike a reasonable balance between increasing predictive accuracy and reducing incentives for over-prescription. One way we sought to do so was by focusing on drugs for which guidelines on when they should be prescribed are clear. However, substantial uncertainty or disagreement across providers exists over the circumstances in which drugs should be prescribed.

In addition, incorporating drug utilization makes risk adjustment sensitive to variations in drug utilization patterns that exist for reasons other than enrollee health status. Health plans with lower prescribing rates, such as health plans primarily covering individuals in rural areas with low access to pharmacies, would incorrectly appear to have healthier populations, and would pay higher risk charges or receive lower risk payments. Other things being equal, drug utilization is expected to be lower in plans with higher cost sharing (such as bronze or silver plans) and with aggressive drug utilization management, such as prior authorization, step therapy, quantity limits, restrictive formularies, and more stringent requirements to qualify for coverage of expensive drugs.

Furthermore, the lack of clear, one-to-one associations between most drug classes and diagnoses makes development of a “hybrid” drug-diagnosis risk adjustment model that incorporates and integrates drug and diagnosis risk markers challenging.

Few drug classes are indicated for only one medical condition. Many drug classes are prescribed “off label” for indications that are not U.S. Food and Drug Administration (FDA)-approved. Utilization of such drug classes can have very different implications for health care expenditures depending on the reasons for which they are prescribed. Presence of a drug class may not discriminate between high and low cost enrollees if it is used for both high and low cost conditions. Some drug classes may be used both for diagnoses that have been included in the HHS–HCC model, as well as for diagnoses that have been intentionally excluded, making it problematic to maintain this distinction in a hybrid drug-diagnosis risk adjustment model. Specific drugs within a drug class may have varying indications; the utilization of such drug classes may not unambiguously indicate the presence of a specific diagnosis.

Acknowledging all of the above considerations, we indicated in the June 8, 2016, guidance noted above that we intended to propose to incorporate a

small number of prescription drug classes as predictors in the HHS risk adjustment methodology for the 2018 benefit year to impute missing diagnoses and to indicate severity of illness.²⁸ We proposed to incorporate a small number of prescription drugs in the risk adjustment model for the 2018 benefit year. We proposed this change to the model with substantial attention to the concerns presented above in determining which drug groups to include and exclude, and the proposed model type used for each drug-diagnosis pair. To ensure this change to the model does not inadvertently increase the perverse incentives described above, we will monitor and evaluate the impact of incorporating prescription drugs in the model on utilization patterns. Using the data that we are proposing to collect in § 153.610, in addition to other relevant data sources, we would seek to evaluate whether incorporation of drugs in the model affects the utilization of drugs included in the model. Based on our evaluation, we would add or remove drug diagnosis pairs to or from the model for future benefit years through rulemaking.

To develop hybrid drug-diagnosis risk adjustment models, we need a reasonable number of clinically and empirically cohesive drug classes. We created several Prescription Drug Categories (RXC) to select and group the drugs to be included in a hybrid diagnoses-and-drugs risk adjustment model.

Each prescription drug is assigned a National Drug Code (NDC) maintained by the FDA. There are over 190,000 NDCs, which include prescription drugs as well as over-the-counter medications. NDC codes are reported in prescription drug claims data. Due to the large number of individual NDCs, it is necessary to use a therapeutic classification system that classifies individual NDCs into aggregated categories of related drugs used for similar therapeutic purposes, or having similar pharmacological properties.

In the White Paper, we had initially based the RXCs on the American Hospital Formulary Service Pharmacologic-Therapeutic Classification®, which is published by the Board of the American Society of Health-System Pharmacists®. We chose at that point to use the American Hospital Formulary Service classification because it is widely used, widely available, comprehensive, and

regularly updated. Because the American Hospital Formulary Service classification and mappings from NDCs are proprietary, however, we determined that using the United States Pharmacopeia (USP) classification would be better suited for use with HHS risk adjustment to maintain consistency with the EHB requirements and for public access and transparency. The USP classification also provides chemical ingredient level identifications for drug classifications; that is, unlike the American Hospital Formulary Service, USP includes comparable levels of detail to identify and group drugs used for only one diagnosis with other drugs used for multiple diagnosis codes. NDC codes are classified into 153 USP therapeutic classes. Drawing on the principles and criteria described below, we selected appropriate USP therapeutic classes and combined and edited those classes in order to create “payment” RXCs, each of which is closely associated with a specific HCC or group of HCCs that are potentially suitable for inclusion in the HHS risk adjustment model. Most USP classes are somewhat heterogeneous. To designate a class of drugs to serve as an indicator that a medical diagnosis is present, we needed to comprehensively review the drugs in each USP class to select only those that are closely associated with the diagnosis.

The development of a hybrid HHS-HCC risk adjustment model requires selecting drug-diagnosis pairs (RXC-HCC pairs) to include in the model. Similar to our approach in the 2014 Payment Notice when initially determining the HCCs to be included in the HHS risk adjustment models, we used a set of principles to guide our decision making. Development of the RXC-HCC pairs was an iterative process that required recurring consultations with a panel of clinicians.

Principle 1—RXC categories should be clinically meaningful. Each RXC is composed of a set of NDCs. These codes should all relate to a reasonably well-specified pharmacologic, therapeutic or chemical characteristic that defines the category. RXCs must be sufficiently clinically specific to minimize opportunities for discretionary coding. Clinical meaningfulness improves the face validity of the classification system to clinicians and the model’s interpretability.

Principle 2—RXC should predict total medical and drug expenditures. NDCs in the same RXC should be reasonably homogeneous with respect to their effect on current year costs.

Principle 3—RXC that will affect payments should have adequate sample

sizes to permit accurate and stable estimates of expenditures. RXCs used in establishing payments should have adequate sample sizes in available datasets. For example, it is difficult to reliably determine the expected cost of extremely rare categories.

Principle 4—When creating an individual’s clinical profile, hierarchies should be used to characterize the person’s illness level within each RXC where appropriate, while the effects of unrelated prescriptions accumulate. Because each new medical event adds to an individual’s total disease burden, unrelated prescriptions in different RXCs should increase predicted costs of care. However, the most severe manifestation of a given disease process principally defines its impact on costs. Therefore, related RXCs should be treated hierarchically, with those associated with more severe manifestations of a condition dominating (and eliminating the effect of) less serious ones.

Principle 5—Providers should not be penalized for prescribing additional NDCs (monotonicity). This principle has two consequences for modeling: (1) No RXC should carry a negative payment weight; and (2) an RXC that is higher-ranked in a drug hierarchy (causing lower-rank drugs in the same hierarchy to be excluded) should have at least as large a payment weight as lower-ranked RXCs in the same hierarchy.

Principle 6—The classification should assign NDCs to only one RXC (mutually exclusive classification). Because each NDC can map to more than one RXC, the classification should map NDCs to the primary RXC based on considerations such as route of administration, intended application of the product, ingredient list identifier, label, dosage form, and strength of the drug.

Principle 7—Discretionary and non-credible drug categories should be excluded from payment models. RXCs that are particularly subject to intentional or unintentional discretionary prescribing variation or inappropriate prescribing by health plans or providers, or that are not clinically or empirically credible as cost predictors, should not be included. Excluding these RXCs reduces the sensitivity of the model to prescribing variation, prescribing proliferation, and gaming.

We used clinical and statistical assessments to appropriately balance all seven principles. In designing the RXCs, principles 5 (monotonicity) and 6 (mutually exclusive classification), were generally followed. Clinical meaningfulness (principle 1) is often

²⁸ March 31, 2016, HHS-Operated Risk Adjustment Methodology Meeting Questions & Answers, June 8, 2016. Available at <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/RA-OnsiteQA-060816.pdf>.

best served by creating a very large number of detailed clinical groupings. However, a large number of groupings conflicts with adequate sample sizes for each category (principle 3). We approached the balancing of our principles by designing a drug classification system using empirical evidence on frequencies and predictive power; clinical judgment on relatedness, specificity, and severity of RXCs; and professional judgment on incentives and likely provider responses to the classification system. The RXC risk adjustment model balances these competing goals to achieve prescription drug-based classes for use in risk adjustment.

In addition to the set of principles described above, we carefully considered selection of high-cost drugs, to avoid overly reducing the incentives for issuers to strive for efficiency in prescription drug utilization. We also carefully considered selection of drugs in areas exhibiting a rapid rate of technological change, as a drug class that is associated with a specific, costly diagnosis in one year may no longer be commonly used for that condition the next, in which case the cost predictions based on previous years of data would be inaccurate.

Based on these considerations, we proposed a small number of drug-diagnosis pairs for the hybrid model. We selected RXCs to impute diagnoses and to indicate the severity of diagnoses otherwise indicated through medical coding. We worked with clinician consultants and staff clinicians to tailor the RXCs used for imputation based on their expertise in treatment patterns as well as statistical indicators such as positive predictive value. Clinicians also informed our determination of RXCs for use as severity-only indicators in the model. For the severity-only RXCs, the presence of a prescription in the drug class signals a more severe case of the related diagnosis, which is likely to incur greater medical expenditures relative to someone with the same diagnosis, but not the drug. Severity-only RXCs are not specified in the model to impute the associated diagnosis when an HCC is not present. We are limiting the number of prescription drug classes included as predictors to only those drug classes where the risk of unintended effects on provider prescribing behavior is low; as described above, we intend to monitor prescription drug utilization for unintended effects and may remove drug classes based on such evidence in future rulemaking. We are finalizing the hybrid drug-diagnosis model as proposed.

Comment: Many commenters supported the inclusion of prescription drugs into the HHS risk adjustment methodology as proposed, with numerous commenters stating that this change will help stabilize the individual and small group markets, protecting the financial solvency of health insurance issuers and helping to ensure a vibrant insurance marketplace that provides ample insurance options for consumers, while reducing the incentives for plans to discriminate against individuals with high-cost conditions or designing formularies that may discourage the use of prescription drugs that ultimately prevent costly complications. Commenters that supported the inclusion of prescription drug data noted that prescription drug data is often more readily available than medical claims data.

Response: We agree with commenters that the incorporation of prescription drug data will help stabilize the individual and small group markets, because the prescription drug data is standardized, and may help reduce the incentives for issuers to avoid making available treatments for high-cost conditions in their formularies.

Comment: Several commenters encouraged HHS to include prescription drug utilization in the HHS risk adjustment methodology beginning for the 2017 benefit year, instead of beginning for the 2018 benefit year as proposed, while two commenters requested that the changes proposed by HHS be implemented in 2016, and applied retroactively to 2014 and 2015.

Response: To promote market stabilization and transparency, we intend to implement the proposed drug classes in Table 1 into the adult risk adjustment models beginning with the 2018 benefit year. We believe that giving issuers the opportunity to build into their rates and benefit designs significant, structural changes to the model, such as predicting enrollees' expenditures based on prescription drug utilization, promotes premium stability because issuers will believe there is less need to raise rates to account for unanticipated changes to the risk adjustment methodology. As such, we will not recalibrate the 2016 or 2017 models to account for this major change, as rates for those benefit years have already been set by issuers who lacked sufficient notice and detail to have reasonably accounted for this change.

Comment: One commenter supported the use of prescription drug data to improve the risk adjustment model's accuracy, but noted that the use of such data should not increase the administrative burdens on physicians.

Another commenter believed that the use of prescription drug information in the model would add administrative burden and complexity, as issuers will have to make substantial changes to the reporting and analytics that support the completeness and accuracy of this reporting. Commenters also stated that HHS would have a more complex model to update each year and to communicate to plans. Commenters requested that if any changes to issuers' EDGE data submissions are needed due to the inclusion of pharmacy data in the risk adjustment model, HHS inform issuers of any changes as early as possible, and well in advance of the 2018 plan year. Another commenter requested that HHS provide the necessary operational and technical guidance on specifications for submissions of drug claims and that HHS consider how the drug data can be properly safeguarded, publicly disclosing well in advance, and soliciting public comment on any plans to use drug claims for any purposes besides risk adjustment.

Response: HHS has required issuers to provide access to pharmacy claims via EDGE servers since the 2014 benefit year. We are not requiring the submission of additional pharmacy claims data elements; thus, there is no additional burden on issuers or physicians. The privacy and security safeguards described at § 153.340 continue to apply to all data collected through the EDGE server, including pharmacy data, which is collected under § 153.710. We note that, because pharmacy data is one component of the EDGE data collection, the pharmacy data will be masked and used in the same manner the EDGE data is used—that is, for risk adjustment model recalibration, analysis, and informing the AV Calculator methodology. Like all EDGE data elements collected, de-identified pharmacy data could also be included in any public use file with the same privacy protections as described in the section on risk adjustment issuer data requirements.

Comment: We received a recommendation that the risk adjustment models incorporate factors that may indirectly affect risk, such as utilization variation due to access to pharmacies or plans' cost-sharing structures.

Response: Access to prescription drugs, whether due to proximity to pharmacies or a plan's cost-sharing structure, is an area we are continuing to evaluate. As we noted in the White Paper, we understand that in some cases higher rates of prescription drug usage may reflect regional pricing and prescribing patterns in addition to

health status. We welcome additional recommendations regarding how we might capture utilization differences not reflective of health status in the model.

Comment: We received many comments in support of HHS evaluating the initial drug classes to determine if the inclusion of the drug classes improves the risk adjustment methodology's ability to account for more severe patient cases and to evaluate the potential for gaming. Commenters requested that HHS release the evaluation results publicly before proceeding with any additional actions to expand or modify the drug classes for inclusion in the risk adjustment model. As part of that evaluation, commenters recommended that HHS monitor the utilization and unit cost of drugs included in the model, and track and study prescription rates for the underlying NDCs in the RXCs chosen for inclusion in risk adjustment, including through studies and the use of EDGE data. Some commenters requested that HHS publish data on the percentage of enrollees with imputation RXCs that also received an HCC and vice versa. Another commenter recommended that HHS begin developing the criteria and metrics it will use to evaluate the hybrid model's performance to reassure stakeholders that the rigor in the consideration of options to include drug data will continue past the first year of implementation, suggesting analytics such as prescribing prevalence of included drugs before and after implementation, the predictive power of the RxC, drug trends for associated drugs, or evaluating the impact had HHS required a minimum days' supply. Two commenters requested that HHS implement levers in the event that RXCs are overcompensating plans. One commenter recommended that HHS carefully track NDCs associated with a RxC so that it includes all NDCs used during the benefit year, including those that expired or were changed. Some commenters expressed concern that incorporating prescription drug utilization more widely could make risk adjustment more susceptible to gaming, perverse incentives, and distorted prescribing patterns, such as policies that encourage providers to prescribe more costly drugs within a therapeutic class or to use prescription drug treatments rather than less-costly alternatives like behavioral modification. One commenter stated qualified support but cautioned that the success of the incorporation of prescription drugs in other countries' risk adjustment programs does not necessarily provide support for

prescription drug use in risk adjustment more generally. Several commenters stated providers would not over-prescribe based on risk adjustment coefficients because there is no direct relationship between the compensation a provider receives from an issuer and the cost of the medication it prescribes.

Response: We agree with commenters who suggested HHS evaluate the initial drug classes to determine if the inclusion of the drug classes improves the risk adjustment methodology's ability to account for more severe patient cases and to evaluate the potential for gaming. We also appreciate the suggestions for the criteria we should use in monitoring prescribing behavior. As we noted in the White Paper, the potential for gaming or perverse incentives is a primary concern in creating models that use prescription drug data. Perverse incentives arise in any risk adjustment model in which utilization indicators (such as prescriptions) trigger additional payments. Treatment decisions may be influenced or distorted by financial considerations, and basing risk adjustment on drug utilization will tend to bias health plans towards drug rather than non-drug treatments, potentially reducing plans' incentives to tightly manage drug utilization. We agree with commenters that HHS must perform analysis to determine which drug classes (or individual drugs) are most susceptible to gaming, with a specific emphasis on the drug classes included in the HHS risk adjustment model for the 2018 benefit year. While we designed the drug classes included in the 2018 benefit year adult models to promote predictive accuracy and reduce susceptibility to gaming, it is not clear that drug utilization is less discretionary than other types of health utilization predictive of expenditures, such as hospitalizations for chronic conditions. We intend to make public our analysis of prescription drug utilization after 2018 EDGE data is available, comparing 2018 with previous years of EDGE data.

Comment: One commenter stated that HHS will not be able to determine through auditing pharmacy data whether the diagnosis that was imputed was in fact made, since clinical providers go to great lengths to ensure the accuracy of their documentation, but prescriptions generally do not include any clinical or diagnostic information, and as such, HHS should not employ a risk adjustment model that is based on data that cannot be adequately audited.

Response: HHS does not perform risk adjustment data validation audits with the intent of determining whether a clinician correctly diagnosed a patient.

Rather, HHS ensures that enrollees' diagnoses on paid claims reflect the appropriately assigned HCCs and were diagnosed by a licensed clinician. Likewise, in validating pharmacy claims, we intend to validate factors such as whether the prescription was filled and paid by the issuer, and whether the appropriate RxC interaction was assigned. We understand commenters' concerns regarding prescription drug data and intend to closely monitor prescribing behavior in the 2018 benefit year.

Comment: One commenter expressed concern that the time lag in the data will not reflect the actual benefit year costs of high-cost treatments such as those for HIV or Hepatitis C.

Response: The data time lag for risk adjustment has been a persistent issue in reflecting accurate drug costs for the applicable benefit year, even prior to the incorporation of RXCs in the risk adjustment models. We have proposed potential solutions to mitigate this time lag, but commenters tend to prefer predictability in coefficients over more recent and more reflective data of the applicable benefit year. We note that, in an effort to reflect changing drug costs as accurately as possible on older data, we do trend drug costs from the MarketScan® data to the applicable benefit year by specialty drugs and traditional (branded and generic) drugs separately.

Comment: A few commenters strongly disagreed with HHS's rationale for using U.S. Pharmacopeia (USP) (in part to maintain consistency with the Essential Health Benefits standards). These commenters stated that using USP does not achieve HHS's stated purpose of assuring appropriate formulary breadth. A few commenters also expressed concern that the drug classes are limited to USP classifications developed for the Medicare Part D model, as not all classes of drugs are covered by Medicare, making the USP classifications an incomplete list of classes for the purposes of the private marketplace. One commenter stated plans are not incentivized to cover drugs that are not included in the USP categories. One commenter noted that the USP drug classes are updated infrequently. One commenter supported the use of the USP classification system, and recommended that HHS apply lessons learned from the use of prescription drug data in other risk adjustment programs. Several commenters requested that HHS provide the link to the USP drug classifications (and an extension of the comment period to evaluate once provided).

Response: We developed the current RXCs as analogues of certain therapeutic classes from the American Hospital Formulary Service system, which is not limited to Part D drugs. We were able to successfully crosswalk all of those original American Hospital Formulary Service classes for inclusion in the HHS risk adjustment model to the USP. In developing the drug classes included in the risk adjustment model, the RXCs are not comprehensive; they include select drug classes (and in some cases, specific drugs) that are closely associated with particular diagnoses. We use the USP classes as a guideline in defining the RXCs. For each RXC, we thoroughly investigated whether there should be additional drugs added to the class, or any drugs removed from the class. We defined each RXC as a collection of NDCs listed in the RxNorm database, which is a comprehensive database of drugs independent of Part D or other formularies.²⁹ We do not believe that drugs excluded from Part D represent a significant concern for coverage under the HHS risk adjustment models, as none of the excluded categories were under consideration for inclusion in the HHS risk adjustment models. We understand that USP is planning to introduce a new drug classification system designed to more broadly apply

to all populations—not only to Part D beneficiaries—which we expect to be effective in early 2017 and revised annually.³⁰ We believe that using the USP drug classification as a starting point in developing the RXCs for inclusion in the risk adjustment model is the most transparent approach, as using the American Hospital Formulary Service as a proprietary categorization would have required additional contractual arrangements to provide the NDC mappings to those classes, which are not freely available to the public. We also note that HHS is already using the USP for other regulatory purposes.

Table 1 shows the list of RXC–HCC pairs that we are including in the initial hybrid model. Each pair is designated as either an imputation/severity or a severity-only relationship. For each pair, Table 1 shows the coefficient for the diagnosis (HCC), the drug utilization (RXC), and the interaction of the two.

The drug-diagnosis pairs can include more than one HCC. For example, the list includes a diabetes drug-diagnosis relationship that includes three HCCs (diabetes with acute complication, diabetes with chronic complication, and diabetes without complication) which are grouped together in the model estimation. This RXC can be interpreted as an indication that the enrollee should

have a diagnosis of one of these three diabetes HCCs. In addition, an RXC can be linked in the model to more than one HCC, and vice-versa. For example, RXC 8 (Immune suppressants and immunomodulators) has an imputation/severity relationship with HCC 056 (Rheumatoid arthritis and specified autoimmune disorders), and also has a severity-only relationship with HCC 048 (Inflammatory bowel disease).

While ten of the RXC–HCC pairs have three levels of incremental predicted costs (diagnosis only, prescription drug only, both diagnosis and prescription drug), indicating that they can be used to impute a particular condition, the model also includes two RXC–HCC pairs that will be used for severity only—that is, they will predict incremental costs for enrollees with the diagnosis only, and with both the diagnosis and the prescription drug. There are no additional costs predicted for an enrollee taking the drug who lacks the associated diagnosis. Table 1 lists the RXC–HCC pairs we are finalizing to incorporate in the adult models for the 2018 benefit year. Table 3 incorporates the full set of HCCs and RXC–HCCs and their associated coefficients that we are finalizing to implement in the 2018 adult models.

TABLE 1—DRUG-DIAGNOSIS (RXC–HCC) PAIRS CHOSEN FOR THE HYBRID RISK ADJUSTMENT MODELS

RXC	RXC label	HCC	HCC label	Proposed RXC use
1	Hepatitis C Antivirals	037C, 036, 035, 034	Chronic Hepatitis C, Cirrhosis of Liver, End-Stage Liver Disease, and Liver Transplant Status/Complications.	imputation/severity.
2	HIV/AIDS Antivirals	001	HIV/AIDS	imputation/severity.
3	Antiarrhythmics	142	Specified Heart Arrhythmias	imputation/severity.
4	End Stage Renal Disease (ESRD) Phosphate Binders.	184, 183, 187, 188	End Stage Renal Disease, Kidney Transplant Status, Chronic Kidney Disease, Stage 5, Chronic Kidney Disease, Severe (Stage 4).	imputation/severity.
5	Anti-inflammatories for inflammatory bowel disease (IBD).	048, 041	Inflammatory Bowel Disease, Intestine Transplant Status/Complications.	imputation/severity.
6a	Anti-Diabetic Agents, Except Insulin and Metformin Only.	019, 020, 021, 018	Diabetes with Acute Complications, Diabetes with Chronic Complications, Diabetes without Complication, Pancreas Transplant Status/Complications.	imputation/severity.
6b	Insulin	019, 020, 021, 018	Diabetes with Acute Complications; Diabetes with Chronic Complications; Diabetes without Complication, Pancreas Transplant Status/Complications.	imputation/severity.
7	Multiple Sclerosis Agents	118	Multiple Sclerosis	imputation/severity.
8	Immune Suppressants and Immunomodulators.	056, 057, 048, 041	Rheumatoid Arthritis and Specified Autoimmune Disorders, Systemic Lupus Erythematosus and Other Autoimmune Disorders, Inflammatory Bowel Disease, Intestine Transplant Status/Complications.	imputation/severity.
9	Cystic Fibrosis Agents	159, 158	Cystic Fibrosis, Lung Transplant Status/Complications.	imputation/severity.
10	Ammonia Detoxicants	036, 035, 034	Cirrhosis of Liver, End-Stage Liver Disease, Liver Transplant Status/Complications.	severity-only.
11	Diuretics, Loop and Select Potassium-Sparing.	130, 129, 128	Congestive Heart Failure, Heart Transplant, Heart Assistive Device/Artificial Heart.	severity-only.

²⁹ RxNorm Database. <https://www.nlm.nih.gov/research/umls/rxnorm/>.

³⁰ USP Drug Classification. <http://www.usp.org/usp-healthcare-professionals/drug-classification>.

We are finalizing incorporating the RXC–HCC pairs—some of which are used to impute a diagnosis and calibrate the severity of the condition, and others of which are used only as an indication of severity—into the adult risk adjustment model, beginning in the 2018 benefit year. We intend to evaluate the effects of this change to determine whether to continue, broaden, or reduce this set of factors in the HHS risk adjustment models.

Comment: Several commenters supported the use of the hybrid model, stating that it will improve the accuracy of risk adjustment. Commenters stated that the hybrid model is a practical approach to risk adjustment and strikes a fair balance between the benefits of utilizing prescription drug data against the potential risks. One commenter believed that the imputation of conditions will help predict the risk of partial-year enrollees, including partial-year enrollees in the small group market due to non-calendar plan years, while the severity component will improve the model's predictive power and increase the model's ability to compensate adequately for high-cost conditions. We received a few comments suggesting that it may make the most sense for HHS to begin with an imputation-only approach in order to limit the potential for confusion on behalf of plans and providers and to avoid the complexity of the hybrid model that undercuts a key purpose of incorporating pharmacy data into risk adjustment, which is to help fill gaps in diagnoses. While one commenter supported the hybrid model, the commenter suggested HHS create a third relationship category for imputation-only, stating that it is not necessarily the case that prescription drug utilization that is indicative of a specific diagnosis is also reflective of the severity of the disease state. One comment expressed concern that this model may create a strong perverse incentive to overprescribe medications that are included in the risk adjustment model and should therefore be avoided. One commenter suggested that HHS ensure that the model take into account enrollees with multiple chronic diseases and put into place safeguards to prevent issuers from using the addition of drug interaction coefficients to penalize patients and providers. A few commenters suggested that HHS include drugs prescribed for multiple conditions, as excluding drugs with multiple indicators may bias the risk adjustment model in favor of high-cost medicines with very specific uses over well-established medicines that are

effective across multiple conditions. Other commenters noted that the inclusion of drug utilization can reduce the model's predictive accuracy since some drugs can be prescribed for multiple conditions and drugs can have “off-label” uses. One commenter recommended that HHS modify its proposal so that a single prescription drug category (RXC) is paired to a single HCC, and focus on incorporating RXCs tied to drugs for which there is only one approved and widespread use. One commenter opposed the use of the presence of a prescription drug to impute diagnoses that are not otherwise contained in the medical record as the result of a clinical contact, as a clinical condition that requires ongoing medication also requires clinical visits to ensure complete, quality care of the patient and appropriate management of the condition. Several commenters requested that HHS describe the iterative process of building an enrollee's risk score when prescription drugs are included.

Response: We agree with commenters that the hybrid model presents a fair balance between allowing for the imputation of missing diagnoses, while ensuring that risk adjustment compensates issuers for high-cost treatments provided for serious conditions. To clarify, in the drug model we are implementing, three different predicted levels of incremental expenditures may be modeled: One for enrollees with the diagnosis only, one for enrollees with the prescription drug claim only, and a third level for people with both indicators. As we discussed in the White Paper, drugs associated with multiple conditions must be evaluated carefully. For example, disease-modifying antirheumatic drugs (RXC 8, DMARDs) are most commonly used for rheumatoid arthritis (HCC 56), and less commonly for inflammatory bowel disease (HCC 48). Most people taking DMARDs have a rheumatoid arthritis diagnosis, which might suggest the drug class can be used to impute missing rheumatoid arthritis diagnoses. However, some enrollees take DMARDs for inflammatory bowel disease and do not have rheumatoid arthritis, so it would be incorrect to always impute rheumatoid arthritis for users of DMARDs. In this model, we impute rheumatoid arthritis for people taking DMARDs only if no diagnosis of inflammatory bowel disease is present. However, for other drug classes indicated for multiple diagnoses where use of the drug is more evenly split among multiple diagnoses, adopting a similar approach is more challenging.

We also ensured that an enrollee's risk score would never be reduced for recording the prescription and diagnosis by imposing constraints on the coefficient estimates. We agree with commenters that an example of the iterative process of building an enrollee's risk score under the hybrid model would be very helpful and have included an example below.

Comment: Several commenters supported the drug classes HHS proposed to incorporate into the HHS risk adjustment methodology and believe they are well-suited to indicate the severity of the associated illnesses. A few commenters commended HHS's decision to include prescription drugs cautiously and incrementally, with some supporting a collaborative approach to including or changing the drug classifications in the risk adjustment model. One commenter specifically supported the inclusion of insulin, while others recommended the exclusion of insulin or similarly low-cost drugs as severity indicators. One commenter supported the inclusion of cystic fibrosis drugs, noting that they are subject to practice guidelines and standards, including standards for prescription drug use, and are prescribed according to the genetic profile of the patient, which protects against overutilization. We received several comments in support of the proposed drug-diagnosis pair specifically related to ESRD phosphate binders, stating that it will help ensure more accurate identification of and payment to issuers for those ESRD patients. Some commenters recommended that the risk adjustment methodology account for HIV pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) by using restrictions on the HIV RXC that were proposed in the White Paper; they indicated that this could be done for HIV by dividing the HIV RXC, imputing HIV if the prescription consists of typical “HIV cocktails” with four or more weeks of drug treatment, and for PrEP by using the other half of the HIV RXC, such as Truvada-only prescriptions. This would still impute a risk score, but one that is lower than HIV to reflect the lower cost of PrEP. Some additional commenters recommended that for PEP, HHS should not impute HIV if there were four or fewer weeks of prescriptions filled (with no diagnostic code for HIV). Several commenters supported full prescription drug incorporation in the risk adjustment model, but acknowledged the challenges of making large adjustments to the dataset without

inadvertently harming the integrity and predictive accuracy of the model. Commenters recommended the addition of other drug classes to the risk adjustment model, such as antidepressants, arthritic agents, and psoriatic disease treatments, while another recommended we evaluate whether or not to add these additional classes. Commenters requested HHS consider the inclusion of oncology drugs and diagnoses and cancer treatments for 2018, noting that treatment guidelines would protect against overutilization of these drugs. Another commenter supported the inclusion of cancer treatments and encouraged HHS to continue its work to improve the accuracy of risk adjustments by ensuring that the model includes both physician-administered and self-administered drugs. One commenter supported the use of RXCs, but suggested limiting the inclusion to only three RXCs (Hep C, HIV, Cystic Fibrosis), and at most 5 RXCs (Insulin, Multiple Sclerosis agents), and refraining from using drugs that aren't indicative of conditions, such as anti-inflammatory drugs, diuretics, and loop- and select-potassium sparing.

Response: The drug classes we proposed for inclusion in the risk adjustment model were carefully chosen, in many cases because of the strict treatment guidelines surrounding some drug classes that commenters noted, which protect against overutilization. We approached the tradeoffs involved in designing a drug classification system using empirical evidence on frequencies and predictive power; clinical judgment on relatedness, specificity, and severity of RXCs; and professional judgment on incentives and likely provider responses to the classification system. We believe the RXC risk adjustment model balances these competing goals to achieve a feasible, prescription drug-based risk adjustment payment system. Regarding the HIV RXC, we carefully considered the face validity of including treatments for a condition that would impute a condition that an enrollee did not actually have (in the case of HIV prophylaxis treatments) and determined that imputing a diagnosis for a preventive treatment would not be consistent with our modeling efforts. We will evaluate this set of drug classes to assess the modifications made to the model's predictive ability and the potential for gaming.

Comment: We received a request that we implement the 181 daily dosage minimum beginning in 2018, with exceptions for single-treatment drugs such as Sovaldi, as the most effective

barrier to the gaming; if not in 2018, then the commenter recommended we begin with EDGE data for 2019.

Response: We are interested in evaluating the use of minimum days' supply requirements for some drugs in the risk adjustment model. At this time, we can analyze days' supply in MarketScan® data, but we do not have the data elements necessary to evaluate days' supply on EDGE data.

Comment: One commenter recommended that HHS provide issuers with a detailed draft model of how a hybrid drug-diagnosis model would work as soon as possible, giving issuers an opportunity to review, beta test, and provide comments, through the release of the risk adjustment software. One commenter requested additional information on the clinician consultants who provided technical expertise on the development of the RXCs. Another commenter requested additional information on how the coefficients were developed and how the principles were applied for the newly added drug classes.

Response: We expect to provide updated EDGE server software, as we have done for previous benefit years of the risk adjustment program, that will allow issuers to approximate enrollees' risk scores under the 2018 risk adjustment models. Our clinical consultants are clinicians with extensive experience in and knowledge of risk adjustment and health care payment policy related to pharmaceuticals and medicine.

Comment: Commenters requested that HHS provide further information about the specific drugs, identified by NDCs, that it has mapped into each RXC category, and share its analysis regarding the conditions for which these drugs may be used, and how it expects to maintain these categories and their linkage to particular conditions as additional indications are added to a drug, or off-label use for other conditions expands. Some commenters recommended that HHS release information related to the drug and RXC mapping through the annual rulemaking process for public comment. One commenter recommended updating the underlying drugs in the selected drug classes annually, including updating to include any new or non-USP drug classes as appropriate. One commenter recommended including arthritis in the risk adjustment methodology since nearly half of enrollees with arthritis have a comorbidity.

Response: We intend to publicly release a mapping of the specific drugs to the drug classes included in the 2018 adult risk adjustment models. We

expect to update the mapping as prescription drug guidance and updates become available, similar to our public release of mapping of ICD-10 codes acceptable for risk adjustment and the corresponding HCCs, and our updates of acceptable service codes for risk adjustment.

iii. High-Cost Risk Pooling

The HHS risk adjustment model reflects the average cost for enrollees with a given set of demographic characteristics and diagnoses. Our experience with the 2014 benefit year risk adjustment demonstrated that the model may underpredict costs for extremely high-cost enrollees, since predicted plan liabilities reflect the average costs for enrollees with the set of demographic characteristics and diagnoses included in the model. As a consequence, even with our risk adjustment methodology in place, issuers may retain an incentive to engage in risk selection in order to avoid these very high-cost enrollees (called "high-cost enrollees" throughout this discussion). Recent research has shown that adjusting for high-cost enrollees in a risk adjustment model will aid the model's fit and predictive ability for the remaining risk population.³¹ To mitigate any residual incentive for risk selection to avoid high-cost enrollees, and to ensure that the actuarial risk of a plan with high-cost enrollees is better reflected in the risk adjustment transfers to issuers with high actuarial risk, we proposed to alter the risk adjustment methodology.

We accordingly proposed to incorporate into our methodology a high-cost risk pool calculation. Under this proposal, beginning for the 2018 benefit year, we would first exclude a percentage of costs above a certain threshold level in the calculation of enrollee-level plan liability risk scores, so that risk adjustment factors would be calculated for risk associated with HCCs and RXCs excluding those extreme costs, because the average risk associated with HCCs and RXCs is better accounted for without inclusion of the high-cost enrollees. Second, to account for the issuers' costs associated with the high-cost enrollees, we proposed to apply an adjustment to the risk adjustment calculation for each issuer of a risk adjustment covered plan to account for a percentage of all high-cost enrollees' costs above the threshold. We proposed to set the threshold and

³¹ Schillo, S., G. Lux, J. Wassem and F. Buchner (2016) "High Cost Pool or High Cost Groups—How to Handle Highest Cost Cases in a Risk Adjustment Mechanism?" Health Policy (120): 141–147.

percentage of costs at a level that would continue to incentivize issuers to control costs while aiding the risk prediction of the risk adjustment model. In the proposed rule, we proposed a threshold of \$2 million for each enrollee, with an adjustment equal to 60 percent of costs above the threshold. Issuers with high-cost enrollee expenses above this threshold would receive an adjustment, reflected in their respective transfers, to account for the percentage of costs above the threshold. Using claims data submitted to the EDGE server by issuers of risk adjustment covered plans, HHS would calculate the total amount of paid claims costs for high-cost enrollees above the threshold. HHS would then calculate an adjustment as a percent of the issuer's total premiums in the respective market, which would be applied to the total transfer amount in that market, maintaining the balance of payments and charges within the risk adjustment program. We proposed a uniform percentage of premium adjustment across all States for the individual (including catastrophic and non-catastrophic plans and merged market plans) and small group markets for all issuers in the program.

To implement this adjustment, we proposed two high-cost risk pools that would be calculated across all States under the program: One for the individual market (including catastrophic, non-catastrophic, and merged market plans), and one for the small group market. The adjustment to the transfer formula described above would be made for all issuers of risk adjustment covered plans in the individual (including catastrophic and non-catastrophic plans and merged market plans) and small group markets in the program, across all States, based on total premiums in the respective market. HHS would calculate an adjustment against each such risk adjustment covered plan's risk adjustment charge or payment to implement the applicable pools. We proposed that if an issuer were to fail the data quality analysis for a risk adjustment transfer and was assessed a default charge under § 153.740(b) on that basis, we would perform additional data quality metrics to determine an issuer's eligibility for high-cost risk pool adjustments.

We believe the inclusion of this policy, in combination with the rest of our methodology, will allow us to better assess total actuarial risk for each risk adjustment eligible plan, and thereby to ensure that the program is appropriately compensating issuers. We are finalizing a threshold of \$1 million and

coinsurance rate of 60 percent, and expect total adjustments as a result of this policy nationally to be very small as a percent of premiums (less than one half of one percent of total premiums for either market). We believe this modified methodology will improve the measurement of actuarial risk within States, and we will implement it, consistent with the statute, to help ensure that transfers within each State from low actuarial risk plans to high actuarial risk plans better reflect the actuarial risk of risk adjustment covered plans in a market. We intend to monitor the results of the program as it is implemented to ensure that the program as a whole and balance of payments operate as intended. We anticipate that applying this adjustment will mitigate the need for issuers to build risk premiums into their rates to account for these cases, by giving issuers greater predictability on expenditures.

Comment: Some commenters supported the proposal as a way to incentivize plans to cover individuals in rural areas and with high-cost diseases. Some commenters did not support this proposal, stating they believe it offers little benefit beyond what issuers receive from commercial reinsurance.

Response: We believe that excluding a portion of very high-cost risk enrollees' costs from the risk adjustment model calibration would improve the model's predictive ability. As we noted in the proposed rule, we expect total adjustments as a result of this policy nationally to be very small as a percent of premiums. We also believe this policy will further mitigate issuers' incentive to seek to avoid these high-cost enrollees and to build risk premiums into their rates.

Comment: Commenters expressed concerns about the potential for issuers to "game" this policy by shifting costs to the risk adjustment program, and not pay sufficient attention to cost containment for costs above the threshold. Commenters also noted that issuers may not have adequate data to price for this program, and could allow providers of high-cost conditions, such as burn centers, to charge extremely high prices. Commenters stated that while increasing the threshold could mitigate some gaming risk, where the provider and the issuer are the same entity, this adjustment would reward less efficient issuers, and would pose additional administrative burden that outweighs the benefits, including audits.

Response: These high-cost enrollee pool adjustments will be subject to HHS's audit authority under § 153.620. We believe that issuers will find it

easier to price for the cost of the policy given the low percentage of premium to be charged across all States than it would be to price for the very high costs of these enrollees, if an issuer were to enroll them. We will seek to implement our audits of this policy in a manner that minimizes administrative burden, to the extent practicable. We also believe that the reduced final percentage of costs covered above the threshold of 60 percent, compared to the 80 percent coinsurance rate that was discussed in the White Paper, should continue to incentivize issuers to contain costs, while a lower threshold of \$1 million could ensure that more issuers benefit from this provision, by covering more high-cost enrollees.

Comment: Comments ranged widely on the threshold level and the coinsurance rate. Some commenters supported the proposed threshold and coinsurance rate in mitigating gaming risk. One commenter noted that a lower threshold and higher coinsurance would be more effective in reducing risk premiums for these high-cost cases, and recommended a lower threshold of \$500,000. Other commenters supported a lower threshold to make the results meaningful. A few commenters specifically preferred parameters closer to the example threshold and coinsurance rate discussed in the White Paper of \$1 million and 90 percent.

Response: We are sensitive to these commenters' concerns, particularly in the first year of this policy in the risk adjustment methodology. We believe the inordinately high costs for certain high risk enrollees reflect random risk selection for certain issuers. We had proposed a \$2 million threshold, with 60 percent of an enrollee's costs above the threshold covered by the pool. To help mitigate concerns raised, while still helping protect issuers from the unpredictable risk of exceptionally high costs, we are finalizing a lower threshold of \$1 million, but maintain a coinsurance rate of 60 percent of costs above the threshold covered by the pool. The 60 percent coinsurance rate will ensure that issuers continue to contain costs, while the \$1 million threshold will ensure that more high-cost enrollees are covered by the pool, benefiting more issuers and a greater portion of these costs. We also note that beginning with the 2018 benefit year recalibration, we will incorporate these parameters in our recalibration of the model by truncating 40 percent of costs above \$1 million in our dataset used to simulate plan liability. Doing so will produce more predictive coefficients that reflect the impact of the high-cost enrollee pool.

Comment: A few commenters supported the proposal but without a national risk pool. Some commenters were also concerned about the cost variations across States and resulting cross-State subsidization, while other commenters supported the national pool as it spreads the risk and is a very small percent of premiums. Some commenters recommended that the costs across States be standardized, or that HHS re-price the costs based on Medicare Fee Schedule for price variations across States and adjust for differences in plan design and networks. One commenter suggested that the proposed multi-State concept would destabilize some insurance markets and contradicts the Affordable Care Act's intention to have the risk adjustment, reinsurance, and risk corridors programs be State-based.

Response: Consistent with the statute, the HHS risk adjustment methodology compares the actuarial risk of plans within a market within a State. As we discuss above, our continuing analysis of our models leads us to believe that the risk adjustment methodology as currently constructed may not account for outlier high-cost enrollees precisely, and may result in slightly overcompensated HCCs for most enrollees, and undercompensated HCCs for enrollees with high costs. Within certain HCCs, some enrollees appear to have particularly high costs. Including outlier costs in the estimation of these HCCs appears to undercompensate for such high-cost risk. To address this issue, the adjustment we proposed will help ensure that these very high-cost enrollee outliers are incorporated into CMS's modeling in a way that more precisely captures the actuarial risk of the plan. As we noted earlier in this final rule, beginning with the 2018 benefit year recalibration, we will incorporate these parameters in our recalibration of the model by truncating 40 percent of costs above \$1 million in our dataset used to simulate plan liability. Implementing this proposal will produce more predictive coefficients that reflect the impact of the high-cost enrollee pool. The resulting improvement in the models' coefficients from incorporating the high-cost enrollee pool into the risk adjustment modeling ensures that risk scores for all enrollees will better reflect actuarial risk.

The high-cost risk pool calculation will function as an adjustment to benefit the modeling accuracy of actuarial risk within a market within a State in order to help calculate risk adjustment transfer amounts between low actuarial risk plans, on the one hand, and high actuarial risk plans, on the other hand,

consistent with the statute. The Secretary has broad discretion under the statute to implement the risk adjustment program, and we note that other risk adjustment programs, such as the risk adjustment model used in the Netherlands,³² have incorporated similar approaches.

We are not making any adjustments to address cross-State pricing variations at this time.

Comment: One commenter did not support this proposal, noting that HHS has interpreted actuarial risk under section 1343 of the Affordable Care Act as whether a plan has very high-cost enrollees. The commenter stated that HHS should not include factors actuaries may have considered in setting premium rates as these likely do not increase an enrollee's actuarial risk compared to average actuarial risk.

Response: The risk adjustment program intends to minimize the risk of greater than average adverse selection of enrollees into certain plans by leveling the playing field for issuers with transfers from issuers with healthier enrollees to issuers with sicker enrollees. The model is based on enrollees' observable health characteristics to provide an estimate of an enrollee's actuarial risk and determine whether a plan enrolled healthier or sicker enrollees compared to the average within a market within a State. We believe that accounting in this manner for the very highest and most unpredictable costs will strengthen the risk adjustment model's predictive ability for the actuarial risk of enrollees based on their age, sex and diagnostic information. The inclusion of this adjustment, in combination with the transfers attributable to the plan liability risk scores, will allow us to better assess total actuarial risk for each risk adjustment covered plan, and thereby ensure that risk adjustment is appropriately compensating issuers. Addressing very high costs in this manner will strengthen the prediction of relative costs associated with enrollees. The model will more efficiently be calibrated based on relative weights for demographic factors, HCCs and RXCs.

Comment: Many commenters supported including the national uniform adjustment calculated as a percent of premium and not capping costs at a certain amount. Commenters

also recommended that HHS evaluate the impact of the adjustment to the model. One commenter suggested a fixed charge on issuers to be assessed with a cap on payments and the fixed charge published in rulemaking to provide issuers certainty. Some commenters wanted clarification on whether the adjustment would be funded through a charge, and inquired how risk adjustment would remain budget neutral, and supported the risk pool through a broad based fund instead of the risk adjustment user fee.

Response: We are finalizing these aspects of the adjustment to the risk adjustment transfers as proposed. The adjustment will be assessed as a percent of the applicable issuer's total premiums in the respective market, which will be applied to the total transfer amount in that market and will maintain the balance of payments and charges within the risk adjustment program. Based on MarketScan® data analysis, we believe the \$1 million threshold and 60 percent coinsurance rate we are finalizing for the high-cost risk pool will be less than 0.5 percent of premiums. Given the small impact of this adjustment, we do not believe this will create significant additional uncertainty for issuers overall.

iv. Other Considerations

We had previously reported that based on the commercial MarketScan® data, the HHS risk adjustment models slightly underpredict risk for low-cost enrollees, and slightly overpredict risk for enrollees with high expenditures.³³ We have received feedback that HHS should adjust the risk adjustment models for the underprediction of risk for low-cost enrollees, and the overprediction of risk for enrollees with high expenditures, which affects the plan liability risk scores of plans that enroll more healthy individuals or plans that enroll more individuals with the most extreme chronic health conditions. We sought comment on approaches to address this issue. We will not implement any of these approaches for 2018, but will consider changes in future years.

More specifically, we have considered the use of a constrained regression approach, under which we would estimate the adult risk adjustment model using only the age-sex variables. We would then re-estimate the model using the full set of HCCs, while constraining the value of the age-sex

³² Van Kleef, R. C. and R. van Vliet (2012), "Improving Risk Equalization Using Multiple-Year High Cost as a Health Indicator," *Medical Care* 50(2): 140–144.

³³ Schillo, S., G. Lux, J. Wasseem and F. Buchner (2016) "High Cost Pool or High Cost Groups—How to Handle Highest Cost Cases in a Risk Adjustment Mechanism?" *Health Policy* (120): 141–147.

³³ The HHS–HCC Risk Adjustment Model for Individual and Small Group Markets under the Affordable Care Act. 2014. Available at https://www.cms.gov/mmrr/Downloads/MMRR2014_004_03_a03.pdf.

coefficients to be the same as those from the first estimation. We believe that this two-step estimation approach would result in age-sex coefficients of greater magnitude, potentially helping us predict the risk of the healthiest subpopulations more accurately. Similarly, we considered approaches in which our first estimation of the model would include additional independent variables intended to account for potential non-linearities in risk for the highest-risk subpopulations, and then removing those additional variables in the second estimation. We considered creating separate models for enrollees with and without HCCs to derive two separate sets of age-sex coefficients. We believe such an approach could also help improve the models' predictive ratios for the healthiest subpopulations, though this model would have a separate set of age-sex coefficients for enrollees with no HCCs and enrollees with HCCs. Finally, we evaluated an approach in which we would directly adjust plan liability risk scores outside of the model for these subpopulations. For example, we could make an adjustment to the plan liability risk scores calculated through the HHS risk adjustment models that would adjust for such an underprediction or overprediction in actuarial risk by directly increasing low plan liability risk scores and directly reducing high plan liability risk scores in order to better match the relative risks of these subpopulations. We noted that while we believe modifications of this type could improve the model's performance along this specific dimension, there is a risk that such modifications could unintentionally worsen model performance along other dimensions on which the model currently performs well. We evaluated the effect of these types of modifications on all aspects of the model's performance before choosing to implement such an approach, and stated that we would not implement these types of modifications if we determined that doing so would have material unintended consequences for the model's performance along other dimensions.

Comment: Commenters generally supported addressing the underprediction of healthy and low-cost enrollees given that approximately 80 percent of enrollees in the MarketScan® sample do not have HCCs. Commenters stated that this revision to the modeling would mitigate risk selection to avoid low-cost enrollees, and that this could result in slightly lower premiums for all enrollees. Commenters noted that the existing risk adjustment methodology

results in insufficient revenue from healthy enrollees to fund costs after risk adjustment charges, coupled with overcompensation of issuers that have enrollees with moderate health conditions, and requested that HHS address this imbalance to promote sustainable individual and small group markets, through increasing enrollment among healthy enrollees. Other commenters noted that HHS should ensure adequate risk adjustment compensation for high-cost enrollees, stating that the lowest priced issuers attract low-risk enrollees, and that attracting enrollment by high risk enrollees is far more complicated and involves taking on a substantial amount of risk, which is not fully accounted for through risk adjustment. A few commenters noted that the estimation bias among children is greater than with the adult model, and recommended that HHS also adjust the child model.

Some commenters did not support any adjustments. One commenter noted that such changes are unnecessary because carriers rate based on the full market and so slight overprediction of high-cost enrollees and slight underprediction of low-cost enrollees in the model calibration allows for accurate cost alignment once the impact of new technologies is considered, and that HHS's changes over the years to add preventive services, an adjustment for partial year enrollment, and prescription drug data should be adequate. Another commenter did not believe they had enough detail to provide sufficient comment on the proposed policy.

Commenters generally supported a two-step constrained approach to separately predict age-sex coefficients for enrollees without HCCs stating this approach is more likely to provide year-to-year stability, and better explains cost differences related to demographic factors. One commenter cautioned that there may be some interplay in effects between enrollees without HCCs and partial year adjustment factors. Another commenter supported a two-step approach noting that this would allow for separate estimations for partial year enrollees. Most commenters did not support an adjustment outside the model. One commenter suggested HHS consider other alternative models, such as the DxCG or Milliman MARA models, stating that these models have a higher predictive power and may help improve the accuracy of the risk adjustment models' predictive ratios. A few commenters also suggested that bronze plans are also specifically disadvantaged by the existing risk

adjustment model, and that HHS should adjust the model for this issue.

A few commenters requested additional detail, with one commenter requesting the most recent model's predictive ratios and another requesting comparative results for all options considered. Some commenters supported further study on this issue and suggested that HHS seek to implement this policy for the 2019 risk adjustment model. A few commenters stated that this adjustment should be implemented prior to the 2018 benefit year, including retroactively for the 2014 and 2015 benefit years. One commenter requested that HHS provide the data driving the policy changes, and cautioned against making changes to the risk adjustment model based on requests from certain groups that had unfavorable results in the risk adjustment program, and that HHS should always aim to improve the model's accuracy.

Response: We believe that some of the modeling approaches we considered could improve the model's predictive ability for certain subgroups of enrollees. However, we are still evaluating the tradeoffs that would need to be made in model predictive power among subgroups of enrollees. We continue to focus on encouraging plans to attract high-risk enrollees through the risk adjustment model, but agree with commenters that we should further evaluate solutions prior to making any adjustments to the model. We will continue to explore these modeling approaches and look forward to comparing our results with the EDGE enrollee-level data collection, which we are also finalizing in this rule.

In addition, we noted in the proposed rule the feedback we have received regarding our transfer methodology in community-rated States. In the 2014 Payment Notice, we stated that billable members exclude children who do not count toward family rates. In the second Program Integrity Rule, we clarified the modification to the transfer formula to accommodate community-rated States that utilize family tiering rating factors. In the case of family tiering States, billable members are based on the number of children that implicitly count toward the premium under a State's family rating factors. We have received feedback that there may be alternative methodologies for calculating billable member months in family tiering States, such as by adjusting for the expected actual number of members on the policy, not the number of members that implicitly count toward the premium. We sought comment on whether our methodology for calculating billable

member months in family tiering States should be altered, and how. Based on comments received, we are not making any changes to the transfer methodology with respect to billable member months at this time.

Comment: Most commenters did not support a change to the transfer methodology with respect to community-rated States because changes in risk scores and allowable rating factors would be offset by changes in the State average premium and billable member counts. Commenters noted our statement in the White Paper that this design allows for incorporating the additional risk for non-billed members leading to higher Statewide average premium, which gets cancelled out because transfers are also multiplied by billable member months. A few other commenters supported such an adjustment, noting that using billable member months inflates risk and transfers.

Response: We believe that our current methodology in community-rated States is consistent with using enrollment that contributed toward premiums for risk adjustment calculations. If we were to use a method that calculated average risk including non-billed members, it would lower risk scores, but would understate transfers, because those transfers would not account for the risk of the non-billed members. We are not making any changes to the transfer methodology with respect to billable member months at this time.

v. Data Timing for Risk Adjustment Recalibrations

We have used the three most recent years of MarketScan® data to recalibrate the 2016 and 2017 benefit year risk adjustment models. This approach has allowed for using the blended, or averaged, coefficients from 3 years of separately solved models, which promotes stability for the risk adjustment coefficients year to year, particularly for conditions with small sample sizes. This approach in previous years has also required that we finalize coefficients based on data that does not become available until after the publication of the proposed payment notice. We received several comments to the proposed 2017 Payment Notice requesting that the payment notice schedule be moved up to accommodate substantive comments and to permit issuers more time between the publication of the payment notice and the commencement of issuers' certification activities. In order to accommodate commenters' request for an earlier payment notice schedule, we would not be able to incorporate an

additional recent year of data. We also received many comments on how to best address the data lag for HHS risk adjustment and better reflect new treatments that may be associated with high-cost conditions. We had discussed in the White Paper the use of only 2014 MarketScan® data for the 2018 benefit year recalibration; using blended, 3-year data coefficients would mitigate any introductions of new costs for particular conditions by 2 years of older data. However, commenters to the White Paper supported continuing to use a 3-year blend for 2018 benefit year recalibration. We proposed to continue to use the 3-year blend for 2018 benefit year recalibration.

We noted at our risk adjustment conference on March 31, 2016, that we were considering releasing updated final coefficients using more recent data after the risk adjustment methodology for the corresponding benefit year has been finalized in the applicable annual payment notice, given the potentially earlier timing of the 2018 Notice of Benefit and Payment Parameters. We proposed to amend our regulations at § 153.320(b)(1)(i) to allow for HHS to provide draft coefficients in an annual payment notice, as well as the intended datasets to be used to calculate final coefficients and the date by which the final coefficients will be released in guidance. In the proposed rule, we stated that we were considering using 2015, 2016, and 2017 MarketScan® data for 2018 risk adjustment, publishing the final, blended coefficients in the early spring of 2019, prior to final 2018 benefit year risk adjustment calculations. We have previously finalized an applicable benefit year's risk adjustment methodology, including the final coefficients, prior to rate setting and benefits being provided to members for the applicable benefit year. We sought comment on this proposal.

We also sought comment on the timing of the publication of the final coefficients, providing a few options to reduce the data lag as much as possible. In the first option, we stated in the proposed rule that we could release final coefficients for the 2018 benefit year risk adjustment model in the spring of 2017 that would reflect the incorporation of 2015 MarketScan® data, after it becomes available, blended with 2013 and 2014 MarketScan® data. Alternatively, we stated we could release final coefficients for the 2018 benefit year risk adjustment model in the spring of 2019, prior to the April 30, 2019, data submission deadline for the 2018 benefit year, which would reflect 2015, 2016, and 2017 blended MarketScan® data. We stated we could

also provide interim coefficients in the spring of 2018 using 2014, 2015, and 2016 blended MarketScan® data, in addition to the interim coefficients that would be published in the 2018 Payment Notice final rule using 2013 and 2014 data. As noted above, we would continue to finalize the risk adjustment methodology for the corresponding year through notice and comment in the applicable annual payment notice. In light of the comments received, we will use 2013, 2014, and 2015 MarketScan® data to calculate the risk adjustment coefficients for the 2018 benefit year, which we will release in guidance in the spring of 2017, in time for rate setting for the 2018 benefit year. We note again that a risk adjustment methodology remains in effect for future benefit years until changed in rulemaking (or, in the case of coefficients for a particular risk adjustment model, until changed in guidance).

We note that, in order to provide greater, earlier estimates to issuers regarding their risk adjustment transfers, we intend to continue providing interim estimated risk scores and risk adjustment transfers in the spring of the year after the applicable benefit year, as we did this past spring for the 2015 benefit year. We continue to explore other ways to provide earlier risk adjustment data to issuers.

Comment: Some commenters supported the use of the most recent MarketScan® data. One commenter stated that providing the most recent claims data to calculate coefficients would ensure the risk adjustment model takes into account changes in health care delivery and would prevent gaming by issuers that use risk adjustment factors to selectively target enrollees with certain conditions. Commenters stated that publishing final coefficients in 2019 would encourage issuers to attract a diverse mix of risk. One commenter noted that once actuaries adjust their rating practices and modeling, the results from the most recent data will improve the overall accuracy of the program and stability of the market. Another commenter supported inclusion of the most recent MarketScan® data, but only if there is still sufficient opportunity to comment on the development of the risk adjustment factors, and requested HHS find more current sources of utilization data. Another commenter supported the proposal contingent on whether the preliminary results released in the spring of 2019, are determined using the same published methodology, so that insurers have accurate risk adjustment data for pricing purposes.

However, many commenters strongly disagreed with any approach that prevents issuers from having final factors at the time of rate setting. The commenters noted that fewer unknowns during rate development far outweigh accuracy of new data, and that waiting even until spring of 2018 to finalize the model weights for plan year 2018 will force plans to determine rates with an additional uncertainty, and therefore is likely to result in higher rates. Changes to the risk adjustment coefficients released too late would preclude issuers from accurately reflecting risk adjustment in their pricing. Two commenters noted that a change in 2018 does not make sense if HHS is considering revising the data source for calibration for 2019.

One commenter requested that HHS run previous risk adjustment transfer results with the newly calibrated coefficients relative to the ones that were used to better enable issuers to understand the changes in the coefficients year over year and their effect on transfers.

Another commenter requested that HHS publish clear guidelines for when it will propose changes to the risk adjustment program outside of the formal rulemaking for that year. The ability to make changes outside of rulemaking would enable HHS to keep the risk adjustment program flexible and current, but also could lead to more uncertainty in the risk adjustment program and has the potential to lead to changes implemented before they have time to be properly vetted and assessed by affected parties.

One commenter requested that HHS publish final coefficients no later than February of the year before the benefit year (for example, publish final coefficients by February 2017 for the 2018 benefit year). One commenter also suggested that HHS give greater weight in the blended dataset to the most recent year's data.

One commenter stated that the 3-year blended coefficients do not reflect the

current cost of prescription drugs. Another commenter stated that while the most recent data would improve the model's accuracy, the extent of such improvement is not clear. The commenter also noted that a one-year change on top of already significant changes to the risk adjustment model could create even more uncertainty.

Response: We recognize that many commenters prefer predictability over using the most recent data so that they will be able to use the precise risk adjustment model coefficients in rate setting for the applicable benefit year. We are sensitive to the tradeoff of predictability and the reflection of most recent claims costs, which reflect the most recent patterns and costs of treatments. However, since risk adjustment estimates must be included in rate setting, we understand commenters' desire for stability in the final coefficients over recency (and, unpredictability). Therefore, HHS will release final risk adjustment coefficients in the spring of 2017 for the 2018 benefit year using blended 2013, 2014, and 2015 MarketScan® data. (4) List of factors to be employed in the model (§ 153.320)

For the 2018 benefit year, in addition to the RXCs we proposed to include in the adult risk adjustment model, we also proposed to separate the Chronic Hepatitis HCC into two new HCCs for Hepatitis C and Hepatitis A and B, in the adult, child, and infant models. This would increase the total HCCs in the HHS risk adjustment methodology from 127 to 128. Based on the comments received, we are finalizing this modification as proposed.

Comment: Most commenters supported this proposal. One commenter requested additional information on the data used to make the decision to separate the Hepatitis HCC, and how HHS intends to do this in the future.

Response: Beginning with the 2018 benefit year, we will separate the Chronic Hepatitis HCC into two new

HCCs for Hepatitis C and Hepatitis A and B, in the adult, child, and infant models. We based this decision to separate the Hepatitis HCC on the varying risk for the Chronic Hepatitis types. HHS will continue to assess HCCs in light of new technologies and the risk implications for issuers.

The draft factors resulting from the blended factors from the 2013 and 2014 separately solved models (with the incorporation of partial year enrollment and prescription drugs reflected in the adult models only) are shown in the Tables 3, 5, and 6. The adult, child, and infant models have been truncated to account for the high-cost enrollee pool payment parameters (\$1 million threshold, 60 percent coinsurance). Table 3 contains factors for each adult model, including the interactions.³⁴ Some interactions of RXCs and HCCs have negative coefficients; however, this does not mean that an enrollee's risk score decreases due to the presence of an RxC, an HCC, or both. For example, consider RxC_03 Antiarrhythmics and HCC_142 Specified Heart Arrhythmias, for a silver plan enrollee. If RxC_03 is first coded, the blended risk score increases by 2.167 (coefficient for RxC_03), and if HCC_142 is then coded, the blended risk score increases again by $1.866 + (-0.062) = 1.804$ (coefficient for HCC_142 + coefficient for interaction of RxC_03 and HCC_142), for a combined increase of $2.167 + 1.804 = 3.971$. Similarly, if HCC_142 is first coded, the blended risk score increases by 1.866 (coefficient for HCC_142), and if RxC_03 is then coded, the blended risk score increases again by $2.167 + (-0.062) = 2.105$ (coefficient for RxC_03 + coefficient for interaction of RxC_03 and HCC_142), for a combined increase of $1.866 + 2.105 = 3.971$.

Table 4 contains the HHS HCCs in the severity illness indicator variable. Table 5 contains the factors for each child model. Table 6 contains the factors for each infant model.

TABLE 2—FINAL ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2017 BENEFIT YEAR

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors					
Age 21–24, Male	0.199	0.148	0.092	0.056	0.055
Age 25–29, Male	0.189	0.137	0.080	0.043	0.043
Age 30–34, Male	0.245	0.180	0.107	0.059	0.059
Age 35–39, Male	0.312	0.234	0.147	0.089	0.088
Age 40–44, Male	0.391	0.301	0.199	0.130	0.129
Age 45–49, Male	0.471	0.369	0.253	0.174	0.173

³⁴ We note that the interaction factors are additive, and not hierarchical in nature—that is, an enrollee could have several, additive interactions.

TABLE 2—FINAL ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2017 BENEFIT YEAR—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Age 50–54, Male	0.611	0.492	0.355	0.260	0.258
Age 55–59, Male	0.701	0.567	0.414	0.306	0.304
Age 60–64, Male	0.810	0.654	0.478	0.349	0.347
Age 21–24, Female	0.339	0.262	0.171	0.111	0.110
Age 25–29, Female	0.399	0.308	0.203	0.132	0.130
Age 30–34, Female	0.539	0.428	0.305	0.224	0.222
Age 35–39, Female	0.633	0.513	0.380	0.294	0.292
Age 40–44, Female	0.713	0.579	0.433	0.336	0.335
Age 45–49, Female	0.724	0.585	0.432	0.327	0.325
Age 50–54, Female	0.821	0.671	0.501	0.382	0.379
Age 55–59, Female	0.829	0.672	0.495	0.367	0.364
Age 60–64, Female	0.876	0.706	0.513	0.372	0.370
Diagnosis Factors					
HIV/AIDS	8.943	8.450	8.099	8.142	8.143
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	10.685	10.510	10.404	10.460	10.461
Central Nervous System Infections, Except Viral Meningitis	6.636	6.535	6.470	6.491	6.492
Viral or Unspecified Meningitis	4.664	4.428	4.269	4.227	4.227
Opportunistic Infections	8.507	8.406	8.340	8.322	8.321
Metastatic Cancer	24.307	23.874	23.573	23.632	23.633
Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	12.629	12.295	12.061	12.065	12.066
Non-Hodgkin's Lymphomas and Other Cancers and Tumors	5.852	5.617	5.440	5.393	5.392
Colorectal, Breast (Age < 50), Kidney, and Other Cancers	5.159	4.924	4.743	4.695	4.694
Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors	2.965	2.792	2.655	2.602	2.601
Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors	1.459	1.304	1.167	1.076	1.074
Pancreas Transplant Status/Complications	5.458	5.236	5.093	5.115	5.115
Diabetes with Acute Complications	1.192	1.053	0.929	0.825	0.824
Diabetes with Chronic Complications	1.192	1.053	0.929	0.825	0.824
Diabetes without Complication	1.192	1.053	0.929	0.825	0.824
Protein-Calorie Malnutrition	13.677	13.685	13.695	13.756	13.757
Mucopolysaccharidosis	2.285	2.165	2.066	2.013	2.013
Lipidoses and Glycogenosis	2.285	2.165	2.066	2.013	2.013
Amyloidosis, Porphyria, and Other Metabolic Disorders	2.285	2.165	2.066	2.013	2.013
Adrenal, Pituitary, and Other Significant Endocrine Disorders	2.285	2.165	2.066	2.013	2.013
Liver Transplant Status/Complications	16.044	15.870	15.760	15.773	15.773
End-Stage Liver Disease	7.110	6.870	6.712	6.730	6.731
Cirrhosis of Liver	3.856	3.694	3.572	3.538	3.537
Chronic Hepatitis	3.856	3.694	3.572	3.538	3.537
Acute Liver Failure/Disease, Including Neonatal Hepatitis	4.429	4.268	4.158	4.147	4.147
Intestine Transplant Status/Complications	32.610	32.560	32.521	32.564	32.563
Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	11.825	11.566	11.387	11.416	11.417
Intestinal Obstruction	6.542	6.277	6.105	6.124	6.124
Chronic Pancreatitis	5.458	5.236	5.093	5.115	5.115
Acute Pancreatitis/Other Pancreatic Disorders and Intestinal Malabsorption	2.710	2.522	2.385	2.337	2.336
Inflammatory Bowel Disease	3.667	3.401	3.197	3.105	3.103
Necrotizing Fasciitis	6.581	6.382	6.243	6.258	6.258
Bone/Joint/Muscle Infections/Necrosis	6.581	6.382	6.243	6.258	6.258
Rheumatoid Arthritis and Specified Autoimmune Disorders	4.854	4.592	4.399	4.389	4.389
Systemic Lupus Erythematosus and Other Autoimmune Disorders	1.212	1.077	0.957	0.872	0.871
Osteogenesis Imperfecta and Other Osteodystrophies	3.126	2.927	2.766	2.706	2.705
Congenital/Developmental Skeletal and Connective Tissue Disorders	3.126	2.927	2.766	2.706	2.705
Cleft Lip/Cleft Palate	1.310	1.149	1.020	0.952	0.951
Hemophilia	46.447	46.159	45.940	45.946	45.947
Myelodysplastic Syndromes and Myelofibrosis	12.671	12.534	12.439	12.449	12.449
Aplastic Anemia	12.671	12.534	12.439	12.449	12.449
Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	9.742	9.580	9.457	9.448	9.448
Sickle Cell Anemia (Hb-SS)	9.742	9.580	9.457	9.448	9.448
Thalassemia Major	9.742	9.580	9.457	9.448	9.448
Combined and Other Severe Immunodeficiencies	5.438	5.290	5.186	5.188	5.188

TABLE 2—FINAL ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2017 BENEFIT YEAR—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Disorders of the Immune Mechanism	5.438	5.290	5.186	5.188	5.188
Coagulation Defects and Other Specified Hematological Disorders	2.810	2.712	2.631	2.603	2.603
Drug Psychosis	3.832	3.576	3.381	3.288	3.286
Drug Dependence	3.832	3.576	3.381	3.288	3.286
Schizophrenia	3.196	2.940	2.749	2.685	2.684
Major Depressive and Bipolar Disorders	1.720	1.552	1.408	1.312	1.311
Reactive and Unspecified Psychosis, Delusional Disorders	1.720	1.552	1.408	1.312	1.311
Personality Disorders	1.190	1.054	0.920	0.823	0.822
Anorexia/Bulimia Nervosa	2.704	2.537	2.400	2.342	2.341
Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	2.648	2.517	2.414	2.364	2.364
Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes	1.073	0.965	0.861	0.788	0.787
Autistic Disorder	1.190	1.054	0.920	0.823	0.822
Pervasive Developmental Disorders, Except Autistic Disorder	1.190	1.054	0.920	0.823	0.822
Traumatic Complete Lesion Cervical Spinal Cord	12.012	11.856	11.742	11.739	11.740
Quadriplegia	12.012	11.856	11.742	11.739	11.740
Traumatic Complete Lesion Dorsal Spinal Cord	9.161	9.003	8.889	8.877	8.877
Paraplegia	9.161	9.003	8.889	8.877	8.877
Spinal Cord Disorders/Injuries	5.641	5.430	5.278	5.249	5.249
Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	3.027	2.790	2.623	2.583	2.583
Quadriplegic Cerebral Palsy	1.229	1.016	0.855	0.791	0.790
Cerebral Palsy, Except Quadriplegic	0.135	0.073	0.039	0.016	0.015
Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies	0.077	0.022	0.000	0.000	0.000
Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	5.252	5.104	4.998	4.975	4.975
Muscular Dystrophy	2.150	1.984	1.862	1.787	1.786
Multiple Sclerosis	13.598	13.194	12.910	12.956	12.957
Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders	2.150	1.984	1.862	1.787	1.786
Seizure Disorders and Convulsions	1.503	1.344	1.213	1.143	1.142
Hydrocephalus	6.394	6.272	6.171	6.144	6.144
Non-Traumatic Coma, and Brain Compression/Anoxic Damage	9.200	9.064	8.958	8.953	8.952
Respirator Dependence/Tracheostomy Status	34.709	34.699	34.698	34.764	34.765
Respiratory Arrest	10.541	10.391	10.296	10.360	10.361
Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes	10.541	10.391	10.296	10.360	10.361
Heart Assistive Device/Artificial Heart	35.115	34.870	34.711	34.771	34.772
Heart Transplant	35.115	34.870	34.711	34.771	34.772
Congestive Heart Failure	3.281	3.173	3.096	3.090	3.090
Acute Myocardial Infarction	10.133	9.797	9.582	9.693	9.695
Unstable Angina and Other Acute Ischemic Heart Disease	5.231	4.955	4.782	4.796	4.797
Heart Infection/Inflammation, Except Rheumatic	6.303	6.168	6.068	6.046	6.046
Specified Heart Arrhythmias	2.834	2.685	2.569	2.515	2.515
Intracranial Hemorrhage	9.426	9.147	8.956	8.965	8.965
Ischemic or Unspecified Stroke	3.167	2.982	2.870	2.875	2.876
Cerebral Aneurysm and Arteriovenous Malformation	3.947	3.748	3.605	3.563	3.563
Hemiplegia/Hemiparesis	5.466	5.372	5.315	5.358	5.359
Monoplegia, Other Paralytic Syndromes	3.457	3.324	3.230	3.211	3.211
Atherosclerosis of the Extremities with Ulceration or Gangrene	10.936	10.837	10.782	10.850	10.852
Vascular Disease with Complications	7.731	7.546	7.419	7.419	7.420
Pulmonary Embolism and Deep Vein Thrombosis	3.845	3.678	3.558	3.531	3.531
Lung Transplant Status/Complications	36.420	36.228	36.104	36.181	36.182
Cystic Fibrosis	18.022	17.696	17.452	17.474	17.474
Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	0.951	0.833	0.723	0.648	0.646
Asthma	0.951	0.833	0.723	0.648	0.646
Fibrosis of Lung and Other Lung Disorders	1.894	1.774	1.685	1.644	1.643
Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	7.595	7.521	7.472	7.486	7.486
Kidney Transplant Status	10.187	9.922	9.747	9.738	9.738
End Stage Renal Disease	38.453	38.219	38.071	38.191	38.193
Chronic Kidney Disease, Stage 5	2.087	1.988	1.924	1.919	1.919
Chronic Kidney Disease, Severe (Stage 4)	2.087	1.988	1.924	1.919	1.919
Ectopic and Molar Pregnancy, Except with Renal Failure, Shock, or Embolism	1.357	1.170	0.991	0.806	0.803

TABLE 2—FINAL ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2017 BENEFIT YEAR—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Miscarriage with Complications	1.357	1.170	0.991	0.806	0.803
Miscarriage with No or Minor Complications	1.357	1.170	0.991	0.806	0.803
Completed Pregnancy with Major Complications	3.651	3.168	2.877	2.726	2.727
Completed Pregnancy with Complications	3.651	3.168	2.877	2.726	2.727
Completed Pregnancy with No or Minor Complications	3.651	3.168	2.877	2.726	2.727
Chronic Ulcer of Skin, Except Pressure	2.360	2.236	2.153	2.137	2.137
Hip Fractures and Pathological Vertebral or Humerus Fractures	9.462	9.246	9.102	9.137	9.138
Pathological Fractures, Except of Vertebrae, Hip, or Humerus	2.011	1.880	1.766	1.695	1.694
Stem Cell, Including Bone Marrow, Transplant Status/Complications	31.030	31.024	31.019	31.037	31.037
Artificial Openings for Feeding or Elimination	10.041	9.948	9.888	9.926	9.927
Amputation Status, Lower Limb/Amputation Complications	5.262	5.111	5.014	5.043	5.044

Interaction Factors

Severe illness x Opportunistic Infections	10.392	10.618	10.787	10.882	10.884
Severe illness x Metastatic Cancer	10.392	10.618	10.787	10.882	10.884
Severe illness x Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	10.392	10.618	10.787	10.882	10.884
Severe illness x Non-Hodgkin's Lymphomas and Other Cancers and Tumors	10.392	10.618	10.787	10.882	10.884
Severe illness x Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	10.392	10.618	10.787	10.882	10.884
Severe illness x Heart Infection/Inflammation, Except Rheumatic	10.392	10.618	10.787	10.882	10.884
Severe illness x Intracranial Hemorrhage	10.392	10.618	10.787	10.882	10.884
Severe illness x HCC group G06 (G06 is HCC Group 6 which includes the following HCCs in the blood disease category: 67, 68)	10.392	10.618	10.787	10.882	10.884
Severe illness x HCC group G08 (G08 is HCC Group 8 which includes the following HCCs in the blood disease category: 73, 74)	10.392	10.618	10.787	10.882	10.884
Severe illness x End-Stage Liver Disease	1.899	2.034	2.136	2.220	2.221
Severe illness x Acute Liver Failure/Disease, Including Neonatal Hepatitis	1.899	2.034	2.136	2.220	2.221
Severe illness x Atherosclerosis of the Extremities with Ulceration or Gangrene	1.899	2.034	2.136	2.220	2.221
Severe illness x Vascular Disease with Complications	1.899	2.034	2.136	2.220	2.221
Severe illness x Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	1.899	2.034	2.136	2.220	2.221
Severe illness x Artificial Openings for Feeding or Elimination	1.899	2.034	2.136	2.220	2.221
Severe illness x HCC group G03 (G03 is HCC Group 3 which includes the following HCCs in the musculoskeletal disease category: 54, 55)	1.899	2.034	2.136	2.220	2.221

Enrollment Duration Factors

One month of enrollment	0.515	0.441	0.396	0.386	0.386
Two months of enrollment	0.454	0.381	0.329	0.318	0.318
Three months of enrollment	0.387	0.321	0.270	0.258	0.258
Four months of enrollment	0.316	0.264	0.221	0.211	0.211
Five months of enrollment	0.273	0.228	0.188	0.176	0.176
Six months of enrollment	0.248	0.208	0.170	0.156	0.156
Seven months of enrollment	0.217	0.186	0.155	0.145	0.144
Eight months of enrollment	0.166	0.142	0.118	0.110	0.109
Nine months of enrollment	0.114	0.103	0.092	0.089	0.089
Ten months of enrollment	0.114	0.103	0.092	0.089	0.089
Eleven months of enrollment	0.100	0.092	0.084	0.082	0.082

TABLE 3—DRAFT ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2018 BENEFIT YEAR

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors						
	Age 21–24, Male	0.177	0.139	0.094	0.052	0.045
	Age 25–29, Male	0.161	0.123	0.079	0.035	0.028

TABLE 3—DRAFT ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2018 BENEFIT YEAR—Continued

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
	Age 30–34, Male	0.208	0.160	0.104	0.049	0.040
	Age 35–39, Male	0.272	0.214	0.147	0.080	0.068
	Age 40–44, Male	0.340	0.273	0.195	0.116	0.102
	Age 45–49, Male	0.413	0.337	0.249	0.158	0.142
	Age 50–54, Male	0.539	0.449	0.347	0.238	0.218
	Age 55–59, Male	0.616	0.514	0.400	0.277	0.256
	Age 60–64, Male	0.714	0.595	0.465	0.321	0.295
	Age 21–24, Female	0.305	0.248	0.177	0.107	0.094
	Age 25–29, Female	0.354	0.287	0.206	0.124	0.110
	Age 30–34, Female	0.488	0.405	0.310	0.216	0.200
	Age 35–39, Female	0.577	0.484	0.383	0.283	0.266
	Age 40–44, Female	0.649	0.546	0.435	0.323	0.303
	Age 45–49, Female	0.657	0.551	0.434	0.313	0.292
	Age 50–54, Female	0.745	0.630	0.502	0.366	0.341
	Age 55–59, Female	0.750	0.630	0.497	0.352	0.326
	Age 60–64, Female	0.791	0.659	0.517	0.358	0.329
Diagnosis Factors						
HCC001	HIV/AIDS	6.235	5.807	5.521	5.516	5.522
HCC002	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock.	9.383	9.212	9.114	9.160	9.174
HCC003	Central Nervous System Infections, Except Viral Meningitis.	6.370	6.277	6.220	6.241	6.247
HCC004	Viral or Unspecified Meningitis	4.473	4.254	4.130	4.074	4.071
HCC006	Opportunistic Infections	6.789	6.696	6.645	6.621	6.616
HCC008	Metastatic Cancer	22.838	22.426	22.159	22.199	22.211
HCC009	Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia.	11.917	11.605	11.406	11.395	11.396
HCC010	Non-Hodgkin's Lymphomas and Other Cancers and Tumors.	5.534	5.319	5.179	5.120	5.110
HCC011	Colorectal, Breast (Age <50), Kidney, and Other Cancers.	4.815	4.600	4.456	4.394	4.383
HCC012	Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors.	2.802	2.646	2.540	2.476	2.465
HCC013	Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors.	1.341	1.207	1.109	1.006	0.986
HCC018	Pancreas Transplant Status/Complications.	4.794	4.593	4.477	4.492	4.501
HCC019	Diabetes with Acute Complications	0.653	0.580	0.514	0.436	0.421
HCC020	Diabetes with Chronic Complications	0.653	0.580	0.514	0.436	0.421
HCC021	Diabetes without Complication	0.653	0.580	0.514	0.436	0.421
HCC023	Protein-Calorie Malnutrition	12.580	12.578	12.571	12.634	12.646
HCC026	Mucopolysaccharidosis	2.029	1.924	1.850	1.788	1.777
HCC027	Lipidoses and Glycogenosis	2.029	1.924	1.850	1.788	1.777
HCC029	Amyloidosis, Porphyria, and Other Metabolic Disorders.	2.029	1.924	1.850	1.788	1.777
HCC030	Adrenal, Pituitary, and Other Significant Endocrine Disorders.	2.029	1.924	1.850	1.788	1.777
HCC034	Liver Transplant Status/Complications	11.397	11.276	11.208	11.197	11.197
HCC035	End-Stage Liver Disease	3.867	3.685	3.578	3.554	3.553
HCC036	Cirrhosis of Liver	1.349	1.227	1.151	1.099	1.090
HCC037C	Chronic Viral Hepatitis C	0.927	0.815	0.739	0.681	0.670
HCC037B	Chronic Hepatitis, Other/Unspecified	0.927	0.815	0.739	0.681	0.670
HCC038	Acute Liver Failure/Disease, Including Neonatal Hepatitis.	3.867	3.685	3.578	3.554	3.553
HCC041	Intestine Transplant Status/Complications	25.865	25.802	25.746	25.800	25.809
HCC042	Peritonitis/Gastrointestinal Perforation/ Necrotizing Enterocolitis.	10.587	10.344	10.191	10.203	10.210
HCC045	Intestinal Obstruction	6.035	5.786	5.642	5.641	5.645
HCC046	Chronic Pancreatitis	4.794	4.593	4.477	4.492	4.501
HCC047	Acute Pancreatitis/Other Pancreatic Disorders and Intestinal Malabsorption.	2.435	2.269	2.165	2.106	2.096
HCC048	Inflammatory Bowel Disease	2.071	1.894	1.772	1.677	1.660
HCC054	Necrotizing Fasciitis	6.018	5.837	5.720	5.726	5.729
HCC055	Bone/Joint/Muscle Infections/Necrosis	6.018	5.837	5.720	5.726	5.729
HCC056	Rheumatoid Arthritis and Specified Auto-immune Disorders.	2.291	2.147	2.045	1.980	1.968

TABLE 3—DRAFT ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2018 BENEFIT YEAR—Continued

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC057	Systemic Lupus Erythematosus and Other Autoimmune Disorders.	1.038	0.924	0.840	0.743	0.725
HCC061	Osteogenesis Imperfecta and Other Osteodystrophies.	2.907	2.726	2.599	2.526	2.513
HCC062	Congenital/Developmental Skeletal and Connective Tissue Disorders.	2.907	2.726	2.599	2.526	2.513
HCC063	Cleft Lip/Cleft Palate	1.167	1.024	0.929	0.850	0.837
HCC066	Hemophilia	39.609	39.350	39.166	39.159	39.162
HCC067	Myelodysplastic Syndromes and Myelofibrosis.	11.869	11.741	11.660	11.665	11.668
HCC068	Aplastic Anemia	11.869	11.741	11.660	11.665	11.668
HCC069	Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn.	8.427	8.278	8.177	8.155	8.153
HCC070	Sickle Cell Anemia (Hb-SS)	8.427	8.278	8.177	8.155	8.153
HCC071	Thalassemia Major	8.427	8.278	8.177	8.155	8.153
HCC073	Combined and Other Severe Immunodeficiencies.	4.892	4.758	4.675	4.667	4.667
HCC074	Disorders of the Immune Mechanism	4.892	4.758	4.675	4.667	4.667
HCC075	Coagulation Defects and Other Specified Hematological Disorders.	2.529	2.440	2.376	2.340	2.333
HCC081	Drug Psychosis	3.781	3.546	3.395	3.284	3.264
HCC082	Drug Dependence	3.781	3.546	3.395	3.284	3.264
HCC087	Schizophrenia	3.128	2.892	2.742	2.660	2.650
HCC088	Major Depressive and Bipolar Disorders	1.641	1.493	1.388	1.283	1.263
HCC089	Reactive and Unspecified Psychosis, Delusional Disorders.	1.641	1.493	1.388	1.283	1.263
HCC090	Personality Disorders	1.148	1.031	0.932	0.823	0.803
HCC094	Anorexia/Bulimia Nervosa	2.744	2.588	2.481	2.417	2.405
HCC096	Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes.	2.458	2.338	2.257	2.195	2.184
HCC097	Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes.	0.830	0.734	0.657	0.573	0.557
HCC102	Autistic Disorder	1.148	1.031	0.932	0.823	0.803
HCC103	Pervasive Developmental Disorders, Except Autistic Disorder.	1.148	1.031	0.932	0.823	0.803
HCC106	Traumatic Complete Lesion Cervical Spinal Cord.	11.049	10.893	10.791	10.778	10.778
HCC107	Quadriplegia	11.049	10.893	10.791	10.778	10.778
HCC108	Traumatic Complete Lesion Dorsal Spinal Cord.	8.671	8.523	8.427	8.408	8.406
HCC109	Paraplegia	8.671	8.523	8.427	8.408	8.406
HCC110	Spinal Cord Disorders/Injuries	5.532	5.332	5.208	5.169	5.164
HCC111	Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease.	2.668	2.450	2.316	2.260	2.251
HCC112	Quadriplegic Cerebral Palsy	1.080	0.938	0.840	0.764	0.749
HCC113	Cerebral Palsy, Except Quadriplegic	0.192	0.134	0.092	0.053	0.046
HCC114	Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies.	0.060	0.001	0.000	0.000	0.000
HCC115	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy.	5.157	5.017	4.930	4.902	4.898
HCC117	Muscular Dystrophy	2.107	1.957	1.867	1.781	1.764
HCC118	Multiple Sclerosis	3.689	3.494	3.369	3.302	3.290
HCC119	Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders.	2.107	1.957	1.867	1.781	1.764
HCC120	Seizure Disorders and Convulsions	1.452	1.310	1.212	1.130	1.115
HCC121	Hydrocephalus	5.899	5.789	5.703	5.670	5.664
HCC122	Non-Traumatic Coma, and Brain Compression/Anoxic Damage.	8.620	8.493	8.401	8.391	8.389
HCC125	Respirator Dependence/Tracheostomy Status.	30.475	30.454	30.436	30.506	30.519
HCC126	Respiratory Arrest	9.375	9.232	9.141	9.195	9.209
HCC127	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes.	9.375	9.232	9.141	9.195	9.209
HCC128	Heart Assistive Device/Artificial Heart	29.127	28.909	28.771	28.795	28.804
HCC129	Heart Transplant	29.127	28.909	28.771	28.795	28.804
HCC130	Congestive Heart Failure	2.083	1.986	1.920	1.881	1.874
HCC131	Acute Myocardial Infarction	9.478	9.159	8.960	9.055	9.080

TABLE 3—DRAFT ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2018 BENEFIT YEAR—Continued

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC132	Unstable Angina and Other Acute Ischemic Heart Disease.	4.795	4.543	4.402	4.400	4.405
HCC135	Heart Infection/Inflammation, Except Rheumatic.	5.529	5.410	5.332	5.302	5.296
HCC142	Specified Heart Arrhythmias	2.066	1.947	1.866	1.801	1.789
HCC145	Intracranial Hemorrhage	8.635	8.374	8.215	8.204	8.206
HCC146	Ischemic or Unspecified Stroke	2.923	2.754	2.664	2.659	2.663
HCC149	Cerebral Aneurysm and Arteriovenous Malformation.	3.711	3.533	3.423	3.368	3.358
HCC150	Hemiplegia/Hemiparesis	5.032	4.940	4.885	4.924	4.933
HCC151	Monoplegia, Other Paralytic Syndromes	3.175	3.053	2.978	2.951	2.948
HCC153	Atherosclerosis of the Extremities with Ulceration or Gangrene.	9.389	9.311	9.262	9.334	9.351
HCC154	Vascular Disease with Complications	7.107	6.934	6.827	6.815	6.816
HCC156	Pulmonary Embolism and Deep Vein Thrombosis.	3.490	3.338	3.244	3.203	3.197
HCC158	Lung Transplant Status/Complications	28.437	28.278	28.176	28.253	28.273
HCC159	Cystic Fibrosis	7.180	6.909	6.724	6.702	6.702
HCC160	Chronic Obstructive Pulmonary Disease, Including Bronchiectasis.	0.912	0.811	0.731	0.645	0.629
HCC161	Asthma	0.912	0.811	0.731	0.645	0.629
HCC162	Fibrosis of Lung and Other Lung Disorders.	1.756	1.648	1.580	1.532	1.522
HCC163	Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections.	6.476	6.409	6.367	6.375	6.378
HCC183	Kidney Transplant Status	6.985	6.756	6.622	6.592	6.590
HCC184	End Stage Renal Disease	23.091	22.895	22.769	22.834	22.850
HCC187	Chronic Kidney Disease, Stage 5	0.407	0.338	0.298	0.292	0.293
HCC188	Chronic Kidney Disease, Severe (Stage 4).	0.407	0.338	0.298	0.292	0.293
HCC203	Ectopic and Molar Pregnancy, Except with Renal Failure, Shock, or Embolism.	1.293	1.135	1.012	0.822	0.778
HCC204	Miscarriage with Complications	1.293	1.135	1.012	0.822	0.778
HCC205	Miscarriage with No or Minor Complications.	1.293	1.135	1.012	0.822	0.778
HCC207	Completed Pregnancy With Major Complications.	3.490	3.045	2.837	2.643	2.632
HCC208	Completed Pregnancy With Complications.	3.490	3.045	2.837	2.643	2.632
HCC209	Completed Pregnancy with No or Minor Complications.	3.490	3.045	2.837	2.643	2.632
HCC217	Chronic Ulcer of Skin, Except Pressure ..	2.013	1.911	1.851	1.833	1.832
HCC226	Hip Fractures and Pathological Vertebral or Humerus Fractures.	9.065	8.860	8.731	8.757	8.765
HCC227	Pathological Fractures, Except of Vertebrae, Hip, or Humerus.	2.062	1.945	1.860	1.782	1.768
HCC251	Stem Cell, Including Bone Marrow, Transplant Status/Complications.	26.861	26.861	26.858	26.884	26.889
HCC253	Artificial Openings for Feeding or Elimination.	9.024	8.933	8.876	8.907	8.915
HCC254	Amputation Status, Lower Limb/Amputation Complications.	4.537	4.406	4.327	4.351	4.360
Interaction Factors						
SEVERE x HCC006	Severe illness x Opportunistic Infections	9.192	9.391	9.511	9.626	9.645
SEVERE x HCC008	Severe illness x Metastatic Cancer	9.192	9.391	9.511	9.626	9.645
SEVERE x HCC009	Severe illness x Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia.	9.192	9.391	9.511	9.626	9.645
SEVERE x HCC010	Severe illness x Non-Hodgkin's Lymphomas and Other Cancers and Tumors.	9.192	9.391	9.511	9.626	9.645
SEVERE x HCC115	Severe illness x Myasthenia Gravis/ Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy.	9.192	9.391	9.511	9.626	9.645
SEVERE x HCC135	Severe illness x Heart Infection/Inflammation, Except Rheumatic.	9.192	9.391	9.511	9.626	9.645
SEVERE x HCC145	Severe illness x Intracranial Hemorrhage	9.192	9.391	9.511	9.626	9.645

TABLE 3—DRAFT ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2018 BENEFIT YEAR—Continued

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
SEVERE x G06	Severe illness x HCC group G06 (G06 is HCC Group 6 which includes the following HCCs in the blood disease category: 67, 68).	9.192	9.391	9.511	9.626	9.645
SEVERE x G08	Severe illness x HCC group G08 (G08 is HCC Group 8 which includes the following HCCs in the blood disease category: 73, 74).	9.192	9.391	9.511	9.626	9.645
SEVERE x HCC035	Severe illness x End-Stage Liver Disease.	2.104	2.217	2.283	2.381	2.397
SEVERE x HCC038	Severe illness x Acute Liver Failure/Disease, Including Neonatal Hepatitis.	2.104	2.217	2.283	2.381	2.397
SEVERE x HCC153	Severe illness x Atherosclerosis of the Extremities with Ulceration or Gangrene.	2.104	2.217	2.283	2.381	2.397
SEVERE x HCC154	Severe illness x Vascular Disease with Complications.	2.104	2.217	2.283	2.381	2.397
SEVERE x HCC163	Severe illness x Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections.	2.104	2.217	2.283	2.381	2.397
SEVERE x HCC253	Severe illness x Artificial Openings for Feeding or Elimination.	2.104	2.217	2.283	2.381	2.397
SEVERE x G03	Severe illness x HCC group G03 (G03 is HCC Group 3 which includes the following HCCs in the musculoskeletal disease category: 54, 55).	2.104	2.217	2.283	2.381	2.397

Enrollment Duration Factors

	One month of enrollment	0.525	0.467	0.425	0.410	0.409
	Two months of enrollment	0.436	0.380	0.334	0.318	0.317
	Three months of enrollment	0.389	0.337	0.292	0.272	0.270
	Four months of enrollment	0.304	0.265	0.227	0.210	0.209
	Five months of enrollment	0.266	0.231	0.196	0.178	0.176
	Six months of enrollment	0.242	0.211	0.180	0.163	0.162
	Seven months of enrollment	0.215	0.190	0.162	0.147	0.145
	Eight months of enrollment	0.166	0.147	0.127	0.116	0.114
	Nine months of enrollment	0.112	0.101	0.089	0.085	0.084
	Ten months of enrollment	0.106	0.097	0.089	0.085	0.084
	Eleven months of enrollment	0.089	0.084	0.079	0.077	0.077
RXC 01	Anti-Hepatitis C (HCV) Agents	24.047	23.595	23.306	23.380	23.398
RXC 02	Anti-HIV Agents	6.347	5.898	5.602	5.441	5.416
RXC 03	Antiarrhythmics	2.340	2.244	2.167	2.098	2.083
RXC 04	Phosphate Binders	12.989	12.879	12.808	12.820	12.826
RXC 05	Inflammatory Bowel Disease Agents	1.960	1.790	1.673	1.509	1.476
RXC 06b	Insulin	1.381	1.257	1.130	0.975	0.943
RXC 06a	Anti-Diabetic Agents, Except Insulin and Metformin Only.	0.578	0.503	0.428	0.327	0.306
RXC 07	Multiple Sclerosis Agents	17.082	16.387	15.941	15.936	15.940
RXC 08	Immune Suppressants and Immunomodulators.	10.202	9.647	9.297	9.303	9.317
RXC 09	Cystic Fibrosis Agents	18.095	17.782	17.584	17.721	17.752
RXC 01 x HCC37C, 036, 035, 034 ...	Additional effect for enrollees with RXC Anti-Hepatitis C (HCV) Agents and HCC (Liver Transplant Status/Complications or End-Stage Liver Disease or Cirrhosis of Liver or Chronic Viral Hepatitis).	3.237	3.376	3.468	3.549	3.565
RXC 02 x HCC001	Additional effect for enrollees with RXC Anti-HIV Agents and HCC HIV/AIDS.	−2.233	−1.878	−1.632	−1.427	−1.393
RXC 03 x HCC142	Additional effect for enrollees with RXC Antiarrhythmics and HCC Specified Heart Arrhythmias.	−0.131	−0.104	−0.062	0.010	0.024
RXC 04 x HCC184, 183, 187, 188 ...	Additional effect for enrollees with RXC Phosphate Binders and HCC (End Stage Renal Disease or Kidney Transplant Status or Chronic Kidney Disease, Stage 5 or Chronic Kidney Disease, Severe (Stage 4)).	8.069	8.146	8.187	8.273	8.285

TABLE 3—DRAFT ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2018 BENEFIT YEAR—Continued

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
RXC 05 x HCC048, 041	Additional effect for enrollees with RXC Inflammatory Bowel Disease Agents and (HCC Inflammatory Bowel Disease or Intestine Transplant Status/Complications).	− 1.265	− 1.176	− 1.092	− 0.997	− 0.978
RXC 06b x HCC018, 019, 020, 021	Additional effect for enrollees with RXC Insulin and (HCC Pancreas Transplant Status/Complications or Diabetes with Acute Complications or Diabetes with Chronic Complications or Diabetes without Complication).	0.283	0.254	0.310	0.390	0.406
RXC 06a x HCC018, 019, 020, 021	Additional effect for enrollees with RXC Anti-Diabetic Agents, Except Insulin and Metformin Only and (HCC Pancreas Transplant Status/Complications or Diabetes with Acute Complications or Diabetes with Chronic Complications or Diabetes without Complication).	− 0.205	− 0.184	− 0.141	− 0.119	− 0.117
RXC 07 x HCC118	Additional effect for enrollees with RXC Multiple Sclerosis Agents and HCC Multiple Sclerosis.	− 1.231	− 0.862	− 0.629	− 0.462	− 0.430
RXC 08 x HCC056 or 057, and 048 or 041.	Additional effect for enrollees with RXC Immune Suppressants and Immunomodulators and (HCC Inflammatory Bowel Disease or Intestine Transplant Status/Complications) and (HCC Rheumatoid Arthritis and Specified Autoimmune Disorders or Systemic Lupus Erythematosus and Other Autoimmune Disorders).	− 0.001	− 0.006	0.008	− 0.018	− 0.020
RXC 08 x HCC056	Additional effect for enrollees with RXC Immune Suppressants and Immunomodulators and HCC Rheumatoid Arthritis and Specified Autoimmune Disorders.	− 1.947	− 1.756	− 1.623	− 1.491	− 1.470
RXC 08 x HCC057	Additional effect for enrollees with RXC Immune Suppressants and Immunomodulators and HCC Systemic Lupus Erythematosus and Other Autoimmune Disorders.	− 0.902	− 0.774	− 0.668	− 0.536	− 0.513
RXC 08 x HCC048, 041	Additional effect for enrollees with RXC Immune Suppressants and Immunomodulators and (HCC Inflammatory Bowel Disease or Intestine Transplant Status/Complications).	0.969	1.219	1.359	1.538	1.567
RXC 09 x HCC159, 158	Additional effect for enrollees with RXC Cystic Fibrosis Agents and (HCC Cystic Fibrosis or Lung Transplant Status/Complications).	17.041	17.236	17.344	17.321	17.312
RXC 10 x HCC036, 035, 034	Additional effect for enrollees with RXC Ammonia Detoxicants and (HCC Liver Transplant Status/Complications or End-Stage Liver Disease or Cirrhosis of Liver).	6.937	6.904	6.880	6.969	6.988
RXC 11 x HCC130, 129, 128	Additional effect for enrollees with RXC Diuretics, Loop and Select Potassium-sparing and (HCC Heart Assistive Device/Artificial Heart or Heart Transplant or Congestive Heart Failure).	2.288	2.296	2.312	2.395	2.412

TABLE 4—HHS HCCs IN THE SEVERITY ILLNESS INDICATOR VARIABLE

Description
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock
Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis
Seizure Disorders and Convulsions
Non-Traumatic Coma, Brain Compression/Anoxic Damage
Respirator Dependence/Tracheostomy Status
Respiratory Arrest

TABLE 4—HHS HCCS IN THE SEVERITY ILLNESS INDICATOR VARIABLE—Continued

Description
Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes
Pulmonary Embolism and Deep Vein Thrombosis

TABLE 5—DRAFT CHILD RISK ADJUSTMENT MODEL FACTORS FOR 2018 BENEFIT YEAR

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors					
Age 2–4, Male	0.212	0.153	0.087	0.033	0.023
Age 5–9, Male	0.147	0.104	0.054	0.014	0.008
Age 10–14, Male	0.208	0.162	0.104	0.060	0.053
Age 15–20, Male	0.277	0.223	0.161	0.106	0.097
Age 2–4, Female	0.167	0.116	0.060	0.019	0.012
Age 5–9, Female	0.120	0.082	0.041	0.010	0.006
Age 10–14, Female	0.196	0.152	0.100	0.062	0.056
Age 15–20, Female	0.316	0.254	0.182	0.114	0.103
Diagnosis Factors					
HIV/AIDS	4.800	4.385	4.113	4.004	3.988
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/ Shock	13.903	13.745	13.654	13.669	13.677
Central Nervous System Infections, Except Viral Meningitis	9.476	9.308	9.201	9.199	9.200
Viral or Unspecified Meningitis	2.562	2.377	2.265	2.168	2.155
Opportunistic Infections	17.772	17.708	17.666	17.654	17.652
Metastatic Cancer	30.910	30.686	30.519	30.503	30.502
Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	10.927	10.674	10.490	10.418	10.407
Non-Hodgkin's Lymphomas and Other Cancers and Tumors	8.816	8.573	8.397	8.296	8.280
Colorectal, Breast (Age < 50), Kidney, and Other Cancers	3.249	3.057	2.915	2.796	2.774
Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tu- mors, and Other Cancers and Tumors	2.874	2.699	2.570	2.457	2.436
Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors	1.540	1.398	1.284	1.166	1.143
Pancreas Transplant Status/Complications	22.703	22.580	22.508	22.512	22.514
Diabetes with Acute Complications	2.327	2.036	1.864	1.604	1.554
Diabetes with Chronic Complications	2.327	2.036	1.864	1.604	1.554
Diabetes without Complication	2.327	2.036	1.864	1.604	1.554
Protein-Calorie Malnutrition	11.735	11.655	11.595	11.624	11.630
Mucopolysaccharidosis	8.061	7.812	7.632	7.583	7.576
Lipidoses and Glycogenosis	8.061	7.812	7.632	7.583	7.576
Congenital Metabolic Disorders, Not Elsewhere Classified	8.061	7.812	7.632	7.583	7.576
Amyloidosis, Porphyria, and Other Metabolic Disorders	8.061	7.812	7.632	7.583	7.576
Adrenal, Pituitary, and Other Significant Endocrine Disorders	8.061	7.812	7.632	7.583	7.576
Liver Transplant Status/Complications	22.703	22.580	22.508	22.512	22.514
End-Stage Liver Disease	10.859	10.717	10.633	10.630	10.631
Cirrhosis of Liver	8.352	8.213	8.110	8.066	8.058
Chronic Viral Hepatitis C	4.120	3.983	3.879	3.824	3.814
Chronic Hepatitis, Other/Unspecified	2.054	1.932	1.829	1.747	1.731
Acute Liver Failure/Disease, Including Neonatal Hepatitis	10.859	10.717	10.624	10.611	10.611
Intestine Transplant Status/Complications	22.703	22.580	22.508	22.512	22.514
Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	13.110	12.802	12.595	12.593	12.597
Intestinal Obstruction	4.707	4.497	4.350	4.253	4.236
Chronic Pancreatitis	9.112	8.902	8.776	8.765	8.766
Acute Pancreatitis/Other Pancreatic Disorders and Intestinal Mal- absorption	2.136	2.022	1.933	1.837	1.819
Inflammatory Bowel Disease	6.142	5.791	5.556	5.440	5.420
Necrotizing Fasciitis	4.093	3.884	3.736	3.663	3.652
Bone/Joint/Muscle Infections/Necrosis	4.093	3.884	3.736	3.663	3.652
Rheumatoid Arthritis and Specified Autoimmune Disorders	3.806	3.585	3.416	3.315	3.299
Systemic Lupus Erythematosus and Other Autoimmune Disorders	1.381	1.259	1.152	1.034	1.010
Osteogenesis Imperfecta and Other Osteodystrophies	1.517	1.404	1.309	1.227	1.212
Congenital/Developmental Skeletal and Connective Tissue Disorders ..	1.517	1.404	1.309	1.227	1.212
Cleft Lip/Cleft Palate	1.540	1.357	1.225	1.100	1.078
Hemophilia	53.113	52.658	52.343	52.302	52.298
Myelodysplastic Syndromes and Myelofibrosis	15.139	14.983	14.876	14.854	14.850
Aplastic Anemia	15.139	14.983	14.876	14.854	14.850
Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	7.221	6.970	6.796	6.707	6.693
Sickle Cell Anemia (Hb-SS)	7.221	6.970	6.796	6.707	6.693
Thalassemia Major	7.221	6.970	6.796	6.707	6.693

TABLE 5—DRAFT CHILD RISK ADJUSTMENT MODEL FACTORS FOR 2018 BENEFIT YEAR—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Combined and Other Severe Immunodeficiencies	6.066	5.904	5.793	5.728	5.716
Disorders of the Immune Mechanism	6.066	5.904	5.793	5.728	5.716
Coagulation Defects and Other Specified Hematological Disorders	4.317	4.196	4.100	4.026	4.012
Drug Psychosis	5.265	5.029	4.880	4.805	4.795
Drug Dependence	5.265	5.029	4.880	4.805	4.795
Schizophrenia	5.132	4.770	4.535	4.420	4.404
Major Depressive and Bipolar Disorders	1.889	1.689	1.536	1.363	1.331
Reactive and Unspecified Psychosis, Delusional Disorders	1.889	1.689	1.536	1.363	1.331
Personality Disorders	0.731	0.623	0.517	0.377	0.352
Anorexia/Bulimia Nervosa	2.978	2.791	2.658	2.587	2.575
Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	3.589	3.400	3.289	3.249	3.242
Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Con- genital Malformation Syndromes	1.786	1.624	1.515	1.424	1.409
Autistic Disorder	1.680	1.518	1.385	1.230	1.201
Pervasive Developmental Disorders, Except Autistic Disorder	0.833	0.721	0.604	0.442	0.411
Traumatic Complete Lesion Cervical Spinal Cord	11.881	11.786	11.732	11.789	11.801
Quadriplegia	11.881	11.786	11.732	11.789	11.801
Traumatic Complete Lesion Dorsal Spinal Cord	11.881	11.786	11.725	11.746	11.752
Paraplegia	11.881	11.786	11.725	11.746	11.752
Spinal Cord Disorders/Injuries	4.351	4.142	4.003	3.914	3.898
Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease ...	8.196	7.981	7.831	7.770	7.760
Quadriplegic Cerebral Palsy	3.417	3.193	3.065	3.070	3.076
Cerebral Palsy, Except Quadriplegic	0.942	0.779	0.674	0.584	0.568
Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies	1.375	1.244	1.151	1.074	1.060
Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/ Inflammatory and Toxic Neuropathy	8.375	8.216	8.105	8.066	8.062
Muscular Dystrophy	2.984	2.806	2.690	2.603	2.589
Multiple Sclerosis	7.910	7.607	7.400	7.343	7.335
Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders	2.984	2.806	2.690	2.603	2.589
Seizure Disorders and Convulsions	1.926	1.770	1.643	1.501	1.475
Hydrocephalus	4.467	4.354	4.282	4.263	4.262
Non-Traumatic Coma, and Brain Compression/Anoxic Damage	6.453	6.327	6.239	6.191	6.181
Respirator Dependence/Tracheostomy Status	32.315	32.208	32.148	32.261	32.283
Respiratory Arrest	11.360	11.164	11.050	11.040	11.042
Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes	11.360	11.164	11.050	11.040	11.042
Heart Assistive Device/Artificial Heart	22.703	22.580	22.508	22.512	22.514
Heart Transplant	22.703	22.580	22.508	22.512	22.514
Congestive Heart Failure	6.223	6.125	6.047	5.996	5.986
Acute Myocardial Infarction	6.605	6.446	6.346	6.347	6.344
Unstable Angina and Other Acute Ischemic Heart Disease	4.221	4.140	4.087	4.096	4.095
Heart Infection/Inflammation, Except Rheumatic	12.729	12.616	12.541	12.513	12.506
Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders	5.537	5.354	5.200	5.075	5.051
Major Congenital Heart/Circulatory Disorders	1.605	1.503	1.388	1.269	1.248
Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders	1.097	1.007	0.903	0.806	0.791
Specified Heart Arrhythmias	3.612	3.450	3.325	3.244	3.231
Intracranial Hemorrhage	13.701	13.470	13.325	13.306	13.306
Ischemic or Unspecified Stroke	7.162	7.052	6.988	6.988	6.988
Cerebral Aneurysm and Arteriovenous Malformation	3.683	3.492	3.370	3.309	3.296
Hemiplegia/Hemiparesis	4.315	4.218	4.161	4.142	4.142
Monoplegia, Other Paralytic Syndromes	2.928	2.794	2.713	2.674	2.670
Atherosclerosis of the Extremities with Ulceration or Gangrene	12.281	12.023	11.868	11.776	11.769
Vascular Disease with Complications	14.433	14.288	14.193	14.195	14.196
Pulmonary Embolism and Deep Vein Thrombosis	13.113	12.971	12.885	12.897	12.903
Lung Transplant Status/Complications	22.703	22.580	22.508	22.512	22.514
Cystic Fibrosis	19.566	19.152	18.864	18.886	18.897
Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	0.406	0.341	0.255	0.161	0.145
Asthma	0.406	0.341	0.255	0.161	0.145
Fibrosis of Lung and Other Lung Disorders	3.944	3.817	3.717	3.645	3.634
Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	9.576	9.531	9.499	9.525	9.530
Kidney Transplant Status	14.807	14.499	14.304	14.289	14.290
End Stage Renal Disease	35.188	35.032	34.934	35.002	35.014
Chronic Kidney Disease, Stage 5	2.921	2.783	2.680	2.565	2.542
Chronic Kidney Disease, Severe (Stage 4)	2.921	2.783	2.680	2.565	2.542
Ectopic and Molar Pregnancy, Except with Renal Failure, Shock, or Embolism	1.061	0.903	0.776	0.575	0.533
Miscarriage with Complications	1.061	0.903	0.776	0.575	0.533

TABLE 5—DRAFT CHILD RISK ADJUSTMENT MODEL FACTORS FOR 2018 BENEFIT YEAR—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Miscarriage with No or Minor Complications	1.061	0.903	0.776	0.575	0.533
Completed Pregnancy With Major Complications	3.029	2.620	2.419	2.194	2.171
Completed Pregnancy With Complications	3.029	2.620	2.419	2.194	2.171
Completed Pregnancy with No or Minor Complications	3.029	2.620	2.419	2.194	2.171
Chronic Ulcer of Skin, Except Pressure	1.955	1.866	1.784	1.717	1.705
Hip Fractures and Pathological Vertebral or Humerus Fractures	5.656	5.408	5.224	5.116	5.096
Pathological Fractures, Except of Vertebrae, Hip, or Humerus	1.397	1.276	1.157	1.026	1.000
Stem Cell, Including Bone Marrow, Transplant Status/Complications	22.703	22.580	22.508	22.512	22.514
Artificial Openings for Feeding or Elimination	12.969	12.866	12.816	12.920	12.941
Amputation Status, Lower Limb/Amputation Complications	7.644	7.390	7.240	7.140	7.125

TABLE 6—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 7—HHS HCCs INCLUDED IN INFANT MODEL SEVERITY CATEGORIES

Severity Category	HCC
Severity Level 5 (Highest)	Metastatic Cancer
Severity Level 5	Pancreas Transplant Status/Complications
Severity Level 5	Liver Transplant Status/Complications
Severity Level 5	End-Stage Liver Disease
Severity Level 5	Intestine Transplant Status/Complications
Severity Level 5	Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis
Severity Level 5	Respirator Dependence/Tracheostomy Status
Severity Level 5	Heart Assistive Device/Artificial Heart
Severity Level 5	Heart Transplant
Severity Level 5	Congestive Heart Failure
Severity Level 5	Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders
Severity Level 5	Lung Transplant Status/Complications
Severity Level 5	Kidney Transplant Status
Severity Level 5	End Stage Renal Disease
Severity Level 5	Stem Cell, Including Bone Marrow, Transplant Status/Complications
Severity Level 4	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/ Shock
Severity Level 4	Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia
Severity Level 4	Mucopolysaccharidosis
Severity Level 4	Major Congenital Anomalies of Diaphragm, Abdominal Wall, and Esophagus, Age < 2
Severity Level 4	Myelodysplastic Syndromes and Myelofibrosis
Severity Level 4	Aplastic Anemia
Severity Level 4	Combined and Other Severe Immunodeficiencies
Severity Level 4	Traumatic Complete Lesion Cervical Spinal Cord
Severity Level 4	Quadriplegia
Severity Level 4	Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease
Severity Level 4	Quadriplegic Cerebral Palsy
Severity Level 4	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/ Inflammatory and Toxic Neuropathy
Severity Level 4	Non-Traumatic Coma, Brain Compression/Anoxic Damage
Severity Level 4	Respiratory Arrest
Severity Level 4	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes
Severity Level 4	Acute Myocardial Infarction
Severity Level 4	Heart Infection/Inflammation, Except Rheumatic
Severity Level 4	Major Congenital Heart/Circulatory Disorders

TABLE 7—HHS HCCs INCLUDED IN INFANT MODEL SEVERITY CATEGORIES—Continued

Severity Category	HCC
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
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

TABLE 7—HHS HCCs INCLUDED IN INFANT MODEL SEVERITY CATEGORIES—Continued

Severity Category	HCC
Severity Level 2	Chronic Ulcer of Skin, Except Pressure
Severity Level 1	Chronic Hepatitis
(Lowest)	
Severity Level 1	Acute Pancreatitis/Other Pancreatic Disorders and Intestinal Mal-absorption
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

(5) Cost-Sharing Reductions (§ 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 reductions adjustment factors for 2018 risk adjustment are unchanged from those finalized in the 2017 Payment Notice and are set forth in

Table 8. These adjustments are effective for risk adjustment for 2016 and later years, and are multiplied against the sum of the demographic, diagnosis, and interaction factors. We anticipate reexamining these factors in the annual HHS notice of benefit and payment parameters for the 2019 benefit year as additional enrollee-level data from the individual market becomes available. We are finalizing the cost-sharing reduction adjustment factors as proposed.

Comment: Commenters supported updating the cost-sharing reduction factors using enrollee-level data for the 2019 benefit year.

Response: We agree with commenters that the data from the individual market will allow HHS to most accurately update the cost-sharing reductions adjustment factors for future benefit years and intend to do so as soon as practicable.

TABLE 8—COST-SHARING REDUCTIONS 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

(6) 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.³⁵ Because we proposed to blend the coefficients from separately solved models based on MarketScan® 2013 and 2014 data in the proposed rule, we are

³⁵ Winkelman, Ross and Syed Mehmud. "A Comparative Analysis of Claims-Based Tools for Health Risk Assessment." Society of Actuaries. April 2007.

publishing the R-squared statistic for each model and year separately to verify their statistical validity. We received no

comments on the R-squared statistics for the models. The R-squared statistic for each model, reflecting the 2018

modeling refinements discussed above, is shown in Table 9.

Risk adjustment model	R-Squared statistic	
	2013	2014
Platinum Adult	0.4185	0.4140
Platinum Child	0.3117	0.3072
Platinum Infant	0.3509	0.3343
Gold Adult	0.4144	0.4093
Gold Child	0.3074	0.3023
Gold Infant	0.3490	0.3322
Silver Adult	0.4112	0.4057
Silver Child	0.3037	0.2984
Silver Infant	0.3480	0.3310
Bronze Adult	0.4089	0.4031
Bronze Child	0.3004	0.2948
Bronze Infant	0.3477	0.3307
Catastrophic Adult	0.4084	0.4025
Catastrophic Child	0.2997	0.2940
Catastrophic Infant	0.3477	0.3306

(7) Overview of the Payment Transfer Formula (§ 153.320)

We previously defined the calculation of plan average actuarial risk and the calculation of payments and charges in the Premium Stabilization Rule. In the 2014 Payment Notice, we combined those concepts into a risk adjustment payment transfer formula. Risk adjustment transfers (total payments and charges including outlier pooling) 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.

The total payment or charge is thus calculated to balance the State market risk pool in question. In addition to the total charge collected and payment made for the State market risk pool, we proposed to add to the risk adjustment methodology additional transfers that would reflect the payments and charges assessed with respect to the costs of high-risk enrollees. We proposed to account for high-cost enrollees through transfer terms (a payment term and a charge term) that would be calculated separately from the State transfer formula. Thus, the non-outlier pooling

portion of plan risk will continue to be calculated as the member month-weighted average of individual enrollee risk scores. In particular, we proposed to add one term that would reflect 60 percent of costs above \$2 million, the proposed threshold for our payments for these enrollees, and another term that would reflect a percentage of PMPM premium adjustment to the transfer formula for the high-cost enrollee pool to maintain the balance of payment and charges within the risk adjustment program. We sought comment on this approach to balance transfers between high and low risk plans. We are finalizing this adjustment to the risk adjustment transfers as proposed, except we are lowering the threshold to \$1 million, and establishing a coinsurance rate of 60 percent for 2018 and future benefit years.

i. Administrative Cost Adjustment in Statewide Average Premium

We received comments to the 2017 Payment Notice and the White Paper from commenters who believe that the inclusion of administrative costs in the Statewide average premium incorrectly increases risk adjustment transfers based on costs that are unrelated to the risk of the enrollee population. Comments ranged from requesting that administrative expenses be removed entirely from the Statewide average premium to requesting that HHS consider basing risk adjustment transfers on a portion of Statewide average premium—namely, the portion representing the sum of claims, claims adjustment expenses, and taxes that are calculated on premiums after risk adjustment transfers by using a specified percentage of Statewide

average premiums. While commenters have stated that the inclusion of administrative costs in the Statewide average premium harms efficient plans, we noted in the 2017 Payment Notice and White Paper that low cost plans do not necessarily indicate efficient plans. Should a plan be low cost with low claims costs, it could be an indication of mispricing, as the issuer should be pricing for average risk. However, we also stated that we recognize that commenters are concerned that including fixed administrative costs in the Statewide average premium may increase risk adjustment transfers for all issuers based on a percentage of costs that are not dependent on enrollee risk. We considered some of the potential effects of excluding certain fixed administrative costs from the Statewide average premium. We noted that this modification to the treatment of administrative costs in the Statewide average premium would lower absolute risk adjustment transfers for all issuers by an equal percentage. We also noted that administrative costs are affected by claims costs and that correctly measuring the portion of administrative costs unaffected by claims costs may be difficult. An incorrect measurement of administrative costs could then result in plans with high-risk enrollees being undercompensated. In the proposed rule, we considered the impact of administrative expenses on risk adjustment transfers and sought comment on removing a portion of administrative expenses from the Statewide average premium for the 2018 benefit year or for future benefit years. Based on comments received, HHS will reduce the Statewide average premium in the risk adjustment transfer formula

by 14 percent to account for the proportion of administrative costs that do not vary with claims beginning for the 2018 benefit year.

Comment: Numerous commenters supported removing a portion of administrative expenses from the Statewide average premium for the 2018 benefit year or for future benefit years. One commenter sought clarification regarding how the exclusion of these expenses would be operationalized across all issuers uniformly since each issuer has its own expense assumptions. Other commenters suggested approaches by which HHS could remove fixed administrative expenses from the Statewide average premium in the payment transfer formula, including reducing the portion of administrative expenses from the Statewide average premium by 20 percent, the amount of non-claims costs, profit and taxes, the administrative expense amount reported through the Unified Rate Review Templates (URRTs), or other categorization of fixed administrative costs that would result in only including claims, claims-related expenses and taxes in the Statewide average premiums. Other commenters generally supported reducing Statewide average premium by a flat percentage. As a way to reflect the elimination of administrative costs in the transfer formula, one commenter suggested that HHS multiply the transfer amount by the amount allowed as administrative costs in each State's MLR laws. One commenter requested that HHS consult the American Academy of Actuaries and move to an approach that relies on market average costs or claims experience and add-on a claims-related adjustment to account for administrative costs that can vary with the level of claims experience.

One commenter supported this proposal beginning with the 2016

benefit year and requested HHS to retroactively implement this policy for the 2014 and 2015 benefit year.

One commenter did not support such an adjustment to the Statewide average premium, noting that there is no easy way to make this adjustment without favoring some issuers and promoting gaming. Another commenter asked HHS to delay this proposal for further study, and accept public comment on the impact of the inclusion of certain administrative costs and profit in the Statewide average premium. One commenter suggested that an iterative or phased-in approach could mitigate concerns about the accuracy of administrative cost allocation.

Response: HHS will reduce the Statewide average premium in the risk adjustment transfer formula by a fixed rate of 14 percent beginning for the 2018 benefit year, which we believe reasonably reflects the proportion of administrative costs that do not vary with claims. To derive this parameter, we analyzed administrative and other non-claims expenses (for example quality improvement expenses) in the MLR Annual Reporting Form, and estimated, by category, the extent to which the expenses varied with claims. We compared those expenses to the total costs that issuers finance through premiums, including claims, administrative expenses, and taxes, netting out claims costs financed through cost-sharing reduction payments. We compared these expenses to total costs, rather than directly to premiums, to ensure that the estimated administrative cost percentage was not distorted by under- or over-pricing during the years for which MLR data are available. Using this methodology, we determined that the mean administrative cost percentage is 14 percent. We believe that this percentage represents the mean administrative cost

percentage in the individual and small group markets, and represents a reasonable percentage of administrative costs on which risk adjustment transfers should not be calculated. Below, we amend the calculation of the Statewide average premium to reflect average premiums in a risk pool, less 14 percent. We have amended the definition of the State average premium below to reflect this change. We are finalizing this adjustment beginning for the 2018 benefit year. However, we are not making this change for 2017 because issuers would not have had an opportunity to incorporate it into their rates for 2017.

Comment: A few commenters requested that HHS use a plan's own actual average premium instead of the Statewide average premium in the transfer formula.

Response: We have considered the use of a plan's own premium instead of the Statewide average premium. However, our analysis determined that this approach is likely to lead to substantial volatility in transfer results and even higher transfer charges for low-risk low-premium plans. Under such an approach, high-risk, high-premium plans would require even greater transfer payments; thus, low-risk, low-premium plans would be required to pay in an even higher percentage of their plan-specific premiums in risk adjustment transfer charges. In other words, the use of a plan's own premium does not reduce risk adjustment charges for low-cost and low-risk issuers, given the budget neutrality of the risk adjustment program.

The revised formula for the calculation of Statewide average premium beginning for the 2018 benefit year risk adjustment is:

$$\bar{P}_S = \left(\sum_i (s_i \cdot P_i) \right) * 0.86$$

Where:

s_i = plan i 's share of Statewide enrollment in the market in the risk pool;

P_i = Average premium per member month of plan i .

ii. The Payment Transfer Formula

The payment transfer formula is unchanged from what was finalized in the 2014 Payment Notice (78 FR 15430 through 15434), except with an adjustment to remove a portion of administrative costs from the Statewide average premium, as discussed above.

Transfers (payments and charges) will be calculated as the difference between the plan premium estimate reflecting risk selection and the plan premium estimate not reflecting risk selection. As finalized in the 2014 Payment Notice, the HHS risk adjustment payment transfer formula is:

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

Where:

\bar{P}_s = Statewide 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 Statewide 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 adjustment charge or receives a risk adjustment 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 (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.

This existing formula would be multiplied by the number of member months to determine the total payment or charge assessed with respect to plan average risk scores for a plan's geographic rating area for the market for the State and this payment or charge will be added to the transfer terms described above to account for the costs of high-risk enrollees.

Comment: A few commenters noted that the budget neutrality of the risk adjustment program leads to inadequate compensation for enrollees' risk and recommended a non-budget neutral risk adjustment program as with Medicare Advantage. Commenters also recommended capping risk adjustment charges if they exceed a certain percent of total premiums, applying issuer-specific caps with lower caps for smaller issuers, and also excluding carriers with experience and significant market share from risk adjustment as these carriers may have a sufficient scale to mitigate adverse selection. One commenter requested additional risk score information at the community- and State-level to allow them to make better decisions.

Response: In the absence of additional funding for the HHS-operated risk

adjustment program, we continue to calculate risk adjustment transfers in a budget neutral manner and note that Medicare Part D risk adjustment transfers are also calculated in a budget neutral manner. We will not cap transfers as a percent of premiums or by issuer size, as this would also reduce the necessary risk adjustment payments for issuers with higher risk enrollees and thereby undermine the effectiveness of the risk adjustment program. We continue to evaluate additional information we may provide States and issuers that would not result in sharing issuers' proprietary information. Last year, we provided interim risk adjustment reports for credible States, as well as final State averages by risk pool, including risk scores, in an appendix to the June 30 Summary Report.³⁶

(8) Risk Adjustment Issuer Data Requirements (§ 153.610)

In the 2014 Payment Notice, HHS established an approach for obtaining the necessary data for reinsurance and risk adjustment calculations through a distributed data collection model that prevented the transfer of individuals' personally identifiable information (PII). Under § 153.700, each issuer must establish an EDGE server through which it provides HHS access to enrollment, claims, and encounter data. To safeguard enrollees' privacy, each issuer must establish a unique masked enrollee identification number for each enrollee, and may not include PII in such masked enrollee identification number. Under the EDGE server approach issuers currently provide plan-level data to HHS.

The lack of more granular data under this approach limits HHS's ability to use data from risk adjustment covered plans to improve the risk adjustment model recalibration. As we discussed in the White Paper, access to enrollee-level data with masked enrollee IDs would permit HHS to recalibrate the risk adjustment model using actual data from issuers' individual and small group populations, as opposed to the MarketScan® commercial database that approximates individual and small group market populations, while continuing to safeguard the privacy and security of protected health information

(PHI). Therefore, beginning as soon as the 2019 benefit year, while maintaining the underlying goals of the distributed data approach, including information privacy and security, we proposed to recalibrate the risk adjustment model using masked, enrollee-level EDGE server data from the 2016 benefit year. A separate report would be run on issuers' EDGE servers to access select data elements in the enrollee, medical claim, pharmacy claim and supplemental diagnosis files, with masked elements for each of enrollee ID, plan/issuer ID, rating area, and State. This approach would allow for the creation of a masked, enrollee-level dataset, avoiding, for example, the collection of information such as the enrollee ID, the plan ID, the issuer ID, rating area, State, or the EDGE server from which the data was extracted. HHS would provide additional information regarding the data elements it would collect and the related process considerations in future guidance.

HHS would use the dataset to recalibrate the risk adjustment model and inform development of the AV Calculator and Methodology, which HHS releases annually, to describe how issuers of non-grandfathered health plans in the individual and small group markets are to calculate AV for purposes of determining metal levels. We also believed the data could be a valuable source for calibrating other HHS programs in the individual and small group markets and creating a public use file to help governmental entities and independent researchers better understand these markets. After fully considering the comments received, we are finalizing our proposal to extract and use the EDGE server data in this manner to help update the risk adjustment methodology and the AV Calculator, which we aim to do for the 2019 benefit year. We will also consider using these data in the future for calibrating other HHS programs in the individual and small group markets and creating a public use file.

We believe that our approach described above, which minimizes the burden for issuers by only requiring them to execute a new EDGE command for the report to be run on their EDGE servers, permits important improvements to the HHS-operated risk adjustment program while continuing to safeguard privacy and security. We are finalizing the enrollee-level data collection as proposed.

³⁶ Appendix to the June 30 Summary Report. Available at <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/Appendix-A-to-June-30-2016-RA-and-RI-Report-5CR-063016.xlsx>.

Comment: A few commenters strongly disagreed with the proposal to not collect information about the specific issuer or EDGE server, stating that more identifiable information could be useful not only in updating the risk adjustment model but also in helping ensure that issuers are fully complying with critical Exchange requirements and individual and small group market reforms, examining changes in the relative health of enrollees in a plan over time, and evaluating the presence of favorable selection among issuers.

Response: We appreciate that identifiable data could be useful in analyzing program data to support more targeted improvements, and to conduct substantive program oversight. However, we believe that our proposed approach will allow us to recalibrate the HHS risk adjustment models. Further we note that in future years, we could also derive general socioeconomic status or demographic information at the plan- or issuer-level to make adjustments to the demographic variables or the induced demand factor in the risk adjustment models without jeopardizing the issuers' proprietary information or individuals' privacy.

Comment: Most commenters supported using enrollee-level EDGE data to recalibrate the HHS risk adjustment models, as proposed. One commenter emphasized that the calibration of risk factors based on actual data from the individual market will more accurately compensate issuers for special enrollment period enrollees. One commenter supported the use of EDGE enrollee-level data for risk adjustment recalibration, as EDGE data reflects the actual risk adjustment program population and is significantly more meaningful than MarketScan® data for purposes of risk adjustment; however, the commenter requested that since 2016 benefit year data would not adequately reflect the most current risk adjustment population for benefit year 2019 risk adjustment, HHS should use 2018 EDGE data for 2019 recalibration. Commenters encouraged HHS to incorporate EDGE data as soon as possible, or beginning for 2017 or 2018 benefit year risk adjustment recalibration. Some commenters requested that HHS delay this EDGE data collection for the next 3 years to first assess the other changes to the HHS risk adjustment models. Other commenters suggested that HHS take steps to ensure that the EDGE data is accurate and complete for all issuers, including through stakeholder collaboration, to understand if a slower schedule or delayed implementation is needed until the 2020 benefit year.

Response: We clarify that EDGE data for a particular benefit year is not available until after the data submission deadline in the year following the benefit year. The 2016 benefit year EDGE data, which will be submitted in the spring of 2017, will be the next benefit year for which we will be able to collect this data to recalibrate the risk adjustment model for the 2019 benefit year, based on our policy finalized above to provide for final risk adjustment model coefficients before rate-setting for the applicable benefit year. The 2016 benefit year EDGE data will be the most complete and recent EDGE data available.

Comment: One commenter expressed concern that it would not be possible to implement risk adjustment data validation using masked, enrollee-level data.

Response: Risk adjustment data validation is a separate process and we would not conduct data validation or audits using the enrollee-level EDGE data. Enrollees chosen for the risk adjustment data validation sample are identified for audit purposes through a separate process.

Comment: A few commenters expressed concern that this EDGE data collection could lead to disclosure of issuer-proprietary information. We received several suggestions to limit the collection to only data elements absolutely necessary to calibrate the risk adjustment model. Commenters noted that HHS's data collection authority for the individual and small group markets is different than in Medicare. We received several comments stating that HHS should be careful to ensure that the EDGE enrollee-level data is masked and secure and does not divulge enrollees' personal health information or issuers' proprietary data. Commenters encouraged HHS to provide more specifics as to how it will ensure that data is complete and masked. Some commenters requested that HHS release an assessment documenting the need for any proposed data elements prior to collection and consideration of the steps taken to ensure that these elements cannot be used in conjunction with other datasets to identify specific issuers or populations. Commenters noted that neither premiums nor the National Provider Identifier (NPI), as suggested in the White Paper, should be part of this EDGE data collection, as those data elements could allow outside parties to link the enrollee-level data with a particular issuer or enrollee.

Response: We clarify that while we proposed a more extensive list of data elements we might collect through the EDGE enrollee-level data report in the

White Paper, we have revised our approach to exclude certain data elements that may be more sensitive. The collection of more granular EDGE data will directly contribute to the improvement of the risk adjustment models and calculations and is authorized as part of HHS's authority under section 1343 of the Affordable Care Act to develop criteria and methods to operate the risk adjustment program.

Comment: Some commenters supported using EDGE data for recalibration, but suggested that HHS consider an alternative approach, such as using EDGE data aggregated up to HCCs to recalibrate the risk adjustment model based on the EDGE data.

Response: We evaluated the possibility of using EDGE data aggregated up to HCCs to recalibrate the risk adjustment models based on the EDGE data. However, we believe that such an approach is not practical. Each year, HHS engages in ongoing analysis for the risk adjustment models, examining and considering a variety of approaches to balance concerns and respond to public comments. An approach like the one suggested by commenters would make such iterative analysis impossible because it would require issuers to rerun EDGE commands on short notice, dozens of times, at HHS's request, and therefore would prevent HHS from developing and executing a risk adjustment model that is as accurate and stable as possible.

Comment: One commenter suggested that the risk adjustment recalibration could take into account the metal level for each enrollee rather than use each enrollee to recalibrate all metal levels. Another commenter requested that the calibrations be done State by State, using State-specific data so that risk adjustment is as accurate as possible. Some commenters noted the challenges inherent in recalibrating based on EDGE data, such as the calibration occurring during the risk adjustment data validation audit process, data completeness if issuers prioritize claims for data submission, and using a single year of data (rather than 3), and questioned whether a blending approach should be considered if there are small sample sizes. Some commenters suggested that HHS perform an analysis comparing the EDGE data (either 2015 or 2016 or both years) to the most recent 3-year MarketScan® data early in the process so health issuers can better anticipate and plan for the upcoming changes, and disclose the volume of data that would be used in the comparison of EDGE data versus MarketScan® data, demonstrating

that the new data is reliable prior to implementation.

Response: We welcome commenters' feedback on appropriate methods for the risk adjustment recalibration. We will take sample sizes into consideration when making these decisions, and will recalibrate at the national level, since we do not intend to collect State information as one of the data elements in the data collection. We will take into account data completeness when determining the recalibration sample, and will consider whether additional, supplemental MarketScan® data is necessary.

Comment: Many commenters supported using the EDGE enrollee-level data to refine the AV Calculator. Another commenter stated that there is not practical utility to the data collection, as the EDGE data will be years old. One commenter strongly supported a prohibition on the use of data gathered from the EDGE servers for purposes other than the recalibration of the risk adjustment models and development of the AV Calculator. A few commenters supported only using this data to recalibrate the risk adjustment model and not for other purposes, and would require that any other uses be established through rulemaking after a period of time.

Many commenters also strongly supported the availability of a public use file derived from these data, which would be an invaluable tool for government entities, including State-based Exchanges and State insurance regulators, as well as independent researchers, to better understand and analyze the individual and small group markets, including the Exchange risk pool. Two commenters encouraged HHS to provide more specifics as to what additional uses of this dataset may be permitted, if any, by HHS or other stakeholders that are granted access. Some commenters opposed the availability of a public use file so that competitors cannot leverage proprietary information, with one opposing at least until HHS and issuers have had an opportunity to assess whether the shift to enrollee-level data is meeting the stated objectives. Several commenters expressed concern about a proposal to create a masked dataset, and expressed strong concern that HHS would create a national database of claims data for all members in the individual and small group markets based on enrollee-level EDGE data, masked or otherwise.

Response: While we believe the EDGE data will be most useful for the risk adjustment recalibration, we believe it could provide valuable information to validate the AV Calculator

methodology. We also believe that in the future this data may prove useful in calibrating other HHS programs in the individual and small group markets, and that, after careful analysis, a public use file derived from these data could also prove useful to governmental entities and outside researchers. We are therefore finalizing our approach as described above. A public use file would be de-identified in accordance with Health Insurance Portability and Accountability Act of 1996 (HIPAA) requirements, would not include proprietary data, and would adhere to HHS rules and policies regarding PHI and PII.

Comment: Several commenters supported the lack of additional burden associated with the proposed data collection approach. Two commenters requested as much notice as possible of any resulting changes to EDGE data submission requirements. One commenter suggested HHS take whatever steps it can to limit the administrative burden imposed on issuers and their vendors. One commenter encouraged HHS to engage with stakeholders to collaborate on the most effective approaches to aggregating and using EDGE server data. One commenter recommended that HHS consider how to gather and incorporate data on prescription drug utilization collected by Electronic Health Records, which may be more reliable and complete than claims data alone. One commenter requested additional information on how HHS intends to collect the necessary data for inclusion of drug data in the risk adjustment model for 2018 onwards. Other commenters expressed concern that collecting enrollee-level EDGE data will require issuers to remake the EDGE server, retrain EDGE submitters, establish additional data warehousing capabilities for the enrollee-level data, and perform analyses on the risk adjustment model requirements. Another commenter requested that HHS produce a detailed cost estimate of the changes necessary to build this capacity and contrast this against projected refinements to the model. One commenter stated that HHS's proposal would expand the data requested through the EDGE servers, impose new record-keeping burdens on issuers, and collect proprietary data.

Response: As we noted in the Information Collection Requirements section, the report that HHS will send for issuers to run on their EDGE servers will collect data that already exists on issuers' EDGE servers, including pharmacy claim data, and will not result in additional burden to issuers of risk

adjustment covered plans. This data collection will not require issuers to remake the EDGE server, retrain EDGE submitters, or establish additional data warehousing capabilities for the enrollee-level data, as this data already exists on their EDGE servers. Further, there is no additional cost for the data collection, as the report will be built by HHS. When the command is sent to issuers' EDGE servers, they will simply need to execute the command, consistent with the current data collection process. Issuers will not be identified, so no proprietary information will be collected.

Comment: One commenter requested that HHS publish the EDGE data collection for public comment under the requirements of the Paperwork Reduction Act, so that issuers have a meaningful opportunity to comment on the practical utility and burden of the data collection.

Response: We will update our data collection for public comment under the requirements of the Paperwork Reduction Act following the finalization of this rule.

Comment: One commenter recommended that HHS use EDGE server data to help meet the Affordable Care Act's section 2715A transparency requirements.

Response: The type of data required of plans under the transparency requirements differs from the data issuers make available on EDGE servers for reinsurance and risk adjustment calculations. We have previously described how we intend to collect information for the transparency requirements for Exchange plans. See Transparency in Coverage Reporting by Qualified Health Plan Issuers (CMS–10572).³⁷

(9) 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, as defined in § 153.20, must remit a user fee to HHS equal to the product of its

³⁷ Transparency in Coverage Reporting by Qualified Health Plan Issuers. April 29, 2016. Available at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10572.html?DLPage=1&DLEntries=10&DLFilter=CMS%20>.

monthly enrollment in the plan and the per enrollee per month risk adjustment user fee specified in the applicable annual payment notice.

To promote operational efficiency, we proposed to amend § 153.610(f)(2) to revise the calculation of the risk adjustment user fee to be equal to the product of an issuer's billable monthly enrollment (billable member months) and the per enrollee per month risk adjustment user fee specified in the annual payment notice. Billable member months exclude children who do not count toward family rates or family policy premiums.³⁸ This revision to base the total risk adjustment user fee on billable member months rather than enrollment member months ensures consistency with calculating risk adjustment user fees based on premium revenue generated by issuers, which aligns with the FFE user fee policy. This change will not affect the PMPM risk adjustment user fee rate due to the small relative difference between billable member months and enrollee member months. Therefore, we are finalizing our proposal to implement this change beginning for the 2016 benefit year risk adjustment user fee collection, which will be collected in the summer of 2017, maintaining the user fee rate set in the 2016 and 2017 Payment Notices, respectively.

Comment: Commenters supported changing the risk adjustment user fee charge to be based on billable member months.

Response: We are finalizing this policy as proposed beginning for the 2016 benefit year risk adjustment user fee collection.

Additionally, in the proposed rule, we noted that 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 OMB 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 will also 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 2017 Payment Notice, we estimated Federal administrative expenses of operating the risk

adjustment program to be \$1.56 per enrollee per year, or \$0.13 PMPM, based on our estimated contract costs for risk adjustment operations. For the 2018 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 billable member months 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.

In the proposed rule, we estimated that the total cost for HHS to operate the risk adjustment program on behalf of States for the 2018 benefit year will be approximately \$35 million, and that the risk adjustment user fee would be \$0.12 PMPM.³⁹ However, in light of updated cost estimates for risk adjustment-related contracts and expected year-to-year cost-based inflation, we now expect the total cost for HHS to operate the risk adjustment program in 2018 on behalf of States to be approximately \$40 million, and are finalizing the risk adjustment user fee rate at \$1.68 per billable enrollee per year or \$0.14 PMPM.

Comment: Commenters supported the proposed risk adjustment user fee rate. A few commenters pointed out an error in calculating the annualized risk adjustment user fee rate in the proposed rule.

Response: The correct proposal was \$0.12 PMPM or \$1.44 per billable enrollee per year, but with updated estimates, we are finalizing a slightly higher user fee rate. The total risk adjustment program costs for the 2018 benefit year will be \$40 million, based on updated contracts through contract rebids that occurred since the publication of the proposed rule and expected year-to-year cost-based inflation. Based on this update, we are

finalizing a user fee rate of \$1.68 per billable enrollee per year or \$0.14 PMPM for 2018 and future benefit years (until updated through rulemaking).

(10) Data Validation Requirements When HHS Operates Risk Adjustment (§ 153.630)

HHS will conduct risk adjustment data validation in any State where HHS is operating risk adjustment on a State's behalf under § 153.630. The purpose of risk adjustment data validation is to ensure issuers are providing accurate high-quality information to HHS, which is crucial for the proper functioning of the risk adjustment program. Risk adjustment data validation consists of an initial validation audit and a second validation audit. Under § 153.630, each issuer of a risk adjustment covered plan must engage an independent initial validation audit entity. The issuer provides demographic, enrollment, and medical record documentation for a sample of enrollees selected by HHS to its initial validation audit entity for data validation.

i. Materiality Threshold for Risk Adjustment Data Validation

HHS has been evaluating the burden associated with the risk adjustment data validation program, particularly considering the fixed costs associated with hiring an initial validation audit entity and submitting results to HHS, which may be a large portion of some issuers' administrative costs. Beginning for the 2017 benefit year risk adjustment data validation program, HHS proposed to implement a materiality threshold, meaning that issuers that fall below a certain threshold would not be required to conduct risk adjustment data validation each year. We proposed to use a threshold of total premiums of \$15 million. Issuers at or below this threshold would not be subject to annual initial validation audit requirements. We estimate that issuers above this threshold represent risk adjustment covered plans that cover approximately 98.5 percent of membership nationally and as such, annual audit of issuers at or below the threshold is not material for purposes of risk adjustment data validation.

Because risk adjustment data validation error rates are applied to the subsequent year's data, we also sought comment on whether to base the participation requirement metric on the benefit year or the subsequent benefit year. On the one hand, risk adjustment data validation is measuring the accuracy of risk scores from the benefit year. On the other hand, risk adjustment data validation results directly adjust

³⁹ We note that in the proposed rule we had incorrectly stated the annual billable enrollee risk adjustment user fee rate as \$1.32, when it should have been \$1.44 per billable enrollee per year, however the \$0.12 PMPM was accurately stated in the proposed rule.

³⁸ See 78 FR 15432.

the risk adjustment transfers of issuers participating in risk adjustment in the following benefit year.

As for issuers that fall below the materiality threshold, we proposed that these issuers would be subject to random and targeted sampling. We proposed that the random sampling would include issuers below the threshold being subject to an initial validation audit approximately every 3 years, barring any risk-based triggers that would warrant annual participation. We proposed that potential risk-based metrics we would consider when selecting issuers at or below this threshold for more frequent initial validation audits would include the issuer's prior risk adjustment data validation results and material changes in risk adjustment data submission, as measured by our quality metrics. We noted that, even if an issuer is exempt from initial validation audit requirements using the proposed materiality threshold, HHS may require issuers to make records available for review or to comply with an audit by the Federal government under § 153.620.

Finally, we proposed that issuers not materially affecting risk adjustment data validation that are not required to perform an initial validation audit would still have their risk adjustment transfers adjusted based on an error rate. We proposed using an error rate for an issuer not subject to an initial validation audit in a particular year that could be the average negative error rate nationally, or the average negative error rate within a State, or its error rate in past audits.

We sought comment on these proposals. In light of the comments received, beginning with the 2017 benefit year of risk adjustment data validation, we are finalizing the proposed materiality threshold of total premiums of \$15 million based on the premiums in the benefit year being validated. Additionally, we are finalizing our proposal that issuers below the materiality threshold for risk adjustment data validation will be subject to a default error rate equal to the lower of the average negative error rate nationally, or the average negative error rate within a State. We will also exercise enforcement discretion for risk adjustment data validation for the 2016 benefit year for issuers below this materiality threshold in the same fashion.

Comment: Numerous commenters supported the materiality threshold for risk adjustment data validation beginning in the 2017 benefit year of total premiums of \$15 million. A few

commenters opposed a materiality threshold, stating that not auditing all issuers every year does not promote a level playing field. One commenter requested that HHS establish a materiality threshold beginning with the 2018 benefit year. Other commenters agreed with HHS's materiality threshold as long as exempted issuers would be subject to random and targeted sampling that would include issuers below the threshold being subject to an initial validation audit approximately every 3 years. Another commenter requested that HHS monitor the variance between these low enrollment plans and their markets to ensure data integrity.

Response: HHS is finalizing the materiality threshold of total premiums of \$15 million beginning with the 2017 benefit year, as proposed, because we agree with the numerous commenters that this threshold would reduce the burden of the risk adjustment data validation process for issuers that do not materially impact risk adjustment transfers. As set forth in the proposed rule and finalized here, although an issuer may not be required to conduct risk adjustment data validation each year, the issuers would be subject to random and targeted sampling that would include issuers below the threshold being subject to an initial validation audit approximately every 3 years.

Comment: Some commenters supported a materiality threshold but requested that HHS establish a threshold higher than total premiums of \$15 million. Other commenters requested that HHS establish a threshold of 12,000 billable member months. One commenter encouraged HHS to ensure that the materiality threshold is set so that no more than 2 percent of membership nationally is exempt.

Response: We believe that setting a threshold representing risk adjustment covered plans that cover approximately 1.5 percent of membership nationally promotes the goals of the risk adjustment data validation process while also considering the burden of such a process on smaller plans. HHS will monitor this threshold and may propose adjustments to the threshold for future benefit years to ensure that issuers above this threshold represent risk adjustment covered plans that cover approximately 98.5 percent of membership nationally.

Comment: One commenter sought clarification that the premiums included in the materiality threshold are only those for plans subject to risk adjustment.

Response: We agree with the commenter that the premiums included in the materiality threshold are only those for risk adjustment covered plans.

Comment: Several commenters requested that HHS base the materiality threshold on the benefit year being validated and not the subsequent benefit year.

Response: We agree with the commenters, and are finalizing a policy that HHS will base the materiality threshold on the benefit year being validated rather than the subsequent benefit year.

Comment: Numerous commenters supported the application of an error rate to issuers not required to conduct risk adjustment data validation. Other commenters suggested that those issuers should be exempt from having their transfers adjusted based on an error rate. The commenters supporting the error rate requested that HHS use the State average error rate for issuers that do not meet the materiality threshold. One commenter requested additional information about the error rate.

Response: We are finalizing a default error rate equal to the lower of the average negative error rate nationally, or the average negative error rate within a State. We believe this protects issuers not required to conduct risk adjustment data validation from large error rates of large issuers in a State, while not permitting them to unduly benefit from this exemption. We clarify that this default error rate would also apply to "new entrant" issuers in a benefit year beginning with the 2016 benefit year whose transfers would be adjusted based on prior year risk adjustment data validation results, which the new entrant issuer was not subject to. For example, the issuer who newly enters the market in the 2017 benefit year would have its June 30, 2018 transfers for the 2018 benefit year adjusted by the same 2017 risk adjustment data validation default error rate applied to issuers not required to conduct 2017 risk adjustment data validation for the 2017 risk adjustment data validation error rate application and payment adjustments on 2018 transfers.

ii. Inclusion of Pharmacy Claims in Risk Adjustment Data Validation

Beginning with the 2018 benefit year, as discussed above, the proposed HHS risk adjustment methodology would take into account prescription drug utilization for purposes of determining an enrollee's risk score. HHS proposed to use a hybrid model that employs prescription drug data to supplement diagnostic data by serving as a proxy for a missing diagnosis in cases where

diagnostic data are likely to be incomplete and as an indicator of the severity of an enrollee's illness. We proposed to require that, with respect to validation of prescription drug utilization of sampled enrollees, an issuer must provide an initial validation audit entity all paid pharmacy claims for an enrollee, against which the initial validation audit entity will validate the associated prescription drug class in the HHS risk adjustment methodology and the impact on the enrollee's risk score. Therefore, we proposed to amend the first sentence of § 153.630(b)(7)(ii) to include enrollees' paid pharmacy claims. In light of the comments received, we are finalizing this provision as proposed.

Comment: Several commenters supported this proposal. One commenter, while in support of the proposal, noted that requiring issuers to provide prescription drug data to initial validation audit entities will not serve to prevent gaming of prescription drugs in the risk models. Additionally, commenters requested more information, including knowing in advance the type of evidence that will be required and the format of the data used for the validation audit.

Response: We are finalizing this policy as proposed. As we noted in our discussion of including prescription drugs in the risk adjustment models, we intend to evaluate prescription drug utilization patterns prior to, during, and after the 2018 benefit year. We will provide guidance on the type of evidence that will be required and the format of the data used for this validation audit in future guidance.

iii. Risk Adjustment Data Validation Discrepancy and Administrative Appeals Process

Under § 153.630(d), an issuer may appeal the findings of a second validation of a risk score error rate to its risk adjustment payments and charges. In the 2015 Payment Notice, we stated that we would "provide additional guidance on the appeals process and schedule in future rulemaking."⁴⁰ As we noted in the 2015 Payment Notice, HHS will not permit an issuer to appeal the results of the initial validation audit, as the initial validation audit entity is under contract with the issuer and HHS does not produce the initial validation audit results. We are amending § 153.630(d) to clarify that an issuer may appeal the findings of a second validation audit or the calculation of a risk score error rate. We make this clarification to distinguish the

calculation of a risk score error rate from the application of a risk score error rate since the calculation is a separate reason on which an issuer could appeal. We further clarify that if an issuer intends to appeal the application of a risk score error rate to its risk adjustment transfer amounts, HHS will deem this a risk adjustment payment or charge amount appeal under § 156.1220(a)(1)(ii). In this final rule, we also finalize an interim and final discrepancy reporting process for the risk adjustment data validation program and we codify the process by which an issuer may file an appeal of the findings of a second validation audit or the calculation of a risk score error rate.

First, we finalize an interim discrepancy reporting process by which an issuer must confirm the risk adjustment data validation initial audit sample provided by HHS under § 153.630(b)(1) or file a discrepancy report. We are amending § 153.630 by removing the introductory language and adding paragraph (d)(1) to provide that in the manner set forth by HHS, within 15 calendar days of notification of the initial validation audit sample set forth by HHS, an issuer must confirm the sample or file a discrepancy report to dispute the HHS risk adjustment data validation initial validation audit sample set forth by HHS. In light of the timing of this interim discrepancy reporting process, we are not permitting issuers to appeal the resolution of any interim discrepancy disputing the initial validation audit sample. We are also requiring confirmation of the sample, in the form of an attestation, in order to ensure that issuers thoroughly review the initial validation audit sample determined by HHS.

Second, we finalize a final discrepancy reporting process, by which an issuer must confirm the findings of the second validation audit or the calculation of a risk score error rate, or notify us if the issuer identifies a discrepancy with the findings of a second validation audit or the calculation of a risk score error rate. We are adding paragraph (d)(2) to § 153.630 to provide that in the manner set forth by HHS, an issuer must attest to or report a discrepancy within 30 calendar days of notification of the findings of a second validation audit or the calculation of a risk score error rate to dispute the findings of a second validation audit or the calculation of a risk score error rate.

As we will discuss in further detail in the preamble to § 156.1220(a), we are also requiring issuers to report a discrepancy if the issue is identifiable prior to filing a request for

reconsideration as set forth in § 156.1220. As such, we are amending § 156.1220(a)(4)(ii), to provide that notwithstanding § 156.1220(a)(1), 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 § 153.630(d)(2) or § 153.710(d)(2), it was so identified and remains unresolved.

Third, we are amending § 153.630 to add paragraph (d)(3) to clarify the process by which an issuer can appeal the findings of a second validation audit or the calculation of a risk score error rate. We are requiring issuers to use the administrative appeals process set forth in § 156.1220.

In light of the comments received, we are finalizing the provisions as proposed.

Comment: Many comments supported the risk adjustment data validation discrepancy reporting and appeals processes. However, some of these commenters requested that HHS provide issuers 30 calendar days to file interim discrepancy reports.

Response: We are finalizing the provisions and timeframes as proposed. We are finalizing a 15 calendar day timeframe to report interim discrepancies related to the initial validation audit sample in order to provide initial validation audit entities maximum time to perform the initial validation audit.

Comment: One commenter requested that HHS clarify who within an issuer would provide the attestation during the interim and final attestation or discrepancy reporting process.

Response: HHS will provide guidance on who can provide the attestation during the interim and final attestation or discrepancy reporting processes. We note that, as with all attestations, it must be an individual who can legally and financially obligate the company.

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

a. Definitions (§ 154.102)

We proposed to revise the definition of "product" in § 154.102 to allow a product to be considered the same product when it is no longer offered by the same issuer, but by a different issuer in the same controlled group, consistent with our proposed interpretation of guaranteed renewability provisions, as discussed in the preamble to § 147.106. We are finalizing the revised definition

⁴⁰ 2015 Payment Notice, See 79 FR 13768.

as proposed. For further discussion please see the preamble for §§ 144.103 and 147.106.

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

a. Standardized Options (§ 155.20)

In the 2017 Payment Notice, HHS finalized six standardized options (also referred to as Simple Choice plans), one each at the bronze, silver, silver cost-sharing reduction variations, and gold levels of coverage, designed to be similar to the most popular QHPs in the 2015 individual market FFEs. In the proposed 2018 Payment Notice, we proposed to change the standardized options from the 2017 versions in order to reflect changes in QHP enrollment-weighted data from 2015 to 2016 and include SBE–FP QHP enrollment-weighted data; and to comply with various State cost-sharing standards. For the 2018 plan year, HHS proposed three sets of standardized options (see Tables 12, 13, and 14 in the proposed 2018 Payment Notice). The second and third sets of proposed standardized options (Tables 13 and 14) differed from the first set only to the extent necessary to comply with State cost-sharing laws. The second set was designed to work in States that: (1) Require that cost sharing for physical therapy, occupational therapy, or speech therapy be no greater than the cost sharing for primary care visits; (2) limit the cost-sharing amount that can be charged for a 30-day supply of prescription drugs by tier; or (3) require that all drug tiers carry a copayment rather than coinsurance. The third set was designed to work in a State with maximum deductible requirements and other cost-sharing standards.

Like the 2017 standardized options, we proposed that the 2018 standardized options would each have a single provider tier, fixed deductible, fixed annual limitation on cost sharing, four drug tiers, and fixed copayment or coinsurance for a key set of EHB that comprise a large percentage of the total allowed costs for a typical population of enrollees. We proposed these fixed cost-sharing values for in-network care only (we did not propose to standardize cost sharing for out-of-network care).

Unlike the 2017 standardized options, we proposed that the first and second set of 2018 standardized options at the silver, silver cost-sharing reduction variations, and gold levels of coverage, would have a separate medical and drug deductible, reflecting the commonality of this cost-sharing structure among 2016 enrollment-weighted QHPs at these levels of coverage. We proposed to

set the drug deductible equal to \$0 for the standardized options at the silver 87 percent cost-sharing reduction plan variation, silver 94 percent cost-sharing reduction plan variation, and gold levels of coverage, meaning no deductible would apply to the drugs.

We noted that the bronze standardized options as proposed would rely on finalization of the proposal at § 156.140, which would permit a broader de minimis range for bronze plans.

We also proposed a fourth standardized option at the bronze level of coverage that would qualify as a high deductible health plan (HDHP) under section 223 of the Code, eligible for use with a health savings account (HSA). We noted that under the terms of the Code, the IRS releases the maximum annual limitation on cost sharing and minimum annual deductible for HDHPs annually in the spring, subsequent to the annual HHS notice of benefit and payment parameters rulemaking process. Therefore, we proposed that if any changes to the HDHP standardized option would be required to reflect differences between the HDHP standardized option finalized in the 2018 Payment Notice and the subsequently released maximum annual limitation on cost sharing and minimum annual deductible for HDHPs, HHS would publish those changes in guidance. Accordingly, HHS proposed to amend the definition of “standardized option” at § 155.20 to provide that a plan would be a standardized option if it is: (1) A QHP offered for sale through an individual market Exchange with a standardized cost-sharing structure specified by HHS in rulemaking; or (2) an HDHP QHP offered for sale through an individual market Exchange with a standardized cost-sharing structure specified by HHS in guidance issued solely to modify the cost-sharing structure specified by HHS in rulemaking to the extent necessary to align with requirements to qualify as an HDHP under section 223 of the Code and meet HHS AV requirements.

In the proposed rule, we noted that for 2018, the *HealthCare.gov* platform remains unable to provide differential display to State-designed standardized plans that differ from the HHS-designed standardized options. However, we proposed that SBE–FPs may choose to allow HHS-designed standardized options, if offered by issuers in their State, to receive differential display on *HealthCare.gov*. We proposed that an SBE–FP must notify HHS if it elects to have HHS-designed standardized options receive differential display by a date to be specified in guidance, which

would be set to provide sufficient time to operationalize the State’s decision on *HealthCare.gov*.

In the proposed rule, we sought to accommodate State cost-sharing requirements by designing three sets of standardized options (in addition to a bronze HDHP) and proposed to select for each FFE State one of the three standardized options at each level of coverage that would meet any existing State cost-sharing requirements (plus the HDHP option at the bronze level, if permissible under State cost-sharing standards). We proposed to do the same for each SBE–FP State that notifies HHS that it chooses to have HHS standardized options receive differential display on the *HealthCare.gov* platform. We proposed that these selections would be published in the Final 2018 Payment Notice.

We also noted that many States have oral chemotherapy access laws, which require coverage of oral chemotherapy to be provided at cost-sharing parity with intravenous chemotherapy, or which cap patients’ monthly cost sharing for chemotherapy drugs (both oral and intravenous). We proposed to clarify that these chemotherapy access requirements do not conflict with the HHS standardized plan designs because issuers may design benefit packages that comply with both the standardized options’ requirements and State oral chemotherapy access laws.

We are finalizing the proposed policies on standardized options and the plan designs in the first, second, and third sets of standardized options as proposed, except for a few modifications, as discussed below.

We are modifying the definition of “standardized option” at § 155.20 to provide not only that HDHP QHPs can be modified to the extent necessary to align with the applicable requirements under section 223 of the Code, but that any QHP can be modified to update the cost-sharing structure specified by HHS in rulemaking to the extent necessary to align with the applicable annual limitation on cost sharing and HHS actuarial value requirements. This will permit us to make minor changes to the standardized options to meet legal requirements through guidance implementing this rule, instead of solely through rulemaking.

We are selecting all of the plan designs in the proposed second set of standardized options (Table 11) to apply in the Exchanges in the States of: Arkansas, Delaware Iowa, Kentucky (if the SBE–FP opts in), Louisiana, Missouri, Montana, and New Hampshire. We are selecting all of the plan designs in the proposed third set

of standardized options (Table 12) to apply in the Exchange in the State of New Jersey, but with some modifications to bring them into full compliance with New Jersey's unique State cost-sharing requirements, as discussed below. The States listed above have specific cost-sharing requirements, which the second and third sets of standardized options were designed to accommodate. We are selecting all of the plan designs in the first set of proposed standardized options (Table 10) (except for the HDHP option, which issuers in all States may choose to offer as long as it complies with State requirements governing high deductible health plans) to apply in all other FFEs, and all other SBE-FPs that opt in to differential display of these options.

New Jersey has a \$2,500 maximum deductible limitation for plans at all levels of coverage except for bronze, and a \$3,000 maximum deductible for plans at the bronze level of coverage. New Jersey also prohibits the use of a separate specialty drug tier. We are thus removing the specialty drug tier from the third set of standardized options. We made other conforming adjustments to ensure that the AVs fall within the de minimis range; and that each of the drug tiers has a different cost-sharing (copayment) value. These changes from the proposed rule remain consistent with the principles and features of standardized options described in the proposed rule. The standardized options finalized in this rule, in Tables 10, 11, and 12 below, apply beginning with the 2018 plan year.

Comment: The majority of commenters were supportive of the proposed policy to continue standardized options into the 2018 plan year. Some commenters requested that standardized options be made a requirement for all QHP issuers, as they are in the SBEs that have implemented standardized plans. These commenters requested that each QHP issuer participating in the 2018 Exchanges be required to offer at least one standardized plan at each level of coverage. A few commenters requested that standardized options be removed altogether, stating that the plans may negatively impact innovation in plan design or limit competition and choice in the Exchanges. A few commenters stated that standardized options are not necessary in many markets due to the participation of only one to two issuers. These commenters requested that if standardized options remain, HHS clarify that they will remain optional for issuers. Some commenters requested that in place of standardized options,

HHS instead move to tighten meaningful difference standards.

Response: We continue to believe that standardized options, which issuers may elect to offer, can simplify the consumer shopping experience in many markets and encourage the availability of plan designs with beneficial features (such as pre-deductible services) that may not otherwise exist in certain markets. We are finalizing the proposal for issuers to be able to offer standardized options if they choose. We recognize that the cost-sharing structures in the standardized options may not be appropriate for all issuers or all markets, and we are not requiring issuers to offer standardized options, nor limiting their ability to offer other QHPs, subject to other applicable law. As a result, we do not believe that standardized options will hamper innovation or limit choice.

Comment: Most of the commenters that commented on the proposed standardized options expressed concern about the proposed high out-of-pocket cost for specialty drugs in the first set of standardized options due to the application of coinsurance instead of copayments. Many of these commenters noted that the use of coinsurance makes it more difficult for consumers to calculate their monthly or yearly cost for drugs because plan formularies often lack cost information for specialty drugs. Many commenters noted that consumers with specialty drug needs often face financial difficulty because they must pay their plan's annual limitation on cost sharing within the first few months of the plan year, solely based on their specialty drug spending. Some commenters requested that HHS consider a capped copayment structure for drugs, or a process whereby a consumer would be able to spread his or her drug cost-sharing obligations evenly over the course of twelve months. Several commenters requested that we adopt the drug cost-sharing structure in the second or third set of standardized options in place of the drug cost-sharing structure in the first set of standardized options. Some issuers and SBEs commented that they are moving towards the use of copayments in place of coinsurance in response to consumer feedback. Many commenters requested clarification regarding the meaning of a separate drug deductible set at \$0, which was the drug deductible proposed for the 87 and 94 percent silver CSR plan variations and the gold plan in the first set of standardized options. One commenter requested additional clarity regarding the use of the asterisk in the standardized options tables, which is

used to mean "not subject to the deductible," and whether it includes both the medical and the drug deductible.

Response: We agree that in some cases coinsurance for specialty drugs may lead to high up-front out-of-pocket spending for consumers with specialty drug needs. However, because we have designed the standardized options to have cost-sharing features similar to those in the most popular (enrollment-weighted) QHPs in the 2016 individual market FFEs and SBE-FPs, we are retaining the proposed coinsurance structure and rates for specialty drugs in the first set of standardized options. The proposed separate medical/drug deductible structure in the proposed first and second set of standardized options was intended to provide cost-sharing protection for patients that require access to specialty drugs by subjecting the drugs to a separate and smaller deductible, rather than subjecting the drugs to a combined medical/drug deductible, which is often in the thousands of dollars. The standardized options with the separate drug deductible set at \$0 (the 87 and 94 percent AV silver plan variations and gold plans in the first and second sets of the proposed standardized options) were designed this way for three reasons. First, under cost-sharing reduction rules, the cost-sharing reduction plan variations should carry the same cost-sharing structure as the standard silver plan to avoid a situation where a less generous plan variation has lower cost sharing than a more generous plan variation. Thus, because the proposed standard silver plan in the second and third sets has a separate medical/drug deductible, the cost-sharing reduction variations must also have a separate medical/drug deductible, even if the drug deductible is \$0. Second, for a plan with a separate medical/drug deductible, a \$0 drug deductible would not accumulate the copayments the consumer pays for drugs towards the medical deductible of the plan. This was the intended plan structure in the proposed rule and is different than a plan with a combined medical/drug deductible where the drug copayments do go towards the medical deductible of the plan because the medical/drug deductible is combined. Third, we proposed this structure in response to confusion regarding the way that coinsurance is applied within the deductible range of a plan under the 2018 AV calculator methodology.⁴¹ We

⁴¹ 2018 AV calculator methodology. Available at [https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/index.html#Plan Management](https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/index.html#Plan%20Management).

are retaining the proposed separate medical/drug deductible structure in the first and second sets of standardized options as well as the proposed separate drug deductible of \$0 for certain plans. We are relying on the asterisk (*), which is used to indicate that the cost sharing is not subject to deductible, to convey to consumers when no deductible applies to the drug tiers. We further clarify that the asterisk (*) used in the standardized options tables means that the benefit cost sharing is not subject to any deductible—not a drug deductible, nor a medical deductible, nor a combined medical/drug deductible.

Comment: Many commenters expressed support regarding the cost-sharing structure for physical, occupational, and speech therapy in the proposed second set of standardized options, which sets cost sharing for these services at parity with cost sharing for primary care services (applying copayments not subject to the deductible, instead of coinsurance subject to the deductible). These commenters were also supportive of the cost-sharing structure proposed for these services in the third set of standardized options, which also uses copayments instead of coinsurance, and, with the exception of the bronze plan, does not subject the services to the deductible. Many commenters expressed concern with the cost-sharing structure proposed for these services in the first set of standardized options (coinsurance subject to deductible) noting that it would create substantial issues for consumers that require physical, occupational, or speech therapy, which are often required several times per week for habilitation or rehabilitation. Several commenters requested that we clarify that these benefit categories apply for both rehabilitative and habilitative care. Some commenters requested that we clarify that occupational therapy and physical therapy are separate and distinct services.

Response: We clarify that occupational therapy, physical therapy, and speech therapy categories include services for both habilitation and rehabilitation. Because these services are services that are expected and used for both rehabilitative and habilitative care, we changed the naming of these inputs in both the proposed 2018 AV Calculator and the proposed standardized options for 2018 in order to remove exclusive reference to rehabilitation. We also clarify that occupational and physical therapy are listed together in the AV Calculator and proposed standardized options tables, but that such listing does not indicate

that these services are one and the same type of services, but rather that they carry the same cost-sharing rate. We agree that consumers who need to utilize these services multiple times during the month or year may not want to select a plan with these services subject to both a deductible and coinsurance. However, because we have designed the standardized options to have cost-sharing features similar to those in the most popular (enrollment-weighted) QHPs in the 2016 individual market FFEs and SBE-FPs, we are retaining the proposed cost-sharing structure for these types of services in the first set of standardized options.

Comment: Some commenters suggested that the second set of standardized options should be used for all States, not just those that have cost-sharing standards. They suggested that a single national set of standardized options would prevent confusion for consumers that move from one State to a different State with different HHS standardized options and would be less burdensome for issuers that participate in multiple States to develop a single set of standardized options, rather than two or three sets. They also commented that by designing standardized options for some States to include co-insurance for some benefits while using copayments for those benefits in other States, HHS would be establishing a two-tiered Exchange system, which would be more difficult to measure.

Response: We understand that the second set of standardized options would comply with cost-sharing standards in all States, except for one—New Jersey—which, as noted, has very specific requirements addressed in the proposed third set of standardized options. However, based on the analysis of median cost-sharing features of enrollment-weighted QHPs in each State, we believe that the set of standardized options selected for each State will reflect the principles of standardized options described in the 2017 Payment Notice without increasing premium rates for consumers. We note that the bronze HDHP standardized option will remain an option for issuers in all States, if permitted in the State.

Comment: Some commenters requested clarity on how issuers can comply with both State requirements related to oral chemotherapy and the standardized options' cost-sharing requirements.

Response: We clarify that where an issuer in a State that requires cost sharing for chemotherapy drugs different from the cost sharing specified in the standardized options' drugs tiers offers a plan that complies with the

standardized options plan designs, except for any deviations to comply with the State's chemotherapy drug requirements, the plan will still be considered to be in compliance with the standardized options requirements. Issuers are expected to clearly indicate the State-required alternative cost sharing for chemotherapy drugs in plan formularies. This approach gives issuers the ability to price the drug tiers at the cost sharing in the standardized designs, but alter cost sharing for the chemotherapy drugs that have specific cost-sharing requirements based on State law.

Comment: Some commenters requested clarity regarding whether in the 2018 proposed standardized options issuers would have the option to create an additional lower-cost drug tier, as was explicitly permitted in the 2017 standardized options. Several commenters requested that the additional lower-cost tier be specifically designated for drugs that are available at no cost sharing, or fall under the preventive services category. Some commenters requested that we clarify that standardized options must cover preventive services at no cost sharing. Some commenters requested that we clarify that the copayment amounts for the drug tiers are for 30-day retail fills. Some commenters requested 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 would represent cost sharing at non-preferred retail pharmacies, with lower cost sharing available at preferred retail or mail-service pharmacies.

Response: We offer the following clarifications. We clarify that each copayment amount listed for the drug tiers in all standardized options is for at least a 30-day prescription fill at retail pharmacies. We clarify that issuers (or their pharmacy 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 clarify that, similar to the standardized options for 2017, issuers may create a single, additional, lower cost generics tier for standardized options. We also clarify that all standardized options must provide coverage for certain preventive services, including drugs as applicable, and may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) with respect to those items and services (see regulations at § 147.130 for rules

regarding coverage of preventive health services).

Comment: One commenter requested additional clarity regarding the number of physician tiers issuers are permitted to use in standardized options.

Response: We clarify that standardized options are limited to a single in-network tier. We do not standardize cost sharing for out-of-network coverage—therefore the cost-sharing structure for care obtained out-of-network can be set by the issuer of the standardized plan, subject to applicable Federal and States rules and regulations governing out-of-network coverage.

Comment: Some commenters expressed concern about the methodology of basing standardized cost-sharing design on enrollment-weighted QHP data, and requested that we incorporate other factors into plan designs.

Response: We examined 2016 enrollment-weighted FFE and SBE–FP QHP data to ensure that the cost-sharing values selected for standardized options were between the 25th and 75th percentile of cost-sharing values for each standardized cost-sharing feature based on enrollment, and generally sought to mirror the requirements at the 50th percentile. However, our standardized designs also take into account a number of other principles, such as deductible-exempt services, and copayments in place of coinsurance where feasible, as detailed in the proposed 2017 Payment Notice.

Comment: Some consumers supported differential display of standardized options, requesting HHS

adopt preferential display with standardized options sorting to the top of the list on *HealthCare.gov*, with premiums as a secondary sorting mechanism. Other commenters disagreed with any differential display, requesting that premiums be the default sorting mechanism.

Response: The differential display of standardized options for 2017 has been implemented in a way that will make plan shopping easier, while educating consumers about the cost-sharing features of standardized options. Consumers are able to filter to view only standardized options; however, standardized options will not automatically sort to the top on *HealthCare.gov* in 2017. Display of standardized options for 2018 will be based on additional consumer testing and consumer experiences with standardized options and comparison shopping for coverage in the 2017 Plan Year.

Comment: Some commenters supported the proposal for a standardized bronze HDHP. Some commenters requested that we also design a standardized silver and gold HDHP. Other commenters raised concerns about HDHPs in general and, in particular, noted that many consumers with HDHPs never actually establish HSAs, which could make it difficult for them to afford out of pocket expenses when care is needed. These commenters requested that HHS raise awareness of HSAs and facilitate enrollees' ability to take advantage of that benefit.

Response: We are finalizing the proposed standardized bronze HDHP.

We will consider comments regarding the need for consumer education with respect to HSAs and HDHPs. We are not developing standardized HDHP options at other levels of coverage at this time, but could do so in the future if we see significant demand for those products.

Comment: Some commenters requested additional clarity regarding the three proposed sets of standardized options. Some requested whether in some States, there would be more than one set of standardized options that issuers would have the choice to offer. Others raised questions regarding whether there could be a State that has both cost-sharing laws as covered under the second proposed set of standardized options as well as deductible maximums as covered under the third proposed set of standardized options.

Response: We clarify, that in each applicable State, there will be one set of standardized options, including one bronze-level, one silver-level, one 73 percent AV silver plan variation, one 87 percent AV silver plan variation, one 94 percent AV silver plan variation, one gold standardized option, and one bronze HDHP option that issuers in the State would have the option to offer. No States have been identified to have cost-sharing requirements that would require a plan to comply with limitations reflected in both the second proposed set of standardized options as well as the third proposed set of standardized options. The only State with applicable requirements for which the third set of standardized options, modified as described above, would be required is the State of New Jersey.

TABLE 10—2018 FINAL STANDARDIZED OPTIONS—SET ONE

	Bronze	HSA-eligible bronze HDHP	Silver	Silver 73% CSR plan variation	Silver 87% CSR plan variation	Silver 94% CSR plan variation	Gold
Actuarial Value (%)	62.68%	61.97%	71.05%	73.95%	87.61	94.69	80.65%
Deductible (Med/Rx)	\$6,650	\$6,000	\$3,500/ \$500	\$3,000/ \$200	\$700/\$0	\$250/\$0	\$1,400/\$0
Annual Limitation on Cost Sharing ..	\$7,350	\$6,000	\$7,350	\$5,850	\$2,450	\$1,250	\$5,000
Emergency Room Services	40%	No charge after deductible	20%	20%	20%	5%	20%
Urgent Care	\$75 (*)	No charge after deductible	\$75 (*)	\$75 (*)	\$40 (*)	\$25 (*)	\$60 (*)
Inpatient Hospital Services	40%	No charge after deductible	20%	20%	20%	5%	20%
Primary Care Visit	\$35 (*)	No charge after deductible	\$30 (*)	\$30 (*)	\$10 (*)	\$5 (*)	\$20 (*)
Specialist Visit	\$75 (*)	No charge after deductible	\$65 (*)	\$65 (*)	\$25 (*)	\$10 (*)	\$50 (*)
Mental Health/Substance Use Dis- order Outpatient Office Visit.	\$35 (*)	No charge after deductible	\$30 (*)	\$30 (*)	\$10 (*)	\$5 (*)	\$20 (*)
Imaging (CT/PET Scans, MRIs)	40%	No charge after deductible	20%	20%	20%	5%	20%
Speech Therapy	40%	No charge after deductible	20%	20%	20%	5%	20%
Occupational Therapy/Physical Therapy.	40%	No charge after deductible	20%	20%	20%	5%	20%
Laboratory Services	40%	No charge after deductible	20%	20%	20%	5%	20%
X-rays and Diagnostic Imaging **	40%	No charge after deductible	20%	20%	20%	5%	20%
Skilled Nursing Facility	40%	No charge after deductible	20%	20%	20%	5%	20%
Outpatient Facility Fee (for example, Ambulatory Surgery Center).	40%	No charge after deductible	20%	20%	20%	5%	20%

TABLE 10—2018 FINAL STANDARDIZED OPTIONS—SET ONE—Continued

	Bronze	HSA-eligible bronze HDHP	Silver	Silver 73% CSR plan variation	Silver 87% CSR plan variation	Silver 94% CSR plan variation	Gold
Outpatient Surgery Physician/Surgical Services.	40%	No charge after deductible	20%	20%	20%	5%	20%
Generic Drugs	\$35 (*)	No charge after deductible	\$15 (*)	\$15 (*)	\$5 (*)	\$3 (*)	\$10 (*)
Preferred Brand Drugs	35%	No charge after deductible	\$50 (*)	\$50 (*)	\$25 (*)	\$5 (*)	\$40 (*)
Non-Preferred Brand Drugs	40%	No charge after deductible	\$100 (*)	\$100 (*)	\$50 (*)	\$10 (*)	\$75 (*)
Specialty Drugs	45%	No charge after deductible	40%	40%	30%	25%	30%

(*) = not subject to the deductible.

**Note: Excludes x-rays and diagnostic imaging associated with office visits (except for high-deductible health plans (HDHPs)).

TABLE 11—2018 FINAL STANDARDIZED OPTIONS—SET TWO—APPLICABLE IN ARKANSAS, DELAWARE, IOWA, KENTUCKY (IF THE SBE-FP OPTS IN), LOUISIANA, MISSOURI, MONTANA, AND NEW HAMPSHIRE

	Bronze	Silver	Silver 73% CSR plan variation	Silver 87% CSR plan variation	Silver 94% CSR plan variation	Gold
Actuarial Value (%)	62.79%	71.03%	73.88%	87.70	94.68	80.60%
Deductible (Med/Rx)	\$6,650	\$3,500/\$500 Rx	\$3,000/\$200 Rx	\$700/\$0	\$250/\$0	\$1,400/\$0
Annual Limitation on Cost Sharing.	\$7,350	\$7,350	\$5,850	\$2,450	\$1,250	\$5,000
Emergency Room Services.	40%	20%	20%	20%	5%	20%
Urgent Care	\$75 (*)	\$75 (*)	\$75 (*)	\$40 (*)	\$25 (*)	\$60 (*)
Inpatient Hospital Services	40%	20%	20%	20%	5%	20%
Primary Care Visit	\$35 (*)	\$30 (*)	\$30 (*)	\$10 (*)	\$5 (*)	\$20 (*)
Specialist Visit	\$75 (*)	\$65 (*)	\$65 (*)	\$25 (*)	\$10 (*)	\$50 (*)
Mental Health/Substance Use Disorder Outpatient Office Visit.	\$35 (*)	\$30 (*)	\$30 (*)	\$10 (*)	\$5 (*)	\$20 (*)
Imaging (CT/PET Scans, MRIs).	40%	20%	20%	20%	5%	20%
Speech Therapy	\$35 (*)	\$30 (*)	\$30 (*)	\$10 (*)	\$5 (*)	\$20 (*)
Occupational Therapy/Physical Therapy.	\$35 (*)	\$30 (*)	\$30 (*)	\$10 (*)	\$5 (*)	\$20 (*)
Laboratory Services	40%	20%	20%	20%	5%	20%
X-rays and Diagnostic Imaging**.	40%	20%	20%	20%	5%	20%
Skilled Nursing Facility	40%	20%	20%	20%	5%	20%
Outpatient Facility Fee (e.g., Ambulatory Surgery Center).	40%	20%	20%	20%	5%	20%
Outpatient Surgery Physician/Surgical Services.	40%	20%	20%	20%	5%	20%
Generic Drugs	\$35 (*)	\$15 (*)	\$15 (*)	\$5 (*)	\$3 (*)	\$10 (*)
Preferred Brand Drugs	\$40 (copay applies only after deductible).	\$50 (*)	\$50 (*)	\$25 (*)	\$5 (*)	\$40 (*)
Non-Preferred Brand Drugs.	\$45 (copay applies only after deductible).	\$100 (*)	\$100 (*)	\$50 (*)	\$10 (*)	\$75 (*)
Specialty Drugs	\$50 (copay applies only after deductible).	\$150 (copay applies only after drug deductible).	\$150 (copay applies only after drug deductible).	\$75 (*)	\$20 (*)	\$100 (*)

(*) Not subject to deductible.

(**) Excludes x-rays and diagnostic imaging associated with office visits.

TABLE 12—2018 FINAL STANDARDIZED OPTIONS NEW JERSEY

	Bronze	Silver	Silver 73% CSR plan variation	Silver 87% CSR plan variation	Silver 94% CSR plan variation	Gold
Actuarial Value (%)	64.84%	71.53%	73.63%	87.61%	94.53%	80.80%
Deductible	\$3,000	\$2,500	\$2,500	\$700	\$250	\$1,000
Annual Limitation on Cost Sharing ...	\$7,150	\$7,150	\$5,850	\$2,450	\$1,250	\$5,000
Emergency Room Services	50%	40%	30%	20%	5%	30%
Urgent Care	\$50 (*)	\$50 (*)	\$50 (*)	\$40 (*)	\$25 (*)	\$40 (*)
Inpatient Hospital Services	\$500 (per day; applies only after deductible).	40%	30%	20%	5%	30%

TABLE 12—2018 FINAL STANDARDIZED OPTIONS NEW JERSEY—Continued

	Bronze	Silver	Silver 73% CSR plan variation	Silver 87% CSR plan variation	Silver 94% CSR plan variation	Gold
Primary Care Visit	\$35 (*first 3 visits; then subject to deductible and \$35 copay after deductible).	\$30 (*)	\$30 (*)	\$10 (*)	\$5 (*)	\$25 (*)
Specialist Visit	\$75 (applies only after deductible).	\$60 (*)	\$60 (*)	\$25 (*)	\$10 (*)	\$40 (*)
Mental Health/Substance Use Disorder Outpatient Office Visit.	\$35 (applies only after deductible).	\$30 (*)	\$30 (*)	\$10 (*)	\$5 (*)	\$25 (*)
Imaging (CT/PET Scans, MRIs)	\$100 (applies only after deductible).	\$100 (*)	\$100 (*)	\$75 (*)	\$40 (*)	\$100 (*)
Speech Therapy	\$35 (applies only after deductible).	\$50 (*)	\$30 (*)	\$10 (*)	\$5 (*)	\$25 (*)
Occupational Therapy/Physical Therapy.	\$35 (applies only after deductible).	\$50 (*)	\$30 (*)	\$10 (*)	\$5 (*)	\$25 (*)
Laboratory Services	50%	40%	30%	20%	5%	30%
X-rays and Diagnostic Imaging **	50%	40%	30%	20%	5%	30%
Skilled Nursing Facility	\$500 (per day; applies only after deductible).	40%	30%	20%	5%	30%
Outpatient Facility Fee (e.g., Ambulatory Surgery Center).	50%	40%	30%	20%	5%	30%
Outpatient Surgery Physician/Surgical Services.	50%	40%	30%	20%	5%	30%
Generic Drugs	\$25 (*)	\$25 (*)	\$25 (*)	\$5 (*)	\$3 (*)	\$10 (*)
Preferred Brand Drugs (***)	50%	\$50 (*)	\$50 (*)	\$25 (*)	\$5 (*)	\$25 (*)
Non-Preferred Brand Drugs	50%	\$75 (*)	\$75 (*)	\$50 (*)	\$10 (*)	\$50 (*)

(*) = Not subject to deductible.

(**) Excludes x-rays and diagnostic imaging associated with office visits.

(***) For compliance with applicable New Jersey State requirements, the standardized options in Table 12 are limited to three drug tiers. These plans do not have a separate specialty drug tier. However, for purposes of calculating AV using the 2018 AV Calculator, which is based on a four-drug tier system, the cost-sharing value for non-preferred brand drugs was assigned to the specialty drug tier.

b. General Functions of an Exchange

(1) Functions of an Exchange (§ 155.200)

In the 2017 Payment Notice, we established that a State Exchange could elect to enter into a Federal platform agreement through which it agrees to rely on HHS for services related to the individual market Exchange, the SHOP Exchange, or both. In § 155.200(f)(2), we required 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 in an FFE. Requiring QHPs and QHP issuers in SBE-FPs to meet these same requirements ensures 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.

We proposed to amend § 155.200(f) by adding a new paragraph (f)(4) that would require State Exchanges that use the Federal platform for certain SHOP functions to establish standards and policies consistent with certain Federally-facilitated Small Business Health Options Program (FF-SHOP) requirements. In contrast to the requirements contained in § 155.200(f)(2), which pertain primarily

to ensuring a consistent experience on *HealthCare.gov*, the proposed additional requirements for SBE-FPs that are listed in paragraph (f)(4) are necessary because the FF-SHOP requirements also referenced there are integral to the FF-SHOP platform's functionality and system build. HHS believes that these requirements are necessary from an operational perspective in order for State Exchanges to use the Federal platform for these SHOP functions. Additionally, requiring compliance with these requirements, rather than customizing the FF-SHOP platform's system build, would avoid sizeable costs associated with permitting State-based Exchanges to use the Federal platform for SHOP functions. Therefore, we proposed to add a new paragraph (f)(4) to require that SBE-FPs that utilize the Federal platform for certain SHOP functions establish standards and policies with respect to the following topics that are consistent with the following rules applicable in FF-SHOPs:

- Premium calculation, payment, and collection requirements as specified at § 155.705(b)(4) (for SBE-FPs using the Federal platform for SHOP eligibility, enrollment, or premium aggregation functions);
- The timeline for rate changes set forth at § 155.705(b)(6)(i)(A) (for SBE-

FPs using the Federal platform for SHOP enrollment or premium aggregation functions);

- Minimum participation rate requirements and calculation methodologies set forth at § 155.705(b)(10) (for SBE-FPs using the Federal platform for SHOP enrollment functions);

- Employer contribution methodologies set forth at § 155.705(b)(11)(ii) (for SBE-FPs using the Federal platform for SHOP enrollment or premium aggregation functions);

- Annual employee open enrollment period requirements set forth at § 155.725(e)(2) (for SBE-FPs using the Federal platform for SHOP enrollment functions);

- Initial group enrollment and group renewal coverage effective date requirements set forth at § 155.725(h)(2) (for SBE-FPs using the Federal platform for SHOP enrollment functions); and
- Termination of SHOP coverage or enrollment rules set forth at § 155.735 (for SBE-FPs using the Federal platform for SHOP eligibility, enrollment, or premium aggregation functions).

We sought comment on this proposal, including on whether it would conflict with current State requirements, and on whether other FF-SHOP requirements should apply in SBE-FPs utilizing the

Federal platform for SHOP functions. We are finalizing the provisions as proposed. These amendments will become effective with the effective date of the final rule.

Comment: We received two comments in support of our proposal to require SBE-FPs using the Federal platform for SHOP functions to establish standards consistent with those applicable in the FF-SHOPs. One commenter stated that the proposal will provide consistency for QHP issuers offering coverage both in Federally-facilitated and in State-based SHOP Exchanges. We did not receive any comments on whether other FF-SHOP requirements should apply in SBE-FPs utilizing the Federal platform for SHOP functions.

Response: We are finalizing the provision as proposed. The provision does not apply to State-based SHOPs that do not use the Federal platform for SHOP functions.

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

Section 155.205(c)(2)(iii)(A) and (B) require Exchanges, QHP issuers, and agents or brokers subject to § 155.220(c)(3)(i) (“Web-brokers”) to provide taglines in non-English languages indicating the availability of language services. These entities must include taglines on Web site content and documents that are critical for obtaining health insurance coverage or access to health care services through a QHP for qualified individuals, applicants, qualified employers, qualified employees, or enrollees. The taglines must indicate the availability of language services in at least the top 15 languages spoken by the limited English proficient (LEP) population of the relevant State, as determined in HHS guidance. In March 2016, HHS issued guidance providing language data and sample taglines in the top 15 languages spoken by the LEP population in each State.⁴² A similar tagline requirement appears in the final rule implementing section 1557 of the Affordable Care Act (81 FR 31375 (May 18, 2016)), which

prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities.⁴³ The regulations implementing section 1557 apply to every health program or activity administered by an Exchange, every health program or activity administered by HHS, and every health program or activity, any part of which receives Federal financial assistance provided or made available by HHS.⁴⁴ The regulations implementing section 1557, as well as other applicable Federal civil rights laws, generally apply independently of the regulations governing Exchanges and health insurance issuers.

In the 2016 Payment Notice and in the March 2016 guidance, we stated that if an entity’s service area covers multiple States, the top 15 languages spoken by LEP individuals may be determined by aggregating the top 15 languages spoken by all LEP individuals among the total population of the relevant States (80 FR 10788). We proposed to amend § 155.205(c)(2)(iii) to provide more specificity about when entities subject to § 155.205(c)(2)(iii)(A) and (B) would be permitted to aggregate LEP populations across States to determine the languages in which taglines must be provided, in light of questions that have arisen about this issue since publication of the 2016 Payment Notice.

At § 155.205(c)(2)(iii)(A), we proposed that if an Exchange is operated by an entity operating multiple Exchanges, or relies on an eligibility or enrollment platform that is relied on by multiple Exchanges, the Exchange may aggregate the LEP populations across all the States served by the entity that operates the Exchange or its eligibility or enrollment platform to determine the top 15 languages required for taglines under § 155.205(c)(2)(iii)(A).

At § 155.205(c)(2)(iii)(A), we also proposed that a QHP issuer would be permitted to aggregate the LEP populations across all States served by the health insurance issuers within the issuer’s controlled group, whether or not those health insurance issuers offer

plans through the Exchange in each of those States, to determine the top 15 languages in which it must provide taglines. For consistency, we proposed to define an issuer’s controlled group using the definition that was proposed at § 147.106(d)(3)(i) of this rule, that is, a group of two or more persons that is treated as a single employer under sections 52(a), 52(b), 414(m), or 414(o) of the Code.

We explained that with respect to summaries of benefits and coverage (SBCs) provided under section 2715 of the PHS Act, consistent with the SBC Instruction Guide for Individual Health Insurance Coverage⁴⁵ and the SBC Instruction Guide for Group Coverage,⁴⁶ QHP issuers would still be required to provide an addendum with their SBCs with language taglines in the top 15 languages spoken by the LEP populations of the relevant State or States for QHPs offered through an Exchange. Any additional taglines required under section 2715 of the PHS Act and the implementing regulations,⁴⁷ and, as the Office for Civil Rights (OCR) has explained, any taglines required under section 1557 of the Affordable Care Act, must also be included in this addendum.⁴⁸ However, any taglines that are included in the addendum are not required to also be included in the SBC document. The addendum, which must only include tagline information required by the applicable language access standards and the nondiscrimination notice required under the regulations implementing section 1557, if applicable, must be provided along with the SBC and is not

⁴⁵ Summary of Benefits and Coverage: Instruction Guide for Individual Health Insurance Coverage. April 2017. Available at <https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/Individual-Instructions-508-MM.pdf>.

⁴⁶ Summary of Benefits and Coverage: Instruction Guide for Group Coverage. April 2017. Available at <https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/Group-Instructions-4-4-clean-MM-508.pdf>.

⁴⁷ 45 CFR 147.200(a)(5) requires that group health plans and health insurance issuers offering group and individual health insurance coverage provide taglines in a particular non-English language if 10 percent or more of the population residing in the county is literate only in that same non-English language.

⁴⁸ OCR has explained that the written summary of benefits and coverage required by § 147.200(a) is a publication that is “significant” under § 92.8 of the rule implementing section 1557 of the Affordable Care Act. Accordingly, a covered entity required to provide a SBC must include the nondiscrimination notice and taglines required by § 92.8(b)(1), (d)(1) in its addendum in addition to complying with other applicable language access standards. See Section 1557: Frequently Asked Questions, available at <http://www.hhs.gov/civil-rights/for-individuals/section-1557/1557faqs/index.html>.

⁴² Ctr. Consumer Info. & Ins. Oversight, Ctrs. for Medicaid & Medicare Serv., Guidance and Population Data for Exchanges, Qualified Health Plan Issuers, and Web-Brokers to Ensure Meaningful Access by Limited-English Proficient Speakers Under 45 CFR 155.205(c) and 156.250. March 30, 2016. Available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Language-access-guidance.pdf>; Appendix A—Top 15 Non-English Languages by State. Available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Appendix-A-Top-15.pdf>; Appendix B—Sample Translated Taglines. Available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Appendix-B-Sample-Translated-Taglines.pdf>.

⁴³ 42 U.S.C. 18116; 45 CFR part 92. Section 92.8(d)(1) requires each covered entity to “post taglines in at least the top 15 languages spoken by individuals with limited English proficiency of the relevant State or States.” The principle of aggregation with respect to the tagline requirement at § 92.8(d)(1) is discussed in the section 1557 final rule at 81 FR 31375, 31400.

⁴⁴ 45 CFR 92.2(a). In addition to the tagline requirement at § 92.8(d)(1), the regulations implementing section 1557 of the Affordable Care Act identify other obligations of a covered entity, such as the obligation to have marketing practices and benefit designs in a health-related insurance plan or policy or other health-related coverage that are nondiscriminatory. See *id.* § 92.207.

considered a part of the SBC document. Therefore, the addendum will not count towards the four double-sided page limit for the SBC under section 2715(b)(1) of the PHS Act. Additionally, we explained that our proposed policy related to aggregating LEP populations to determine the top 15 languages in which taglines must be provided would not apply to the tagline requirements under rules implementing sections 2715 and 2719 of the PHS Act.

We explained that we believe our proposed approach to when entities can aggregate under § 155.205(c)(2)(iii)(A) balances two important policy objectives: Ensuring that LEP individuals have notice of language assistance services, and minimizing burden on the entities subject to the rule. We also indicated that we believe that this approach would help promote consistency with the tagline requirements at § 92.8(d)(1) and 81 FR 31400, which permit covered entities that serve individuals in more than one State to aggregate the number of individuals with LEP in those States to determine the top 15 languages required by § 92.8(d)(1).

We proposed amendments to § 155.205(c)(2)(iii)(B), to specify that Web-brokers that are licensed in and serving multiple States would be permitted to aggregate the LEP populations in the States they serve to determine the top 15 languages in which they must provide taglines under § 155.205(c)(2)(iii)(B). We explained that we intended our approach to aggregation under § 155.205(c)(2)(iii)(B) to balance the policy objectives of ensuring that LEP individuals have notice of language assistance services and of minimizing burden on the entities subject to the rule.

We proposed amendments to § 155.205(c)(2)(iii)(A) and (B) to specify that Exchanges, QHP issuers, and Web-brokers may satisfy tagline requirements with respect to Web site content if they post a Web link prominently on their home page that directs individuals to the full text of the taglines indicating how individuals may obtain language assistance services, and if they also include taglines on any stand-alone document linked to or embedded in the Web site, such as one in portable document format (PDF) or word processing software format, that is critical within the meaning of the rule. We explained that in the case of “critical” stand-alone documents linked to or embedded in the Web site, there is a good chance that a consumer might land on such documents without going through an entity’s home page first (for example, from a link on another Web

site), and it is also likely that such documents would not contain a link to the entity’s home page. In contrast, Web pages within the Web site that are not stand-alone linked or embedded documents are more likely to contain a prominent link to the home page. Under our proposal, if an entity subject to § 155.205(c)(2)(iii)(A) or (B) includes the required taglines in a stand-alone “critical” document linked to or embedded in the Web site of another entity subject to § 155.205(c)(2)(iii)(A) or (B), then the taglines standard would be deemed to be met by the entity that links to or embeds the “critical” document in its Web site, for purposes of that document.

Additionally, we noted that we were considering whether there is a need for the separate language access tagline requirements for Exchanges, QHP issuers, and Web-brokers under § 155.205(c)(2)(iii)(A) and (B), because the final rule implementing section 1557 of the Affordable Care Act (81 FR 31375 (May 18, 2016)) imposes on the covered entities to which that rule applies a similar set of obligations with respect to language access taglines. We sought comment on what, if any, additional protections for LEP consumers the standards under § 155.205(c)(2)(iii)(A) and (B) provide that are not included in 45 CFR part 92, and on whether the § 155.205(c)(2)(iii)(A) and (B) requirements are largely duplicative of the regulations implementing section 1557. We noted that not every entity subject to § 155.205(c)(2)(iii)(A) or (B) is a “covered entity” subject to section 1557 of the Affordable Care Act and its implementing regulation, and we indicated that we were considering replacing the tagline requirements currently set forth at § 155.205(c)(2)(iii)(A) and (B) with a provision requiring Exchanges, QHP issuers, and Web-brokers to follow certain standards under § 92.8 when providing the taglines required under § 155.205(c)(2)(iii), and requested comments on these approaches.

We are finalizing these provisions generally as proposed, but with several modifications. We are providing that Exchanges, and QHP issuers that are also subject to § 92.8, will be deemed to be in compliance with § 155.205(c)(2)(iii)(A) if they are in compliance with § 92.8, and are modifying regulation text to more clearly reflect the aggregation policy applicable to Exchanges under § 155.205(c)(2)(iii)(A). We have also removed references to an applicability date of these provisions (the first day of the individual market open enrollment

period for the 2017 benefit year, or November 1, 2016) because it has already passed. Finally, because the definition of controlled group at § 147.106(d) that is being finalized in this rule has changed from the proposed definition in ways that would be difficult to implement for purposes of § 155.205(c)(2)(iii)(A), we are replacing the cross-reference to § 147.103(d)(3)(i) in § 155.205(c)(2)(iii)(A) with the definition that was originally proposed at § 147.103(d)(3)(i).

Comment: In response to our request for comment on whether the § 155.205(c)(2)(iii)(A) and (B) requirements are largely duplicative of the tagline requirements in the regulations implementing section 1557 of the Affordable Care Act, and whether we should replace them with cross-references to § 92.8 or delete them entirely, many commenters stated that the § 92.8 requirements largely encompass the § 155.205(c)(2)(iii)(A) and (B) requirements. Commenters stated that, as a result, complying with these two sets of regulations will add significant administrative complexity and costs for issuers without any attendant advantage for consumers. Some commenters recommended that we eliminate § 155.205(c)(2)(iii)(A) and (B) entirely, and some recommended replacing them with cross-references to § 92.8, deeming entities to be in compliance with § 155.205(c)(2)(iii)(A) and (B) if they are in compliance with § 92.8. They stated that these efforts to streamline the two standards would reduce inconsistencies and overlapping requirements, reducing administrative burden and costs, while ensuring appropriate protections for consumers. A few commenters suggested that entities not already subject to § 92.8 should comply only with the tagline provisions of that section, while another recommended limiting the scope of § 155.205(c)(2)(iii)(A) and (B) to entities that are not considered “covered entities” under section 1557 of the Affordable Care Act, rather than including exceptions for non-covered entities in § 92.8. One commenter requested that the treatment afforded to small-sized significant publications and significant communications under § 92.8 be applied to the requirements under § 155.205(c). Other commenters recommended that we retain the requirements in § 155.205(c)(2)(iii)(A) and (B), explaining that greater specificity and greater requirements are justified in this rule given the fact that the goals of the two rules are different, and the entities covered under this rule do not always overlap with those

covered by section 1557 of the Affordable Care Act. They stated that many of the entities covered under § 155.205(c)(2)(iii)(A) and (B) are large, with financial and programmatic capabilities to provide taglines.

Response: Section 1557 of the Affordable Care Act and its implementing regulations establish a range of important protections for individuals with LEP in Federally-funded health programs and activities across the country. As commenters noted, the tagline requirements in the section 1557 regulations are in several ways broader than those applicable to Exchanges and QHP issuers under § 155.205(c)(2)(iii)(A). Given the comprehensiveness of the regulations implementing section 1557 of the Affordable Care Act, and in consideration of the difficulties and costs that arise for Exchanges, QHP issuers subject to both sets of requirements, and regulators when two separate but overlapping rules are in force, we are finalizing § 155.205(c)(2)(iii)(A) with a modification specifying that Exchanges, and QHP issuers that are also subject to § 92.8, will be deemed to be in compliance with § 155.205(c)(2)(iii)(A) if they are in compliance with § 92.8. Different, yet overlapping requirements are difficult for entities to implement and create confusion for the public, and our approach permits Exchanges, and those QHP issuers that are also subject to § 92.8, to follow a single set of tagline requirements. We will continue to work closely with OCR to ensure that the deeming process under § 155.205(c)(2)(iii)(A) works smoothly and that § 92.8 is consistently applied and enforced, and will facilitate State-based Exchanges doing so as well. The rest of § 155.205(c)(2)(iii)(A), as amended, would apply to any QHP issuer that is not also a covered entity under § 92.8. Such an issuer would be required to comply with § 155.205(c)(2)(iii)(A), as amended in this rule.

We have not extended an option to comply with § 155.205(c)(2)(iii)(A) or (B) by complying with § 92.8 to QHP issuers that are not subject to § 92.8 or to Web-brokers, because those entities are generally not required to comply with § 92.8 (most Web-brokers are not covered entities under section 1557 of the Affordable Care Act) and thus OCR would generally not have jurisdiction to enforce § 92.8 with regard to those entities. We are therefore finalizing § 155.205(c)(2)(iii)(B) as proposed, without deeming Web-brokers to be in compliance with that provision if they comply with § 92.8.

Comment: Many commenters supported our proposal to further articulate our interpretation of the aggregation policy under § 155.205(c)(2)(iii)(A) mentioned in the preamble to the 2016 Payment Notice⁴⁹ by permitting QHP issuers to aggregate the top 15 languages spoken by the LEP populations in the States served by the health insurance issuers in the issuer's controlled group. Several commenters supported the proposed aggregation policy for Web-brokers. The commenters supporting the proposals indicated that the proposals would allow entities to more efficiently provide important information to LEP populations and that the proposals strike the appropriate balance between facilitating language access for LEP populations and minimizing the burden on the entities subject to the rule. Other commenters cautioned that this policy would reduce language access for groups that have a large presence in certain States but whose languages would not fall within the top 15 languages spoken by LEP populations if LEP populations were aggregated across multiple States. Many commenters suggested that HHS allow aggregation only if an entity documents that it would be a hardship not to aggregate due to increased costs, or that HHS prohibit aggregation in circumstances where the applicable aggregation rule would result in a significantly different list of taglines compared to the State-specific approach. Many of these commenters posited that State-specific taglines should not require significant resources since HHS provides sample taglines, and that issuers likely have to tailor materials to meet State-specific standards in any case. Several commenters suggested that since Web pages do not have the space limitations that paper does, links from a home page to a page with taglines could easily include all disaggregated taglines. A number of commenters requested that if aggregation is permitted for QHP issuers, it should only be allowed across States in which an issuer's controlled group offers Exchange plans. One commenter requested that HHS give QHP issuers the option to use either the newly proposed aggregation principles or to maintain a State-specific methodology. One commenter proposed that issuer associations be allowed to aggregate across States.

Response: As we stated in the preamble to the proposed rule, we believe the amendments we proposed to § 155.205(c)(2)(iii)(A) help promote consistency with the tagline

requirements at § 92.8(d)(1) and 81 FR 31400, which permit covered entities that serve individuals in more than one State to aggregate the number of individuals with LEP in those States to determine the top 15 languages required by § 92.8(d)(1). We are finalizing the proposals generally as proposed, except for the modifications noted above, including a modification under which Exchanges, and QHP issuers that are also subject to § 92.8, will be deemed in compliance with § 155.205(c)(2)(iii)(A) if they are in compliance with § 92.8.

Although we have already provided sample taglines, we appreciate issuers' concerns that adding 15 different taglines in each State served by the health insurance issuers in the issuer's controlled group entails information systems changes and paper and printing costs. We believe our approach allows QHP issuers that are part of controlled groups to more efficiently provide important information to LEP consumers. For example, many insurance companies that would fit our definition of a controlled group use a common technology platform across multiple States that is shared by their component health insurance issuers. Requiring each QHP issuer in the controlled group to use State-specific taglines without taking account of these kinds of technological structures would pose difficult operational challenges for many QHP issuers. Our approach helps ensure compliance for such issuers without imposing undue administrative burden. Because issuer associations do not generally share technology platforms, we decline to extend the policy to issuer associations.

We recognize that under the aggregation approaches we proposed, some languages that are spoken by a significant number of individuals in one or two States might not be included in the top 15 languages in which taglines must be provided by an Exchange, QHP issuer, or Web-broker across multiple States, particularly if the number of States across which the Exchange, QHP issuer, or Web-broker is aggregating is high. We are not, however, modifying the proposals as recommended by the commenters. We believe our finalized aggregation approaches strike an appropriate balance between helping ensure that LEP consumers have notice of language assistance services and minimizing the burden on the entities subject to the rule. We will continue to monitor this approach to determine whether speakers of certain languages are significantly or disproportionately impacted. We also remind QHP issuers, Web-brokers, and Exchanges that notwithstanding the aggregation policies

⁴⁹ See 80 FR 10788.

finalized in this rule, they would be permitted to provide non-aggregated, State-specific taglines, or taglines in more than the required 15 languages, as could be required to meet State-specific standards. We encourage this as a best practice. We also agree that QHP issuers, Web-brokers, and Exchanges may have more space on Web pages than on paper documents, and encourage them where practicable to include disaggregated, State-specific taglines, or taglines that reach as many LEP populations as possible in the States where they are operating.

We note that for the purposes of § 155.205(c)(2)(iii)(A), we intend to apply the regulatory definition of controlled group that was originally proposed at § 147.106(d)(3)(i), and will not apply any State-law definitions of that term, in contrast to the manner in which HHS is finalizing that definition in the context of guaranteed renewability, as discussed in the preamble to § 147.106, above. We have therefore replaced the proposed cross-reference to § 147.106(d)(3)(i) in § 155.205(c)(2)(iii)(A) with the definition of controlled group that was originally proposed at § 147.106(d)(3)(i). We are adopting this approach to ensure that § 155.205(c)(2)(iii)(A) applies consistently to QHP issuers across multiple States. In contrast to the way that the guaranteed renewability provisions are applied and enforced at the State level, the aggregation policy under § 155.205(c)(2)(iii)(A) is specifically intended to apply to issuers across States and potentially among States in which different definitions of “controlled group” under the guaranteed renewability provision finalized in this rule at § 147.106(d)(4) would apply. Therefore, to ensure that issuers can implement this aggregation policy consistently within each controlled group, we believe it is important that the definition of controlled group that is applicable under § 155.205(c)(2)(iii)(A) be uniform across all States.

Comment: With regard to our proposal to allow an Exchange to aggregate the LEP populations across all the States served by the entity that operates the Exchange or its eligibility or enrollment platform, several commenters were concerned that our reference in the proposed rule text to an entity that operates an Exchange’s eligibility or enrollment platform could be read to include a contractor that might contract with a number of States to develop eligibility or enrollment information technology for State-based Exchanges. Several others were concerned that the most common non-

English languages spoken across the 39 States with FFEs or SBE-FPs that use the Federal eligibility and enrollment platform, are likely to vary, and that by aggregating them we risk excluding populations.

Response: We believe our approach strikes an appropriate balance between helping ensure that LEP consumers have notice of language assistance services and minimizing the operational challenges on the entities subject to the rule. The aggregation approach we proposed for Exchanges was intended to permit an Exchange that is operated by an entity that operates multiple Exchanges, or an Exchange that relies on an entity to conduct its eligibility or enrollment functions that conducts such functions for multiple Exchanges, to aggregate the LEP populations across all the States served by the entity that operates the Exchange or the entity that conducts its eligibility or enrollment functions to determine the top 15 languages required for taglines. We have modified the language in the final rule to make it clearer that the rule allows aggregation only by an Exchange that is operated by an entity operating multiple Exchanges, or by an Exchange that relies on an entity to conduct its eligibility or enrollment functions that provides those services to more than one Exchange. An entity contracting with more than one State or Exchange to develop an Exchange’s eligibility or enrollment information technology platform is not an entity operating multiple Exchanges or conducting their eligibility or enrollment functions for the purposes of this rule. For example, two State-based Exchanges whose information technology platforms were developed by the same contractor are not permitted to aggregate the LEP populations across their States. On the other hand, HHS provides eligibility and enrollment functionality for FFEs and State-based Exchanges in 39 States that rely on the Federal *HealthCare.gov* platform to conduct eligibility and enrollment functions. Under this rule, the Exchanges using the Federal platform can aggregate the LEP populations across those 39 States to determine the languages in which taglines must be provided. We remind SBE-FPs that the language access requirements under § 155.205(c) and § 92.8 apply to all of the SBE-FP’s documents, communications, and other materials that are subject to those rules, not just documents, communications, and other materials that the SBE-FP relies upon *HealthCare.gov* to generate and send. Accordingly, SBE-FPs also must comply with § 155.205(c)(2)(iii)(A)

when sending any communications subject to § 155.205(c)(2)(iii)(A) through means other than through the *HealthCare.gov* platform, and with respect to the SBE-FP’s informational Internet Web site operated under § 155.205(b)(7). Additionally, because Exchanges are covered entities under section 1557 of the Affordable Care Act, the notice and tagline requirements at § 92.8 also apply to any significant publications and communications sent by the SBE-FP through means other than the *HealthCare.gov* platform, and to the SBE-FP’s informational Internet Web site. Again, under the final rule we are deeming all Exchanges to comply with § 155.205(c)(2)(iii)(A) as long as they comply with § 92.8.

Comment: Several commenters supported our proposal that Exchanges, QHP issuers, and Web-brokers may satisfy tagline requirements with respect to Web site content if they post a Web link prominently on their home page that directs individuals to the full text of the taglines, and if they also include taglines on any stand-alone document linked to or embedded in the Web site, such as one in PDF or word processing software format, that is “critical” within the meaning of the rule. Several commenters requested that HHS limit the critical documents that must have taglines when posted online to stand-alone formularies, SBCs, and provider directory documents, since these are the critical documents that are most often linked to by third-party Web sites. One commenter suggested that these tagline requirements should also apply to health education and other consumer engagement communications. A few commenters suggested that HHS require that the link from an entity’s home page be in-language, since a link that is in English provides little aid to LEP populations looking for language access assistance. One commenter requested that HHS ensure that the link from the home page is displayed prominently, in large font, and “above the fold” so that LEP consumers can easily and quickly understand their right to access information in other languages.

Response: As some commenters mentioned, HHS has provided in-language links on the *HealthCare.gov* home page. These are links written in non-English languages posted conspicuously on the home page that direct the individual to the full text of the tagline indicating how the individual may obtain language assistance services. Additionally, covered entities can comply with the tagline requirements under the rules implementing section 1557 of the Affordable Care Act, at § 92.8, by

posting in-language Web links. Although § 155.205(c)(2)(iii)(A) and (B) do not require that links from a home page be in-language links, we agree that it is important that these links be displayed prominently and be in-language so that non-English speakers are able to recognize the languages listed. We decline to alter our definition of “critical” documents at this time because we continue to believe it is important for LEP consumers to have notice of translation services on any document that is required by law or regulation to be provided to a qualified individual, applicant, qualified employer, qualified employee, or enrollee.

Comment: Two commenters requested that we delay enforcement of § 155.205(c)(2)(iii)(A) and (B), and a few commenters proposed alternative models for our language access provisions, such as the HIPAA Privacy Rule standards and the Medicare Marketing Guidelines.

Response: Because we finalized § 155.205(c)(2)(iii)(A) and (B) in the 2016 Payment Notice on February 27, 2015, more than a year and a half before Exchanges, QHP issuers, and Web-brokers are required to comply with these tagline requirements, we believe Exchanges, QHP issuers, and Web-brokers have had ample time to prepare to implement these provisions. Therefore, it is CMS’s view that compliance with § 155.205(c)(2)(iii)(A) and (B) should not pose a significant challenge for most entities subject to those provisions, particularly in light of the amendments made in this rule. In particular, we expect that deeming Exchanges, and QHP issuers that are also subject to § 92.8, to be in compliance with § 155.205(c)(2)(iii)(A) if they are in compliance with § 92.8 will help alleviate concerns about multiple and inconsistent tagline requirements. We also remind entities that they must also comply with any other applicable Federal or State law regarding language access and taglines, including the regulations implemented under section 1557 of the Affordable Care Act, the HIPAA Privacy Rule standards, and the Medicare Marketing guidelines, if applicable. Additionally, because the applicability date for § 155.205(c)(2)(iii)(A) and (B) has passed (with the exception of Web-brokers that have not yet been registered with the Exchange for at least 1 year), we have modified the rules to eliminate reference to that date. The amendments made in this rule will take effect when the rule takes effect.

Comment: One commenter suggested that we should require all entities

operating as part of Affordable Care Act Exchanges to have comprehensive language access plans, and to have processes to ensure the accuracy and quality of written translations of all documents and communications.

Response: We note that for entities covered under Affordable Care Act section 1557, developing and implementing an effective written language access plan that is appropriate to the entity’s particular circumstances is a factor that the Director of OCR will take into account in evaluating whether a covered entity has met its obligation with respect to meaningful access for individuals with LEP under § 92.201. As a best practice, we recommend that Exchanges, QHP issuers, and Web-brokers have comprehensive language access plans and quality controls for written translations.

Comment: One commenter supported our statement that the required taglines do not count towards the Summary of Benefit and Coverage page limit. Several commenters requested that HHS amend the tagline requirements under § 147.136(e) (internal claims and appeals and external review) and § 147.200(a)(5) (Summary of Benefits and Coverage) to deem issuers in compliance with those rules if they comply with the requirements under § 92.8. One commenter requested that we extend the 10 percent of county threshold to all critical documents.

Response: Because it is important that consumers have sufficient notice of translation services for SBCs and internal claims and appeals documents, we decline to alter the language thresholds for the tagline requirements that apply to those documents under § 147.136(e) and § 147.200(a)(5). Because the language thresholds for SBCs and internal claims and appeals documents have been in place for years, and most issuers are already in compliance with them, we do not believe it is necessary to amend these thresholds. As we indicated in the proposed rule preamble, our policy allowing QHP issuers to aggregate the LEP populations in the States served by the health insurance issuers within the issuer’s controlled group to determine the languages in which taglines must be provided under § 155.205(c)(2)(iii)(A) does not apply to the tagline rules for SBCs under § 147.200(a)(5) or to the tagline rules for internal claims and appeals under § 147.136(e). For issuers subject to section 1557 of the Affordable Care Act, if the tagline requirement at § 92.8(d)(1) would require that taglines be provided in languages additional to those required under § 147.136(e) and § 147.200(a)(5), the additional languages

may be determined by following the aggregation policies that apply under § 92.8(d)(1). Additionally, if an issuer subject to both § 155.205(c)(2)(iii)(A) and § 92.8 chooses to comply with § 155.205(c)(2)(iii)(A) by complying with § 92.8, that does not mean that the issuer can comply with § 147.200(a)(5) or § 147.136(e) by complying with § 92.8. For documents other than the SBC and internal claims and appeals documents, we continue to believe that the standard set forth in this final rule is the appropriate standard.

Comment: Two commenters requested that HHS clarify that § 155.205(c)(2)(iii)(A) and (B) do not preclude a State-based Exchange from setting its own standards for identifying the top 15 languages, rather than relying on HHS’s guidance.

Response: Section 155.205(c)(2)(iii)(A) and (B) specifically provide that the top 15 languages in which taglines are required must be determined in guidance published by the Secretary. However, we agree that Exchanges, QHP issuers, and Web-brokers may have current and reliable data about the LEP populations in their States that differ from the data used to develop HHS’s guidance. To promote the use of accurate and localized demographic data and methodologies, and to help streamline our approach with OCR’s approach under the section 1557 rule, we now explain, as a supplement to the March 2016 guidance referenced above, and thus, as part of the guidance published by the Secretary that is referenced in the rule, that in implementing § 155.205(c)(2)(iii)(A) and (B), Exchanges, QHP issuers, and Web-brokers may refer to sources other than HHS’s list of the top fifteen languages in each State, if they have a reasonable basis for relying on such sources when considering characteristics such as the currency, reliability, and stability of the data. These entities may use such sources even if the list of languages produced from those sources is different from HHS’s list or has variations in the relative rank of the languages. If such alternative sources are used, relevant documentation should be maintained in accordance with applicable record retention requirements to demonstrate compliance with § 155.205(c)(2)(iii)(A) and (B).

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

In the proposed rule, we proposed building on our existing oversight efforts by adopting additional consumer

protection standards for agents and brokers who assist with enrollments through Exchanges. We proposed to require differential display of standardized QHP options and enlisting agents and brokers in post-enrollment support activities. We also solicited comments to inform the development and implementation of the enhanced direct enrollment pathways, including comments on consumer protection standards, privacy and security standards, and oversight processes for the enhanced direct enrollment pathway.

i. Differential Display of Standardized Options on the Web Sites of Agents and Brokers

In the proposed 2018 Payment Notice, we recommended requiring Web-brokers and issuers that use the direct enrollment pathways to differentially display standardized options. However, we noted that system constraints may prevent Web-brokers and issuers from mirroring the *HealthCare.gov* display, and therefore proposed that a Web-broker or issuer that uses the direct enrollment pathway may deviate from the display on *HealthCare.gov* with approval from HHS. We proposed that requests from Web-brokers and issuers seeking approval for an alternate differentiation format would be reviewed based on whether the same level of differentiation and clarity is being provided under the requested deviation as is provided on *HealthCare.gov*. Therefore, we proposed adding § 155.220(c)(3)(i)(H), for Web-brokers, and adding § 156.265(b)(3)(iv), for QHP issuers engaged in direct enrollment, to require differential display of all standardized options in accordance with the requirements under § 155.205(b)(1), in a manner consistent with that adopted by HHS for display on the FFE Web site, or with an HHS-approved deviation. We are finalizing our proposal. We believe differential display of standardized options will not require significant modification of Web-broker and issuer platforms, but that such display will provide an important service for consumers seeking to enroll in a standardized option. To provide additional flexibility for Web-brokers and issuers with respect to this display, we intend to provide “safe harbor” guidelines with respect to deviations that will be deemed to be approved because deviations within those guidelines will be deemed to have the same level of differentiation and clarity as provided on *HealthCare.gov*.

Comment: Several commenters opposed this requirement because they believe Web-brokers without contractual

relationships with issuers offering standardized options would not be able to implement the requirement. Other commenters stated that direct enrollment issuers should not be required to display plans, including standardized options, of other issuers. Some commenters were also concerned that the lack of flexibility to display these standardized options will negate the value Web-brokers provide to consumers.

Some commenters supported the proposal because it promotes consistent messaging across all platforms for enrollment including *HealthCare.gov*, Web-brokers, and direct enrollment issuers. One commenter recommended that HHS require standardized options to be displayed above all QHP listings. Several commenters also supported the HHS standard to review deviations from the differential display of standardized plans. These commenters stated that HHS should rigorously review such requests and grant permission for deviations sparingly to encourage consistency across platforms. Some commenters cautioned that requiring direct enrollment partners to seek approval for deviations would be burdensome.

Response: We clarify that under § 155.220(c)(3)(i)(B) and (D) a Web-broker must provide consumers the ability to view QHPs offered through the Exchange and must display all QHP data provided by the Exchange. Beginning with the 2018 plan year, this includes the differential display of the standardized options available in a State. We intend to provide access to information on standardized options to Web-brokers through the Health Insurance Marketplace Public Use Files and QHP Landscape file. We remind Web-brokers that if they do not have access to the additional required comparative information for a QHP offered through an Exchange (including premium or benefit information on standardized options), in accordance with 45 CFR 155.220(c)(3)(i)(A), the standardized Plan Detail Disclaimer must be prominently displayed for the specific QHP. A direct enrollment issuer, however, need only differentially display those standardized options that it offers.

ii. Enhanced Direct Enrollment Process

Under the direct enrollment process today, a consumer is redirected from the Web site of the direct enrollment partner (issuer or Web-broker) to *HealthCare.gov* to complete the eligibility application and obtain an eligibility determination. We requested comments on a proposal that would

allow consumers to remain on the direct enrollment Web site to complete the eligibility application without being redirected to *HealthCare.gov*. The enhanced direct enrollment partner would then pass the information collected in the eligibility application to the Exchange. The Exchange would then generate the eligibility determination and send the eligibility results back to the enhanced direct enrollment partner. This would allow the consumer to see the eligibility results on the direct enrollment partner's Web site. The Exchanges would continue to make the eligibility determinations, and the eligibility verification information received by the Exchanges from other government agencies would not be disclosed to the enhanced direct enrollment partner. In preparation for plan year 2017, we have made a number of improvements to the “double redirect” process in order to improve the consumer experience with the existing direct enrollment pathway. Under an enhanced direct enrollment process, the Exchange must ensure an accurate eligibility determination and must protect the privacy and security of all consumers that interact with it via the direct enrollment partner. We will not implement this process until we can ensure technical readiness and sufficient oversight of the eligibility application processes. In this and previous rules, we have begun to establish the regulatory framework for an enhanced direct enrollment program in which we would provide an ability for consumers to apply for coverage on a non-Exchange Web site while we explore the technical, operational, privacy, and security requirements to implement such a program. We continue to explore the program implementation details of such a program, and are maintaining the current “double redirect” direct enrollment approach at this time.

Comment: The enhanced direct enrollment process received support from many commenters, who believe that enabling applicants to remain on the direct enrollment partner's non-Exchange Web site would improve the consumer experience. Many commenters stated that enhanced direct enrollment would reduce consumer frustration and confusion, leading to increased enrollments.

One commenter supported enhanced direct enrollment but expressed concern that direct enrollment partners might elect to not participate in the FFEs for plan year 2018 if the enhanced direct enrollment process were not available. Another commenter recommended that HHS delay the enhanced direct

enrollment process until it has developed sufficient oversight methods to protect consumer privacy and security and the integrity of the eligibility and enrollment processes.

One commenter recommended that HHS allow direct enrollment partners to use this process for plan year 2017. Several commenters wanted HHS to clarify that HHS will continue to be responsible for the eligibility determination. Several commenters requested that HHS establish minimum standards for security. Some commenters specifically recommended that HHS require a Minimum Acceptable Risk Standard for Exchanges (MARS-E) compliance manual from direct enrollment partners prior to allowing them to participate in the enhanced direct enrollment process. Other commenters expressed concerns about HHS imposing burdensome privacy and security requirements, such as National Institute of Standards and Technology (NIST) standards or MARS-E 2.0. Another commenter was concerned about HHS's ability to monitor direct enrollment partners' privacy and security plans. One commenter was concerned also about the potential that direct enrollment partners will collect PII and store it on their systems. One commenter was concerned about direct enrollment partners' ability to connect to the Data Services Hub directly.

Many commenters were concerned that enhanced direct enrollment would damage the consumer experience and consumer's connections with the FFEs. Several commenters expressed concern that consumers may be unaware or lack access to notices from the FFEs and SBEs, specifically concerning data inconsistencies, verifications, or Forms 1095-A. Some commenters recommended that HHS require direct enrollment partners to provide each consumer with their FFE Application ID number and information on how to access *HealthCare.gov*. Multiple commenters suggested that HHS require that direct enrollment partners adequately inform consumers about the nature of the enhanced direct enrollment process and their relationship with the FFEs. Several commenters expressed concerns about the appearance, content, and structure of the eligibility application on the direct enrollment partners' Web sites as part of enhanced direct enrollment. Another commenter expressed concerns that consumers will have limited access to consumer assistance, including the FFE and SBE call centers and their direct consumer assistance capabilities.

Response: We thank commenters for their input, which we will take into account as we work towards readying the enhanced direct enrollment process.

We intend to conduct any required privacy and security impact assessments and will address regulatory changes to implement the enhanced direct enrollment process in future rulemaking, as may be necessary.

iii. Additional Protections for the Current Direct Enrollment Process and FFE Standard of Conduct for Agents and Brokers

In order to ensure adequate consumer protections, we proposed a number of modifications to existing requirements and the establishment of new requirements for agents and brokers that use the current direct enrollment process. We also proposed the same changes to § 156.1230 (where appropriate), which governs QHP issuers using direct enrollment, to ensure that consumers have similar protections when enrolling through a direct enrollment channel, whether they enroll using a Web-broker or a QHP issuer. For further discussion of the amendments to the QHP issuer direct enrollment partner requirements please see the preamble section on § 156.1230.

First, we proposed to add new paragraph § 155.220(c)(3)(i)(I) to require Web-brokers to display information provided by HHS pertaining to eligibility for the APTC and cost-sharing reductions in a prominent manner. This will help assure that consumers understand their potential eligibility for APTC, cost-sharing reductions and potential liability for excess APTC repayment.

Second, under § 155.310(d)(2), an Exchange may only provide APTC if the Exchange receives certain attestations from the tax filer, and must permit an enrollee to accept less than the full amount of APTC for which the enrollee is eligible. Therefore, in order for an Exchange to provide APTC to a consumer who enrolls through a direct enrollment pathway, the direct enrollment partner must provide enrollees with an opportunity to input their desired amount of APTC and provide the required APTC-related attestations. We are aware that some Web-brokers are not consistently permitting enrollees to select an amount for APTC under the existing direct enrollment pathway. Accordingly, we proposed to add § 155.220(c)(3)(i)(J) to require Web-brokers to allow consumers to select an APTC amount and make related attestations in accordance with the requirements of § 155.310(d)(2).

Comment: Commenters were in favor of these proposals, stating that they would protect consumers and increase successful enrollments.

Response: We are finalizing these policies as proposed in § 155.220(c)(3)(i)(I) and 155.220(c)(3)(i)(J). We note that these new requirements are not related to the eligibility application (and thus relevant regardless of whether an enhanced direct enrollment process is implemented), will increase transparency, and are consistent with § 156.1230(a)(1)(v), under which QHP issuer direct enrollment partners are currently required to allow consumers to select an APTC amount and make related attestations.

Third, we proposed § 155.220(c)(3)(i)(K) to require that the agent or broker of record who assisted the consumer with enrollment through the Exchange (that is, the agent or broker whose National Producer Number (NPN) is listed on the Exchange application) support post-enrollment activities necessary for the consumer to effectuate his or her coverage or resolve issues related to his or her enrollment, including discrepancies related to eligibility. We solicited comments on types and extent of support that agents and brokers should be required to provide. We also solicited comments on what additional safeguards, if any, should be put in place to protect consumers and their data.

Comment: Several commenters opposed the proposal, cautioning that agents and brokers may not all have the necessary capabilities, expertise, data, or technology required to assist with all post-enrollment activities or consumer scenarios. A number of commenters sought clarification on the scope of the post-enrollment activities. Several commenters also cautioned that certain populations might require unique assistance that only specialized agents and brokers may be able to provide. One commenter suggested HHS allow agents and brokers to refer consumers to Navigators and certified application counselors as an alternative. One commenter expressed concern that the proposal would raise significant financial burden on small agencies and requested whether the requirement would still apply if the issuer ceases to compensate the agent or broker. One commenter expressed concern that this proposal would further distance consumers from *HealthCare.gov*. One commenter requested that HHS clarify that an issuer would not incur any liability based on any activities that an agent or broker might be obligated to perform, unless the activities involve a

captive agent conducting activities on behalf of the issuer. Several commenters cited reports over the past three open enrollment periods that some agents or brokers have been enrolling consumers in Exchange plans without providing them with the information necessary to access or update their *HealthCare.gov* account information.

Response: In light of the comments and the significant burden that could be placed on agents and brokers, we are not finalizing this policy at this time. However, we encourage agents and brokers to assist consumers with post-enrollment activities as we believe it is in the shared interest of helping consumers maintain continuous enrollment. We believe that this would build on the existing support provided by agents and brokers today, and would help ensure that consumers who work with agents and brokers are able to effectuate or maintain their QHP coverage, and to update their eligibility as necessary. Specifically, we encourage agents and brokers to generally offer similar support as Navigators under § 155.210(e)(9)(i), (iii), and (iv). As such, the agent or broker of record on an enrollment transaction should help the enrollee understand open and special enrollment periods, help enrollees understand the process of filing Exchange eligibility appeals, help consumers resolve data matching inconsistencies, help consumers generally understand the premium tax credit reconciliation process, and help consumers understand basic concepts and rights of health coverage (coverage to care). We understand the concerns commenters have raised related to consumer access to information regarding their enrollments. Accordingly, in future rulemaking, HHS will consider the best means to ensure that consumers receive enrollment support from agents and brokers.

Fourth, we proposed to add § 155.220(c)(3)(i)(L) to require Web-brokers to demonstrate operational readiness, including compliance with applicable privacy and security requirements, prior to accessing either the current or enhanced direct enrollment pathway, including using the Web-broker's Web site to complete the QHP selection. We intend for this process to build upon the onboarding and testing process that Web-brokers undergo under existing procedures for the current direct enrollment process. This process would require that prior to accessing the Exchange, a Web-broker must demonstrate that required privacy and security measures and the technical specifications, testing requirements, and onboarding procedures applicable to the

direct enrollment process are functional. Consistent with § 155.220(c)(5), we stated our intent to conduct ongoing monitoring and audits to verify compliance throughout the term of the Web-broker's registration with the Exchange.

Comment: All commenters were in favor of this proposal.

Response: We are finalizing this provision as proposed in § 155.220(c)(3)(i)(K). We note that this requirement generally formalizes the current onboarding process. Under an enhanced direct enrollment process, we anticipate additional readiness components would be added in line with the additional features provided to enhanced direct enrollment partners.

Fifth, we proposed adding § 155.220(c)(3)(i)(M), to allow HHS to immediately suspend the agent's or broker's ability to transact information with the Exchange as part of the direct enrollment pathway if we discover circumstances that pose unacceptable risk to Exchange operations or its information technology systems. Under the proposal, the suspension would last until HHS is satisfied that the risk has been removed or sufficiently mitigated. In addition, we proposed to add language to § 155.220(c)(3)(i)(E) to require an agent or broker to cooperate with any audit under this section. This would include responding to requests for information in a timely fashion, as well as providing access upon request to documents or other materials necessary to confirm compliance with applicable requirements.

Comment: Most commenters agreed with our proposal regarding HHS's ability to immediately suspend an agent or broker's ability to transact information with the Exchange through the direct enrollment pathway. However, many commenters suggested that HHS specify criteria or guidance outlining how the agency would identify risks. One commenter who disagreed with the proposal recommended that HHS establish an appeals mechanism for a determination. All commenters agreed with our proposal to require an agent or broker to cooperate with an audit under this section. One commenter requested that HHS clearly define what it means to respond to requests in a "timely fashion" and clearly outline how Federal compliance activities will be coordinated with the State regulators.

Response: Based on the comments we received, we are finalizing these provisions as proposed in § 155.220(c)(3)(i)(L). As an example of criteria HHS would invoke under the suspension provision, a Web-broker's

access to the direct enrollment pathway may be suspended, for example, if HHS determines—based on transaction volumes, audits, or other reports—that the Web-broker is using an enrollment process other than the HHS-approved processes, presenting a risk of inaccurate eligibility determinations, is presenting an operational risk to the FFE, or presenting unacceptable security or privacy risks to Exchange operations or Exchange information technology systems. The ability to immediately suspend a Web-broker's connection to HHS's systems is critical to mitigate further damages and potential harm to the Exchanges and consumers. The temporary suspension would provide HHS with the ability to conduct an investigation and work with the Web-broker to mitigate or otherwise resolve any risk(s). While there is no formal appeals mechanism, the Web-broker will have an opportunity during the HHS investigation to remedy or mitigate the risk, as well as provide information to respond to the risk(s) identified. We also clarify that we interpret "timely fashion" to mean reasonably responding within the time specified in the request (including any agreed-upon extensions).

Sixth, we noted in the proposed rule that, consistent with § 155.220(c)(4), Web-brokers are permitted to provide access, through a contract or other arrangement, to their non-Exchange Web site to another agent or broker seeking to help an applicant complete the QHP selection process through the direct enrollment pathway. We understand that a number of Web-brokers provide access to their non-Exchange Web site to other agents and brokers registered with the FFEs who, in turn, host their own third-party Web sites to facilitate enrollment in the Exchange. To better protect consumers accessing these downstream third-party Web sites connected to the Web-broker's non-Exchange Web site, we proposed to add language to § 155.220(c)(4)(i)(E) to require Web-brokers that provide this access to be responsible for ensuring those Web sites are compliant with this section.

Comment: One commenter supported our proposal. Several others were concerned about its breadth, stating that Web-brokers do not have direct control over the entirety of a third-party agent or agency's Web properties.

Response: We are finalizing this proposal, with some modifications described below. We understand that there are various models under which a Web-broker may provide a third-party agent or broker with access to the direct enrollment pathway. For example, some

Web-brokers may allow an agent or broker to access the direct enrollment pathway exclusively through the Web-broker's non-Exchange Web site. Other web-brokers may provide a technological platform for the third-party agent's or broker's Web site to facilitate the exchange eligibility and enrollment processes, for example, through an embedded frame-based platform on the third-party agent's or broker's Web site. We clarify that this provision is primarily concerned with Web-broker and third-party agent and broker arrangements that utilize the latter approach, and with respect to the compliance of those third-party agent or broker Web sites with the applicable Web site standards detailed at § 155.220(c)(3). We believe that in such circumstances, the Web-broker should obtain adequate assurances from the downstream third party agent or broker that they will comply with the applicable Web site standards at § 155.220(c)(3) prior to permitting access to its non-Exchange Web site or ability to transact information with HHS to help an applicant complete the QHP selection process through the existing or enhanced direct enrollment pathways. Furthermore, HHS considers these arrangements to be an assignment of the Web-broker's rights and obligations under the Web-broker agreement with CMS. As such the Web-broker is required under the terms of the agreement to notify CMS and obtain prior, express written consent for such arrangements. Moreover, the third party agent or broker is responsible for compliance with the relevant provisions of the Web-broker's agreement with CMS; and the Web-broker is responsible for ensuring the third party agent's or broker's compliance with those provisions. Therefore, we are finalizing a requirement that Web-brokers ensure compliance with the applicable standards in § 155.220(c)(3) with respect to any Web pages of the third-party agent's or broker's Web site through which the third-party agent or broker assists consumers, applicants, qualified individuals, and enrollees in applying for APTC and cost-sharing reductions for QHPs or in completing the QHP selection or the Exchange eligibility application for QHPs offered in the Exchanges. We may require these downstream entities to enter into an agreement with HHS as a condition of CMS approval of such arrangements in order to ensure compliance with requirements that ensure the security of HHS systems. This process is one that HHS has used with any entity that requests such access.

Seventh, we noted in the proposed rule that we were considering different methods for completing the monitoring and audits authorized by § 155.220(c)(5). We discussed a model under which HHS, its designee, or an approved third party could perform the onboarding testing or audit. Where approved third parties perform onboarding reviews and audits, we stated that we anticipated that they would be approved by HHS and would need the capability to audit Web-brokers' ability to securely collect, maintain, and transmit eligibility application information in a manner determined by HHS and to otherwise review compliance with HHS rules. For third parties to be approved to conduct these activities, we stated that we expected that the auditor would need to submit an application to HHS demonstrating prior experience in verifying these sorts of capabilities, and, if approved, enter into an agreement with HHS governing the auditor's compliance with HHS audit and verification standards, interface with HHS systems, and data use. We stated that the auditor would be required to collect, store, and share data with HHS on these verifications, and protect that data in accordance with HHS standards, would be subject to monitoring and periodic certification by HHS, and would be compensated by the agents or brokers who engaged the auditor. We stated that if we were to allow third parties to perform such verifications, we would establish a process for evaluating and approving third party vendors in a manner similar to the one established in § 155.222. We solicited comment on our proposal to allow third parties to perform monitoring and audits authorized by § 155.220(c). We also solicited comment on whether we should establish a process for recognizing third parties to perform such monitoring, what protections are needed, and the factors HHS should consider in evaluating and approving organizations for this type of role.

Comment: All commenters were in favor of our proposal to allow third parties to perform monitoring and audits authorized by § 155.220(c). However, commenters requested that HHS ensure the auditors demonstrate compliance with standards to be defined by HHS. One commenter requested that HHS not impose any new requirements on Web-brokers to use third-party auditors until HHS makes enhanced direct enrollment available. Another commenter that noted support for asking agents and brokers to compensate an auditor if the agent or

broker engages the auditor asked that in situations where HHS engages an auditor, HHS should compensate the auditor. One commenter expressed concern that third-party auditors may not be able to provide adequate and consistent oversight and that the cost of overseeing third-party auditors may not outweigh the cost of HHS conducting all oversight. One commenter requested that HHS evaluate whether third-party auditors have experience evaluating Web sites and systems from the perspective of diverse consumers.

Response: We are finalizing this proposal. Please refer to the discussion pertaining to § 155.221 in the preamble for more information on the specifics of this approach.

We proposed to amend § 155.220(j)(2)(i) to provide that an agent or broker that assists with or facilitates enrollment of qualified individuals in a manner that constitutes enrollment through an FFE or SBE-FP, or assists individuals in applying for APTC and cost-sharing reductions for QHPs sold through an FFE or SBE-FP, must refrain from having a Web site that HHS determines is likely to mislead consumers into believing they are visiting *HealthCare.gov*. For example, our experience shows that Web sites that utilize combinations of colors, text sizes, or fonts, similar to those used on *HealthCare.gov* have caused confusion among consumers. Web sites whose URL address or marketing name could suggest the Web site is owned or endorsed by *HealthCare.gov* would also be inappropriate. We believe that it is important to avoid consumer confusion around which Web sites are operated by an FFE or SBE-FP, and which ones are operated by issuers or agents or brokers. We solicited feedback on criteria for determining whether a Web site could reasonably cause confusion with a Federal program or Web site.

Comment: Most comments received on this topic were supportive of this proposal. However, many commenters also requested that HHS establish specific criteria for determining if a Web site is misleading. Several commenters requested that HHS adopt a "totality of the circumstances approach." One commenter expressed concern that HHS would use a single criterion to trigger a determination (for example, a color or font). In addition, some commenters requested that HHS acknowledge that some entities have used words such as "Exchange" and "Marketplace" in their name or URL for years prior to the creation of the FFE, and that by maintaining their longstanding corporate identities, these Web sites may not inherently cause consumer

confusion. One commenter requested that HHS grandfather Web sites with such domain names.

Response: We are finalizing this provision as proposed. We do not intend for this requirement to target minor similarities to *HealthCare.gov*, but rather significant similarities that could mislead a consumer into believing they were enrolling directly through *HealthCare.gov*. As outlined in preamble to the 2017 Payment Notice,⁵⁰ we 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”, “Exchange,” or other potentially misleading 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 use a “totality of the circumstances” test for investigation and enforcement under this provision.

(4) Standards for HHS-Approved Vendors To Perform Audits of Agents and Brokers Participating in Direct Enrollment (§ 155.221)

In the proposed rule, we noted that we were considering different methods for completing the monitoring and audits authorized by § 155.220(c)(5). We also solicited comment on our proposal to allow third parties to perform monitoring and audits authorized by § 155.220(c) and the proposed establishment of a process to evaluate and approve such vendors in a manner similar to the one established in § 155.222.

After reviewing comments on our proposal, we are adding a new § 155.221 to establish an application and approval process for evaluating and approving third party audit vendors of Web-broker compliance with direct enrollment requirements. The process established under § 155.221 is designed to mirror the one for evaluating and approving third party vendors of FFE training for agents and brokers under § 155.222. Specifically, we are adding § 155.221(a)(1) to require that such a third party vendor must be approved by HHS, in a form and manner to be determined by HHS, to have its auditing services recognized for Web-brokers assisting with or facilitating enrollment in the individual market or SHOP coverage through the Exchanges consistent with § 155.220. In paragraph (a)(2), we establish an annual approval process. Similar to FFE training vendors, these auditor vendors will be

approved for one-year terms, and organizations seeking to continue their recognition as HHS-approved vendors the following year will need to be reapproved through a process to be determined by HHS.

For a third party vendor to be approved by HHS to conduct these activities, we are adding § 155.221(b) to establish standards that a vendor must meet to be approved by HHS. In paragraph (b)(1), a vendor must submit a complete and accurate application by the deadline established by HHS that demonstrates prior experience and expertise in conducting auditing or similar services for a large customer base. We note that vendors eligible for recognition will need to demonstrate expertise in the areas implicated by the design of the current direct enrollment process and, later, by the design of the enhanced direct enrollment process that is still under development. HHS standards for vendors eligible for recognition will develop as the design of the enhanced direct enrollment process is finalized. Accordingly, we will issue further guidance or rulemaking on these standards if necessary.

We are adding § 155.221(b)(2) to require the vendor, in performing the services, to adhere to certain standards with respect to content, format, privacy and security, including by ensuring that Web-brokers are in compliance with the applicable privacy and security standards. We are adding § 155.221(b)(3) to require the vendor to collect, store, and share data with HHS from Web-broker users of the vendor's services in a manner specified by HHS, and protect that data in accordance with HHS standards. In paragraph (b)(4), we require approved vendors to permit any Web-broker registered with the FFEs to access the vendor's auditing services. We are also adding § 155.221(c) to provide that HHS may monitor and audit approved vendors and their records related to the audits described in this section to ensure ongoing compliance with the standards in this section. If HHS determines that the vendor is not in compliance, the vendor may be removed from the approved list described in paragraph (d) of this section and may be required to cease performing the functions described under this section.

In paragraph (d), once the approval process has been completed for a given year, HHS will publish a list of approved entities on an HHS Web site. Finally, in paragraph (e), we provide that a vendor may appeal HHS's decision (to either not approve an application or to revoke approval of a vendor) by notifying HHS in writing

within 15 days of receipt of the notification of not being approved, or having its approval revoked, and submitting additional documentation demonstrating how the vendor meets the standards in paragraph (b) and (if applicable) the terms of their agreement with HHS. HHS will review the submitted documentation and make a final determination within 30 days from receipt of the submission of the additional documentation.

(5) General Standards for Exchange Notices (§ 155.230)

Section 155.230 outlines standards for notices required to be sent by the Exchange to individuals or employers. We proposed amending paragraph § 155.230(d)(2) to make electronic notices the default method for sending notices required to be sent by SHOP Exchanges,⁵¹ unless otherwise required by Federal or State law. The proposed amendment would make mailed paper notices optional, at the election of the employer or employee, as applicable, unless other Federal or State law prohibits making paper notices optional. This change was proposed in response to feedback from SHOP consumers and issuers indicating a preference for electronic notices. In addition, electronic notices provide a more cost effective way for SHOPS to distribute required notices. However, HHS is aware that some employees and employers may still prefer mailed paper notices and therefore proposed that paper notices distributed through standard mail would continue to be available for those that select paper notices as the preferred method of communication. Employers and employees participating in FF-SHOPS or in SBE-FPs utilizing the Federal platform for SHOP functions will continue to be able to select their preferred communication method when completing the eligibility applications online at *HealthCare.gov*. HHS also notes that SHOPS might be required to provide notices in a particular format in order to comply with the obligation to perform effective communication with an individual with a disability under the Americans with Disabilities Act of 1990, section 504 of the Rehabilitation Act, or section 1557 of the Affordable Care Act. HHS also noted that this amendment would not change the requirement that a SHOP comply with

⁵¹ See Federally-facilitated Marketplace (FFM) and Federally-facilitated Small Business Health Options Program (FF-SHOP) Enrollment Manual available at https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/ENR_FFMSHOP_Manual_080916.pdf, for a list of the FF-SHOP Exchange notices.

⁵⁰ See 81 FR 12263 (March 8, 2016).

the requirements for electronic notices in 42 CFR 435.918(b)(2) through (5) for the employer or employee. We sought comment on this proposal.

HHS also proposed to add a new paragraph § 155.230(d)(3) to give individual market Exchanges and SHOPs flexibility to send notices through standard mail, even if an election was made to receive electronic notices, if an individual market Exchange or SHOP is unable to send electronic notices due to technical limitations. Our regulation currently requires that individual market Exchanges send required notices according to an individual's or employer's selected preference. Our proposed amendment to paragraph (d)(2) would require that a SHOP provide electronic notices unless paper notices are selected as the preferred communication method, or unless otherwise required by State or Federal law. However, HHS recognizes that some Exchanges or SHOPs may have technological limitations that prevent them from sending certain notices electronically. In these situations, HHS proposed to provide flexibility for an individual market Exchange or SHOP to notify the individual, employee, or employer through standard mail. HHS encouraged individual market Exchanges or SHOPs that might need to exercise this option to explain to individuals, employees, or employers that some required notices may be sent through standard mail. HHS further encourages these individual market Exchanges and SHOPs to conduct additional outreach with individuals, employees, and employers, as needed, in order to ensure their understanding that they may receive certain notices via standard mail.

We are finalizing these amendments as proposed.

Comment: Some commenters supported the proposal to make electronic notices the default method of communication in the SHOPs. One commenter did not support the proposal due to concerns about consumers who lack adequate internet access. One commenter also recommended that copies of electronic notices to employers also be provided to any certified health insurance agent or broker assisting an employer with its SHOP coverage. One commenter supported the proposal to add flexibility to send notices by postal mail when technical limitations prevent an Exchange from sending notices electronically. Two commenters did not support our proposal at § 155.230(d)(3) because of its potential to conflict with Exchange obligations to provide

effective communication in compliance with the Americans with Disabilities Act of 1990, section 504 of the Rehabilitation Act, or section 1557 of the Affordable Care Act. We received one comment that consumers should be alerted to expect paper communications from the Exchange if the Exchange needed to use the flexibility provided by § 155.230(d)(3). The commenter expressed concern that if a consumer opts to receive information electronically, the consumer will not be expecting communication in any other manner.

Response: We are finalizing the amendments as proposed. Because employers and employees will continue to be able to elect to receive paper notices, consumers without internet access will not be adversely impacted by the amendments at § 155.230(d)(2). We note that in FF-SHOPs and SBE-FPs using the Federal platform for SHOP functions, if Federal or State law requires that a SHOP send a notice through a method that is not electronic, HHS will ensure that the notice is sent through the required means. Due to operational limitations, the FF-SHOPs and SBE-FPs utilizing the Federal platform for SHOP functions are not currently able to provide copies of electronic notices to any FFE-registered health insurance agent or broker assisting an employer with its FF-SHOP coverage. State-based SHOPs may elect to provide copies of electronic notices to licensed health insurance agents or brokers assisting employers and enrollees with SHOP coverage. Exchanges will still be required to meet effective communication requirements under the Americans with Disabilities Act of 1990, section 504 of the Rehabilitation Act, or section 1557 of the Affordable Care Act. Further, we encourage individual market Exchanges or SHOPs that need to send paper notices due to technical limitations to perform additional outreach, as needed, so the individual, employee, or employer is alerted to the paper notices. The Federal platform has a variety of means of communication when electronic means are not available, including communication through the call center, which will help Exchanges using the Federal platform to comply with notice requirements for persons with disabilities.

(6) Payment of Premiums (§ 155.240)

We sought comment regarding the scope of any potential problem related to unexpected electronic funds transfer (EFT) withdrawal amounts, especially when an enrollee stops receiving the benefit of APTC. For individuals who

have agreed to pay premiums via EFT, such a change in subsidy amount could mean the withdrawal of a larger-than-expected amount from the enrollee's bank account, resulting in financial hardship. We also sought comment on stakeholders' experiences with these transactions. Finally, we sought comment on industry best practices, State regulations in this area, and whether Federal rulemaking, such as reversal or termination of EFTs with or without simultaneous paper-billing, is needed.

Comment: Several commenters approved of rulemaking to protect consumers who have larger-than-expected EFT amounts withdrawn from their accounts, stating that severe financial consequences can result from such an unexpectedly large withdrawal, but several commenters opposed such rulemaking. Some commenters stated that Federal rules would be harmful to industry innovation or duplicative of existing regulatory schemes that already protect consumers from the danger of unexpectedly large EFT withdrawals. Other commenters feared that additional Federal regulation might cause issuers to take actions that might conflict with existing State laws. Some commenters expressed concerns that further regulation would limit their flexibility to assist their customers, pose operational problems for their billing systems, and would rely on vague standards to define what amount of change in EFT amounts would trigger a remedy for consumers. A few commenters stated that better communication between the FFEs, SBEs, and SBE-FPs and their consumers would be a superior solution to the problem. One of these commenters stated, however, that standard noticing requirements would force issuers to utilize different notices for consumers in different product or business groups, causing unnecessary administrative complexities and costs.

Response: We appreciate the comments related to this issue, and recognize that any solution must take into account the operational needs of industry partners, the wellbeing of consumers, and existing State and Federal regulations. We also realize that issuers have different procedures in place to provide notice to enrollees affected by a larger-than-expected EFT withdrawal and to avoid potential consumer hardship. We will continue, in conjunction with our governmental and industry partners, to examine all methods of preventing consumer harm from unexpectedly large EFT withdrawals.

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

(1) Eligibility Standards (§ 155.305)

Comment: In response to the proposed rule at § 155.330(e)(2), a number of commenters raised issues relating to ongoing challenges for consumers and Exchanges in implementing the requirement at § 155.305(f)(4) that Exchanges not determine a consumer eligible for APTC if APTC payments were made on behalf of the tax filer for the consumer's household (or either spouse, if the tax filer is a married couple) for a previous year and the tax filer or his or her spouse did not comply with the requirement to file an income tax return and reconcile APTC received for a previous year. The commenters stressed the importance of Exchanges implementing the requirement in a manner that clearly notifies tax filers regarding possible risk to their eligibility for APTC. One commenter stated it was important to explain to the consumer how to correct the problem and regain APTC eligibility, and to provide timetables for action, and to provide this information within the bounds of IRS privacy rules, which limit the disclosure of Federal tax information. In addition, some commenters discussed Exchanges' challenges in accurately assessing whether a tax filer has met this requirement at the time of the eligibility determination due to the time needed to process a Federal income tax return and make information about the return available to the Exchange. One commenter stated it was important to provide Exchanges with flexibility to allow consumers to attest to having filed a tax return in order to overcome delays in processing and data availability. Another commenter supported any options that would provide more flexibility to Exchanges to determine how to continue enrollment with APTC when IRS is not able to confirm that the tax filer has complied with the filing and reconciliation requirement, such as by submitting a copy of a filed tax return.

Response: We agree that targeted and detailed messaging to tax filers that highlights the specific requirement to file an income tax return and reconcile APTC paid on their behalf—and the potential adverse impact on APTC eligibility for future coverage years—is essential. In addition, we recognize the need for Exchange flexibility in enforcing the requirement under § 155.305(f)(4). Accordingly, we have

restructured § 155.305(f)(4), moving previous paragraph (f)(4) to new paragraph (f)(4)(i), and adding paragraph (ii). In new paragraph § 155.305(f)(4)(ii), we are providing that eligibility for APTC may not be denied under this paragraph unless a direct notification is first sent to the tax filer, consistent with the standards set forth in § 155.230, that his or her eligibility will be discontinued as a result of the tax filer's failure to comply with the requirement specified under § 155.305(f)(4)(i).

We also agree that providing a consumer the opportunity to either attest that the tax filer in the consumer's tax household has filed an income tax return and reconciled APTC paid on the tax filer's behalf for a previous benefit year, or to submit documentary proof of filing, can protect compliant tax filers from erroneously losing APTC because of data processing and reporting delays. Section 155.305(f)(4) should not be construed to require an Exchange to follow the procedures in § 155.315(f) for the purposes of verifying whether a tax filer meets the requirements of § 155.305(f)(4).

(2) Eligibility Redetermination During a Benefit Year (§ 155.330)

We proposed to amend § 155.330(d)(1)(ii) to require the Exchange to periodically examine data sources for information on either eligibility determinations for or enrollment in certain government health programs, including Medicare, Medicaid, and the Children's Health Insurance Program (CHIP), for Exchange enrollees on whose behalf APTC or the cost-sharing reduction portion of advance payments are being paid. Currently, paragraph (d)(1)(ii) requires the Exchange to periodically examine available data sources only for eligibility determinations for the specified government programs. We proposed that Exchanges should consider which data source best meets the criteria of timeliness, accuracy, and availability when deciding whether to examine data sources for eligibility determinations or enrollment information, noting that the proposed flexibility may be particularly valuable if data on eligibility determinations (as distinct from enrollment) are not available.

We also proposed to add a new paragraph § 155.330(e)(2)(iii) regarding redetermination and notifications of eligibility for APTC related to compliance with the income tax filing and reconciliation requirement under § 155.305(f)(4). Due to certain operational and legal impediments described in the proposed rule, we

noted that specific procedures for handling these redeterminations may be warranted that balance Exchange operational flexibility, the need for program integrity protections, and procedural protections for enrollees and tax filers. Therefore, we proposed to require an Exchange to choose among three options when the Exchange identifies updated information regarding compliance with the income tax filing and reconciliation requirement: (A) Follow the periodic data matching procedures specified in paragraph (e)(2)(i); (B) follow alternative procedures specified by the Secretary in guidance; or (C) follow an alternative process proposed by the Exchange and approved by the Secretary based on a showing that the process meets specified approval criteria.

Finally, in paragraph (g), we proposed to allow alternate methods of recalculating APTC during the benefit year, based on Exchange feedback and the need to account for differences in Exchange systems and mitigate complexities. We proposed that for coverage years through 2023, the Exchange may recalculate APTC in accordance with an eligibility redetermination under § 155.330 using an alternate method approved by the Secretary, instead of as currently provided under § 155.330(g). Approval would require a showing by the Exchange that the alternative procedure provides adequate program integrity protections, minimizes administrative burden on the Exchange, and limits negative impacts on consumers, where possible.

We are finalizing the changes to § 155.330 paragraphs (d)(1)(ii) and (e)(2)(i) and adding new paragraph (e)(2)(iii) as proposed. For paragraph (g), we are removing the time limit associated with the proposal and are otherwise finalizing the provision as proposed.

Comment: Commenters supported our proposal to require the Exchange to periodically examine data sources for information on either eligibility determinations for or enrollment in certain government health programs. Commenters noted that the proposed change could help ensure consumers are enrolled in the correct health program and minimize enrollment in duplicate coverage. Other commenters noted that the proposed rule, if finalized, could help State-based Exchanges avoid costly system updates. One commenter suggested that the Exchange periodically examine data sources for information on both eligibility for and enrollment in the specified government programs.

Response: We agree that this policy may help consumers enroll in the correct type of health coverage, minimize duplicate enrollment, and provide flexibility for State-based Exchanges. We believe that the Exchange should have the flexibility to periodically examine data sources for information on eligibility for or enrollment in the specified government programs, or both, provided that data sources meet the criteria of timeliness, accuracy, and availability.

Comment: One commenter recommended that the Exchange begin periodically examining data sources for information on either eligibility determinations for or enrollment in Medicare for Exchange enrollees on whose behalf APTC or the cost-sharing reduction portion of advance payments are being paid.

Response: The FFEs have begun conducting periodic data matching, as described in § 155.330(d), to identify Exchange enrollees on whose behalf APTC or the cost-sharing reduction portion of advance payments are being paid who may be enrolled in Medicare that is considered minimum essential coverage. A sample notice sent for such Exchange enrollees is available at <https://marketplace.cms.gov/applications-and-forms/medicare-pdm-notice.pdf>.

Comment: One commenter recommended that the Exchange periodically examine data sources to verify offers of employer-sponsored coverage, and sought guidance on the subject.

Response: This comment is beyond the scope of the proposed rule, which did not address periodic data matching for verification of enrollment in an eligible employer-sponsored plan and eligibility for qualifying coverage in an eligible employer-sponsored plan. Exchange regulations at § 155.320(d) describe the process of verification related to enrollment in an eligible employer-sponsored plan and eligibility for qualifying coverage in an eligible employer-sponsored plan. Exchange regulations do not require periodic examination of such data sources.

Section 155.320(d)(2) requires the Exchange to obtain data about enrollment in and eligibility for an eligible employer-sponsored plan from any electronic data sources that are available to the Exchange and that have been approved by HHS based on evidence showing that such data sources are sufficiently current, accurate, and minimize administrative burden; from any data sources covering employer-sponsored coverage based on Federal employment using verification

data obtained by HHS; and from any data sources about SHOP coverage using any available data from the SHOP that corresponds to the State in which the Exchange is operating. Section 155.320(d)(4) provides that for any benefit year for which the Exchange does not reasonably expect to obtain sufficient verification data as described in paragraph (d)(2) of that section, the Exchange must conduct a process referred to as “sampling” described in paragraph (d)(4)(i), or for benefit years 2016 and 2017, an alternate process approved by HHS as described in (d)(4)(ii).

For 2016, the FFE conducted an alternate process that included many components of sampling. It involved contacting certain employers to inquire whether specified employees who were determined eligible for Exchange financial assistance and enrolled in a QHP through the Exchange were enrolled in an eligible employer-sponsored plan or were eligible for qualifying coverage in an eligible employer-sponsored plan for the 2016 plan year. The goal was to help the FFE ascertain if sampling is an effective method of examining whether employees correctly attest to their enrollment in and eligibility for qualifying coverage in an eligible employer-sponsored plan and the effectiveness of the FFE’s verification efforts.

We expect Exchanges to develop such alternate processes to gain insight into whether employees provide accurate information on their application for coverage through the Exchange regarding enrollment in and eligibility for qualifying coverage in an eligible employer-sponsored plan and the effectiveness of an Exchange’s verification of such information. Our hope is that these alternate processes provide insight and information allowing the Exchange to move closer to an effective method of verification related to enrollment in and eligibility for qualifying coverage in an eligible employer-sponsored plan.

Comment: Of the commenters that commented on our proposal at § 155.330(e)(2)(iii), all were supportive of the proposal, which proposed flexibility for Exchanges when periodically obtaining data from IRS regarding tax filers’ compliance with the requirement to file income tax returns and reconcile APTC paid on their behalf for previous benefit years. Overall, commenters expressed support for the proposal’s flexibility in accounting for differences in Exchange systems and mitigating Exchange burden and complexity, while providing adequate

program integrity protections and limiting negative impacts on consumers.

Response: We agree that the proposed rule at § 155.330(e)(2)(iii) would help address the challenges Exchanges and consumers have experienced with periodic APTC eligibility redetermination related to tax filing and APTC reconciliation status. Therefore, in response to comments, we are finalizing new paragraph § 155.330(e)(2)(iii) as proposed, which provides flexibility to Exchanges when periodically obtaining data from IRS regarding tax filers’ compliance with the requirement to file tax returns and reconcile APTC paid on their behalf for previous benefit years. We believe that these options will effectively allow Exchanges to select the best way for them to comply with these APTC eligibility redetermination requirements related to tax filing status in a manner that reduces administrative complexity and burden and minimizes confusion and other negative effects on consumers, while providing adequate program integrity protections.

Comment: We received comments both in support of and against the proposed amendment to paragraph (g) to allow alternate methods of recalculating APTC during the benefit year through 2023. Commenters in support noted the potential to accommodate for different Exchange systems and mitigate complexities. Commenters against the proposal expressed concern that an alternate method of recalculating APTC during the benefit year may harm consumers if it does not take into account APTC already paid on the tax filer’s behalf and results in a tax liability for the tax filer. One commenter suggested that the option to implement an alternative procedure should end before 2023. A few commenters requested that we provide more information on the approval criteria and methodologies by which an alternative procedure would be evaluated.

Response: We take seriously commenters’ concerns about the potential harm to consumers if an alternate method of recalculating APTC during the benefit year does not take into account APTC already paid on the tax filer’s behalf. We proposed that, in order for an alternate method of recalculating APTC during the benefit year to be approved by the Secretary, the Exchange must show, among other criteria, that the alternative method limits negative impacts on consumers where possible. This criterion is intended to protect tax filers from increased tax liability as a result of recalculating APTC during the benefit year as well as any other unintended

consequences, and will be weighed along with the other two criteria—providing adequate program integrity protections and minimizing administrative burden on the Exchange. We also note that certain tax filers whose APTC for the taxable year exceeds their premium tax credit may be subject to statutory repayment caps that limit their excess APTC repayment liability.

We are finalizing this rule so that the alternative method described in paragraph (g)(1)(ii) is available for all benefit years. We received one comment recommending that the alternate method sunset before 2023. We did not receive any other comments for or against the proposed sunset date. Upon further consideration of this issue, we believe that establishing a sunset date based on currently available information would be premature as we do not yet know how long Exchanges may need to mitigate system complexities. We will continue to evaluate the future need for an alternative method of recalculating APTC during the benefit year as Exchange systems develop.

Finally, we will consider providing additional guidance about the approval criteria and methodologies that the Secretary will use to evaluate alternative procedures for recalculating APTC during the benefit year.

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

(1) Enrollment of Qualified Individuals Into QHPs (§ 155.400)

We proposed to amend § 155.400 to add additional flexibility to the binder payment rules. Specifically, we proposed to add § 155.400(e)(2) to give Exchanges the discretion to allow issuers experiencing billing or enrollment problems due to high volume or technical errors to implement a reasonable extension of the binder payment deadlines the issuer has set under § 155.400(e)(1). We proposed that the FFEs and SBE-FPs will, and State Exchanges may, allow these reasonable extensions which, in the case of most high volume situations or technical errors, we would not expect to be more than 45 calendar days' duration. Based on our experience from multiple open enrollment periods, billing or enrollment problems, particularly in cases where an issuer experienced technical errors or a processing backlog caused by a large volume of enrollments, can affect enrollees' ability to submit timely binder payments. We believe providing issuers with the option to allow reasonable binder

payment deadline extensions, which must be implemented in a uniform and nondiscriminatory manner, would prevent enrollees from having their coverage cancelled due to non-payment when those enrollees did not have adequate time to make their binder payments and appropriately balances issuer flexibility and consumer protectiveness. We are finalizing this provision as proposed.

We also proposed to specify that all binder payment rules, including the proposed amendment in § 155.400(e), apply to SBE-FPs in addition to FFEs. We believe that all entities on the Federal platform should utilize the same binder payment rules in order to simplify operational implementation of enrollment processing and confirmation using the Federal platform, and consider these rules to fall within the regulations pertaining to issuer eligibility and enrollment functions with which a QHP must comply in order to participate in an SBE-FP, under § 156.350. We are also finalizing this provision as proposed and are adding regulation text at § 156.350(a)(4) to reflect this amendment.

Additionally, in the preamble to § 156.270 in the 2017 Payment Notice, we stated as part of our interpretation of § 156.270(d) that a binder payment is not necessary when an enrollee enrolls, either actively or passively without a gap in coverage, in a plan within the same insurance product. We understand that this may be different than some issuers' practices prior to the Affordable Care Act and that issuers may have operational challenges in distinguishing between enrollment in the same product versus a different product. To minimize operational concerns, we sought comment on whether we should amend the binder payment requirement in § 155.400(e) to not require a binder payment when a current enrollee enrolls, either actively or passively, in any plan with the same issuer—not only a plan within the same product—and on the appropriate timeframe for making such a change. After considering the comments we received related to this proposed policy, we are not finalizing the proposed policy; we will continue to examine this issue.

Comment: Most commenters supported our proposed rule to give Exchanges the discretion to allow issuers experiencing billing or enrollment problems due to high volume or technical errors to implement a reasonable extension of the binder payment deadlines the issuer has set under § 155.400(e)(1). These commenters observed that the proposed rule balances flexibility for issuers and

consumer protection and could help to avoid enrollment cancellations and other problems, which often result in time-consuming fixes such as retroactive coverage reinstatements. Some commenters supported the proposed rule but sought an expanded version, which would allow issuers the flexibility to extend consumer's binder payment deadlines under a greater variety of situations. One commenter opposed the proposed rule as an interference with issuers' ability to make business decisions related to billing. The commenter also expressed concern that the proposed rule might complicate the logic used in issuers' billing systems, and recommended that HHS rely on issuer initiatives and State rules to provide consumer protection. One commenter expressed concern that the proposed rule would cause undue complications for issuers operating in different States.

Response: We agree that the extension, when implemented uniformly at the option of an issuer experiencing processing backlogs or technical errors during enrollment, will help to protect consumers from unnecessary coverage cancellations while giving issuers flexibility in billing and consumer outreach. We believe that the limits imposed by the proposed rule provide the necessary balance between flexibility for issuers and consumer protection. We do not agree that the proposal will interfere with issuers' billing prerogatives or cause complications for issuers operating in different States, since it makes adoption of the binder payment deadline extensions optional, and allows for flexibility in implementation.

Comment: All of the comments received that related to applying all binder payment rules to SBE-FPs in addition to FFEs expressed support for the proposal.

Response: We are finalizing the proposal to extend the binder payment rules to the SBE-FPs as written.

Comment: Some commenters supported the proposal to treat as a renewal, meaning no effectuation (binder payment) would be necessary, a consumer's re-enrollment in any plan with the same issuer. The commenters believed that such a policy would be more easily understood by consumers, prevent avoidable gaps in coverage, and adhere to many issuers' long-standing approach to premium billing. However, several commenters were critical of the proposal, with some expressing concern that relaxation of binder payment rules could lead to financial risks on the part of issuers. Other commenters stated that paying the binder payment for coverage

constitutes an affirmative statement that the consumer wants coverage with the issuer. Still other commenters requested that the enrollment rules be amended to require full payment of all premium owed to an issuer by a consumer before that consumer can re-enroll in coverage with the same issuer.

Response: We appreciate the comments related to this proposed policy. Due to the uncertain effects of this policy on consumer enrollment and payment of premiums, we are declining to finalize the policy at this time.

(2) Special Enrollment Periods (§ 155.420)

Special enrollment periods, a longstanding feature of employer-sponsored coverage, exist to ensure that people who lose health insurance during the year, or who experience other qualifying events, have the opportunity to enroll in coverage. We are committed to making sure that special enrollment periods are available to those who are eligible for them and equally committed to avoiding any potential misuse or abuse of special enrollment periods.

In 2016, we added warnings on *HealthCare.gov* about inappropriate use of special enrollment periods, eliminated special enrollment periods that are no longer needed as the Exchanges mature, and tightened eligibility rules for special enrollment periods. In addition, we introduced a Special Enrollment Confirmation Process under which consumers enrolling through the most common special enrollment periods are directed to provide documentation to confirm their eligibility for their special enrollment period.

We have heard competing concerns about how these actions are affecting the Exchange risk pools. Some have stated that additional changes are needed to prevent individuals from misusing special enrollment periods to sign up for coverage only after they become sick. Others have stated that any differential costs for the special enrollment period population reflect the very low take-up rates for special enrollment periods among eligible individuals. They claim that verification processes worsen the problem by creating new barriers to enrollment, with healthier, less motivated individuals, the most likely to be deterred.

In the proposed 2018 Payment Notice, we sought comment on these issues, especially on data that could help distinguish misuse of special enrollment periods from low take-up of special enrollment periods among healthier eligible individuals, evidence on the

impact of eligibility verification approaches, including pre-enrollment verification, on health insurance enrollment, continuity of coverage, and risk pools (whether in the Exchange or other contexts), and input on what special enrollment period-related policy or outreach changes could help strengthen risk pools.

We also sought comment on similar concerns about potential gaming and adverse selection that could result from the grace period for payment of premiums for qualified individuals receiving APTC, noting the limited regulatory options available to change grace period policy. We examined attrition rates in our enrollment data. We have found that the attrition rate for any particular cohort is no different at the end of the year than at points earlier in the year, suggesting that any such gaming, if it is occurring, does not appear to be occurring at sufficient scale to produce statistically measurable effects.

We stated that we seek to ensure transparency, stability, and appropriate utilization of special enrollment periods by codifying certain special enrollment periods that were made available through prior guidance. Therefore, in order to provide clarity and certainty to all stakeholders, we proposed to codify:

- Paragraph (d)(8)(ii) for the special enrollment period for dependents of Indians who are enrolled or are enrolling in a QHP through an Exchange at the same time as an Indian;
- Paragraph (d)(10) for the special enrollment period for victims of domestic abuse or spousal abandonment and their dependents who seek to apply for coverage apart from the perpetrator of the abuse or abandonment;
- Paragraph (d)(11) for the special enrollment period for consumers and their dependents who apply for coverage and are later determined ineligible for Medicaid or CHIP;
- Paragraph (d)(12) for the special enrollment period that may be triggered by material plan or benefit display errors on the Exchange Web site, including errors related to service areas, covered services, and premiums; and
- Paragraph (d)(13) for the special enrollment period that may be triggered when a consumer resolves a data matching issue following the expiration of an inconsistency period or has an annual household income under 100 percent of the Federal poverty level and did not enroll in coverage while waiting for HHS to verify that he or she meets the citizenship, national, or immigration status described in section 1401(c)(1)(A)(ii) of the Affordable Care Act.

We proposed to codify the special enrollment period for dependents of Indians who are enrolling at the same time as the Indian, as defined by section 4 of the Indian Health Care Improvement Act, in paragraph (d)(8)(ii) so that Indians and non-Indian members of the household may maintain the same coverage and so that this special enrollment period is consistently applied across Exchanges. This special enrollment period has enabled mixed status Indian families to enroll in or change coverage together through the Exchange. We proposed to codify the special enrollment period for victims of domestic abuse or spousal abandonment in paragraph (d)(10) so that, as specified in July 2015 guidance,⁵² victims of domestic abuse or spousal abandonment, along with their dependents, can enroll in coverage separate from their abuser or abandoner. This special enrollment period has provided a needed pathway to new coverage for consumers in these situations. We proposed to codify the special enrollment period for consumers who apply for coverage during the Exchange annual open enrollment period or due to a qualifying event and are determined ineligible for Medicaid or CHIP in paragraph (d)(11), so that consumers who applied for coverage when they were eligible to do so can ultimately enroll in coverage through the Exchange. This special enrollment period has ensured that consumers have a pathway to coverage when they have been assessed as potentially eligible for Medicaid or CHIP, but are ultimately determined ineligible. We proposed to codify the special enrollment period for material plan or benefit display errors in paragraph (d)(12), so that consumers who enrolled in a QHP offered through the Exchange based on incorrect plan or benefit information can select a new QHP that better suits their needs. We proposed to codify the special enrollment period for data matching issues that are cleared after the deadline for resolution has passed or, for those with an annual household income under 100 percent of the Federal poverty level, meet the citizenship, national, or immigration status described in section 1401(c)(1)(A)(ii) that is verified through the data matching process in paragraph (d)(13), so that consumers who submit required documents to prove that they are

⁵² Department of Health & Human Services. "Updated Guidance on Victims of Domestic Abuse and Spousal Abandonment." July 27, 2015. Available at https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Updated-Guidance-on-Victims-of-Domestic-Abuse-and-Spousal-Abandonment_7.pdf.

qualified individuals or that they qualify for APTC, may enroll in coverage through the Exchange. This special enrollment period has enabled consumers who are not able to submit required documents prior to the deadline associated with their data matching issue or those who were not able to receive an eligibility determination for APTC until verifying that they meet the citizenship, national, or immigration status described in section 1401(c)(1)(A)(ii) to enroll in coverage upon submitting sufficient documents. We sought comments on these proposals to codify existing special enrollment periods.

We also proposed to make a variety of technical corrections to correct punctuation in paragraphs (d)(1)(i) and (iii), and to update the cross-references in paragraph (b)(2)(iii) (regarding coverage effective dates) to reflect the applicable newly codified special enrollment periods. All of these changes reflect existing FFE practice in implementing special enrollment periods authorized by the Affordable Care Act and existing regulations, and do not create new special enrollment periods for consumers.

We noted that certain special enrollment periods in § 155.420 are incorporated into the individual market guaranteed availability regulations at § 147.104(b) and apply to all issuers offering non-grandfathered individual market coverage, whether through or outside of an Exchange. Additionally, certain special enrollment periods in § 155.420 also apply in the SHOPS and are incorporated into the SHOP regulations at §§ 155.725(j) and 156.285(b). Except for the proposed additions of paragraphs (d)(8)(ii) and (d)(13), which are applicable only with respect to coverage offered through an Exchange, the proposed changes to special enrollment periods would apply throughout the individual market, and we therefore proposed conforming amendments to § 147.104(b). We sought comment on this approach to aligning the proposed amendments with the individual-market-wide and SHOP special enrollment periods.

We are finalizing these policies as proposed, with the addition of paragraph (b)(5) in response to comments to give the consumer the option for a later coverage effective date when an Exchange's verification of eligibility for a special enrollment period would cause a consumer to pay two or more months in retroactive premiums. We also modify § 147.104(b)(2) to make clear that the special enrollment period for material plan or benefit display errors in

paragraph (d)(12) only creates an opportunity to enroll in coverage through the Exchange. Additionally, we finalize a modification to clarify that the income we are referring to in paragraph (d)(13) is annual household income.

Comment: The majority of commenters supported our proposal to codify the existing special enrollment periods for (1) dependents of Indians on the same application as the Indian at § 155.420(d)(8)(ii); (2) victims of domestic abuse or spousal abandonment at § 155.420(d)(10); (3) Medicaid or CHIP denials at § 155.420(d)(11); (4) material plan or benefit display errors at § 155.420(d)(12); and (5) data matching issues that are cleared post-expiration of an inconsistency period or individuals who are verified through the data matching process to meet the citizenship, national, or immigration criteria described in section 1401(c)(1)(A)(ii) of the Affordable Care Act at § 155.420(d)(13). Commenters appreciated the transparency of adding these special enrollment periods to regulation, so that consumers, regardless of the State in which they live, have access to the same special enrollment periods, and that all individuals involved in enrollment assistance have a better understanding of the special enrollment periods that are available. In addition, one commenter requested that all available special enrollment periods be codified and another commenter wanted to confirm that HHS retains its authority to codify additional special enrollment periods in the future, if needed.

However, some commenters opposed our proposal to codify additional special enrollment periods. These commenters expressed concern that some of the proposed special enrollment periods are no longer needed or that individuals who might qualify for one of these special enrollment periods may also qualify for another special enrollment period that already exists in regulation. Commenters expressed concern that codifying these special enrollment periods would extend them to both State-based Exchanges and the off-Exchange market and recommended that HHS develop additional methods for handling operational issues outside of creating new special enrollment periods. A few commenters recommended that HHS continue to focus on eliminating and further streamlining special enrollment periods so that special enrollment periods on the Exchange more closely align with those in other coverage programs, such as Medicare or those found in HIPAA and related regulations. Finally, one commenter expressed concern that HHS

is amending its rule at § 155.420 prior to releasing results from the Special Enrollment Confirmation Process.

Response: We agree with commenters about the benefit of codifying these five special enrollment periods and that doing so provides clarity for stakeholders and consumers across Exchanges. We also agree that consumers who experience these qualifying events should have access to the same special enrollment periods, regardless of the State that they live in. We clarify that by codifying these five special enrollment periods, we are putting into regulation all special enrollment periods that have been consistently needed and utilized by the FFEs. In an effort to increase transparency, we believe it is essential to ensure awareness that all special enrollment periods continually being utilized by the Exchanges are explicitly stated in regulation.

In addition, we believe that codifying these special enrollment periods provides increased stability to the Exchange market. However, as the health insurance market continues to evolve and consumer needs change, we will continue to monitor the utilization of these and other special enrollment periods in order to identify opportunities to further streamline available special enrollment periods in the future. For now, we believe that all of the special enrollment periods currently in regulation, and those being finalized in this rulemaking, are needed.

Comment: Commenters expressed strong support for codifying the special enrollment period for dependents of Indians in paragraph (d)(8)(ii), so that mixed status Indian families may have access to the same special enrollment periods regardless of the State in which they live. One commenter requested that we expand the definition of Indians to include State-recognized tribes. Another commenter requested an explanation of whether a dependent of an Indian must be enrolled in the same QHP as the Indian and whether this special enrollment period impacts the special benefits available to Indians.

Response: We agree with commenters that codifying this special enrollment period for dependents of Indians ensures that all mixed status Indian families have the same ability to enroll in or change QHPs and we believe that this provides an important protection for all mixed status Indian families across the country. Section 1311(c)(6)(D) of the Affordable Care Act defines Indians by cross-referencing section 4 of the Indian Health Care Improvement Act, which limits the definition of Indians to members of Federally

recognized tribes or Alaska Native Claims Settlement Act Shareholders. Thus, legislative action would be necessary to change that definition to include State-recognized tribes.

We clarify that codifying this special enrollment period does not amend any of the rules for special benefits available to Indians, including their ability to qualify for additional cost-sharing reductions, as described at section 1402(d). In order to qualify for this special enrollment period, a dependent of an Indian must be on the same application as the Indian and enrolling in or changing QHPs at the same time as the Indian. However, it is not a requirement of this special enrollment period that the dependent of the Indian and the Indian enroll in the same QHP. This is because we recognize that adding a requirement that the Indian and his or her dependent enroll in the same QHP may result in the Indian forfeiting any special Indian cost-sharing reductions he or she is entitled to.

Comment: Commenters supported codifying the special enrollment period for victims of domestic abuse and spousal abandonment at § 155.420(d)(10); however, one commenter requested clarification on when a consumer could qualify for this special enrollment period.

Response: Qualified individuals who are victims of domestic abuse or spousal abandonment may qualify for this special enrollment period when they need to enroll in coverage apart from their abuser or abandoner. For victims of domestic abuse or spousal abandonment who are married to their abuser or abandoner and wish to receive an eligibility determination for financial assistance, this should also coincide with a change in tax filing status. Additional information about this special enrollment period is available in our Updated Guidance on Victims of Domestic Abuse and Spousal Abandonment published on July 27, 2015.⁵³

Comment: We received strong support for codifying the special enrollment period for material plan or benefit display errors at § 155.420(d)(12) because it provides needed protections to consumers who may have been misled when deciding which QHP to enroll in. Some commenters requested that we expand this special enrollment period to include errors to provider

directories and drug formularies, as well as to errors on the Web sites of Web-brokers. A few commenters requested that we further define material plan or benefit display errors and expressed concern about this special enrollment period applying off-Exchange.

Response: We agree with commenters that codifying the special enrollment period for material plan or benefit display errors through the Exchange provides consumers an opportunity to select a new QHP that better meets their health coverage needs, if there was a material plan or benefit display error that impacted their earlier health coverage decision. We also believe that codifying this special enrollment period clarifies that the notice requirement at § 156.1256 only pertains to this type of error. However, we clarify that this special enrollment period is limited to plan or benefit display errors, such as those related to plan benefits, service area, or premium, presented to the consumer by the Exchange at the point at which he or she enrolls in a QHP. By this we mean that the consumer must have already completed his or her Exchange application, the Exchange must have determined that the consumer is eligible for Exchange coverage and any applicable APTC or cost-sharing reductions, and the consumer must have viewed this error while making a final selection to enroll in the QHP. In order to qualify for this special enrollment period, consumers must demonstrate to the Exchange that this error impacted his or her decision to purchase a QHP.

We clarify that QHP plan or benefit information is considered to be material for purposes of this special enrollment period if that information was actually displayed by the Exchange after the consumer received a final eligibility determination and was otherwise reasonably close in time to the point at which he or she enrolled in the QHP. Because plan information displayed on *HealthCare.gov* or other Exchange Web sites, or any plan or benefit information otherwise available from Exchanges or issuers may be revised at various times if errors are detected, we believe it would be inappropriate to allow a special enrollment period where a consumer enrolls in a plan an appreciable amount of time after the error has been corrected.

While we understand that errors to provider networks and drug formularies are a serious concern, especially to those with specialized health care needs, we also note that in these cases, other consumer protections might apply. For instance, if a drug is no longer on the plan's formulary, the plan

is still required to have processes in place that allow the enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber, as appropriate) to request and gain access to clinically appropriate drugs not otherwise covered by a health plan (a request for exception) in accordance with § 156.122(c). For this reason, these cases do not qualify a consumer for this special enrollment period. We are continuing to work with issuers and States to improve the accuracy and timeliness of provider and drug information made available to consumers.

In addition, we clarify that this special enrollment period only applies to material plan or benefit display errors through the Exchange, and does not include plan or benefit display errors outside of the Exchange. This special enrollment period is intended for consumers who made the decision to purchase health coverage through the Exchange and their decision about which QHP to enroll into was impacted by this material plan or benefit display error. Through existing data correction processes, the Exchange will typically be made aware of these errors and any corrections that were made. For other plan errors that may exist outside of the Exchange, we note that a special enrollment period in paragraph (d)(5) already exists and applies marketwide for situations where a plan has substantially violated a material provision of its contract in relation to the enrollee.

Comment: Commenters requested clarification about the special enrollment period for data matching issues that are cleared post expiration of an inconsistency period at § 155.420(d)(13), including whether there is a limit on the time since the initial application for a consumer to qualify for this special enrollment period, or whether this special enrollment period can be restricted to only allow consumers to enroll in the QHP in which they were previously enrolled.

Response: In order to qualify for the special enrollment period for a data matching issue that has been cleared post expiration of an inconsistency period, documentation must be submitted that proves that the consumer was a qualified individual at the time that the data matching issue was triggered during the same coverage year. The qualified individual may then enroll in the same or a different QHP back to the date that he or she was previously expired from coverage, at his or her option, in order to eliminate a gap in coverage.

⁵³ Updated Guidance on Victims of Domestic Abuse and Spousal Abandonment. Jun. 27, 2015. Available at https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Updated-Guidance-on-Victims-of-Domestic-Abuse-and-Spousal-Abandonment_7.pdf.

Additionally, those who have an annual household income under 100 percent of the Federal poverty level and did not enroll in coverage while waiting for HHS to verify through the data matching process that they meet the citizenship, national, or immigration status described in section 1401(c)(1)(A)(ii) of the Affordable Care Act may also qualify for the special enrollment period in paragraph (d)(13) after verifying that they meet this criteria. These individuals may receive a coverage effective date and any applicable Exchange financial assistance retroactive to the coverage effective date associated with the application that triggered this data matching issue. For these consumers who have an annual household income under 100 percent of the Federal poverty level and did not enroll while waiting for HHS to verify their eligibility through the data matching process, they will receive the option for a retroactive coverage effective based on the date that they completed their application using the coverage effective date rules outlined in paragraph (b)(1) of this section.

Comment: Several commenters requested that new special enrollment periods be added, including a special enrollment period for pregnancy or a special enrollment period for qualified individuals who are automatically re-enrolled into a QHP that does not meet their health coverage needs.

Response: We thank commenters for making their suggestions about special enrollment periods. However, these issues are outside of the scope of this specific rulemaking.

Comment: Many commenters provided input and suggestions about the impact an eligibility verification would have on the Exchange market, and about changes they believe could help strengthen risk pools and reduce possible misuse of special enrollment periods. Commenters also shared thoughts about methods and criteria for monitoring and evaluating QHP enrollments through special enrollment periods.

Some commenters expressed concerns about limiting access to special enrollment periods prior to receiving adequate information about misuse and abuse, while other commenters supported expansive verification efforts where HHS verifies all QHP enrollments through special enrollment periods. In cases where HHS does verify special enrollment period enrollments, commenters requested that we conduct robust training for all individuals and entities involved in assisting consumers with enrolling in QHPs, automate the verification process to the extent

possible, and monitor and collect data across a variety of enrollee characteristics and behaviors in order to better understand the populations and identify possible trends. One commenter also requested that States operating SBEs maintain flexibility to verify eligibility for enrollments in the manner that makes the most sense for their State.

Many commenters asked about the FFE's pre-enrollment verification pilot and its parameters.

Commenters also suggested that improved data collection could also be used to curb possible misuse of special enrollment periods, in addition to expanding the Exchanges' use of electronic data sources, and improving education efforts to make sure all stakeholders understand the eligibility criteria for all special enrollment periods.

To improve the risk pool, commenters submitted a variety of ideas, including enhanced and more targeted outreach efforts, improving coordination with other entities in order to gain and retain QHP enrollments, increasing enrollment assistance for consumers who have qualified for special enrollment periods, and amending grace period rules to further incentivize qualified individuals to maintain continuous coverage.

Response: We appreciate the ideas and recommendations shared by commenters about anticipated impacts of an eligibility verification for special enrollment periods and how HHS may reduce possible misuse and abuse of special enrollment periods, while continuing to strengthen risk pools. We also appreciate the suggestions about the methods we should use to monitor special enrollment period enrollments and criteria we should evaluate in order to better understand consumer behavior and increase appropriate utilization of special enrollment periods.

We recognize the importance of providing clarity about how an Exchange may verify a consumer's eligibility for a special enrollment period, as well as about how the FFE plans to verify special enrollment period eligibility through its pre-enrollment pilot. Therefore, we have recently issued guidance describing how we will conduct our Pre-Enrollment Verification Pilot.

Comment: In addition to comments about the impact an eligibility verification would have on the Exchange market, some commenters expressed specific concerns about the potential consumer impacts of verification efforts, especially if an Exchange were to verify eligibility through a manual process prior to

enrollment. Commenters stated that making it more difficult for consumers to enroll in coverage would discourage consumers, particularly young and minority consumers, from completing their enrollments. Commenters were also concerned that delaying access to coverage for a period of time while a consumer's eligibility is being verified could harm the consumer's health if the consumer is thereby unable to access needed medical care or prescriptions during that time. One commenter warned that delaying enrollment could lead to unintended pregnancy, if consumers have a gap in access to contraceptive coverage. Further, stakeholders have expressed concern about the financial hardship or disincentives to enrollment that could result if a consumer's enrollment is delayed until after verification, but they are then ultimately required to pay months of retroactive premium because coverage effective dates are generally set based on the date a consumer selects a plan.

Response: We appreciate commenters' concerns and are committed to making a verification for eligibility to enroll in QHP coverage through a special enrollment period as consumer-friendly as possible. We are particularly cognizant of the potential effects of delays in the effective date of coverage, including gaps in coverage that result from a prolonged verification process, and the potential financial hardships or disincentives to enrollment that could result if a consumer's enrollment is delayed until after verification, but they are ultimately required to pay months of retroactive premium. In response to these concerns, we are adding paragraph (b)(5) to provide an Exchange with the flexibility to provide a consumer with a later coverage effective date, at the consumer's option, if his or her ability to enroll in coverage is delayed so that he or she would owe two or more months of premiums retroactively if his or her coverage effective date were set based on their plan selection date under existing coverage effective date rules. Doing so will avoid penalizing the consumer for delays in the process, while avoiding selection effects on the risk pool.

In addition, to help ensure program integrity and consumer protections, we note that § 155.220(j)(2)(i) requires agents and brokers to provide consumers with correct information without omission of material fact, and § 155.220(j)(2)(ii) requires them to provide the FFEs with correct information under section 1411(b) of the Affordable Care Act; § 155.210(e)(2) requires Navigators (and certain non-

Navigator assistance personnel by cross-reference at § 155.215(a)(2)(i) to provide information and services in a fair, accurate, and impartial manner; § 155.225(d)(4) requires certified application counselors to act in the best interest of the applicants assisted, and § 155.225(c)(1) requires them to provide fair, impartial, and accurate information. These duties help protect consumers and also help to safeguard against potential gaming, misinformation, and confusion when consumers are applying for and enrolling in coverage through an Exchange. Encouraging, convincing, or knowingly assisting a consumer to abuse the special enrollment process by facilitating enrollment based on false attestations, false documents, or other false information, would be a violation of these standards. Persons or entities determined to have violated these requirements may be subject to applicable penalties designed to ensure the integrity of persons and entities that assist consumers with enrollment through an Exchange. For example, consumer assistance entities in FFEs (as defined at § 155.206(b)) that violate the standards described above are subject to civil money penalties described in § 155.206; and any person who provides false or fraudulent information to an Exchange is subject to civil money penalties described in § 155.285. Agents and brokers in FFEs are subject to suspension or termination of their agreements with HHS under § 155.220(g). Organizations that are designated by an Exchange to certify their staff and volunteers as certified application counselors risk withdrawal of their designations, and individual certified application counselors risk termination of their certifications, under § 155.225(e). Navigators are subject to remedies available pursuant to the terms and conditions of Navigator grant awards, and non-Navigator in-person-assistance entities and their personnel who provide enrollment assistance pursuant to contracts or agreements with Exchanges may be subject to any remedies available under the entity's contract or agreement with the Exchange.

(3) Termination of Exchange Enrollment or Coverage (§ 155.430)

We proposed to amend § 155.430(b)(2)(iii) to specify that when an issuer seeks to rescind coverage, in accordance with § 147.128, in a QHP purchased through an Exchange, the issuer must first demonstrate, to the reasonable satisfaction of the Exchange, that the rescission is appropriate, if so required by the Exchange. In FFEs and

SBE-FPs, HHS anticipates generally requiring such a demonstration. Section 2712 of the PHS Act and § 147.128 prohibit an issuer from rescinding coverage unless the individual (or a person seeking coverage on behalf of the individual) performs an act, practice, or omission that constitutes fraud, or makes an intentional misrepresentation of material fact, as prohibited by the terms of the plan or coverage. We do not seek to restrict issuers' ability to rescind coverage when an individual or a party seeking coverage on behalf of an individual fraudulently enrolls the individual in coverage. However, because the Exchanges generally must be involved in all enrollment processes, including the process of rescinding coverage for plans purchased through the Exchange, it is necessary for the issuer to provide information to the Exchange in order to implement the rescission. Additionally, it is important for consumer protection and the orderly functioning of Exchanges that individuals whose eligibility has been verified and enrollments processed according to Exchange rules can be sure that their coverage will not be rescinded by issuers without a showing that the enrollment was fraudulent or due to an intentional misrepresentation of material fact as prohibited by the terms of the plan or coverage, meeting the requirements for rescission under § 147.128. The FFEs or SBE-FPs would not hinder an issuer seeking to rescind on grounds demonstrating fraud or intentional misrepresentation of material fact, such as the enrollment of a non-existent or deceased person.

We are finalizing this provision as proposed.

Comment: The majority of commenters were in favor of the proposed amendment and supported additional Exchange oversight of the rescission process. These commenters saw the proposed rule as providing an important consumer protection that does not unduly burden issuers. However, one commenter stated that the proposal would add another step to a rescission investigation, causing a delay in the process. Other commenters stated that issuers are in the best position to determine which coverage should be rescinded and that enrollees with rescinded coverage have a sufficient remedy in their right to an appeal. A few commenters expressed conditional support for the proposal, but expressed hope that the requirements for permissible rescissions would be well defined and that the Exchange oversight process could be structured to cause minimal delay.

Response: We believe that because the decision to rescind coverage has such serious consequences for enrollees, it is important for consumer protection and the orderly functioning of Exchanges that Exchange oversight be provided to ensure that individuals who have been determined eligible under Exchange eligibility rules do not have their coverage rescinded unless that enrollment is shown to be fraudulent or due to an intentional misrepresentation of material fact, as prohibited by the terms of the plan or coverage, meeting the requirements for rescission under § 147.128. We do not believe that additional oversight will harm consumers or issuers by adding a step to the rescission process, or that appeals conducted after a wrongful rescission are as protective of consumers as prevention of wrongful rescissions. We intend to provide further guidance on the process for issuers to demonstrate the appropriateness of rescissions to the FFEs and SBE-FPs.

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

(1) General Eligibility Appeals Requirements (§ 155.505)

In § 155.505, we proposed to add paragraph (h) permitting the Exchange appeals entity to utilize a secure and expedient paper-based appeals processes for the acceptance of appeal requests, the provision of appeals notices, and the secure transmission of appeals-related information between entities, when the Exchange appeals entity is unable to establish and perform otherwise required related electronic functions. We proposed this flexibility to accommodate some Exchange appeals entities that are continuing to work towards full compliance with regulatory requirements related to electronic appeals processes. These required electronic functions include: accepting appeal requests submitted by telephone or internet (§ 155.520(a)(1)(i) and (iv)), sending electronic notices (§ 155.230(d)), and establishing secure electronic interfaces to transfer eligibility and appeal records between appeals entities and Exchanges or Medicaid or CHIP agencies (§ 155.345(i)(1); § 155.510(b)(1)(ii) and (b)(2); § 155.520(d)(1)(ii) and (iii) and (d)(3) and (4); § 155.545(b)(3); § 155.555(e)(1); and § 155.740(h)(1)). We proposed this flexibility for individual market eligibility appeals, employer appeals, and SHOP employer and employee appeals as described in part 155, subparts C, D, F, and H.

We are finalizing these provisions as proposed.

Comment: We received comments in support of and against our proposal to permit the Exchange appeals entity to utilize a secure and expedient paper-based appeals processes for certain functions (the acceptance for appeals requests, the provision of appeals notices, and the secure transmission of appeals-related information between entities), when the Exchange appeals entity is unable to establish and perform such functions electronically. Most commenters noted the importance of a timely, streamlined appeals process, whether electronic or paper-based. Those against the proposal expressed concern that a paper-based process would contribute to delays in appeals processing. A few commenters recommended that we provide a deadline by which the Exchange appeals entity must fully comply with electronic appeals requirements. Some commenters recommended that the Exchange appeals entity accept appeals requests by email, perhaps using a fillable PDF, even if it is not able to comply with the electronic appeals requirements described in part 155, subparts C, D, F, and H. Commenters also recommended that a future electronic system have the ability to track appeals so that consumers and assisters can get status updates on appeals that are in progress.

Response: We agree with commenters about the importance of a streamlined and expedient appeals process. We also believe that appeals entities should continue to work towards modernizing and updating their appeals processes, to the extent they are able in view of competing system development priorities, in an effort to further achieve those goals. Nevertheless, we decline to finalize this rule with a deadline by which the Exchange appeals entity must fully comply with electronic appeals requirements because different appeals entities may have different operational constraints. We note that paper-based processes under this rule must be expedient, secure, and provide appropriate procedural protections for appellants. We also note that the format of appeals documents provided by an Exchange appeals entity must continue to meet the requirements of effective communications under the Americans with Disabilities Act of 1990, section 504 of the Rehabilitation Act, and section 1557 of the Affordable Care Act.

We will explore the possibility of accepting appeal requests via email, provided that any email system complies with the privacy and security requirements in § 155.260, especially

those pertaining to safeguards of PII described in paragraphs (a)(3)(vii) and (a)(4). We will take other operational suggestions under advisement when designing an electronic system for the HHS appeals entity in the future.

(2) Employer Appeals Process (§ 155.555)

Section 155.555(b) sets forth the requirements for employer appeals processes established either by an Exchange or HHS. We proposed to amend § 155.555(b) to include cross-references to proposed § 155.505(h), described above, which would permit an employer appeals process to utilize paper-based appeals processes for the acceptance of appeal requests, the provision of appeals notices, and the secure transmission of appeals-related information between entities, when the Exchange appeals entity is unable to establish and perform otherwise required related electronic functions. We are finalizing these provisions as proposed.

Comment: The comments we received for the proposed amendment to § 155.555(b) were substantially similar to those we received for the proposed amendment to § 155.505(h) described above.

Response: For the reasons described in the discussion of § 155.505(h), we are finalizing § 155.555(b) as proposed.

Comment: We also received a comment more generally about the employer appeals process and employer notices required under § 155.310(h). The commenter expressed concern that the employer appeals process “does not resolve anything” because the IRS independently determines whether an employer is liable for a payment assessed under section 4980H of the Code and whether an individual is entitled to receive the premium tax credit under section 36B of the Code. The commenter also expressed concerns with the accuracy of the notices, including a concern that employers receive notices about former employees because the Exchange does not verify the employment information an employee provides on his or her application for coverage through the Exchange. The commenter noted that the notices to employers lack information that would enable an employer to submit an informed appeal request and supporting documents, such as the months for which an employee was determined eligible for Exchange financial assistance and was enrolled in a QHP through the Exchange. The commenter recommended that the Exchanges suspend the employer notice and appeals process altogether.

Response: This comment is outside the scope of the proposed rule. However, we note that the employer notices and appeals processes are required under sections 1411(e)(4)(B)(iii) and (f)(2), respectively, of the Affordable Care Act. In the proposed 2017 Payment Notice, we stated that an employer notice described in § 155.310(h) serves two purposes: it notifies an employer that it may be liable for the payment assessed under section 4980H of the Code,⁵⁴ and it may lead to a reduction in an employee's tax liability because a successful employer appeal could lead to a discontinuation of financial assistance for which the employee is not eligible. Through our experience with employer notices that we sent for 2016, we have learned that the second purpose of the employer notice and appeals process—reducing an employee's potential tax liability—can be better achieved by verifying eligibility before enrollment in a QHP through the Exchange. We believe the Exchange can limit confusion among employers and maximize efficiency by focusing employer notices on the goal of notifying employers that they may be liable for a payment assessed under section 4980H of the Code, as required by section 1411(e)(4)(B)(iii) of the Affordable Care Act.

We recognize that concepts relating to section 4980H of the Code are complex and that the IRS ultimately determines whether the conditions outlined in those provisions have been met. However, we also believe that Exchanges may be able to appropriately streamline the employer notice and appeals processes and reduce confusion among employers, and we will consider such modifications in the future.

To ensure that employees continue to be protected from a potential tax liability, the FFEs continue to look for ways to improve their process of verifying enrollment in and eligibility for qualifying coverage in an eligible

⁵⁴ Only certain employers (called applicable large employers) are subject to the employer shared responsibility provisions under section 4980H of the Code. In general, applicable large employers must either offer minimum essential coverage that is “affordable” and that provides “minimum value” to their full-time employees (and their dependents), or make an employer shared responsibility payment to the IRS if at least one full-time employee receives the premium tax credit under section 36B of the Code. For more information on which employers are subject to the employer shared responsibility provisions and under what circumstances an applicable large employer will be subject to a payment (and how the payments are calculated), see Shared Responsibility for Employers Regarding Health Coverage; Final Rule, 79 FR 8544 (Feb. 12, 2014). Liability for the employer shared responsibility payment is determined independently by the IRS. More information on the IRS process can be found at www.irs.gov.

employer sponsored plan through the use of electronic data sources and other means. We also strongly encourage employers and employer groups to be active participants in this verification effort. For example, at minimal cost, employers can complete a Marketplace Employer Coverage Tool available at <http://www.HealthCare.gov/downloads/employer-coverage-tool.pdf> and provide it to their employees. If an employee applies for coverage through the Exchange, the employee will have information about his or her enrollment in and eligibility for qualifying coverage in an eligible employer sponsored plan so that the Exchange can make a correct determination about the employee's eligibility for Exchange financial assistance.

Finally, we understand that some employers, especially large employers, may benefit from additional information on the employer notice to identify the employee listed on the notice in order to make an accurate appeal. However, we must also be cautious to protect the personally identifiable information of the employee, as discussed in more detail in the Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers final rule and interim final rule, 77 FR 18309, 18356–18357 (Mar. 27, 2012). The FFEs will consider providing additional information, such as the date the employee was determined eligible to begin receiving financial assistance through the Exchange, on employer notices in the future.

f. 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(d)(2), an individual is exempt if his or her required contribution exceeds the required contribution percentage of his or her projected household income for a year. Finally, under § 155.605(d)(2)(iv), 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 of the Code 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 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 stated 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.⁵⁵

As the measure of premium growth for a calendar year, we established in the 2015 Market Standards Rule that we 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.⁵⁶ (Below, in § 156.130, we finalize the 2018 premium adjustment percentage of 16.17303196 (or an increase of about 16.2 percent) over the period from 2013 to 2017. This reflects an increase of about 2.6 percent over the 2017 premium adjustment percentage (1.1617303196/1.1325256291).)

⁵⁵ 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.

⁵⁶ 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.

As the measure of income growth for a calendar year, we established in the 2017 Payment Notice that we would use per capita personal income (PI). Under the approach finalized in the 2017 Payment Notice, and using the NHEA data, the rate of income growth for 2018 is the percentage (if any) by which the most recent projection of per capita PI for the preceding calendar year (\$51,388 for 2017) exceeds per capita PI for 2013 (\$44,528), carried out to ten significant digits. The ratio of per capita PI for 2017 over the per capita PI for 2013 is estimated to be 1.1540603665 (that is, per capita income growth of about 15.4 percent). This reflects an increase of about 4.0 percent relative to the increase for 2013 to 2016 (1.1540603665/1.1101836394).

Thus, using the 2018 premium adjustment percentage finalized in this rule, the excess of the rate of premium growth over the rate of income growth for 2013 to 2017 is 1.1617303196/1.1540603665, or 1.0066460588. This results in a required contribution percentage for 2018 of 8.00×1.0066460588 , or 8.05 percent, when rounded to the nearest one-hundredth of one percent, a decrease of 0.11 percentage points from 2017 (8.05317 from 8.16100). 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) of the Code and the required contribution percentage in section 36B(c)(2)(C) of the Code. We received no comments on this proposal, as such, we are finalizing as proposed. We may update the premium adjustment percentage and the required contribution percentage (for years beyond 2018) in guidance, calculating those parameters using the methodologies established through rulemaking. We are updating the regulatory text to permit this update.

g. Enrollment Periods Under SHOP (§ 155.725)

Section 155.725(g) describes the process for newly qualified employees to enroll in coverage through a SHOP and the coverage effective date for newly qualified employees. We proposed to amend paragraphs (g)(1) and (2) and add new paragraph (g)(3).

Currently, § 155.725(g)(1) requires both that: (1) The enrollment period for an employee who becomes a qualified employee outside of the initial or annual open enrollment period starts on the first day of becoming a newly qualified employee; and (2) a newly qualified employee must have at least 30 days from the beginning of his or her enrollment period to make a plan

selection. The latter requirement is intended to guarantee that the employee has sufficient time to make an informed decision about his or her health coverage needs. We did not propose changes to this latter requirement, but we proposed to change the day the enrollment period begins.

Before a newly qualified employee may make a plan selection through a SHOP, his or her employer must notify the SHOP about the newly qualified employee. Qualified employers in an FF-SHOP or SBE-FP using the Federal platform for SHOP eligibility or enrollment functions generally report newly qualified employees by adding the employee to the employee roster or by calling the FF-SHOP call center. If, however, a qualified employer waits to take either action, a newly qualified employee might not be able to begin the enrollment process until after the date upon which the employee became eligible, and might not have a full 30 days to make a coverage decision. We noted that we were concerned there might be a similar delay in State-based SHOPS.

To ensure that newly qualified employees have the full 30 days to enroll, we proposed, at § 155.725(g)(1), that SHOPS would be required to provide an employee who becomes a qualified employee outside of the initial or annual open enrollment period with a 30-day enrollment period beginning on the date that the qualified employer notifies the SHOP about the newly qualified employee. We also proposed that qualified employers would be required to notify the SHOP about a newly qualified employee on or before the 30th day after the day that the employee becomes eligible for coverage. We also proposed a conforming amendment to the requirements for qualified employers at § 157.205(f)(1). Together with the other proposed amendments to paragraph (g) discussed below, this proposal was intended to ensure that a 30-day enrollment period starting on the date of the qualified employer's notice to the SHOP would not delay the effective date of coverage beyond the limits on waiting periods imposed under § 147.116. This proposal would also ensure that newly qualified employees are provided with a full 30 days to make their health coverage decisions.

We also proposed to remove the requirement in current § 155.725(g)(1) that enrollment periods for newly qualified employees must end no sooner than 15 days prior to the date that any applicable employee waiting period longer than 45 days would end if the employee made a plan selection on the

first day of becoming eligible. We proposed to remove this requirement because we expected the proposed amendments at paragraphs (g)(2) and (3) discussed below would minimize the risk of employers exceeding waiting period limitations, as defined at § 147.116, and because we believe that removing this requirement would in some circumstances give newly qualified employees a longer period of time to make coverage decisions.

Current paragraph (g)(2) provides that a newly qualified employee's coverage effective date must always be the first day of a month and must generally be determined in accordance with paragraph (h), unless the employee is subject to a waiting period consistent with § 147.116, in which case the effective date may be on the first day of a later month, but in no case may the effective date fail to comply with § 147.116. Thus, in an FF-SHOP, under the current rule, coverage for a newly qualified employee generally takes effect the first day of the following month for a plan selection made on or before the 15th day of a month and takes effect the first day of the second following month for a plan selection made after the 15th day of a month, unless coverage must take effect on a later date due to the application of a waiting period consistent with § 147.116. We proposed to modify paragraph (g)(2) to specify that the coverage effective date for a newly qualified employee would be the first day of the month following the plan selection, (rather than being determined in accordance with paragraph (h)), unless the employee is subject to a waiting period consistent with § 147.116 and proposed paragraph (g)(3). Under the proposal, if an employee is subject to a waiting period, the effective date would be on the first day of the month following the end of the waiting period, but in no case may the effective date fail to comply with § 147.116. The proposed amendments to paragraph (g)(2) also specified that: (1) If a newly qualified employee's waiting period ends on the first day of a month and the employee has already made a plan selection by that date, coverage would also be effective on that date; and (2) if a newly qualified employee makes a plan selection on the first day of a month and any applicable waiting period has ended by that date, coverage would be effective on that date. These amendments were intended to minimize the risk of an employer exceeding the limitations on waiting period length at § 147.116 due to SHOP enrollment timelines and processes.

Additionally, in order to ensure that SHOP operations consistent with these proposed amendments would not cause a qualified employer to exceed the limits on waiting periods under § 147.116, we proposed to amend § 155.725(g)(2) to require that if a qualified employer with variable hour employees makes regularly having a specified number of hours of service per period (or working full-time) a condition of employee eligibility for coverage offered through a SHOP, any measurement period that the qualified employer uses to determine eligibility under § 147.116(c)(3)(i) must not exceed 10 months with respect to coverage offered through the SHOP (rather than the 12-month measurement period otherwise allowed under § 147.116(c)(3)(i)). This aspect of the proposal was intended to ensure that coverage takes effect within the limitations on waiting period length at § 147.116(c)(3)(i) for variable hour employees, under which coverage must take effect no later than 13 months from the employee's start date, plus, if the employee's start date is not the first day of a calendar month, the time remaining until the first day of the next calendar month. Specifically, for qualified employers that condition eligibility for coverage on an employee regularly having a specified number of hours of service per period (or working full-time), if it cannot be determined that a newly-hired employee is reasonably expected to regularly work that number of hours per period (or work full-time), the qualified employer may take a reasonable period of time, not to exceed 10 months and beginning on any date between the employee's start date and the first day of the first calendar month following the employee's start date, to determine whether the employee meets the eligibility condition.

We sought comment on whether any of the proposed timeframes might result in a situation in which an employer or issuer falls out of compliance with § 147.116.

Consistent with § 147.116, as long as the employee subject to a waiting period may make a plan selection that results in coverage becoming effective within the timeframes required under § 147.116, coverage that begins later as a result of the employee's delay in making a plan selection would not constitute a failure to comply with the waiting period limitations under § 147.116. As a result of our proposal at paragraph (g)(2) of this section, when a newly qualified employee subject to a waiting period makes a plan selection, coverage would begin the first day of the first month that follows the expiration

of the waiting period, as long as that date is consistent with the requirements in § 147.116. However, if the first day of the first month following the expiration of the waiting period for this employee would be outside the limits under § 147.116, the SHOP would be required under paragraph (g)(2) to ensure that coverage takes effect within the required timeframe. To avoid this scenario and the operational complications it would cause for SHOPs, we proposed to specify in a new paragraph (g)(3) that waiting periods in a SHOP may not exceed 60 days in length. If an individual subject to a waiting period could have had an effective date within the timeframes in § 147.116 by making a plan selection at the beginning of the enrollment period, but delays making a plan selection, consistent with § 147.116(a), coverage would begin the first day of the first month following the end of the waiting period, even if this would not be within the timeframes in § 147.116.

In addition to specifying that waiting periods in SHOPs would not exceed 60 days, we also proposed at paragraph (g)(3) to specify the calculation methodology for waiting periods in SHOPs. Under the proposed amendment, waiting periods in SHOPs would be calculated beginning on the date the employee becomes eligible—regardless of when the qualified employer notifies the SHOP about the newly qualified employee. For example, a 60-day waiting period would be calculated as the date an employee becomes otherwise eligible plus 59 days. Under this methodology, the date the employee becomes otherwise eligible counts as the first day of the waiting period. We proposed this amendment to ensure that employers would remain in compliance with § 147.116 when factoring in certain aspects of the SHOP enrollment timeline, such as the 30 days employers would have under the proposed amendments to notify the SHOP about a newly qualified employee, the 30 days newly qualified employees have to make a plan selection, and the coverage effective dates that would apply under the proposed amendments to § 155.725(g). To minimize operational complexity in the Federal platform for the SHOP, we also proposed amendments to paragraph (g)(3) to specify that a Federally-facilitated SHOP or a State-based SHOP that uses the Federal platform for SHOP eligibility or enrollment functions would only allow waiting periods of 0, 15, 30, 45, and 60 days.

Our proposed amendments would not change the rule that in no case may the

effective date for a newly qualified employee fail to comply with § 147.116 and our proposals would only apply for purposes of SHOPs, and would not change § 147.116.

We also proposed to amend paragraph (j)(2)(i) to reflect the proposed codification of existing special enrollment periods discussed in the preamble to § 155.420, specifically those proposed to be codified at § 155.420(d)(10), (11), and (12).

We are finalizing these policies with modifications that will generally maintain the status quo with respect to enrollment periods and coverage effective dates for newly qualified employees in State-based Exchanges that are not using the Federal platform for SHOP functions. These modifications generally preserve the current version of § 155.725(g) in State-based Exchanges that are not using the Federal platform for SHOP functions, and make most of the proposed amendments to § 155.725(g) applicable only in FF-SHOPs and in SBE-FPs using the Federal platform for SHOP functions. The only proposed amendment that we are finalizing to apply in all SHOPs (both State-based and Federally-facilitated) is the amendment we proposed at (g)(3) specifying when waiting periods in SHOPs begin. Additionally, we are modifying the proposed amendments to specify that, in an FF-SHOP or in an SBE-FP using the Federal platform for SHOP functions, if a newly qualified employee makes a plan selection on the first day of a month and any applicable waiting period has ended by that date, coverage must be effective on the first day of the following month (rather than, as was proposed, on the date of the plan selection). We are also making some modifications to the text of the proposed regulation to indicate that employees are considered to have received a qualified employer's offer of coverage, and thus, to have become qualified employees, as soon as they become otherwise eligible for coverage under the terms of the group health plan, before any applicable waiting period has elapsed.

Comment: One commenter agreed with all of the proposed changes. This commenter stated that without the proposed changes, incompatible deadlines would make it difficult for employers to meet enrollment timeframes and waiting period rules. We also received several comments stating that the proposed requirements are too prescriptive. These commenters believe that State-based SHOPs should have flexibility to establish their own policies for employees enrolling in

coverage for the first time outside of the group's initial or annual enrollment period. The commenters further believed that the proposed requirements should be optional for State-based SHOPs.

Response: We recognize that under HHS's SHOP regulations, State-based SHOPs have generally enjoyed significant flexibility to establish their own enrollment operations and timeframes. In order to ensure that State-based Exchanges that are not using the Federal platform for SHOP functions continue to have flexibility to establish enrollment timeframes for newly qualified employees based on State rules, definitions, and operational functions, we have decided to make most of the proposed amendments to § 155.725(g) applicable only in FF-SHOPs and SBE-FPs using the Federal platform for SHOP functions in this final rule, and generally to preserve the current version of § 155.725(g) for State-based SHOPs that are not using the Federal platform. The only proposed amendment that will apply in all SHOPs, including State-based SHOPs that are not using the Federal platform, is the amendment proposed at § 155.725(g)(3) (finalized at § 155.725(g)(1)(iii) and (g)(2)(iii)) regarding when waiting periods in a SHOP begin. We would continue to expect that, as is the case under the current rule, all SHOPs would establish enrollment timeframes and coverage effective dates for newly qualified employees that enable qualified employers administering group health plans to remain compliant with § 147.116.

Comment: We received some comments in support of the proposal to begin the enrollment period for a newly qualified employee on the day that the qualified employer notifies the SHOP about the newly qualified employee. We also received some comments that did not support this proposal. One commenter believed that the proposal is not necessary because there are sufficient requirements under ERISA that govern employer-imposed waiting periods. This commenter also believed that qualified employees are not offered coverage, and therefore are not "qualified employees," until after they have already successfully completed any applicable waiting period, and that our proposal requiring employers to notify the SHOP about a newly qualified employee on or before the 30th day after the employee becomes eligible thus permits a qualified employer to notify the SHOP up to 30 days after any applicable waiting period has ended. Further, this commenter believed that

requiring employers to notify the SHOP about a newly qualified employee is administratively unnecessary because the employee may decline coverage and there is nothing for the SHOP to do if the employee declines coverage. Another commenter expressed concern that an employer could wait weeks or months before notifying the SHOP regarding a new employee. One commenter also believed that because there is little to no indication that the current enrollment period is not sufficient for making an informed decision, the current rules should be maintained.

Response: We do not agree with the commenter's premise that an individual does not become a qualified employee until after any applicable waiting period has elapsed. Under § 155.20, a qualified employee is defined as any employee or former employee of a qualified employer who has been offered health insurance coverage by such qualified employer through the SHOP. For SHOP purposes, once an employee is offered coverage through the SHOP by a qualified employer, the employee is considered to be a qualified employee even if, consistent with § 147.116(b), a waiting period must pass before coverage for the individual can become effective. Thus, for SHOP purposes, a qualified employee is considered to be "otherwise eligible" within the meaning of § 147.116(c). Moreover, under § 155.710(b)(2), a qualified employer must offer coverage in a QHP through the SHOP to all full-time employees. If an employer is not considered to have offered coverage (for SHOP purposes) to all current full-time employees until all applicable waiting periods had elapsed, this could delay the employer's eligibility determination and thus delay the initial group enrollment. We are modifying the rule text in this final rule to make our position clearer.

HHS also does not believe that it is administratively unnecessary for a qualified employer to notify a SHOP about a newly qualified employee, even if that employee ultimately declines the offer of coverage. This notification is necessary in order for the SHOP to provide newly qualified employees with an enrollment period, particularly in circumstances where employee choice is offered and where employees choose a plan online. Moreover, qualified employers in all SHOPs are already required to notify the SHOP of newly qualified employees under existing rules at § 157.205(f)(1), and that general requirement will not be modified in this final rule, although § 157.205(f)(1) will be modified in this final rule to establish a deadline for this notification

in FF-SHOPs and in SBE-FPs using the Federal platform for SHOP functions.

Qualified employers administering group health plans are ultimately responsible for ensuring that they remain compliant with § 147.116. However, our proposals were intended to make it easier for such employers to comply with § 147.116, while also providing for more uniform enrollment timeframes and rules that permit SHOPs, particularly FF-SHOPs and SBE-FPs using the Federal platform for SHOP functions, to operate more efficiently.

In order to prevent circumstances where employers potentially wait weeks or months before notifying a SHOP regarding a newly qualified employee, HHS is finalizing our proposal to require qualified employers to notify the SHOP about a newly qualified employee on or before the 30th day after the day that the employee becomes eligible for coverage, but (as discussed above) with modifications to limit this requirement to FF-SHOPs and to SBE-FPs using the Federal platform for SHOP functions, and to make it clear that this notification should occur when the employee becomes a newly qualified employee, that is, when the employee becomes otherwise eligible for coverage. HHS is also making a conforming change to the proposed requirements for qualified employers at § 157.205(f)(1). We are also amending § 157.205(e)(1) in this final rule to align that provision with our amendments to § 155.725(g).

Comment: HHS received one comment supporting the proposal to remove the requirement that enrollment periods for newly qualified employees end no sooner than 15 days prior to the date that any applicable waiting period that is longer than 45 days would end.

Response: We are finalizing this amendment as proposed for FF-SHOPs and for SBE-FPs using the Federal platform for SHOP functions, because removal of this requirement in these SHOPs, where our other proposed amendments will apply, may in some circumstances provide newly qualified employees with a longer period of time to make coverage decisions, as discussed in the preamble to the proposed rule.

Comment: We received one comment supporting the proposal to specify that the coverage effective date for a newly qualified employee be the first day of the month following the plan selection (rather than being determined in accordance with paragraph (h)), unless the employee is subject to a waiting period consistent with § 147.116 and proposed paragraph (g)(3), in which case the effective date would be on the

first day of the month following the end of the waiting period. We also received some comments that did not support the proposal to remove the cross-reference to the requirements at paragraph § 155.725(h) for newly qualified employees. One commenter believed that QHP issuers would not have sufficient time to process new enrollments and create and distribute welcome packages under the proposal at (g)(2). Other commenters stated they believe the new requirements are too prescriptive for State-based SHOPs and that State-based SHOPs should maintain flexibility to establish effective dates for employees enrolling in coverage for the first time.

Response: We are making most of the amendments proposed at § 155.725(g) applicable only in FF-SHOPs and in SBE-FPs using the Federal platform for SHOP functions (as discussed above), and are also modifying the provision regarding the coverage effective date for newly qualified employees that make a plan selection on the first day of a month, after any applicable waiting period has ended. For FF-SHOPs and SBE-FPs utilizing the Federal platform for SHOP functions, we believe that for operational reasons, removing the cross-reference to the 15th day of the month coverage effective date rule described in paragraph § 155.725(h)(2) will help to ensure that qualified employers administering group health plans are in compliance with the limitations on waiting period length at § 147.116. In order to further minimize the risk that qualified employers administering group health plans would exceed waiting period length limitations at § 147.116, we are finalizing our proposal that if plan selection is made prior to the first day of the month and any applicable waiting period ends on the first day of the month, coverage will be effective on that day, but are limiting the applicability of this provision to FF-SHOPs and to SBE-FPs using the Federal platform for SHOP functions.

We are modifying the proposed requirement to effectuate coverage on the first day of the month when a plan selection happens on the first day of the month and any applicable waiting period has already ended. First, due to operational limitations of the Federal platform, and in consideration of the concerns expressed in some of the comments received, we are modifying the provision so that coverage will take effect in these circumstances on the first day of the following month. Second, like most of the proposed amendments, this provision will apply only in FF-SHOPs and in SBE-FPs using the Federal platform for SHOP functions.

The coverage effective date timelines that will be established in this final rule for FF–SHOPS and SBE–FPs using the Federal platform for SHOP functions are similar to timelines required for certain special enrollment periods, and we believe issuers are equipped to effectuate coverage consistent with the rule, even if it means that some newly qualified employees might not receive their welcome packages until after the coverage effective date.

Comment: We received one comment expressing concern about the proposals on variable-hour measurement periods for SHOP employers. The commenter believed that this new requirement would create a barrier to entry and compliance issues for large employers considering purchasing coverage through a SHOP.

Response: We are finalizing the proposed amendment relating to variable-hour measurement periods, but are making it applicable only in FF–SHOPS and in SBE–FPs using the Federal platform for SHOP functions, in order to help qualified employers—including large employers—administering group health plans in those SHOPs remain in compliance with waiting period rules for variable hour employees as described at § 147.116(c)(3)(i). This requirement helps to ensure that coverage takes effect for variable hour employees no later than 13 months from the employee's start date plus, if the employee's start date is not the first day of a calendar month, the time remaining until the first day of the next calendar month.

Comment: Some commenters did not support our proposals requiring that waiting periods in the SHOP not exceed 60 days and the proposal to specify the calculation methodology for waiting periods in SHOPs. One commenter stated that because SHOPs do not monitor employer waiting periods, the proposal to only allow up to 60 days for a waiting period would unnecessarily require the SHOP to begin monitoring employer benefit plans. Further, commenters stated that certain States have laws that allow employers to impose up to a 90-day waiting period and more restrictive requirements would discourage employer participation and invite compliance errors. Another commenter supported our proposal on waiting periods.

Response: We are finalizing the proposal that waiting periods in SHOPs not exceed 60 days with a modification to make it apply only in FF–SHOPS and in SBE–FPs using the Federal platform for SHOP functions, for the reasons discussed above. We would continue to

expect that, as is the case under the current rule, State-based SHOPs that are not using the Federal platform for SHOP functions would establish enrollment timelines and coverage effective dates for newly qualified employees that enable qualified employers administering group health plans to remain compliant with § 147.116.

Due to the operational functionality of the Federal platform, permitting qualified employers in FF–SHOPS and in SBE–FPs utilizing the Federal platform for SHOP functions to opt for a 90-day waiting period creates heightened risk that the waiting period limitations at § 147.116 would be exceeded under the standard systems logic, and thus creates operational complexity for these SHOPs, which under our rule are obligated to ensure a coverage effective date that does not exceed the limitations under § 147.116.

Because the proposal requiring that waiting periods in SHOPs be calculated beginning on the date that the employee becomes eligible for coverage is generally consistent with § 147.116, we are finalizing that proposal to apply in all SHOPs, including State-based SHOPs that are not using the Federal platform. We are modifying that proposal to reflect that the waiting period should begin on the day that the employee becomes a qualified employee who is otherwise eligible for coverage, for the reasons discussed above.

Comment: We did not receive any comments on our proposed amendment to § 155.725(j)(2)(i) to reflect the proposed codification of existing special enrollment periods discussed in the preamble to § 155.420, specifically those proposed to be codified at § 155.420(d)(10), (11), and (12).

Response: We are finalizing this amendment as proposed.

h. SHOP Employer and Employee Eligibility Appeals Requirements (§ 155.740)

We proposed to amend § 155.740(b)(2) to include a cross-reference to proposed § 155.505(h). This amendment would permit SHOP employer and employee eligibility appeals entities to use a secure and expedient paper-based process if the appeals entity cannot fulfill certain electronic requirements. We are finalizing this amendment as proposed.

Comment: We received one comment supporting our proposal to cross-reference proposed § 155.505(h) to permit SHOP employer and employee eligibility appeals entities to use a secure and expedient paper-based process if the appeals entity cannot fulfill certain electronic requirements.

Response: We are finalizing our proposal without modification.

i. Request for Reconsideration (§ 155.1090)

In the proposed rule, HHS proposed a new § 155.1090 to allow an issuer to request reconsideration of denial of certification of a plan as a QHP for sale through an FFE. We proposed that an issuer that has applied to an FFE for certification of QHPs and has been denied certification must submit to HHS a written request for reconsideration within seven calendar days of the date of written notice of denial of certification in the form and manner specified by HHS in order to obtain a reconsideration. We further proposed that the issuer must include any and all documentation in support of its request when it submits a request for reconsideration. We proposed that requests may be submitted and considered only after an issuer has submitted a complete, initial application for certification and been denied. In § 155.1090(a)(3), we proposed that HHS would provide the issuer with a written reconsideration decision, and that decision would constitute HHS's final determination. In the preamble of the proposed rule, we noted this approach would afford issuers an opportunity to furnish any additional facts and information that might not have been considered as part of an FFE's initial decision to deny certification. We also indicated our intent is for the Office of Personnel Management to maintain authority over reconsideration of applications from issuers to offer a multi-State plan. We are finalizing these provisions as proposed.

Comment: All commenters supported the proposal to allow an issuer to request reconsideration of denial of certification. One commenter expressed concern about the short timeline to submit the request for reconsideration, but indicated additional guidance on the process should allow issuers to navigate the process successfully. One commenter requested HHS provide more information about the timeline for this process.

Response: We believe the short timeline for submission of the reconsideration requests is required to allow HHS the opportunity to implement a decision to certify a plan prior to open enrollment. We intend to provide future guidance on the form and manner through which issuers should submit requests for reconsideration.

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

a. General Provisions

(1) FFE User Fee for the 2018 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 2017, issuers seeking to participate in an FFE in benefit year 2018 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, certification 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 are not 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 2018 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 through 2017 FFE user fee rate. 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 we have sought and expect to receive an exception from 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, to ensure that the FFEs 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, in cases where user fee collections do not cover the full cost of the special benefit. We are finalizing the FFE user fee rate as proposed. We will maintain this user fee rate for future benefit years until changed in rulemaking.

Additionally, we have received feedback suggesting that the FFEs would be able to increase enrollment by allocating more funds to outreach and education, a benefit to both consumers and issuers. We sought comment on how much funding to devote to outreach and education, and on whether HHS should expressly designate a specific portion or amount of the FFE user fee to be allocated directly to outreach and education activities, recognizing the need for HHS to continue to adequately fund other critical Exchange operations, such as the call center, *HealthCare.gov*, and eligibility and enrollment activities.

Comment: Commenters supported the proposed FFE user fee rate. Commenters also noted that the FFE user fee rate should decrease over time. One commenter opposed HHS's request for a waiver from OMB Circular A–25R.

Response: For the initial years of FFE operation, we set the user fee rate lower than the full costs of the FFEs and did not collect user fee revenue to cover the

full costs of FFE operations. We have not collected user fees to cover the full cost of the Federal functions for the first years of FFE operations. However, we do anticipate gaining economies of scale from functions with fixed costs, and if so, may consider reducing the FFE user fee based on increased enrollment and premiums in the future. We will continue to assess the user fee each year and set the user fee rate to equal the amount necessary to cover the full cost of the special benefits provided. The exception from the OMB circular A–25R allows HHS to ensure that the FFEs 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, in cases where user fee collections do not cover the full cost of the special benefit.

Comment: One commenter requested that the FFE user fee rate be charged as a fixed dollar amount instead of a percent of premium.

Response: As we have stated in prior payment notices, 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.

Comment: We received several comments supporting HHS increasing the amount of funds allocated to outreach and education, with some commenters suggesting HHS allocate certain amount of funds to outreach and education efforts for certain subgroups, such as American Indian/Native Alaskan groups and residents in rural areas. A few commenters suggested designating up to 30 percent of user fee revenue for outreach and education for adequate enrollment of young and healthy consumers. One commenter noted that a FFE user fee rate up to 4 percent of premium would be acceptable, particularly since this rate would be spread across plans on- and off-Exchange. Another commenter stated that HHS should evaluate the consumer experience end-to-end to determine which aspects need improvement.

Response: We believe that continuing to use an established portion of FFE user fees for outreach and education

will help expand access to health coverage while benefiting issuers, including by providing issuers and regulators greater confidence that the FFEs' issuers' risk pools will continue to improve. In 2016 and prior years, we designated approximately two to three percent of FFE user fees for consumer education and outreach. We are finalizing a policy to designate approximately three percent (at least) of FFE user fees for those purposes in the future. As enrollment in the FFEs grows, we will continue to adjust our investment in outreach and education efforts to help increase enrollment and also improve the FFEs' issuers' risk pools by enrolling additional young and healthy individuals.

(2) SBE-FP User Fee for the 2018 Benefit Year (§ 156.50)

SBE-FPs enter into a Federal platform agreement with HHS to leverage the systems established by the FFEs to perform certain Exchange functions, and to enhance efficiency and coordination between State and Federal programs. Accordingly, in § 156.50(c)(2), we specify that an issuer offering a plan through an SBE-FP 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, unless the State-based Exchange and HHS agree on an alternative mechanism to collect the funds. The functions provided to issuers in the SBE-FPs 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 fee charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public. The user fee rate for SBE-FPs is 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 the SBE-FP user fee rate charged for issuers offering QHPs in the SBE-FPs. A significant portion of expenditures for FFE services are associated with the

information technology, call center infrastructure, and 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 personnel who perform the functions set forth in § 155.400 to facilitate enrollment in QHPs. Based on this, 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 for the 2018 benefit year. This fee would support FFE operations costs incurred by the Federal government associated with providing the services described above.

We sought comment on this proposed SBE-FP user fee rate. In the 2017 Payment Notice, we set the user fee rate for SBE-FPs at 1.5 percent of premiums charged, rather than the full rate of 3.0, in order to provide a transition year during which States could adjust to the assessment of a user fee in SBE-FP States. We also sought comment on whether the impact of increasing the SBE-FP user fee rate to the full rate should be spread over one additional year.

We intend to review the costs incurred to provide these special benefits each year, and revise the user fee rate for issuers in the FFEs and SBE-FPs accordingly in the annual HHS notice of benefit and payment parameters.

Comment: Some commenters requested that HHS keep the reduced SBE-FP user fee rate of 1.5 percent for the 2018 benefit year and beyond, and that a user fee rate of 3.0 percent allows only 0.5 percent of total premium as revenue for SBE-FPs to carry out their functions. One commenter stated a preference for a lower user fee rate for the 2018 benefit year, supporting an SBE-FP user fee rate of up to 2.0 percent of premiums. Another commenter stated that a SBE-FP user fee rate of 3.0 percent of premiums for issuers offering plans through a SBE-FP does not reflect the scalability of the Exchanges that HHS has noted.

Response: The SBE-FP user fee rate is based on the percent of FFE costs that are attributed to Federal functions associated with the information technology, call center infrastructure, and eligibility determinations for enrollment in QHPs and other applicable State health subsidy programs. We believe issuers offering QHPs through the Federal platform ought to be charged proportionally for the special benefits provided. We have calculated the costs to yield a user fee

rate of 3.0 percent for issuers benefiting from functions provided by the Federal platform. However, we understand the need to provide another year to adjust to the increased user fee rate in the SBE-FP States, and so, are finalizing an SBE-FP user fee rate of 2.0 percent for the 2018 benefit year. We will maintain this SBE-FP user fee rate for future benefit years unless changed in future rulemaking. We will continue to assess the SBE-FP user fee rate each year, and 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.

Comment: Another commenter suggested HHS require SBE-FPs to allocate a certain portion of a State's assessments on outreach and education.

Response: We are not requiring SBE-FPs to allocate a certain share of the State's assessments at this time, and note that we also do not require the SBE-FPs to set the State assessment at any specific rate.

(3) Single Risk Pool (§ 156.80)

We proposed to amend § 156.80(d) to remove the reference to the transitional reinsurance program, which was established for benefit years 2014 through 2016. To more explicitly reflect how the rating factors under § 147.102 and the single risk pool index rating methodology under § 156.80 work together, we also proposed to restructure paragraph (d)(1) as paragraphs (d)(1)(i) through (iv), adding new proposed paragraph (d)(1)(iii) to provide that the index rate must be calibrated on a market-wide basis to correspond to an age rating factor of 1.0, a geographic rating factor of 1.0, and a tobacco rating factor of 1.0, in a manner specified by the Secretary in guidance. We are finalizing both amendments to § 156.80(d) with minor modifications as described below. Technical guidance will be provided through Unified Rate Review Instructions to ensure accurate and uniform application of the calibration methodology.

Comment: Some commenters thought calibration should be applied at the plan level as opposed to the market level, while another commenter recommended including "calibrated base rates" in the Unified Rate Review Template.

Response: The purpose of calibration is to allow the premium rating factors under § 147.102 to be directly and accurately applied to the plan-adjusted index rate to generate the appropriate premium charged to an individual or small employer based on age, geography, and tobacco use. For

example, calibration with respect to the age curve identifies the value on the applicable age curve associated with the weighted average age on the standard age curve. After applying age calibration, the plan-adjusted index rate and the standard age curve can then be used to generate the schedule of premium rates for all ages for each plan.

We proposed that calibration must be applied at the market level because calibration is a common adjustment for all of an issuer's plans in the single risk pool of the State market, even though it only occurs after the plan-adjusted index rate has been determined. However, in response to commenters' concerns, we recognize that it may reduce confusion to codify the calibration provision as a separate step in the index rate setting methodology. Therefore, we are relocating the calibration provision to new paragraph (d)(3) and redesignating existing paragraph (d)(3) as paragraph (d)(4). We are also adding regulation text to reflect the purpose described in the proposed rule—ensuring that any rating variation under § 147.102 may be accurately applied with respect to a particular plan or coverage. We are also specifying in the regulation text that, notwithstanding the codification of the provision as a new step after the application of plan-level adjustments, calibration must be applied uniformly to all plans within the single risk pool of the State market and cannot vary by plan.

b. Essential Health Benefits Package

(1) 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 used to determine eligibility for certain 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 CMS Office of the Actuary. Accordingly, using the employer-sponsored insurance data, the premium adjustment percentage for 2018 is the percentage (if any) by which the most recent NHEA projection of per enrollee employer-sponsored insurance premiums for 2017 (\$5,962) exceeds the most recent NHEA projection of per enrollee employer-sponsored insurance premiums for 2013 (\$5,132).⁵⁷ Using this formula, we proposed and are finalizing the premium adjustment percentage for 2018 at 16.17303196 percent. We note that the 2013 premium used for this calculation has been updated to reflect the latest NHEA data. Based on the final 2018 premium adjustment percentage, we are also finalizing the following cost-sharing parameters for calendar year 2018.

As described above, we may update the annual premium adjustment percentage in guidance in the future, pursuant to the methodology that has been established through rulemaking. Consistent with § 156.130(e), we also will publish any annual revision to the premium adjustment percentage in the annual HHS notice of benefits and payment parameters.

Maximum Annual Limitation on Cost Sharing for Calendar Year 2018. Under § 156.130(a)(2), for the 2018 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 2018, 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 16.17303196 percent for 2018 that 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, 2013,⁵⁸ we are finalizing the 2018 maximum annual limitation on cost sharing at \$7,350 for self-only coverage and \$14,700 for other than self-only coverage. This represents a 2.8 percent increase above the 2017 parameters of \$7,150 for self-only coverage and \$14,300 for other than self-only coverage. We may update the maximum annual limitation on cost sharing (for benefit years beyond 2018) in guidance in the future, pursuant to the methodology that has been established through rulemaking.

Comment: We received several comments in support of the increase in the maximum annual limitation on cost sharing. One commenter requested that HHS coordinate with the IRS in setting the maximum out-of-pocket limits for HDHPs so that the maximums are the same.

Response: HHS understands that the annual limitation under § 156.130(a)(2) in a given benefit year may be different than the annual limitation on out-of-pocket expenses for HDHPs, as defined in section 223(c)(2) of the Code. However, HHS and IRS are bound by different statutory parameters when calculating annual out-of-pocket limitations. HHS uses the premium adjustment percentage described above, and, in accordance with section 223(g) of the Code, IRS uses the Consumer Price Index (CPI), a measure of inflation, to set the out-of-pocket limit for HDHPs.

(2) Reduced Maximum Annual Limitation on Cost Sharing (§ 156.130)

Section 1402 (a) through (c) of the Affordable Care Act direct issuers to reduce cost sharing for EHB for eligible individuals enrolled in a silver level QHP. In the 2014 Payment Notice, we established standards related to the provision of 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

⁵⁷ “NHE Projections 2015–2025—Tables”. Available at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html> in Tables 1 and 17. A detailed description of the NHE projection methodology is available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ProjectionsMethodology.pdf>.

⁵⁸ See <http://www.irs.gov/pub/irs-drop/rp-13-25.pdf>.

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 proposed to continue 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. Using the proposed 2018 maximum annual limitation on cost sharing of \$7,350 for self-only coverage and \$14,700 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 2018 benefit year and our results.

Consistent with our analysis in the past 2014 through 2017 Payment Notices, we developed three silver level QHPs for purposes of testing, and analyzed the impact on AV of the reductions described in the Affordable Care Act to the estimated 2018 maximum annual limitation on cost sharing for self-only coverage (\$7,350). The test plan designs are based on data collected for 2017 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 2018, the test plans included a PPO with typical cost-sharing structure (\$7,350 annual limitation on cost

sharing, \$2,215 deductible, and 20 percent in-network coinsurance rate), a PPO with a lower annual limitation on cost sharing (\$4,950 annual limitation on cost sharing, \$2,895 deductible, and 20 percent in-network coinsurance rate), and an HMO (\$7,350 annual limitation on cost sharing, \$3,375 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 \$55 specialist office visit). All three test plans meet the AV requirements for silver level QHPs.

We then entered these test plans into the proposed 2018 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 level (FPL) ($\frac{2}{3}$ reduction in the maximum annual limitation on cost sharing), and 150 and 200 percent of the FPL ($\frac{1}{2}$ reduction), would not cause the AV of any of the model QHPs to exceed the statutorily specified AV level (94 and 87 percent, respectively). In contrast, the reduction in the maximum annual limitation on cost sharing specified in the Affordable Care Act for enrollees with a household income between 200 and 250 percent of FPL ($\frac{1}{3}$ 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 2018 benefit year with a household income between 200 and 250 percent of FPL be reduced by approximately $\frac{1}{5}$, rather than $\frac{1}{2}$,

consistent with what we have proposed in previous years. This would allow issuers flexibility to design innovative plans with varying lower maximum annual limitations on cost sharing and deductibles for the 73 percent plans. 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 $\frac{2}{3}$, as specified in the statute, and as shown in Table 13. 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 are finalizing the reductions in the maximum annual limitation on cost sharing for 2018 as proposed. Again, for benefit years beyond 2018, we may reduce the maximum annual limitations on cost sharing for these silver plan variations in guidance by the fractions established through rulemaking (for example, $\frac{1}{5}$ for enrollees with incomes between 200–250 percent of the FPL, and $\frac{2}{3}$ s for enrollees with incomes between 100–200 percent of the FPL).

We also note that for 2018, as described in § 156.135(d), States were permitted to submit for approval by HHS State-specific datasets for use as the standard population to calculate AV. No State submitted a dataset by the September 1, 2016 deadline.⁵⁹

TABLE 13—REDUCTIONS IN MAXIMUM ANNUAL LIMITATION ON COST SHARING FOR 2018

Eligibility category	Reduced maximum annual limitation on cost sharing for self-only coverage for 2018	Reduced maximum annual limitation on cost sharing for other than self-only coverage for 2018
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(i) (that is, 100–150 percent of FPL)	\$2,450	\$4,900
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(ii) (that is, 150–200 percent of FPL)	2,450	4,900
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(iii) (that is, 200–250 percent of FPL)	5,850	11,700

⁵⁹ The annual deadline for submitting State specific data for the actuarial value calculator was

announced August 15, 2014. See [https://](https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/final-state-avc-guidance.pdf)

www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/final-state-avc-guidance.pdf.

(3) Levels of Coverage: Bronze Plans (§ 156.140)

Section 2707(a) of the PHS Act and section 1302 of the Affordable Care Act directs issuers of non-grandfathered individual and small group health insurance plans, including QHPs, to ensure that these plans adhere to the levels of coverage specified in section 1302(d)(1) of the Affordable Care Act. A plan's coverage level, or AV, is determined based on its coverage of the EHB for a standard population. Section 1302(d)(1) of the Affordable Care Act requires a bronze plan to have an AV of 60 percent, a silver plan to have an AV of 70 percent; a gold plan to have an AV of 80 percent; and a platinum plan to have an AV of 90 percent. Section 1302(d)(3) further directs the Secretary to establish guidelines for the allowable de minimis variation in AVs in the level of coverage of a plan.

Currently, § 156.140(c) permits a de minimis variation of ± 2 percentage points.⁶⁰ In the proposed rule, we proposed to amend the de minimis range for bronze plans that cover and pay for at least one major service, other than preventive services (for which certain services already are required by Federal law to have zero cost sharing), before the deductible to allow a variance in AV of ± 2 percentage points and ± 5 percentage points. We further proposed a list of major services which may be covered and paid for before deductible in order to make a bronze plan eligible for the broader de minimis range. The major services proposed were primary care visits, specialist visits, inpatient hospital services, generic drugs, specialty drugs, preferred branded drugs, or emergency room services. Additionally, we proposed that the major service covered before the deductible must apply a reasonable cost-sharing rate to the service to ensure that the service is affordably covered. Finally, we proposed that a bronze plan that covers at least three primary care services before the deductible would qualify as having a major service covered before the deductible.

We proposed this amendment because, without a de minimis adjustment, future calibrations of the AV Calculator may limit issuers' flexibility in designing bronze plans. Further, we believe that bronze plans were not intended to be less generous than catastrophic plans, which are required to provide at least three primary care visits before the deductible. We also proposed that

bronze plans that are HDHPs be permitted to have the same adjusted de minimis AV range in order to maintain those plans' eligibility to become HDHPs that could be paired with a health savings account while still adhering to the bronze level of AV.

We are finalizing § 156.140(c) as proposed, with a technical correction to the regulation text to change "high deductible high plan" to "high deductible health plan." We are also finalizing the 2018 AV Calculator, which provides the option for issuers to calculate AV for a bronze plan with the broader de minimis range.⁶¹

Comment: Many commenters supported our proposal to expand the de minimis range to ± 2 and ± 5 percentage points for certain types of bronze plans. These commenters supported the increased flexibility in plan design for issuers. Further, these commenters believed that the proposed changes would generate benefits to consumers by promoting creative plan designs and plans with more generous benefits than catastrophic plans. Other commenters supported the proposed requirement that this policy be limited to plans with at least one major service covered before the deductible in applicable plans and to HDHPs. Finally, some commenters supported allowing plans which cover at least three primary care visits before the deductible to qualify for the broader de minimis range. A few commenters did not support this policy because some of these commenters believed that an expanded de minimis range created the potential of higher premiums for bronze plans. Some of these commenters believed that these higher premiums may hurt enrollees in zero cost-sharing plans since these enrollees would see no benefit from changes in the cost-sharing structure of these plans. Some commenters also expressed concerns that increasing the de minimis range of bronze plans would make them indistinguishable from silver plans and inhibit plan design innovation.

Response: We are finalizing the policy as proposed. We believe that this policy provides a balanced approach by ensuring that a variety of bronze plans can be offered, including HDHPs, while ensuring that bronze plans can remain at least as generous as catastrophic

plans. We are also finalizing our proposal that a bronze plan with at least three primary care services before the deductible would qualify for the expanded de minimis range. Issuers are not required to utilize the expanded bronze de minimis range, and we do not anticipate that this policy will have a significant impact on average bronze plan premiums. We also note that the purpose of the AV Calculator is to calculate AV to determine the level of coverage (metal level) of a plan, and it was not developed for pricing purposes.

Comment: Most commenters supported the list of major services. Some commenters requested the addition of services, such as habilitative services, rehabilitative services, laboratory services, and urgent care services. A commenter also requested that SBEs have flexibility in determining eligible major services. Other comments included a request for assurances that the policy would only require at least one category of services before the deductible and a request that HHS require at least one formulary tier to be provided before the deductible. Some commenters also requested further guidance on our list of major services.

Response: To qualify for the increased de minimis range, the plan must cover at least one major service before the deductible, with reasonable cost sharing, or meet the requirements to be a HDHP. We consider a major service to include the category of benefits within that service type before the deductible. For example, if a Bronze plan is covering specialist visits before the deductible as the major service to trigger the expanded de minimis range, we would expect that the before deductible cost sharing would apply to the range of specialist visits that the issuer covers. We are finalizing the list of major services as proposed. Therefore, the finalized definition of major services will include primary care visits, specialist visits, inpatient hospital services, generic drugs, preferred brand drugs, specialty drugs, and emergency room services. These major services are applicable to a wide variety of enrollees and could have a significant AV impact. In response to commenters' requests for a wider list of major services, we considered adding services, such as urgent care and laboratory outpatient and professional services to the list of major services. However, these services were omitted due to feasibility concerns. Based on the claims data used in the 2018 AV Calculator, overall utilization of urgent care services is

⁶⁰ Under § 156.400, the de minimis variation for a silver plan variation means a single percentage point.

⁶¹ It is the responsibility of the bronze plan issuer to ensure that its bronze plan meets the requirements under this policy at 45 CFR 156.140(c) if the issuer uses the expanded bronze plan de minimis range in the AV Calculator. For more information on the operation of this feature in the 2018 AV Calculator, please refer to the 2018 AV Calculator User Guide and Methodology that are posted at [https://www.cms.gov/ccio/resources/regulations-and-guidance/#Plan Management](https://www.cms.gov/ccio/resources/regulations-and-guidance/#Plan%20Management).

relatively low.⁶² Moreover, given that laboratory services are often accessed in conjunction, or as the result of, access to other services, such as office visits, which may not be covered before the deductible, it is unlikely that the majority of enrollees would access laboratory services before the deductible without having to access other services first. However, we note that nothing in this policy precludes plans (other than HDHPs) from covering additional services before the deductible, subject to applicable AV requirements. Also, nothing is in this policy precludes States from applying other cost-sharing requirements in addition to this policy.

We remind issuers that this policy does not exempt issuers from mental health and substance use disorder parity requirements.⁶³ This includes the rule that a separate deductible cannot be applied to mental health or substance use disorder benefits and that any deductible applied to such benefits be no more restrictive than the predominant level of the deductible applicable to substantially all medical/surgical benefits in a particular category of benefits as described in 45 CFR 146.136. Section 1302(d)(2)(A) of the Affordable Care Act requires that AV be determined based a standard population (and without regard to the population the plan may actually provide benefits to), which is not the population required for mental health and substance use disorder parity testing. Therefore, the AV Calculator is not intended to demonstrate parity.

Comment: Some commenters made recommendations for reasonable cost-sharing rates for services being covered before the deductible. These suggestions included the use of current cost-sharing review tools, tying reasonable cost sharing to the bronze standardized option rates, using no more than 50 percent enrollee coinsurance; and requiring copays on the cost sharing for the major service. Other commenters had recommendations for display and aggregation of these plans on *HealthCare.gov* and for education to consumers on these types of plans.

Response: We recognize that States are the primary enforcers of AV policy. Further, we recognize that services vary in costs by region and that issuers need flexibility in plan design. However, at a

minimum, for the purposes of this bronze plan policy, we believe that any cost-sharing rate that requires the enrollee to pay for more than 50 percent of the coinsurance (or the equivalent copay rate) could be considered an unreasonable cost-sharing rate for the major service.

(4) Application to Stand-Alone Dental Plans Inside the Exchange (§ 156.150)

In the 2017 Payment Notice, HHS finalized § 156.150(a), which establishes a formula to increase the annual limitation on cost sharing for stand-alone dental plans. Specifically, HHS finalized that for plan years beginning after 2017, the annual limitation for an SADP for one covered child would be \$350 increased by the percentage increase of the CPI for dental services for the year 2 years prior to the applicable plan year over the CPI for dental services for 2016; and, the annual limitation for an SADP for two or more covered children is twice that.

The formula increases the dollar limit for one covered child (currently set at \$350) by the percentage increase of the CPI for dental services for the year 2 years prior to the applicable plan year over the CPI for 2016. For plan year 2018, the percentage increase of the CPI for dental services for the year 2 years prior to the applicable plan year would be equal to the CPI for 2016, resulting in a zero percent increase. Therefore, for plan year 2018, the dental annual limitation on cost sharing is \$350 for one child and \$700 for two or more children. For plan years after 2018, we may adjust the annual limitation on cost sharing for stand-alone dental plans in guidance based on the formula established by regulations at § 156.150.

We have also received questions on the percentage of premium properly allocable to EHB for plans offered or intended to be offered in the individual market through Exchanges. Under § 156.470, issuers of medical and stand-alone dental plan QHPs must provide to Exchanges an allocation of their QHP premiums to EHBs and other services or benefits. Because non-pediatric dental benefits (sometimes referred to as dental benefits for “adults,” meaning individuals age 19 and older) are not EHB under § 156.115(d), no portion of the premium allocable to dental benefits for adults should be included in the allocation to EHB. Any portion of the premium allocable to dental benefits for adults should instead be included in the allocation to other services or benefits.

Comment: We received a number of comments seeking clarification of our description in the proposed rule that stated that, for plan year 2018, the

dental annual limitation on cost sharing would be “\$350 for one child and \$700 for one or more children.” Commenters sought clarification of whether the \$700 limitation applies to one or more children or two or more children.

Response: The application of the \$700 limit to one or more children was in error and we establish the annual limitation on cost sharing for SADPs certified by Exchanges for plan year 2018 as \$350 for one child and \$700 for two or more children.

Comment: We received a number of comments seeking clarification of how the annual limitations on cost sharing for SADPs certified by Exchanges apply to families with more than one child. Commenters sought clarification of whether a SADP may require additional cost sharing for one child in a family when that child has reached \$350 in cost sharing but the family’s children collectively have not reached \$700 in cost sharing.

Response: In the 2016 Payment Notice, we addressed comments on the application of annual limits on cost sharing under § 156.130 (applicable to all plans covering EHB). We clarified in the rule’s preamble that “The annual limitation on cost sharing for self-only coverage applies to all individuals regardless of whether the individual is covered by a self-only plan or is covered by a plan that is other than self-only.” (80 FR 10825). Similarly, we clarify that under § 156.150 (applicable to stand-alone dental plans covering the pediatric dental EHB that are certified by an Exchange), the annual limitation on cost sharing for stand-alone dental plans that are certified by an Exchange for one child applies to all children regardless of whether the child is covered by a self-only plan or is covered by a plan that is other than self-only. Therefore, a stand-alone dental plan covering the pediatric dental EHB must limit cost sharing to \$350 for each individual child. A stand-alone dental plan covering the pediatric dental EHB must also limit cost sharing to a total of \$700 when the plan covers two or more children.

c. Qualified Health Plan Minimum Certification Standards

(1) QHP Issuer Participation Standards (§ 156.200)

Section 156.200(c)(1) implements section 1301(a)(1)(C)(ii) of the Affordable Care Act to require, as part of QHP participation standards, that each QHP issuer offer at least one QHP in the silver coverage level and at least one QHP in the gold coverage level. Section 1311(c)(1) and 1321(a)(1)(A) and

⁶² Additional information on the consideration of urgent care services in the 2018 AV Calculator is discussed in the AV Calculator Methodology under the Section entitled “Consideration of Additional Updates Not Made in the 2018 AV Calculator” that is available at: <https://www.cms.gov/ccio/resources/regulations-and-guidance/#PlanManagement>.

⁶³ See 45 CFR 156.115(a)(3).

(B) of the Affordable Care Act provide the Secretary of HHS with the authority to establish certification criteria for QHPs and Exchanges. Therefore, HHS proposed to require QHP issuers to offer at least one silver and one gold coverage level QHP through the Exchange throughout each service area in which the issuer offers coverage through the Exchange. We further clarified that an issuer can meet this standard by offering a Multi-State Plan option in both silver coverage and gold coverage levels throughout each service area in which it offers other QHPs through an Exchange.

Specifically, we proposed to amend paragraph (c)(1) to require a QHP issuer to offer through the Exchange at least one QHP in the silver coverage level and at least one QHP in the gold coverage level, as described in § 156.140, throughout each service area in which it offers coverage through the Exchange. This added specificity would ensure that issuers applying for certification of their QHPs offer a silver and gold plan throughout each service area in which they offer coverage through the Exchange.

We are finalizing these provisions as proposed.

Comment: We received several comments in support of this proposal as consistent with the intention of section 1301(a)(1)(C)(ii) of the Affordable Care Act. Other commenters suggested that HHS work with the Office of Personnel Management to assure that a similar rule applies to Multi-State Plans.

Response: As evidenced by QHP application submissions to the FFEs, QHP issuers have generally interpreted this requirement to apply at the service area level, as opposed to at the Exchange level, meaning that an issuer must offer at least one QHP in the silver coverage level and at least one QHP in the gold coverage level throughout each service area in which it offers a QHP through the Exchange (that is, one QHP that has an AV of 70 percent and one QHP that has an AV of 80 percent, plus or minus up to two percentage points). If the requirement were to be interpreted at the Exchange level, a QHP issuer could be in technical compliance with the requirement by offering at least one QHP in the silver coverage level and at least one QHP in the gold coverage level in a very limited service area, and not offer such coverage through its full service area in a meaningful way. HHS believes that the Affordable Care Act did not intend to allow an issuer to offer a silver and gold QHP through the Exchange in merely one service area in a State, while offering other products through the Exchange, such as bronze or catastrophic QHPs, in other service

areas. This modification will ensure that consumers have an adequate choice of QHPs at different coverage levels. Further, the Affordable Care Act assumed calculation of both APTC and the premium tax credit based on the availability of a second lowest cost silver plan. As such, we are finalizing the rule as proposed to modify our regulations to more accurately align with QHP issuer practice and our interpretation of the intention of section 1301(a)(1)(C)(ii) of the Affordable Care Act. HHS continues to work with OPM to align MSP requirements with QHP certification standards where applicable.

Comment: Another commenter requested that determinations of silver/gold standards be delegated to the States. An additional commenter requested that the rule be expanded to include bronze level plans.

Response: We maintain that the intent of section 1301(a)(1)(C)(ii) of the Affordable Care Act was to require all QHP issuers in all States to meet the standard to offer silver and gold level plans in each service area they serve in the Exchange. We believe that requiring QHP issuers to offer QHPs at both the silver and gold levels of coverage will provide enough consumer choice without the need to require bronze level coverage under a similar standard. Therefore, we are finalizing with no additional modifications. Because this standard applies to QHPs, and because the Secretary was directed to establish criteria for certification of QHPs, it is appropriate for HHS to establish this requirement, and not to delegate the determination of the standard to the States.

In the 2014 Payment Notice, in order to help ensure that qualified employers and qualified employees enrolling through an FF-SHOP are offered a robust set of QHP choices, we finalized a policy at § 156.200(g) under which an individual market FFE will certify a QHP only if the QHP issuer (or an issuer in the same issuer group) offers through the FF-SHOP of the State at least one QHP in the silver coverage level and at least one QHP in the gold coverage level, unless no issuer in the issuer group has a greater than 20 percent share of the small group market in the State, based on earned premiums. We indicated in the preamble of the 2014 Payment Notice, in response to a commenter who suggested we reevaluate the policy in 2 years, that we would evaluate the effectiveness of the tying provision on an ongoing basis.

HHS sought comment, based on feedback from stakeholders, on whether the policy at § 156.200(g) is still

necessary or appropriate in the FF-SHOPs. This provision does not apply in State-based Exchanges or State-based SHOPs, and we are not aware of any State-based SHOPs that have implemented a similar policy. We are also cognizant that the policy may be discouraging issuer participation on the individual market FFEs. Therefore, we requested comment on whether we should eliminate this policy for the FF-SHOPs, for plan years beginning on or after January 1, 2018.

HHS recognizes that eliminating the SHOP participation provision could have the effect of reducing FF-SHOP issuer participation in States, and sought comment on the implications for small businesses and how to accommodate such an effect. For example, in such a circumstance, in consideration of the ongoing investments that would be required to maintain the FF-SHOPs, including for premium aggregation services, we considered providing for elimination of enrollment through FF-SHOP Web sites and providing for alternative means of enrollment into SHOP QHPs, either in States that would be particularly affected by this change or in all FF-SHOPs. In addition, we sought comment on how entities such as Web-brokers or third party administrators could help to facilitate enrollment in available SHOP QHPs. We sought comment on what other regulatory provisions would need to be modified or eliminated in such a circumstance, and on whether provisions relating to the operation of enrollment through a SHOP Web site should generally be optional at the election of the Exchanges, including State-based SHOPs.

For the reasons expressed below, HHS is modifying the SHOP participation provision at § 156.200(g) so that it is applicable only for plan years beginning before January 1, 2018; thus, the current participation requirement will not apply as an FFE certification standard for QHPs for plan years beginning on or after January 1, 2018. We will monitor the impact that this modification may have on employers seeking coverage through an FF-SHOP and on State small group markets in general, to assess whether additional adjustments need to be made moving forward. At this time, HHS is not making or finalizing any proposals to provide for new alternatives for enrollment through the FF-SHOPs. HHS may propose new alternatives for enrollment through the FF-SHOPs through future rulemaking.

Comment: Many commenters supported removing the SHOP participation provision. One commenter supported removing this provision

because small employers have indicated a preference for enrolling in off-Exchange coverage. Commenters also stated that they believed that issuers should be allowed to participate in FF-SHOPs on a voluntary basis and that the FF-SHOPs should rely on an open and competitive model that attracts issuers and employers without requiring certain issuers to participate. Additionally, while FF-SHOP enrollment for certain issuers subject to the SHOP participation provision is low, the issuers are still required to pay user fees in addition to financing administrative and operational implementation costs to comply with HHS criteria. Another commenter supported the removal of the SHOP participation provision as a means to promote issuer participation in the individual market FFEs and provide more choices for consumers in individual market FFEs. Other commenters stated that the SHOP participation provision is misaligned with HHS's desire to treat all issuers consistently and uniformly and with the Exchanges' purpose as a market-driven program in which participation is voluntary.

In contrast, other commenters were against our proposal to remove the SHOP participation provision and stated that they believe that this provision strengthens the FF-SHOPs. They stated that removing the provision would have severe impacts on FF-SHOP issuer participation and QHP availability in various States, and would hinder access to the Small Business Health Care tax credit under section 45R of the Code. Another commenter stated that eliminating the tying provision could hamper employers' ability to provide employee choice. A commenter stated that the current requirement is not an undue burden.

Response: After careful reevaluation of the SHOP participation provision at current § 156.200(g), we are amending the SHOP participation provision so that it applies as an FFE certification standard only for plan years beginning before January 1, 2018. We have considered the feedback provided by various stakeholders that issuer participation in a SHOP should be voluntary. While the provision was initially promulgated to promote issuer participation in the FF-SHOPs, we believe that issuers should be able to make decisions about whether to participate in an FF-SHOP that are independent of their decision to participate in an individual market FFE. We acknowledge that eliminating this requirement may affect issuer participation in the FF-SHOPs, and thus may affect the availability of

employee choice and access to the Small Business Health Care tax credit under section 45R of the Code; however, we believe that removing this requirement will encourage more issuers to participate more fully in the individual market FFEs, and we believe that increased participation will help to ensure that more participants in the individual market have access to financial assistance through Exchange plans. Therefore, we are amending § 156.200(g) to make the provision no longer applicable for plan years beginning on or after January 1, 2018, in order to promote issuer participation in the individual market FFEs and provide more choices for consumers in individual market FFEs for plan years beginning on or after January 1, 2018. As stated above, we will monitor the impact that this modification may have on employers seeking coverage through the FF-SHOPs and on State small group markets in general, to assess whether additional adjustments need to be made moving forward.

Comment: Some commenters were opposed to doing away with online enrollment in the FF-SHOPs. One commenter believed that replacing the online enrollment system with an alternative would undermine the FF-SHOP program and reduce key benefits of choice, transparency and competition, purchasing power for employers, and simplicity. The commenter further believed the online FF-SHOP enrollment process enables employers to compare all plans impartially and was concerned that enrollment through a broker or issuer would not provide such impartiality. Another commenter recommended that the FF-SHOP enrollment process be streamlined through the development of broker resources. An additional commenter was concerned about removing premium aggregation services. The commenters believed that without a platform to facilitate multi-issuer employee choice, FF-SHOPs will suffer from even lower enrollment because they will have very little to distinguish themselves from the small group market outside the SHOPs. Another commenter was concerned about the transfer of Exchange functions to other entities, such as Web-brokers, and allowing these entities increased responsibilities that had been delegated to Exchanges under the Affordable Care Act and in regulation. This commenter also requested increased freedom for Exchanges to develop State-based approaches to SHOP sustainability and growth. We also received a comment opposing the elimination of the FF-

SHOP enrollment Web site unless enhanced direct enrollment is in place through the Web sites of Web-brokers and issuers.

We also received a comment that recommended that HHS formally seek stakeholder input to ensure that alternative enrollment approach proposals are workable to meet the needs of small employers. The commenters believed that any such approach should account for how small employers seek determinations of their SHOP eligibility and access the Small Business Health Care tax credit under section 45R of the Code.

We also received several comments and proposed alternative solutions for FF-SHOP enrollment. These ideas included not only working with Web-based entities, but also with traditional agents, brokers, and general agents, working with third-party administrators and brokers (including Web-brokers), using an application programming interface or a reporting process to provide HHS with FF-SHOP application information to make eligibility determinations, relying on technology sites to support enrollment activities, pivoting to the private sector for FF-SHOP operations, and maintaining employee choice. We also received comments that HHS should capitalize on lessons learned from Web-broker participation in the Individual Market Exchanges and that Web-brokers should only be required to display plans for which they have established relationships with issuers. Additionally, we received comments stating that some Web-based entities have been providing online enrollment capabilities, plan management, call center support, notification capabilities, automated premium payment functions, effectuation, and reconciliation capabilities to State-based SHOPs and are positioned to assist the FF-SHOPs. One commenter suggested not providing any additional regulation or oversight on how plans should be displayed or any additional requirements in addition to what is already codified in regulation. The commenter recommended that HHS remain involved in FF-SHOP functions required by statute and retain control over key data, consumer protections, and program integrity. The commenter also recommended that HHS allow vendors to support all remaining functions.

Response: We thank commenters for their input, and will consider the suggestions provided. As mentioned above, at this time, HHS is not making or finalizing any proposals to provide for new alternatives for enrollment through the FF-SHOPs.

(2) Network Adequacy Standards
(§ 156.230)

In the 2017 Payment Notice, HHS finalized a policy to provide information about QHP network breadth on *HealthCare.gov* that will assist consumers with plan selection. For the 2017 plan year, HHS is piloting the network breadth indicator in four States on *HealthCare.gov* as an indicator of a QHP's relative network coverage.⁶⁴ The results of this pilot will determine if HHS expands the pilot to additional States for the 2018 plan year and beyond. In the final 2017 Letter to Issuers in the Federally-facilitated Marketplaces, we described how the network breadth indicator is calculated. In the proposed rule, HHS proposed to incorporate more specificity into these indicators for the 2018 plan year, and more specifically to assist consumers in identifying whether a particular plan is offered as part of an integrated delivery system. We noted that for integrated delivery systems, the breadth of the network for a plan as calculated through the network breadth methodology in the final 2017 Letter to Issuers in the Federally-facilitated Marketplaces may not accurately reflect the relative ability of a consumer to access providers compared to consumers enrolled in plans in the same county that are not part of an integrated delivery system. For plan year 2018, HHS proposed incorporating this specificity into the network information displayed in all States where network breadth is displayed. To define which plans use an integrated delivery system, HHS proposed to use the alternate essential community provider (ECP) standard in § 156.235(b) and solicited comments on whether some plans, which should be categorized as within an integrated delivery system, would not meet this definition. We are finalizing this policy, with certain modifications described below.

Comment: Many commenters supported identifying QHPs that are part of an integrated delivery system. Additionally, many commenters requested that the identification be done in a way that consumers will understand. Some commenters did not support the idea of specifying which plans are offered as part of an integrated delivery system, because the commenters believe that it may be confusing to consumers. One

commenter supported the use of the alternate ECP definition to define integrated delivery systems. However, many commenters believe that the definition lacked sufficient focus on coordination or accountability. Some commenters recommended expanding the indicators beyond integrated delivery systems to display when a QHP's network is significantly similar to the issuer's Medicaid network.

Response: We agree that providing information to consumers about plans that are part of an integrated delivery system will be beneficial to consumers. We intend to make classifications as clear as possible with the intent of avoiding consumer confusion. We also understand commenters' concerns about using the alternate ECP standard for integrated delivery systems. We are finalizing the use of the alternate ECP standard in § 156.235(b), but will also allow issuers that do not meet the alternate ECP standard to be classified as using an integrated delivery system if they are able to provide a justification for this classification. The criteria for this justification will be included in the 2018 Letter to Issuers in the Federally-facilitated Marketplaces.

In the proposed rule, we reminded issuers that § 156.230(e) takes effect in plan year 2018. This provision, finalized in the 2017 Payment Notice, requires QHP issuers to count the cost sharing paid by the enrollee for an essential health benefit provided by an out-of-network ancillary provider at an in-network setting towards the enrollee's in-network annual limitation on cost sharing for QHPs in certain circumstances. That is, if a QHP enrollee received an EHB in an in-network setting, such as an in-network hospital, but as part of the provision of the EHB the enrollee was charged out-of-network cost sharing for an EHB provided by an out-of-network ancillary provider, that cost sharing would apply towards the annual limitation on cost sharing. Alternatively, the QHP issuer could 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 by 48 hours before the provision of the benefit. The written notice would notify the enrollee that additional costs may be incurred for the 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. HHS proposed that this policy apply to QHPs, both on and off

Exchanges, regardless of whether the QHP covers out-of-network services, and sought comment on other policy changes that could limit "surprise bills" for consumers. We are finalizing our policy as proposed.

Comment: Some commenters supported the proposal to apply § 156.230(e) to QHPs that do not cover out-of-network services. Other commenters opposed the expansion of the policy's application because of concerns that these QHPs were specifically designed not to cover out-of-network services. Commenters had further concerns that costs and premiums will be increased from the expansion of this policy to other types of plans. Additionally, a commenter requested clarification regarding the cost sharing for these plans. Some commenters also supported applying the policy both on and off the Exchanges while other commenters opposed its application off the Exchanges. Other commenters expressed opposition to § 156.230(e) as the commenters believe the policy does not encourage providers to contract with issuers and allows providers to charge unlimited rates. Certain commenters also suggested alternative options, such as requiring the issuer to demonstrate its attempts to contract with the ancillary provider or specifying that the issuer not be held liable for failure of timely notice if the issuer is not made aware of potential out-of-network charges. Other commenters requested more specificity on the scope of the application of the policy, such as defining the list of ancillary services that this policy would apply to or limiting the regulation to facilities instead of settings.

Commenters were also concerned that the 48-hour timeframe was infeasible, given that every service does not require prior authorization and therefore, the issuer may not have the opportunity to send the notice. Several commenters wanted a requirement for issuers to count the cost sharing towards the annual limitation on cost sharing even when notice is given (or otherwise hold the enrollee harmless). Some commenters also wanted more specificity in the notices so that they can better assist the enrollees and wanted to ensure that the policy did not replace requiring an adequate network. Certain commenters wanted emergency services to apply and other commenters did not want emergency services to apply. One commenter requested for a safe harbor from § 156.230 for plans that experience a substantial increase in enrollment.

Response: We are finalizing our proposal to apply § 156.230(e) to QHPs

⁶⁴ Updated CMS Bulletin on Network Breadth Information for Qualified Health Plans on *HealthCare.gov*. Sept. 30, 2016. Available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/NA-Pilot-Final-Guidance-Clean-093016.pdf>.

regardless of whether the QHP covers out-of-network services and we are reaffirming that this policy applies to all QHPs, although this policy is not intended to, and does not, preempt any State law on this topic. Applying this policy to all QHPs provides a level playing field for all QHPs, and ensures that all QHP enrollees will be given this protection. As discussed in the 2017 Payment Notice, while this policy is not a full solution to the adverse financial consequences of inadvertently receiving treatment from an out-of-network provider, we believe this policy will increase transparency and ensure that consumers receive notice of the possible consequences of using an out-of-network ancillary provider. We also believe that this policy, when proper, timely notice is not provided by the issuer, will provide some mitigation of these consequences. We intend to continue to monitor these situations, including issuers' timely compliance with this provision, to consider whether further rulemaking is needed. As for the cost sharing for plans that do not cover out of network services, if timely notice is not provided, issuers must count the in-network charge for the EHB service provided by an out-of-network ancillary provider at an in-network setting towards the in-network annual limitation on cost sharing for the QHP, with any other charge assessed by the out-of-network ancillary provider treated as balance billing.

Comment: Commenters submitted a variety of comments on other policy changes that could limit consumer "surprise billing." Suggestions from commenters included increased transparency on plans' out-of-network coverage, a more targeted focus on enrollee education, requiring similar provisions to the NAIC model act requirements⁶⁵ (including facility notices and a provider and issuer remediation process), limiting the amount out-of-network providers can charge for services, banning balance billing, focusing efforts at a State level to address the unique conditions of the different markets, requiring providers to disclose all charges before the service, and having HHS exercise its Medicare conditions of participation authority to ensure hospitals have available physicians in each specialty who contract with the same health plans as the hospital. Some commenters also recommended considering certain State laws or incorporating hospital networks and providers into the solution. Many

commenters submitted comments about other network adequacy issues beyond the scope of the proposed rule.

Response: We will take these comments into consideration as we continue to address the complex issue of surprise billing of consumers for out-of-network providers at in-network settings.

(3) Essential Community Providers (§ 156.235)

In the 2017 Payment Notice, we finalized that, for QHP certification cycles beginning with the 2018 benefit year, HHS would credit issuers for multiple contracted or employed full-time equivalent (FTE) practitioners at a single location, up to the number of available FTE practitioners reported to HHS by the essential community provider (ECP) facility through the ECP petition process and published on the HHS ECP list. However, in the proposed rule, we proposed to continue the 2017 benefit year ECP calculation methodology for the 2018 QHP certification cycle—that is, a methodology that would 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. We similarly proposed to continue the 2017 benefit year calculation methodology for certain plans seeking to demonstrate that 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 level satisfies a minimum percentage of available ECPs in the plan's service area. We stated that HHS is conducting provider outreach to collect provider data necessary to implement a methodology that would credit issuers for multiple contracted or employed full-time equivalent practitioners at a single location. We sought comment on these proposals. We also sought comment on the best approach for measuring hospital ECP participation in a health plan's provider network for the 2019 benefit year.

We are finalizing these provisions as proposed.

Comment: Many commenters, including providers, provider associations, consumer advocacy groups, and health insurance issuers strongly supported our proposal to continue counting multiple providers at a single location as a single ECP toward the 30 percent ECP standard. Some of these commenters opposed reliance on FTE practitioners in future years, stating that issuers do not keep track of FTEs,

the number of FTEs at each location is too fluid to serve as a reliable measure of an issuer's satisfaction of the ECP standard, and that practitioner credentialing variances at each facility further complicates the validity of using FTEs as a proxy for access to care for Exchange enrollees. Some commenters stated that reliance on FTEs alone might not ensure geographic distribution of ECPs and an adequate range of health care services provided by ECPs. These commenters recommended that HHS conduct an impact analysis on consumer access prior to implementing an FTE practitioner methodology.

In contrast, several consumer advocacy groups, an alliance of health insurance plans, and one State opposed our proposal to continue counting multiple providers at a single location as a single ECP toward the 30 percent ECP standard. These commenters urged HHS to calculate an issuer's satisfaction of the 30 percent ECP standard based on counting multiple contracted FTE practitioners at a single location as multiple ECPs, stating that the wide variability in the number of available practitioners at each ECP facility supports this methodology for more accurately measuring consumer access to ECPs. These commenters recommended that HHS not rely solely on issuer satisfaction of the 30 percent ECP threshold to ensure adequate access to care for low-income medically underserved individuals. They recommended that HHS continue to recognize the importance of the geographic distribution and range of health care services provided by ECPs.

Two commenters opposed HHS's proposal to continue the 2017 benefit year ECP calculation methodology, as well as an FTE practitioner counting methodology for calculating an issuer's satisfaction of the 30 percent ECP standard. Instead, these commenters recommended that HHS work with issuers to identify an appropriate counting methodology.

Response: We are finalizing our proposal to continue the 2017 benefit year ECP calculation methodology for general ECP standard issuers described in § 156.235(a)(2)(i) and alternate ECP standard issuers described in § 156.235(b)(2)(i). Continuing the 2017 benefit year ECP calculation methodology will allow HHS to continue collecting provider data necessary to consider alternative calculation methodologies. We remain committed to partnering with stakeholders to identify an appropriate counting methodology.

Comment: In response to our solicitation for best approaches for

⁶⁵ Health Benefit Plan Network Access and Adequacy Model Act. Available at <http://www.naic.org/store/free/MDL-74.pdf>.

measuring hospital ECP participation in a health plan's provider network for the 2019 benefit year, two commenters recommended the counting of hospital beds as an accurate and appropriate measure of a health plan's provider network capacity to provide hospital ECP access to consumers. These commenters cautioned, however, that bed counts alone do not fully assess a hospital's capacity to provide certain services, especially children's special need services. These commenters suggested that HHS consider a combination of bed counts with analysis of a hospital's core set of service lines to ensure that the hospital has the expertise to provide the care needed by vulnerable populations. One commenter recommended that HHS continue to use bed count data collected from the Children's Hospital Association Annual Benchmark Report (ABR) and the American Hospital Association Annual Survey, when available, and allow hospitals to verify those counts through the online ECP petition.

In contrast, one commenter expressed concern that hospital bed counts may not be a reliable measure, stating that health plans do not track bed counts and they do not factor into provider contracting or health plan operations. Another commenter recommended that HHS continue to count hospital ECPs as one entity, rather than counting practitioners who provide services within the hospital but may not all participate in a health plan's network.

Finally, one commenter recommended that HHS remove children's hospitals and freestanding cancer centers from the definition of an ECP, noting that they are both already accounted for in network adequacy requirements. The commenter expressed concern that their inclusion has had the unintended consequence of vesting in these providers undue influence in their negotiations with QHPs, rather than enhancing the safety net. The commenter stated that, in contrast, critical access hospitals, rural referral centers, disproportionate share hospitals (DSH) and DSH-eligible hospitals, and sole community hospitals might be overlooked in the formation of a network if not for the ECP requirement, as there is no other mechanism to ensure their inclusion in a payer's network. 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, and children's hospitals) in the plan's service area. We also received several additional comments on topics specific to disaggregation of certain ECP categories, clarifications to the definition of an ECP, and additional regulatory recommendations pertaining to family planning providers.

Response: We appreciate suggestions on the best approach for measuring hospital ECP participation in a health plan's provider network for the 2019 benefit year. As we continue to collect provider data necessary to consider alternative approaches for measuring hospital ECP participation in a health plan's provider network, we remain committed to partnering with stakeholders to identify and analyze such alternative approaches.

(4) Enrollment Process for Qualified Individuals (§ 156.265)

We proposed an amendment to § 156.265 requiring differential display of standardized options. A discussion of the provision is contained in the preamble discussion regarding § 155.220, which concerns standards for agents and brokers using the direct enrollment process.

(5) Issuer Participation for the Full Plan Year (§ 156.272)

We proposed adding § 156.272 to provide, as a condition of certification, that QHP issuers in all individual market Exchanges make their QHPs available for enrollment through the Exchange for the full plan year for which the plan was certified, unless a basis for suppression under § 156.815 applies. We also proposed that issuers in all SHOP Exchanges must make their QHPs available for enrollment through the SHOP Exchange for the full plan year for which the plan was certified, unless a basis for suppression under § 156.815 applies.

Under our existing civil money penalty authority at § 156.805(a)(1), QHP issuers in FFEs and FF-SHOPs that do not comply with § 156.272(a) or (b) could be subject to civil money penalties (CMPs). (Issuers would not be subject to CMPs if a basis for suppression under § 156.815 applies.) We also proposed at § 156.272(c) that if an issuer fails to comply with § 156.272(a) or § 156.272(b), HHS could, at its discretion, preclude that issuer from participating in the FFEs and FF-SHOPs, for up to the two succeeding plan years. We sought comments on this proposal, including on the applicability of this section to all Exchanges and the potential use of CMPs for QHP issuers

in the FFEs and FF-SHOPs. We are finalizing the provision as proposed.

Comment: We received several comments in support of the proposal. A few commenters opposed applying the proposal to the individual market Exchanges, SHOPs, or both. These commenters suggested that the States should maintain authority over the participation requirements of QHPs and that there should be exceptions when issuers face financial capacity constraints.

Response: We are finalizing the provision as proposed. While States maintain primary regulatory authority over issuers' market participation, this requirement ensures that consumers enrolling in the individual market Exchanges during limited open enrollment periods have the same plan choice as those enrolling during open enrollment, and that qualified employers and qualified employees have generally consistent plan choices throughout the plan year. Consistent with § 155.1000(d), in a SHOP that certifies QHPs on a calendar-year basis, we interpret § 156.272(b) to require issuers to make a SHOP QHP available for enrollment through the SHOP for the duration of any employer's plan year that began in the calendar year for which the QHP was certified, even if the plan year ends after the calendar year for which the QHP was certified.

We note that the regulation contains an exception to the obligation to make a QHP available through the Exchange or SHOP (as applicable) for the full plan year for which it was certified if a basis for suppression applies under § 156.815. One of these bases relates to financial capacity limits under § 147.104(d)(1). To operationalize such a suppression, an FFE would accept a reasonable request on these grounds from the applicable State regulatory authority. A plan subject to such a suppression would be prohibited from offering coverage in the applicable market for a period of 180 days from when it denied coverage under the financial capacity limit, under § 147.104(d)(2).

(6) Non-Certification and Decertification of QHPs (§ 156.290)

Currently, under § 156.290(b), when a QHP issuer elects not to seek certification from the Exchange for a subsequent, consecutive certification cycle, that QHP issuer is required to provide notification to enrollees. However, a QHP issuer is not required to provide notification to enrollees when it is denied certification for a subsequent, consecutive certification cycle by the Exchange. HHS proposed to require that issuers denied QHP

certification provide notice to enrollees within 30 days of the date of an Exchange's denial of certification for a subsequent, consecutive certification cycle. HHS also proposed to amend the section title from Non-renewal and decertification of QHPs to Non-certification and Decertification of QHPs, and revise the paragraph headings for § 156.290(a) and (b) to reflect that QHPs are certified on an annual basis rather than renewed. We sought comment on each of these proposals. We are finalizing the proposal with a modification that accounts for the discontinuation notices required under § 147.106.

Comment: Several commenters supported our proposal. Other commenters suggested HHS not impose a new notice requirement. Instead these commenters suggested that HHS rely on notices issuers are already obligated to send to inform enrollees of renewals and product discontinuances under § 147.106. Some commenters responded that a new notice may be duplicative or confusing for consumers.

Response: We are finalizing the requirement with a modification to specify that the form and manner of the notices required under this provision will be the same as the form and manner for the discontinuation notices required under § 147.106. Under the final § 156.290(b), both issuers that do not seek certification for a subsequent, consecutive certification cycle and those that seek and are denied such certification are required to notify enrollees. They are required to do so in the manner specified by the Secretary under § 147.106. On September 2, 2016, we published a Bulletin with updated Federal standard renewal and product discontinuation notices, which specify the form and manner for the notices required under these sections.

(7) Other Considerations

Increasingly, the Exchanges serve as laboratories for innovations through which QHPs develop new ways to provide quality, cost-effective health care coverage that responds to consumers' preferences and needs. We have heard from issuers about innovations around paying for high-quality care, working with health care professionals to encourage coordinated care, standardizing benefits in ways that promote high-value care, and using analytics to engage with consumers in creative ways that improve their health and bolster retention. We also continue to seek to foster market-driven programs in the Exchanges that can improve the management of costs and care, and that provide consumers with quality, person-

centered coverage. We continue to believe that innovative issuer, provider, Exchange, and local programs or strategies can successfully promote and manage care, in a manner that contributes to better health outcomes and lower rates while creating important differentiation opportunities for market participants. In the proposed rule, 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 for 2018 in order to better meet the goals of affordability, quality, and access to care. We note that our past solicitations for means of facilitating innovation have prompted questions about whether an individual market plan is permitted to offer a wellness program. We are confirming that a plan is permitted to offer a participatory wellness program in the individual market provided that such a program is consistent with applicable State law and available to all similarly situated individuals enrolled in the individual health insurance coverage. As we explained in the preamble to the final regulations under section 2705(j) of the PHS Act⁶⁶ and as reflected in the definition at § 146.121(f)(1)(ii), a participatory wellness program is a program that does not condition a reward on an individual satisfying a standard related to a health factor or that does not provide a reward.

Comment: A majority of commenters supported our efforts to drive innovation in a variety of areas including benefit design, plan offerings, care coordination, consumer education and support tools, and technology infrastructure. Several commenters expressed support for continuing efforts related to patient-centered, high-value, coordinated care. The commenters suggested that HHS ensure that the Affordable Care Act's core consumer protections and coverage improvements be preserved, and one encouraged that HHS go farther to encourage use of preventive services. A few commenters requested that HHS ensure that further flexibility for plans does not produce policies that impede access for individuals with high-cost, chronic conditions or rare conditions. They also requested that we require that innovative benefit designs include predictable, simple appeals processes so that individuals can access needed treatments and services. A few commenters made suggestions about coordinated care noting the importance of community health and ensuring

sufficient and sustainable support for providers.

We received a few comments requesting that we require QHP issuers to accept charitable premium assistance on behalf of members. These commenters requested that we clarify the role of nonprofits, hospitals, hospital-affiliated foundations and other charitable organizations, in making third-party premium payments. One commenter commended HHS for not proposing to change current rules regarding when a QHP issuer must accept third-party payments from private grantees.

We also received comments requesting that we dedicate more Federal resources toward both general and targeted outreach to increase the number of insured and improve the insurance market risk pools. Specifically, one commenter noted the importance of attracting and enrolling middle income enrollees and another commenter noted the importance of attracting younger, healthier enrollees.

A number of commenters encouraged HHS to continue developing additional consumer tools that provide consumers with information that enables them to choose health plans based on the quality and effectiveness of care they will receive. We also received comments requesting that we develop and promote quality initiatives or programs that focus on clinical improvement, on the unique needs of children, and on women of reproductive age.

One commenter requested that we build the technical infrastructure for a single-streamlined application and the ability to screen for eligibility for Medicaid family planning-only coverage. Another commenter encouraged HHS to explore options that would provide Exchanges flexibility to offer products such as vision insurance, disability, and other products that small businesses want as part of their full benefits package, as well as products that are hard to access in the individual market compared to the group market.

Commenters encouraged HHS to work with States to permit innovative State-level solutions, including oversight of and consistency of rate review. One commenter encouraged us to combine coverage expansion with quality improvement and delivery system reform by working through a multi-stakeholder process including working with purchasers, health plans, providers and consumer advocates to develop a robust set of initiative. One commenter discouraged us from interfering in private markets for insurance.

A few commenters suggested that we work on stabilizing the risk pool,

⁶⁶ See 78 FR 33157 (June 3, 2013).

explore options for extending the reinsurance program, and ensure the viability of the individual market. They requested that we work with Congress to ensure sufficient risk corridor funds are available and are paid to make issuers whole.

Two commenters requested that we make changes to policies surrounding pharmacy benefits and prescription drugs. One commenter requested that restrictions on use of mail-service pharmacy offerings should be made less restrictive to facilitate more mail order usage, encouraged HHS to revisit its decision to impose dual standards on formulary development, and requested that we assess whether we can waive (or allow States to waive) the Medicaid best price rebate program requirement in the Exchange. Another commenter requested that we revisit the regulation related to external review of pharmacy exception requests (§ 156.122(c)(3)(ii)) and noted their concern with adherence to external review timeliness standards by issuers.

Response: We appreciate these comments and will take them under consideration.

d. Eligibility and Enrollment Standards for Qualified Health Plan Issuers on State-Based Exchanges on the Federal Platform (§ 156.350)

In the 2017 Payment Notice we established, in § 156.350, that in order to participate in an SBE-FP, 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 in an FFE. These regulations and guidance include those requirements specified in paragraphs (a)(1) through (3) of § 156.350, which currently include § 156.285(c)(8)(iii). For the same reasons that we proposed to add new paragraph § 155.200(f)(4), we also proposed to amend paragraph § 156.350(a)(2) to specify that, in order to participate in an SBE-FP using the Federal platform for SHOP enrollment functions, a QHP issuer would be required to send enrollment reconciliation files on at least a monthly basis according to a process, timeline, and file format established by the FF-SHOPs, consistent with § 156.285(c)(5). Under our proposal, issuers in States operating an SBE-FP that uses the Federal platform for SHOP enrollment functions would be required to follow the process applicable in the FF-SHOPs, as described in § 156.285(c)(5). We are finalizing this amendment and as noted in the proposed rule, this amendment will become effective with the effective date of the final rule.

For a discussion of the addition of § 156.350(a)(4) in this final rule, please see the preamble to § 155.400.

e. Reconciliation of the Cost-Sharing Reduction Portion of Advance Payments Discrepancies and Appeals (§ 156.430(h))

As implemented in the regulations at § 156.430, HHS reconciles the cost-sharing reduction portion of advance payment amounts by comparing what the enrollee in a cost-sharing reduction plan variation actually paid in cost sharing to what the enrollee would have paid if enrolled in a standard plan. In order to facilitate reconciliation of the cost-sharing reduction portion of advance payments to the actual amount provided for enrollees in cost-sharing reduction variation plans, issuers must report the amount they paid for each eligible medical claim, the amount enrollees paid for the claims, and the amount of cost sharing that would have been paid for the same services under the corresponding standard plan. This information is used to reconcile the actual cost-sharing amounts provided for each policy in a plan variation to the estimated payments that the issuer had been paid in advance.

As set forth at § 156.410(d)(3), issuers are not reimbursed for any cost-sharing reductions provided to enrollees who were erroneously assigned to a plan variation more generous than the one for which they are eligible. Any cost-sharing reductions, to the extent thereby or otherwise erroneously provided (such as cost-sharing reductions for non-EHB or non-covered services, or cost-sharing reductions provided after a policy has been terminated) must be excluded from the reconciliation process.

In order to ensure the integrity of reconciliation of the cost-sharing reduction portion of advance payments for the 2014 and 2015 benefit years, we implemented automatic system checks that validated data at the time of data submission, for example, matching QHP or subscriber IDs to HHS data for a benefit year, and verifying the issuer used the applicable methodology and submitted applicable attestations. This resulted in the rejection of some cost-sharing reduction amounts submitted by issuers. Additionally, some issuers were unable to prepare complete data files in time to meet the cost-sharing reduction data submission deadline. In order to provide issuers with an opportunity to address potential errors that would have directly impacted the calculation of their reconciled cost-sharing reduction amounts, HHS implemented a process

for reporting data discrepancies for the 2014 and 2015 benefit year.⁶⁷

We proposed and are finalizing the addition of new paragraph (h)(1) to § 156.430 to require that any issuer that reports a discrepancy and seeks to dispute the notification of the amount of reconciliation of the cost-sharing reduction portion of advance payments in the manner set forth by HHS, must report the discrepancy to HHS within 30 calendar days of notification of the amount of reconciliation of the cost-sharing reduction portion of advance payments as described in § 156.430(e).

We are also finalizing our proposal to codify § 156.430(h)(2), which provides that an issuer may appeal the amount of reconciliation of the cost-sharing reduction portion of advance payments under the process set forth in § 156.1220 of this subchapter only if it has submitted a discrepancy report, where a discrepancy is identifiable, for its cost-sharing reduction reconciled amounts for the applicable benefit year. We note that irrespective of whether an issuer has filed a discrepancy report under § 156.430(h)(1), a request for reconsideration under § 156.1220 may only be filed to contest a processing error by HHS, HHS's incorrect application of the relevant methodology, or HHS's mathematical error, as required under § 156.1220. In light of the comments received, we are amending § 156.1220(a)(3)(v) to provide that issuers may request reconsideration for reconciliation of cost-sharing reductions, within 60 calendar days of the date of the discrepancy resolution decision.

Comment: Several commenters supported the discrepancy reporting process; however some commenters requested that HHS provide more than 30 calendar days to file a discrepancy report.

Response: HHS believes 30 calendar days is adequate time to file a discrepancy. The process will be similar to the first year of reconciliation for 2014 and 2015 benefit year cost-sharing reductions, when issuers were able to file discrepancies in a timely manner and HHS worked with issuers to resolve data issues. However, in light of the comments received, we are amending § 156.1220(a)(3)(v) to provide that

⁶⁷ On June 23, 2016 HHS released FAQs and technical specifications on the discrepancy resolution process for issuers to follow to report a discrepancy related to reconciliation of the cost-sharing reduction portion of advance payments. The technical specifications are available on the Center for Consumer Information and Insurance Oversight Web site: <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Cost-Sharing-Reduction-Reconciliation-Discrepancy-Resolution-Inbound-Specification.pdf>.

issuers may request reconsideration for reconciliation of the cost-sharing reduction portion of advance payments, within 60 calendar days of the date of the cost-sharing reduction reconciliation discrepancy resolution decision.

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

In § 156.715, HHS established that QHP issuers are subject to compliance reviews in order to ensure ongoing compliance with Exchange requirements and standards. In § 156.715(b), HHS requires QHP issuers to make records that pertain to their activities on an FFE available to HHS. In the first few years of FFE operations, the vast majority of QHP issuers were responsive and cooperative with the compliance reviews. QHP issuers generally submitted requested documents on time and were responsive to requests for additional information. However, a few QHP issuers were less responsive to HHS, which has resulted in unnecessary delays of the compliance reviews. In the proposed rule, HHS proposed to amend this section to specify HHS's authority to impose remedies authorized under subpart I of part 156 in situations where the QHP issuer is non-responsive or uncooperative with the compliance reviews authorized under this section. We are finalizing the amendments as proposed.

Comments: Several commenters fully supported the proposal to require QHP issuers to be responsive to compliance reviews. Other commenters did not support the proposal. However, all commenters who were opposed indicated that additional clarification to define "non-responsiveness" would alleviate their concerns.

Response: We are finalizing the amendments as proposed. We further clarify that examples of non-responsive or uncooperative QHP issuer behavior could be the failure to submit requested documentation on time, or repeated delays in submitting documentation. We expect QHP issuers to respond to documentation request timelines that are articulated in compliance review materials.

g. Qualified Health Plan Issuer Responsibilities

(1) Administrative Appeals (§ 156.1220)

As discussed in the preamble to § 153.630 above, we are adding paragraphs (a)(1)(vii) and (viii) to § 156.1220, providing an administrative appeal right to issuers to contest only a processing error by HHS, HHS's

incorrect application of the relevant methodology, or HHS's mathematical error with respect to the findings of a second validation audit as a result of risk adjustment data validation; or the calculation of a risk score error rate as a result of risk adjustment data validation, respectively.

Because risk adjustment payments and charges for the 2015 benefit year will not be adjusted for results of the risk adjustment data validation process, we do not believe an administrative appeal right for risk adjustment data validation results is necessary for the 2015 benefit year. Therefore, we proposed that the first year of risk adjustment data validation appeals would be the 2016 benefit year, which is the first year that risk adjustment data validation will affect the amount of risk adjustment payments and charges. We received no comments on this proposal, and are finalizing the provision to limit the new § 156.1220(a)(1)(vii) and (viii) finalized above (specifying that an issuer may file a request for reconsideration under this section to contest a processing error by HHS, HHS's incorrect application of the relevant methodology, or HHS's mathematical error, with respect to the findings of a second validation audit or the calculation of a risk score error rate as a result of risk adjustment data validation) to administrative appeals with respect to risk adjustment data for the 2016 benefit year and beyond. We are finalizing our proposal to amend § 156.1220(a)(2) regarding the materiality threshold for filing a request for reconsideration to include a reference to the administrative appeals related to the risk adjustment data validation process. We also finalize our proposed amendment to § 156.1220(a)(3)(ii) to add a reference to risk adjustment data validation and to provide that issuers have 30 calendar days to request reconsideration from the date of the notification of the findings of a second validation audit and the calculation of a risk score error rate as a result of risk adjustment data validation. We believe 30 calendar days is sufficient for issuers to review the findings of a second validation audit or the calculation of a risk score error rate as a result of risk adjustment data validation and to submit a request for reconsideration.

Also as discussed in the preamble to §§ 153.630 and 156.430(h), we proposed requiring issuers to report discrepancies related to risk adjustment data validation and discrepancies related to the reconciliation of the cost-sharing reduction portion of advance payments, if the issue is identifiable, prior to filing

a request for reconsideration under § 156.1220. In light of comments received, we are finalizing our proposal to § 156.1220(a)(4)(ii), to provide that, notwithstanding § 156.1220(a)(1), 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, the issuer notified HHS of the dispute through the applicable process for reporting a discrepancy set forth in § 153.630(d)(2), § 153.710(d)(2), or § 156.430(h)(1), and the dispute has not been resolved.

Additionally, in light of comments received to § 156.430(h)—the reconciliation of the cost-sharing reduction portion of advance payments discrepancies and appeals—we are amending § 156.1220(a)(3)(v) to clarify that issuers may request reconsideration for reconciliation of cost-sharing reductions, within 60 calendar days of the date of the cost-sharing reduction reconciliation discrepancy resolution decision. In light of experience from the 2014 and 2015 benefit year reconciliation of the cost-sharing reduction portion of the advance payments process, HHS believes that resolution of discrepancies may resolve many, if not all issues an issuer may appeal. HHS believes that finalizing an appeal window which begins once issuers receive a discrepancy resolution decision from HHS will provide an informal opportunity for the issuer and HHS to resolve any issues and will result in reduced burden on issuers to file appeals. For clarity, we provide the following example. On June 30, 2018, an issuer receives the notification of the amount of reconciliation of the cost-sharing reduction portion of advance payments as described in § 156.430(e). Under § 156.430(h), within 30 calendar days of receiving this notification, the issuer files a discrepancy, in this example, on July 30, 2018. If applicable, the issuer submits additional or corrected data in response to HHS validations. On August 30, 2018, HHS notifies the issuer of the discrepancy resolution decision. The issuer will then have 60 calendar days to request reconsideration of the discrepancy resolution decision, that is, by October 30, 2018. Therefore, we are amending § 156.1220(a)(3)(v) to clarify that issuers may request reconsideration for reconciliation of cost-sharing reductions within 60 calendar days of the date of the cost-sharing reduction reconciliation discrepancy resolution decision, effective beginning with the 2016

benefit year cost-sharing reduction reconciliation cycle.

Comment: Numerous commenters supported our proposed amendment to § 156.1220(a)(3)(ii) to add a reference to risk adjustment data validation and to provide that issuers have 30 calendar days to request reconsideration from the date of the notification of the findings of a second validation audit and the calculation of a risk score error rate as a result of risk adjustment data validation. Some commenters requested that HHS allow issuers to appeal the resolution of interim discrepancies related to the risk adjustment data validation initial audit sample provided by HHS under § 153.630(b)(1).

Response: HHS is finalizing the provisions as proposed. The initial validation audit entity is under contract with the issuer and HHS does not produce the initial validation audit results. Additionally, we believe that providing an interim discrepancy reporting process prevents the initial validation audit and subsequent second validation audit from being performed on an inaccurate sample of enrollees, thereby ensuring that the second validation audit can occur based on a valid and accurate initial validation audit sample. This allows issuers to identify any issues with the initial validation audit sample while those issues can still be addressed, rather than allowing an inaccurate sample of enrollees to permeate the initial validation audit, the second validation audit, and the calculation of error rates. Therefore, to ensure HHS can meet the June 30th requirement to report benefit year risk adjustment transfer amounts, including payment adjustments reflecting risk adjustment data validation error rates, we believe that it is more efficient to resolve any issues related to the risk adjustment data validation initial audit sample provided by HHS under § 153.630(b)(1) during an interim discrepancy reporting process.

Comment: One commenter requested that HHS permit issuers potentially impacted by risk adjustment appeals to resubmit risk corridors and MLR forms and issue MLR rebates after the resubmission period closes.

Response: HHS provided direction on this issue in § 153.710(g)(2), which provides that 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.

(2) Direct Enrollment With the QHP Issuer in a Manner Considered To Be Through the Exchange (§ 156.1230)

We proposed a number of modifications and new requirements in § 155.220 which would apply to Web-brokers using the direct enrollment channel. We proposed to add a number of these standards to §§ 156.265 and 156.1230(b) so that they also apply to issuers using direct enrollment on a FFE. Specifically, in § 156.1230, we proposed to: (1) Specify that HHS may immediately suspend the QHP issuer's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to Exchange operations or Exchange information technology systems until the incident or breach is remedied or sufficiently mitigated to HHS's satisfaction; (2) require QHP issuers to demonstrate operational readiness and compliance with applicable requirements prior to their Web sites being used to complete QHP selections; and (3) require QHP issuers to provide consumers with correct information regarding FFEs, QHPs offered through the FFEs and insurance affordability programs, and refrain from marketing or conduct that is misleading, coercive, or discriminatory. A more detailed discussion of these provisions is contained in the preamble discussion regarding § 155.220.

(3) Other Notices (§ 156.1256)

Section 156.1256 requires health insurance issuers offering coverage through an FFE or an SBE-FP to notify enrollees of material plan or benefit display errors under certain circumstances. We proposed to change the paragraph cross-referenced in § 156.1256 from § 155.420(d)(4) to § 155.420(d)(12) to reflect our proposal to codify in § 155.420(d)(12) the special enrollment period for material plan or benefit display errors. Since the noticing requirement in § 156.1256 is limited to

material plan or benefit display errors and resulting special enrollment periods, proposed § 155.420(d)(12) is a more appropriate reference for this section. We also proposed to make some minor non-substantive changes to the regulation text. We sought comments on this proposal.

We are finalizing this change as proposed.

Comment: One commenter expressed support for aligning the noticing requirement at § 156.1256 with the proposed special enrollment period for material plan or benefit display errors at § 155.420(d)(12) to provide clarity to stakeholders about this noticing requirement. One commenter requested that this noticing requirement be extended to State-based Exchanges and that it be extended to include errors on the Web site, in marketing materials, or in other information provided by an issuer, a direct enrollment entity, or an agent or broker.

Response: While we agree that clear and timely notification by an issuer of a material plan or benefit display error and the availability of a special enrollment period is most beneficial to an enrollee, we defer to States that operate State-based Exchanges, other than SBE-FP, to determine the appropriate timing and content of such requirements for issuers participating on their Exchanges. Similarly, while we recognize that incorrect QHP information, regardless of source, can be confusing to consumers, this noticing requirement is limited to those material plan or benefit display errors that may qualify an individual for a special enrollment period, as described at § 155.420(d)(12).

10. Part 157—Employer Interactions With Exchanges and SHOP Participation

For a discussion of the provisions of this proposed rule related to part 157, please see the preamble to § 155.725. We are finalizing the proposal with modifications. For the reasons discussed in the preamble discussion of § 155.725(g), we are finalizing the proposed amendments at § 155.725(g) so that they generally do not apply to State-based Exchanges that are not using the Federal platform for SHOP functions. We are therefore modifying our proposed amendments to § 157.205 so that they generally apply only in FF-SHOPs and in SBE-FPs utilizing the Federal platform for SHOP functions. We are also modifying the proposed rule text for consistency with our position regarding when a newly qualified employee becomes otherwise eligible for coverage within the meaning of § 147.116, which is discussed further

above in the preamble to § 155.725(g). Additionally, in this final rule we are making a conforming amendment to § 157.205(e)(1) to reflect the amendments made at § 155.725(g).

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

a. Newer Experience (§ 158.121)

(1) Deferred Reporting of Newer Business

The MLR December 1, 2010 interim final rule (75 FR 74863) adopted 45 CFR 158.121 to allow issuers to defer reporting of experience of policies newly issued and with fewer than 12 months of experience until the following reporting year, if such policies contribute to 50 percent or more of the issuer's total earned premium for the MLR reporting year. This flexibility is intended to take into consideration the special circumstances of newer plans, consistent with section 2718 (c) of the PHS Act. As explained in the interim final rule, the rationale for deferring experience of newly issued policies is that claims experience can be substantially lower than the premium revenue from those policies during the year in which the coverage is issued (although this may occur to a lesser extent now than it did prior to introduction of the Affordable Care Act market reforms), and could create a barrier to the entry of new issuers into a market. To align MLR reporting with the 2014 market reform requirement that non-grandfathered coverage generally must provide coverage for a consecutive 12-month period (see definitions of “plan year” and “policy year” in § 144.103), in the proposed rule we proposed to modify § 158.121 to allow issuers to defer, for MLR purposes, reporting of data for newer experience if 50 percent or more of the issuer's total earned premium for the MLR reporting year is attributable to newly issued policies with 12 full months of experience, rather than only policies with less than 12 months of experience. We are finalizing this provision as proposed.

Comment: Most commenters supported our proposal. Several commenters stated that the option to defer MLR reporting for a full 12 months will encourage new issuers to enter the market and allow issuers to gather data in order to make sound actuarial calculations. Many commenters who expressed support for the proposal recommended that HHS take action to recognize the special circumstances of newer plans and mitigate the impact of the MLR on growth, competition, and

innovation. However, some commenters cautioned HHS to ensure that modifications to the MLR regulations preserve the MLR's objective of protecting consumers and providing transparency in public reporting. One commenter also requested clarification regarding the definitions of “total earned premium” and “newly issued policies with 12 full months of experience” as used in this section.

Response: We agree with those commenters that suggested that the amendment will encourage new issuers to enter the market. We also recognize the importance of ensuring that modifications to the MLR regulations do not erode consumer protections promised by the law, and we will continue to monitor issuers' usage of this provision closely and its impact on consumers. We intend to clarify the definition of “newly issued policies” used in this section when we update the MLR Annual Reporting Form Instructions for the future reporting years; we believe that “earned premium” is adequately defined in § 158.130. We are finalizing this proposal. Consistent with the comments received that recommended that HHS mitigate the impact of the MLR on newer plans, as well as to align with the accompanying option to limit rebate liability for new and rapidly growing issuers (discussed below), this amendment will be implemented for the 2016 MLR reporting year.

b. Rebating Premium if the Applicable Medical Loss Ratio Standard Is Not Met (§§ 158.232, 158.240)

(1) Limit on Rebate Liability

Section 2718(b)(1)(B)(ii) of the PHS Act requires, beginning on January 1, 2014, the MLR to be calculated as an average of 3 consecutive years of experience. When an established issuer's MLR falls below the applicable MLR standard in a given year, the 3-year averaging spreads the actual payment of the rebate over the period of 3 years. This allows issuers to offset low and high MLRs within any 3-year period, enabling issuers to potentially pay a lower overall rebate. However, issuers that newly enter the market are only able to calculate their first two MLRs based on 1 or 2 years of experience, which can lead to distorted MLR calculations and could be a barrier to the entry of new issuers into a market.

In the proposed rule, we proposed to amend §§ 158.232 and 158.240 to mitigate the impact of 3-year averaging on new and rapidly growing issuers and thereby reduce barriers to entry and promote competition in health

insurance markets. This flexibility is intended to take into consideration the special circumstances of smaller and newer plans, consistent with section 2718(c) of the PHS Act. Under our proposal, if an issuer elects this flexibility, the maximum single-year rebate liability attributable to a given calendar year would be limited to no more than the amount determined based on the issuer's MLR calculated using only that year's experience. In these circumstances, we additionally proposed to adjust the maximum rebate liability attributable to a given calendar year in each of the two subsequent reporting years to reflect restatement of claims incurred in that calendar year as of March 31 following each of those 2 subsequent reporting years, as well as to reflect the credibility adjustment applicable in each of those 2 subsequent reporting years.

We further proposed that for an issuer that elects this option, the outstanding rebate liability with respect to each year in the aggregation would be determined by reducing the maximum rebate liability with respect to that year by any rebate payments made toward it in the two prior years (as applicable), starting with the earliest year in the relevant aggregation. Finally, we proposed that the actual rebate payable by the issuer for a given reporting year would be limited to the lesser of the amount of the combined outstanding rebate liability for all calendar years included in the aggregation or the amount calculated for the reporting year based on a multi-year average MLR. By design, our proposal would operate such that it would only benefit new issuers and established issuers that experience rapid growth and whose MLR falls below the standard in 1 year and increases within the following 2 years.

We further proposed to make the use of the rebate liability limit optional for issuers, as well as to clarify § 158.232 by defining the term “preliminary MLR” to refer to an MLR calculated without applying any credibility adjustment, and to explicitly specify instances where § 158.232 was intended to refer to experience of a single year, rather than 3 years.

We are finalizing these provisions as proposed.

Comment: Most comments received on this topic supported our proposal. Several commenters suggested that HHS implement this modification for the 2016 MLR reporting year. Several commenters suggested that HHS provide clarification by: (1) Providing an example on how the process will work for an issuer that is not a start-up; and (2) discussing the methodology for the

two subsequent reporting years after the rebate limiting option is applied. Again, some commenters cautioned HHS to ensure that modifications to the MLR regulations preserve the MLR's objective of protecting consumers, and one commenter suggested that HHS impose limits on the proposed provision in order to prevent gaming.

Response: We are finalizing this provision as proposed. We agree with those commenters that suggested that the modification should be implemented for the 2016 MLR reporting year. Additionally, we agree that it is important to ensure that modifications to the MLR regulations do not result in a loss of value to consumers. However, we note that the option to limit the rebate liability generally does not reduce rebates to consumers below the required value, but rather only limits it in a given calendar year in order to recognize the special circumstances of newer and smaller issuers by ensuring the equitable treatment of new or growing issuers. We also note that this option by design can benefit issuers only when they are disproportionately impacted by the 3-year averaging. For the same reason, this option will benefit such issuers proportionately to the size of their experience in the relevant State and market in each of the years included in the aggregation. For established issuers that do not experience rapid growth, the combined outstanding rebate liability for all years included in the aggregation will generally equal or exceed the rebate calculated for the reporting year based on a 3-year average MLR; thereby making this option unattractive. We offered a simplified illustration in the proposed rule (81 FR 61517) and intend to publish on our Web site an updated MLR Calculator and Formula Tool in the near future that will enable users to evaluate the impact of this provision under various circumstances, and illustrate the application of rebate payments made in prior years against the maximum rebate liability of each year.

III. Amendments to Special Enrollment Periods and the Consumer Operated and Oriented Plan Program

A. Background

1. 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 1311(c)(6)(C) of the Affordable Care Act directs the Secretary of HHS to require an Exchange to provide for special enrollment periods specified in section 9801 of the Code and other special enrollment periods under circumstances similar to such periods under part D of title XVIII of the Act.

Section 1322 of the Affordable Care Act directs the Secretary to establish the CO–OP program to foster the creation of consumer-governed, private non-profit health insurance issuers to offer QHPs in the individual and small group markets in the States in which they are licensed. The CO–OP program, in addition to improving consumer choice and plan accountability, also seeks to promote integrated models of care and enhance competition in the Exchanges. Section 1322 establishes eligibility standards for the CO–OP program and terms for loans, and provides basic standards that organizations must meet to participate in this program and become a CO–OP, including market participation and governance requirements.

a. Special Enrollment Periods

In the July 15, 2011 **Federal Register** (76 FR 41865), we published a proposed rule establishing special enrollment periods for the individual Health Insurance Exchange. We implemented these special enrollment periods in a final rule published in the March 27, 2012 **Federal Register** (77 FR 18309) (Exchange Establishment Rule). In the January 22, 2013 **Federal Register** (78 FR 4594), we published a proposed rule amending certain special enrollment periods, including the special enrollment periods described in § 155.420(d)(3) and (7). We finalized these rules in the July 15, 2013 **Federal Register** (78 FR 42321).

In the June 19, 2013 **Federal Register** (78 FR 37032), we proposed to add a special enrollment period at § 155.420(d)(10). We finalized this proposal in the Oct. 30, 2013 **Federal Register** (78 FR 65095). In the May 27, 2014 **Federal Register** (79 FR 30348), we published a proposed rule amending § 155.420(b), (c), (d)(4), (d)(5), (d)(9), (d)(10), and (e). We finalized these

provisions in the May 27, 2014 **Federal Register** (79 FR 30348). In the October 1, 2014 **Federal Register** (79 FR 59138), we published a correcting amendment related to § 155.420(b).

In the November 26, 2014 **Federal Register** (79 FR 70673), we proposed to amend § 155.420(b), (c), (d)(1), (d)(2), (d)(4), and (d)(6). We finalized these provisions in the February 27, 2015 **Federal Register** (80 FR 10866). In the July 7, 2015 **Federal Register** (80 FR 38653), we issued a correcting amendment to § 155.420(d)(2). In the December 2, 2015 **Federal Register** (80 FR 75487) (proposed 2017 Payment Notice), we sought comment and data related to existing special enrollment periods, including data relating to the potential abuse of special enrollment periods. In the March 8, 2016 **Federal Register** (81 FR 12203) (2017 Payment Notice), we stated that in order to review the integrity of special enrollment periods, the FFEs will conduct an assessment by collecting and reviewing documents from consumers to confirm their eligibility for the special enrollment periods under which they enrolled.

In the May 11, 2016 **Federal Register**, we published an interim final rule with comment (81 FR 29146) implementing amendments to the parameters of select special enrollment periods. This final rule finalizes these amendments.

b. CO–OP Program

In the July 20, 2011 **Federal Register** (76 FR 43237), we published a proposed rule governing the CO–OP program (proposed CO–OP Rule). On December 13, 2011, we published the final CO–OP Rule (76 FR 77392).

In the March 27, 2012 **Federal Register**, we published a final rule implementing components of the Exchanges and setting forth standards for eligibility for Exchanges (77 FR 18474) (Exchange Establishment Rule). This rule amended the regulations regarding the CO–OP program.

In the May 11, 2016 **Federal Register**, we published an interim final rule with comment (81 FR 29146) implementing amendments to the governance requirements established for Consumer Operated and Oriented Plans (CO–OPs) under the CO–OP Rule. This final rule finalizes these amendments.

2. Stakeholder Consultation and Input

HHS has consulted stakeholders on the policies related to implementation of the Affordable Care Act, including special enrollment periods and CO–OPs. 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, and meetings with health insurance issuers, organizations participating in the CO-OP program, trade groups, consumer advocates, employers, and other interested parties. We have held a number of recent meetings with issuers (including CO-OPs), regulators, and consumer groups relating to the effects of special enrollment periods on the risk pool, and on CO-OPs' attempts to raise private capital. We considered all public input we received as we developed the policies in this interim final rule with comment.

3. Structure of Final Rule

The regulations outlined in this final rule will be codified in 45 CFR parts 155 and 156. The regulations in part 155 amends certain special enrollment periods. The regulations in part 156 establish eligibility criteria, CO-OP standards, and loan terms under the CO-OP Program. We finalize amendments related to the definitions of pre-existing issuer and representative as well as revisions to the governance requirements for CO-OPs in order to provide flexibility and support their financial stability.

B. Provisions of the Interim Final Rule and Analyses and Responses to Public Comments

In the May 11, 2016 **Federal Register** (81 FR 29146), we published the "Patient Protection and Affordable Care Act; Amendments to Special Enrollment Periods and the Consumer Operated and Oriented Plan Program" interim final rule with comment. We received 13 comments, including from 3 issuers/ issuer trade associations, 2 providers/ provider associations, 2 research/policy groups, 3 advocacy groups, and 3 individuals. The comments received included a number of comments and suggestions that will not be addressed in this final rule because they were outside the scope of the interim final rule.

1. Special Enrollment Periods (§ 155.420)

Special enrollment periods provide a critical pathway to coverage for qualified individuals who experience qualifying events and need to enroll in or change plans outside of the annual open enrollment period or during open enrollment with a coverage effective date earlier than generally provided during the open enrollment period. One such special enrollment period

described in § 155.420(d)(7) may be granted to a qualified individual or enrollee, or his or her dependent, who gains access to new QHPs as a result of a permanent move.

As discussed in the Exchange Establishment Rule (77 FR 18310, 18392), the special enrollment period in § 155.420(d)(7) was intended to afford individuals the full range of plan options when they relocate, which maximizes consumer choice and increases competition in the health insurance market. However, this special enrollment period was never intended to provide an opportunity for enrollment in coverage where individuals make a permanent move solely for the purpose of gaining health coverage outside of the annual open enrollment period. Stakeholders have raised concerns that, while such use of this special enrollment period may be consistent with the plain language of the rule, it is not aligned with the provision's intent. This use has the potential to destabilize the health insurance market by creating an opportunity for adverse selection where persons undertake a permanent move solely for the purpose of gaining health coverage, in which they would otherwise not be qualified to enroll. Because of concerns that unintended uses of the permanent move special enrollment period will lead to adverse selection and immediate, unexpected losses in the remaining months of this year, which could lead to significant premium increases or issuers exiting the market, we believed that action was needed as soon as possible, and delaying the rule revisions would be impracticable and contrary to the public interest, so we made these changes effective May 11, 2016 through 81 FR 29155.

We amended the eligibility parameters for this special enrollment period by adding requirements in § 155.420(d)(7)(i) and (ii). In paragraph (i), we require that individuals be enrolled in minimum essential coverage as described in 26 CFR 1.5000A-1(b) for one or more days in the 60 days preceding the date of the permanent move in order to qualify for the special enrollment period based on a permanent move.

The addition of paragraph (i) required further amendments to the rule to maintain the availability of the permanent move special enrollment period for certain other individuals who should continue to be able to access this special enrollment period without the requirement of being previously enrolled in minimum essential coverage. Specifically, we made a

necessary addition in paragraph (d)(7)(ii) to maintain eligibility for a special enrollment period for individuals previously living outside of the United States or in a United States territory who move to a location within the United States, so long as they seek to enroll in coverage within 60 days of completing their permanent move.

In light of the addition of these new requirements, we made a further change to § 155.420(d)(7) and to (d)(3) related to incarcerated individuals. As noted in the preamble to the Exchange Establishment Rule (77 FR 18392), qualified individuals newly released from incarceration are eligible for the special enrollment period afforded to individuals under the current version of paragraph (d)(7). However, paragraph (d)(7) as amended in this rule no longer enabled these individuals to qualify for the special enrollment period because the health care coverage offered to incarcerated individuals in correctional facilities is generally not considered minimum essential coverage. Incarcerated individuals are also not eligible for Exchange coverage.

Therefore, we amended paragraph § 155.420(d)(3) to include individuals who become newly eligible for a QHP due to a release from incarceration (other than incarceration pending disposition of charges), in addition to those who become newly eligible for a QHP by becoming a United States citizen or national or a lawfully present non-citizen already included in this paragraph. In so doing, we removed the current language in paragraph (d)(3) that stated that a qualified individual or his or her dependent "which was not previously a citizen, national, or lawfully present individual gains such status" and replaced it with a cross reference to § 155.305(a)(1). This did not change the scope of the current special enrollment period and the population who qualified. We added a cross reference to § 155.305(a)(2) for individuals who are no longer incarcerated, other than incarcerated pending disposition of charges.

In order that, at their option, Exchanges could continue to offer advanced availability of the special enrollment period for those who become newly eligible for a QHP due to a release from incarceration now included in paragraph (d)(3), we amended paragraph § 155.420(c)(2) to include this population. If an Exchange should or already has exercised this option to offer advance availability to those who become newly eligible for a QHP due to a release from incarceration, it must ensure that the coverage effective date is on the first day of the month following

the release from incarceration, as was required when this population was included in the special enrollment period in paragraph (d)(7) of this section. Accordingly, we amended § 155.420(b)(2)(iv) to include those who become newly eligible for a QHP due to a release from incarceration now included in paragraph (d)(3).

The amendment to § 155.420(d)(7) also made the special enrollment period for a permanent move inaccessible to qualified individuals who were previously living in a non-Medicaid expansion State and, during the same timeframe, were ineligible for APTC solely because of a household income below 100 percent of the Federal poverty level (FPL), but who become newly eligible for APTC as a result of a permanent move to another State. By being previously ineligible for both Exchange coverage with APTC (because of their household income) and Medicaid (solely because of the State's decision not to expand), these individuals likely would have been exempted from the requirement under section 5000A(e)(1) of the Code and its implementing regulations to maintain minimum essential coverage; or they would likely have been eligible for an exemption from the minimum essential coverage requirement under § 155.605(d) or (e). As a result, these individuals were therefore unlikely to qualify for the special enrollment period for a permanent move, as amended. In order to continue to provide for a special enrollment period for these individuals, we amended § 155.420(d)(6)(iv) to include individuals who were previously living in a non-Medicaid expansion State and, during the same timeframe, were ineligible for Medicaid, but who become newly eligible for APTC as a result of a permanent move. This change secured the continued availability of a special enrollment period to qualified individuals who move out of a non-Medicaid expansion State to a State where they may newly qualify for APTC, but who might no longer qualify for the special enrollment period under § 155.420(d)(7), as amended in this rule, because they did not previously have minimum essential coverage for one or more days in the 60 days preceding the date of the permanent move.

In addition, as discussed in the 2017 Payment Notice, we are conducting an assessment of QHP enrollments that were made through special enrollment periods in the FFEs to ensure that consumers' eligibility for these special enrollment periods were properly determined.

We considered the information technology system resources that would be needed to implement by January 1, 2017, advance availability of the special enrollment period for a permanent move and the special enrollment period for loss of a dependent or no longer being considered a dependent due to divorce, legal separation, or death. We were concerned that the requirement to meet the January 1, 2017 deadline could cause needless expenditures of Exchange funds. In light of the competing financial and operational priorities of Exchanges, we believed it was contrary to the public interest to require that Exchanges meet the January 1, 2017 deadline. Therefore, we determined that there was a need to take immediate action to delete this future deadline, rather than engaging in notice and comment rulemaking on this change, in order to avoid the unnecessary expenditure of funds by Exchanges to comply with the January 1, 2017, implementation deadline. Therefore, effective May 11, 2016, we amended the following special enrollment period provisions to leave the implementation timeline for advanced availability at the discretion of the Exchange.

Section 155.420(c)(2) provides for advanced availability of the special enrollment period for a qualified individual or enrollee, or his or her dependent who gains access to new QHPs as a result of a permanent move as described in paragraph (d)(7) of this section, meaning that a qualified individual or enrollee, or his or her dependent, has 60 days before or after the triggering event (the permanent move) to select a QHP. Paragraph (c)(2) also provides that this advanced availability be available by January 1, 2017 or earlier, at the option of the Exchange. We amended this paragraph, effective May 11, 2016, to remove the requirement for Exchanges to offer advanced availability of the permanent move special enrollment period by January 1, 2017, which kept this provision at the option of the Exchange.

We also amended paragraph (d)(2)(ii), which provides for a special enrollment period for an enrollee who loses a dependent or is no longer considered a dependent due to divorce, legal separation, or death, to remove the requirement that Exchanges offer this special enrollment period by January 1, 2017. We noted that, if a loss of a dependent or no longer being considered a dependent due to divorce, legal separation, or death results in a loss of minimum essential coverage, such individuals may qualify for the special enrollment period for loss of

minimum essential coverage. Effective May 11, 2016, implementation of this provision remains at the option of the Exchange.

We noted that certain special enrollment periods in § 155.420 are incorporated into the guaranteed availability regulations at § 147.104(b) and apply to issuers offering non-grandfathered individual coverage through or outside of the Exchange, and incorporated in the SHOP regulations at § 155.725(j) and § 156.285(b) and applied to QHP coverage offered through the SHOPS. The changes made to special enrollment periods in this rule therefore applied to the guaranteed availability and SHOP regulations, to the extent applicable.

In this rule, we are finalizing the interim final rule with comment and the corresponding provisions as proposed.

Comment: Commenters were divided in their support for or opposition to the addition of a prior minimum essential coverage requirement to the special enrollment period for a permanent move at § 155.420(d)(7). Those who supported this amendment believe that this addition will help eliminate misuse and abuse of this special enrollment period by preventing consumers from moving and enrolling in coverage only when they have health coverage needs. One commenter recommended that the 60 day prior minimum essential coverage requirement be reduced to 30 days.

Those who opposed this amendment expressed concerns about adding additional barriers to coverage for disadvantaged populations, especially migrant workers who often cross State lines for work, individuals who previously lived in rural areas with unaffordable coverage and have moved to a more competitive service area where affordable health coverage is now available, and family caregivers who have left the workforce to care for a sick relative. Commenters also expressed concern that making it more difficult to qualify for special enrollment periods will have a negative impact on risk pools and will further decrease already low special enrollment period enrollment rates, citing a recent study that showed that five percent of consumers who could qualify for special enrollment periods actually utilized a special enrollment period to enroll in 2015 coverage.⁶⁸ Commenters raised concern that by amending this special

⁶⁸ Dorn, Stan. "Helping Special Enrollment Periods Work under the Affordable Care Act." The Urban Institute. June 23, 2016. Accessed at <http://www.urban.org/sites/default/files/alfresco/publication-pdfs/2000834-Helping-Special-Enrollment-Periods-Work-Under-the-Affordable-Care-Act.pdf> on June 29, 2016.

enrollment period, HHS is restricting access to a special enrollment period prior to sharing evidence of misuse or abuse.

Response: We agree with commenters that adding a prior coverage requirement to the special enrollment period for a permanent move protects against misuse and abuse of this special enrollment period by preventing consumers who are moving for the sole purpose of obtaining medical treatment from newly enrolling in a QHP. We also believe that this requirement will encourage consumers to remain in coverage, even if they are anticipating a move in the future.

However, we appreciate the concerns raised by commenters about legitimate reasons consumers may experience a gap in coverage and will no longer be able to qualify for this special enrollment period. Migrant workers who live and work in one service area, but maintain a home in another service area where they live other than during the seasonal employment, can establish residency in either or both service areas to enroll in QHP coverage. We encourage commenters to review the FAQs on the Marketplace Residency Requirement and the Special Enrollment Period due to a Permanent Move, published on January 19, 2016 for more information on this topic.⁶⁹ We will also continue to monitor utilization of this special enrollment period so that we can evaluate whether consumers are being prevented from enrolling in coverage for legitimate reasons that are beyond their control due to this change to our regulation.

Comment: Commenters were opposed to the elimination of the January 1, 2017 implementation deadline for offering advance availability of the special enrollment period for a permanent move at § 155.420(c)(2) and for implementing the special enrollment period for enrollees for loss of a dependent or no longer being considered a dependent due to divorce, legal separation, or death at § 155.420(d)(2)(ii). Commenters expressed concerns that delaying implementation of advance availability of the special enrollment period for permanent move may lead to an unavoidable gap in coverage for someone who moves during the coverage year due to the fact that consumers can currently only qualify for this special enrollment period after

they have moved and the associated coverage effective date is always prospective. This can result in negative health outcomes, especially for consumers with chronic conditions. Commenters pointed out that Medicare currently offers advance availability for their special enrollment period for a permanent move. In addition, commenters expressed concerns that consumers' health coverage needs may likely change after a divorce, legal separation, or death, when consumers' household composition has changed and especially if a dependent with greater health care needs is no longer part of the household. Commenters suggested that, since this special enrollment period would only be available to current QHP enrollees, HHS will be able to implement it in a way that prevents misuse or abuse.

Lastly, one commenter recommended that HHS update, rather than eliminate, implementation deadlines for these provisions to minimize variation across States in terms of their availability. Failure to do so could lead to confusion to both enrollees and issuers about what special enrollment periods are available.

Response: We appreciate the concerns raised by commenters about the elimination of the implementation deadlines for both offering advance availability for the special enrollment period for a permanent move and for the special enrollment period for enrollees who have lost a dependent or are no longer considered a dependent due to divorce, legal separation, or death. As mentioned above, we are conducting an assessment of QHP enrollments that were made through special enrollment periods in the FFEs, and, given the information technology system requirements necessary to implement these provisions by January 1, 2017, we were concerned that the requirement to meet the January 1, 2017, deadline could cause needless expenditures of Exchange funds.

Comment: One commenter suggested HHS clarify how the special enrollment period provisions in the Exchange regulations at § 155.420 apply in the individual market outside the Exchange.

Response: With the exception of certain triggering events specified in § 147.104(b)(2), which are only relevant to enrollment in a QHP through the Exchange, the same special enrollment periods (also referred to as limited open enrollment periods) apply throughout the individual market, both inside and outside of the Exchange.

Under the guaranteed availability and Exchange provisions at §§ 147.104 and 155.420, respectively, when an individual (and, where specified, his or

her dependent) experiences an event that triggers a special enrollment period at § 155.420, the individual has a right to enroll in or change QHPs offered through the Exchange, and except for certain specified triggering events, also has the opportunity to purchase or enroll in any non-grandfathered individual health insurance coverage offered outside the Exchange pursuant to § 147.104(b)(2). These special enrollment rights apply to any individual described in the regulations and are not limited solely to individuals who experience a triggering event while enrolled through the Exchange.

To provide greater clarity about how these provisions apply in the context of the individual market outside the Exchange, we are adding a sentence in § 147.104(b)(2) to specify that in applying special enrollment periods under the marketwide regulations, a reference in § 155.420 to a "QHP" is deemed to refer to a plan, a reference to "the Exchange" is deemed to refer to the applicable State authority, and a reference to a "qualified individual" is deemed to refer to an individual in the individual market.

Furthermore, consistent with similar exclusions under the marketwide regulations for Exchange-specific special enrollment periods, we are also clarifying that the triggering event described at § 155.420(d)(6) will not create a special enrollment period to enroll outside the Exchange to the extent it concerns an individual who becomes newly eligible for APTC or who has a change in eligibility for cost-sharing reductions other than a total elimination of eligibility, since financial assistance is only available for coverage purchased through an Exchange. Individuals who become newly ineligible for APTC or who have a change in eligibility for cost-sharing reductions as described in paragraphs (d)(6)(i) and (ii) will continue to qualify for a special enrollment period to enroll in individual market coverage through or outside of an Exchange.

We intend to monitor the application of these special enrollment period rules and may provide additional guidance in the future to ensure that individuals eligible for special enrollment periods receive the protections they are entitled to under the law.

2. CO-OP Program

Subpart F of part 156 of title 45 of the Code of Federal Regulations sets forth the standards applicable to the CO-OP Program. In the interim final rule with comment, we made a number of changes to the rules governing CO-OPs to provide additional flexibility for CO-OP

⁶⁹ U.S. Department of Health and Human Services, "FAQs on the Marketplace Residency Requirement and the Special Enrollment Period due to a Permanent Move" January 19, 2016. Available at: https://www.regtop.info/uploads/library/ENR_FAQ_ResidencyPermanentMove_SEP_5CR_011916.pdf.

issuers to enter into strategic financial transactions with other entities. Given the financial challenges faced by some CO-OPs and the lack of opportunity for further Federal funding, these changes were implemented to improve their capital position and to further the ability of the program to facilitate the offering of competitive, high-quality health insurance on Exchanges. Furthermore, these amendments were made in response to CO-OPs' requests for maximum flexibility in governance requirements to assist their efforts to enter into new, beneficial business relationships. We received five comments in response to the changes to CO-OP regulations set forth in the interim final rule with comment. Two of the five were not applicable to the changes in the interim final rule with comment and therefore are not addressed below.

a. Definitions (§ 156.505)

In the interim final rule with comment, we amended the definitions of "pre-existing issuer" and "representative" to permit CO-OPs increased flexibility to explore and advance business opportunities, and increase the pool of eligible candidates for their boards of directors. The definition of the term "pre-existing issuer" was amended to limit the definition to State-licensed health insurance issuers that competed in the individual or small group commercial health insurance markets on July 16, 2009, as required by section 1322(c)(2)(A) of the Affordable Care Act). The definition of the term "representative" was revised to mean an officer, director, or trustee of an organization, or group of organizations; or a senior executive or high level representative of the Federal government, or a State or local government or a sub-unit thereof.

The amended definitions expand the universe of individuals eligible for membership on a CO-OP board of directors, while ensuring that appropriate standards remain in place to protect against conflicts of interest and insurance industry involvement and interference. We are finalizing these provisions as implemented in the interim final rule with comment.

Comment: One commenter recommended amending the revised definition of representative by adding the word "current" before "officer, director, or trustee of an organization, or group of organizations; or a senior executive or high-level representative". The commenter stated that this change would make clear that former or retired officers, directors, trustees, or senior

executives are not included in the exclusion.

Response: We agree that former or retired officers, directors, trustees, or senior executives should not be included in the definition of "representative." However, we do not believe that the requested change is necessary. The amended definition of the term "representative" in the interim final rule with comment currently does not include former or retired officers, directors, trustees, or senior executives. Therefore, we are finalizing the definition of "representative" as implemented in the interim final rule with comment.

b. CO-OP Standards (§ 156.515)

Under § 156.515(b)(1), a CO-OP must be governed by a board of directors, with all of its directors elected by a majority vote of a quorum of the CO-OP's members that are age 18 or older, and the voting directors on the board must be members of the CO-OP. In the interim final rule with comment, we amended these standards to require that only a majority of directors be elected by the members and to remove the requirement that a majority of voting directors be members of the CO-OP. This revision allows entities offering loans, investments, and services to participate on the board of directors, as is common practice in the private sector, while maintaining the overall control of the board by the members of the CO-OP. We made this change in response to program experience demonstrating that the inability to grant designated board positions to prospective partners or investors may create obstacles to potentially favorable business arrangements for CO-OPs. This amendment also provides opportunities for CO-OPs to enlist qualified individuals from outside their membership to participate in board governance.

We also revised § 156.515(b)(2)(i) to comport with the changes in the types of representatives permitted to sit on the board of directors while still retaining ethical, conflict of interest, and disclosure standards. Section 156.515(b)(2)(ii) was revised to provide that each director has one vote. Section 156.515(b)(2)(iv), which provided that positions on the board designated for individuals with specialized expertise, experience, or affiliation cannot constitute a majority of the board, was removed and reserved. Section 156.515(b)(2)(v) was revised to permit representatives of State or local governments or organizations described in § 156.510(b)(1)(i) to participate on CO-OP boards of directors, provided the

CO-OP does not issue policies in the State in which the government representative serves or the organization operates. These amendments are intended to provide CO-OPs with increased flexibility regarding board membership, as well as to increase business opportunities for CO-OPs. We note that any fiduciary duties that exist under State law would continue to apply for all members of a CO-OP's board.

We also noted that the requirements of § 156.515(c)(1) requiring that at least two-thirds of the policies issued by a CO-OP must be QHPs issued in the individual and small group markets, have at times posed an obstacle to potential strategic partners of CO-OPs. In the interim final rule with comment, HHS clarified that, if a CO-OP fails to meet the standard in a given year, it would not necessarily require immediate loan repayment as long as the CO-OP is in compliance with § 156.515(c)(2); has a specific plan and timetable to meet the two-thirds requirement, and acts with demonstrable diligence and good faith to meet the standard. A CO-OP must ultimately come back into compliance with the two-thirds standard in future years. We are finalizing these provisions as implemented in the interim final rule with comment.

Comment: One commenter objected to the new provision at 45 CFR 156.515(b)(1) to the effect that no board members must be CO-OP members. Another commenter objected to the requirement that only a majority of directors be elected by the CO-OP's members. Both commenters indicated that these changes would compromise the mandate that CO-OPs be member run and consumer-focused.

Response: CO-OPs are obligated to be, and remain, consumer-operated and consumer-focused entities. These broad principles are overarching, ongoing obligations of all CO-OP health plans. More generally, both principles are not specifically defined and admit wide application by each CO-OP under various circumstances, under its obligations to the public as a private, non-profit company that has assumed the task of fulfilling the goals of the CO-OP program. For these reasons, HHS believes the changes to the governance requirements implemented in the interim final rule with comment will assist CO-OPs in their efforts to remain viable over time, while maintaining their mission as consumer focused organizations.

Comment: One commenter voiced support for the revisions HHS made to the definition of a prohibited

representative of State government or a preexisting issuer at 45 CFR 515.505, and expressed that the amendment will assist CO-OPs in their efforts to attract board members with sufficient expertise. The commenter also supported the amendments to § 156.515(b)(1) that limit the prohibition against representatives of preexisting issuers from sitting on a CO-OP board to such issuers that do business in the individual and small group health insurance markets. The commenter indicated the amendment will help CO-OPs attract new business alliances and enter into new lines of business that could promote overall business objectives.

Response: We appreciate and agree with the commenter and thus, are finalizing the changes.

c. Loan Terms (§ 156.520)

Under § 156.520(f), a CO-OP may not convert or sell to a for-profit or non-consumer operated entity, or undertake a transaction that would result in the CO-OP implementing a governance structure that does not meet our regulatory standards. In the preamble of the interim final rule we provided clarification regarding whether this provision prohibits the sale or conversion of policies to a non-CO-OP issuer in connection with the wind-down of a CO-OP. We clarified that if a CO-OP is out of compliance with this provision, the CO-OP will cease to be a qualified non-profit health insurance issuer, and certain rights under the CO-OP Loan Agreement will become available to HHS, including the right to accelerate repayment of the loans or terminate the Loan Agreement itself. In addition, we indicated that we recognize that a CO-OP could elect to enter into such a transaction in the appropriate circumstances, to preserve coverage for enrollees upon the insolvency of the issuer, notwithstanding the aforementioned remedies. We did not implement any changes to the regulation and thus, are not finalizing any changes to this section. Accordingly, the preamble as published previously will also remain unchanged.

3. Risk Adjustment

Based on our experience operating the 2014 and 2015 benefit years risk adjustment program, HHS is aware that certain issuers, including some new, rapidly growing, and smaller issuers, owed substantial risk adjustment charges that they did not anticipate. HHS has had, and continues to have discussions with issuers and State regulators on ways to help ease issuers'

transition to the new health insurance markets and the effects of unanticipated risk adjustment charge amounts. HHS believes that a robust risk adjustment program that addresses new market dynamics due to rating reforms and guaranteed issue requirements is critical to the proper functioning of these new markets. However, we are sympathetic to these concerns and recognize that States are the primary regulators of their insurance markets. As such, we encouraged, and continue to encourage States to examine whether any local approaches, under State legal authority, are warranted to help ease this transition to new health insurance markets.

In addition to actively engaging in conversations with States, we are updating the risk adjustment methodology as described elsewhere in this final rule for the 2017 and 2018 benefit years to address some of the foregoing issues.

Comment: One commenter requested that HHS improve the risk adjustment program. This commenter supported many of the changes discussed in the "March 31, 2016, HHS-Operated Risk Adjustment Methodology Meeting: Discussion Paper" (White Paper),⁷⁰ especially the use of prescription drugs to help identify missing diagnoses, and transitioning from a concurrent model to a prospective risk adjustment model.

Response: In the HHS Notice of Benefit and Payment Parameters for 2018 Proposed Rule (81 FR 61456)⁷¹ (September 6, 2016), consistent with our discussion in the White Paper, HHS proposed a number of updates to the risk adjustment model. We respond to comments about proposed updates to the risk adjustment methodology elsewhere in this final rule.

Comment: One commenter commented that States should explore State-level solutions, including State wrap-around risk adjustment, reinsurance, and risk corridors programs. This commenter suggested that States should also evaluate their role in approving plan pricing, ensuring that issuers are accurately accounting for risk adjustment and permitting plans to make adjustments to rates that would enable them to mitigate predictable losses after rates have been set.

⁷⁰ March 31, 2016, HHS-Operated Risk Adjustment Methodology Meeting: Discussion Paper. March 24, 2016. Available at <https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/RA-March-31-White-Paper-032416.pdf>.

⁷¹ "HHS Notice of Benefit and Payment Parameters for 2018" available at <https://www.gpo.gov/fdsys/pkg/FR-2016-09-06/pdf/2016-20896.pdf>.

Response: We agree that States play a critical role in ensuring that State markets are competitive and sustainable.

Comment: One commenter disagreed with HHS's approach of encouraging States to explore local approaches to helping plans with this transition. The commenter stated that allowing States to modify the HHS-operated risk adjustment program after rates are filed would increase uncertainty in the market and further complicate pricing and financial forecasting, which are key to long-term stability. This commenter stated that State-level variations in an already complex program would increase complexity and administrative costs for issuers, suggesting that HHS consider policies and opportunities to help stabilize the individual market and avoid those that make it more difficult for the market to function well.

Another commenter requested that HHS clarify that the language in the interim final rule with comment does not encourage States to adopt proposals that would undermine the HHS-operated risk adjustment program. The commenter stated a concern with any proposed State solution that would limit risk adjustment transfers based on a risk corridor approach, which assumes that all issuers should end up with similar financial results after risk adjustment. This commenter requested HHS to clarify that any proposal to exempt, limit, or artificially cap risk adjustment payments would undermine the purpose of the HHS-operated risk adjustment program, and could hurt consumers and the market as a whole.

Response: We reiterate that States in which HHS is operating its risk adjustment methodology are not permitted to modify the methodology, but that States may take temporary, reasonable measures under State authority to mitigate effects under their own authority.

IV. Waiver of Delay in Effective Date

We ordinarily provide a 60-day delay in the effective date of the provisions of a rule in accordance with the Administrative Procedure Act (APA) (5 U.S.C. 553(d)), which requires a 30-day delayed effective date, and the Congressional Review Act (5 U.S.C. 801(a)(3)), which requires a 60-day delayed effective date for major rules. However, we can waive the delay in the effective date if the Secretary finds, for good cause, that the delay is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons in the rule issued (5 U.S.C. 553(d)(3); 5 U.S.C. 808(2)).

We have determined that it is appropriate to issue this regulation with an effective date 30 days from the date of display in the **Federal Register**. HHS has determined that delaying action on the provisions in this rule is contrary to the public interest. Prompt action is necessary to provide for certain critical changes to our programs for 2017—including adjustments to incorporate partial year enrollment duration factors into risk adjustment; MLR policies allowing deferred reporting of new policies with a full 12 months of experience and providing the option to limit rebate liability; risk adjustment data validation policies to apply the default error rate to new entrants for 2016 risk adjustment data validation; a policy to allocate a portion of FFE user fee eligible costs directly to outreach and education; policies around CSR reconciliation appeals and discrepancies for 2016 benefit year; a policy allowing issuers to implement a reasonable extension of the binder payment deadlines when an issuer is experiencing billing or enrollment problems due to high volume or technical errors; a policy regarding termination of Exchange enrollment or coverage to require that issuers demonstrate the rescission is appropriate; policies permitting Exchanges to recalculate APTC; policies allowing an Exchange appeals entity to utilize a secure and expedient paper-based appeals processes; and language access policies allowing Exchanges, QHP issuers, and Web-brokers to more efficiently provide important information to LEP consumers. HHS has determined that implementation of these changes beginning early in 2017 is important for issuer confidence. Issuer confidence is necessary to maintain robust issuer participation in and competition on the Exchanges and to encourage affordability of coverage for enrollees and the continuity of care that is supported by the continued availability of plans on the Exchanges. We believe that the later effective date for the 2017 Payment Notice added to issuers' uncertainty in preparing their products for the 2017 benefit year, which may have led to uncertainty in the market and may have resulted in premium increases. We are seeking a shorter effective date in order to allow issuers ample time to prepare for the 2018 benefit year and help stabilize the Exchanges for issuers and consumers. We also believe consumers' confidence in the Exchanges is especially important this time of year when they are making enrollment decisions, with Open Enrollment in the individual market

ongoing and the Medicare General Enrollment period about to begin on January 1. Stakeholders, including States and issuers, have also requested that this rule become effective earlier in order to establish rates for 2018 in a timely fashion. Therefore, a 60-day delay in the effective date would be contrary to the public interest. We have therefore determined that the rule will become effective on January 17, 2017.

V. 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 14. In the September 6, 2016 (81 FR 61456) proposed rule, we requested public comment on each of the following collection of information requirements. The comments received and our responses to them are discussed below. The May 11, 2016 interim final rule with comment (81 FR 29146) did not impose information collection requirements.

A. ICRs Regarding Upload of Risk Adjustment Data (§ 153.610)

Under the HHS-operated risk adjustment program, HHS uses a distributed data collection approach for enrollee-level enrollment, claims, and encounter data that reside on an issuer's dedicated data environment. Under § 153.710(a), an issuer of a risk adjustment covered plan in a State where HHS is operating the risk adjustment or reinsurance program on behalf of the State, as applicable, must provide HHS, through the dedicated data environment, access to enrollee-level plan enrollment data, enrollee claims data, and enrollee encounter data, as specified by HHS. Under § 153.610(a) as finalized, an issuer must submit or make accessible all required risk adjustment data for its risk adjustment covered plans in accordance with the risk adjustment data collection approach established by the State, or by HHS on behalf of the State. In order to collect enrollee-level data that will be used to recalibrate the HHS risk adjustment models, HHS will send a command to all issuers' EDGE servers that issuers must execute, which will

provide HHS with a dataset that does not identify the EDGE server, plan, issuer, geographic rating area, State, or enrollee. Because this EDGE report requires no new data elements and only requires an issuer to execute the command, we do not believe this provision imposes additional burden on issuers of risk adjustment covered plans described under the information collection currently approved under OMB Control Number 0938–1155. We note, however, that in the future, HHS intends to add the applicable data elements to the 2018 benefit year EDGE server collection. If HHS were to pursue that option, we would revise the information collection currently approved under OMB Control Number 0938–1155 to reflect any extra burden.

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

Under § 153.630(b), an issuer that offers at least one risk adjustment covered plan in a State where HHS is operating risk adjustment on behalf of the State for the applicable benefit year must have an initial validation audit performed on its risk adjustment data. The cost associated with this requirement is the issuer's time and effort to provide HHS with source claims, records, and enrollment information to validate enrollee demographic information for initial and second validation audits, and the issuer's cost to employ an independent auditor to perform the initial validation audit on a statistically valid sample of enrollees. We estimate that each issuer sample will consist of approximately 200 enrollees, and we stated in the proposed rule that this audit would affect approximately 825 issuers. Given the finalization of a materiality threshold beginning for 2017 benefit year risk adjustment validation and the implementation of pharmacy claim validation beginning for the 2018 benefit year risk adjustment data validation, we are revising our total number of issuers affected per year. We estimate that approximately 399 issuers have total premiums of \$15 million or less, and that approximately one-third of these issuers would be subject to an initial validation audit each year. Therefore, we revise the total number of issuers affected annually for this provision from 825 issuers to 559 issuers. Under this final rule, beginning with risk adjustment data validation for the 2018 benefit year, HHS will require the review of paid pharmacy claims for all sample enrollees in the initial validation audit. Based on 2015 EDGE reinsurance data, and after a review of

risk adjustment data validation sampling strata, we are revising our estimate. We now estimate that, because two-thirds of risk adjustment data validation initial validation audit sample enrollees will be enrollees with HCCs, these enrollees are likely to have more pharmacy claims than on average in the EDGE data. As such, we estimate these enrollees with HCCs will have on average, 24 pharmacy claims each. We estimate the remaining half of the one-third of sample enrollees without HCCs will have on average approximately 4 pharmacy claims each, with the other half of the one-third sample enrollees having no pharmacy claims. Therefore, for 133 enrollees with 24 pharmacy claims each, 34 enrollees with 4 pharmacy claims each, and 33 enrollees without pharmacy claims, we would estimate 3,328 pharmacy claims per issuer, or on average, 17 pharmacy claims per enrollee within a sample of 200 enrollees. We continue to believe it would take approximately 5 minutes per pharmacy claim to validate, but are revising our estimate per enrollee to require 85 minutes for an auditor (at a labor cost of \$72 per hour) and would cost approximately \$102 per enrollee to validate paid pharmacy claims. We assume that an initial validation audit would be performed on 111,800 enrollees, with an average of 17 pharmacy claims each. Based on the information above, we estimate that the total additional burden per issuer for initial validation auditors to review and validate paid pharmacy claims would be approximately 283 hours (283 hours and 20 minutes) and cost approximately \$20,400. Therefore, for 559 issuers, the total annual burden of conducting initial validation audits is approximately 158,383 hours with an equivalent cost of approximately \$11,403,600. We will revise the information collection currently approved under OMB Control Number 0938–1155 with an October 31, 2017 expiration date to account for this additional burden.

Comment: A commenter asked HHS to present statistical data based on program experience rather than “beliefs” as a basis for regulatory cost analysis, and requested HHS to provide the basis for its “belief” that half of all enrollees will have pharmacy claims and, of these, HHS expects six pharmacy claims per enrollee. The commenter also inquired how HHS determined the audit would be performed on 165,000 enrollees and take 30 minutes per enrollee.

Response: HHS based its initial estimate of pharmacy claims for sample enrollees on 2015 EDGE claims data

submitted by issuers for reinsurance. We estimated initial validation audits would be performed on 200 enrollees per issuer, and multiplied that by 825 issuers to arrive at the total enrollees affected by the audit. Our estimate of the additional time it would take to examine pharmacy claims is consistent with previous estimates of the burden on issuers to submit EDGE data. However, upon further examination, because the risk adjustment data validation sample is weighted toward enrollees with HCCs, who likely have disproportionately high pharmacy claims, we reviewed and increased the burden, but also reduced the number of issuers affected annually, due to the finalization of the materiality threshold. The new burden estimated above in this ICR is based on an initial validation sample that includes two-thirds of the sample of 200 enrollees as enrollees with HCCs, and the remaining one-third including enrollees without HCCs, with and without pharmacy claims, and approximately 559 issuers being subject to the initial validation audit annually.

C. ICR Regarding the Interim and Final Discrepancy Reporting Processes for Risk Adjustment Data Validation When HHS Operates Risk Adjustment (§ 153.630(d))

This final rule provides that under § 153.630(d)(1), in the manner set forth by HHS, an issuer must confirm the sample or file a discrepancy report within 15 calendar days to dispute the HHS risk adjustment data validation sample set forth by HHS in the HHS–RADV Final Reports. As finalized in § 153.630(d)(2), in the manner set forth by HHS, an issuer may file a discrepancy report within 30 calendar days to dispute the findings of a second validation audit or the calculation of a risk score error rate.

We estimate that 825 issuers of risk adjustment covered plans are subject to this requirement, and that issuers will review the HHS-risk adjustment data validation final reports, specifically, the initial validation audit sample set for the interim discrepancy reporting process. For the final discrepancy reporting process, as finalized in § 153.630(d)(2), issuers will review the results of the second validation audit and the calculation of a risk score error rate. On average, we estimate that it would take a business operations specialist (at an hourly labor cost of \$78) approximately 2 hours to respond to an interim report and 6 hours to respond to the interim and final discrepancy reporting process. The total burden for each issuer would be 8 hours at a cost of \$624. Therefore, we estimate an

aggregate annual burden of 6,600 hours and \$514,800 for 825 issuers as a result of these requirements.

Comment: A commenter requested the basis for estimating a response time of 8 hours and inquired whether HHS considered alternatives to reduce the burden of compliance.

Response: HHS’s estimate of response time is based on experience with previous discrepancy reporting processes for other financial programs, such as risk adjustment and reinsurance, *see* § 153.710(d). The burden estimates for the risk adjustment and reinsurance discrepancy reporting processes were subject to notice and comment rulemaking in the 2015 Payment Notice. Additionally, we believe the burden on issuers will be reduced over time, as the risk adjustment data validation program matures and issuers gain experience with the process.

D. ICR Regarding Standardized Options in SBE-FPs (§ 155.20)

In § 155.20, we are finalizing that an SBE-FP must notify HHS if it wants HHS-designed standardized options to receive differential display, by a date to be specified in guidance. We anticipate that fewer than 10 SBE-FPs will submit this information to HHS annually. Under 5 CFR 1320.3(c)(4), this ICR is not subject to the PRA as it will affect fewer than 10 entities in a 12-month period.

E. ICR Regarding Differential Display of Standardized Options on the Web Sites of Agents and Brokers (§ 155.220) and QHP Issuers (§ 156.265)

We are finalizing requirements that Web-brokers and QHP issuers that utilize the direct enrollment pathway to differentially display standardized options in the 2018 plan year and beyond, consistent with the approach adopted by HHS for display on the Exchange Web site, unless HHS approved a deviation. This policy will require direct enrollment entities to prominently display standardized options in a manner that makes them clear to consumers. We estimate that a total of 160 Web-brokers and QHP issuers participate in the FFEs and SBE-FPs and will be required to comply with the standard. We estimate it will take a mid-level software developer (at a rate of \$96.82 per hour) approximately 2 hours annually to develop a differential display for standardized options. We estimate an annual cost burden of approximately \$193.64 per direct enrollment entity. The total annual burden will be 320 hours with an

equivalent cost of approximately \$30,982.40.

We anticipate that fewer than 10 Web-brokers and issuers will submit a request to deviate from the manner adopted by HHS for display on *HealthCare.gov* and from the standards defined by HHS. Under 5 CFR 1320.3(c)(4), this ICR is not subject to the PRA as it will affect fewer than 10 entities in a 12-month period.

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

We are finalizing a number of requirements for Web-brokers related to the direct enrollment process such as prominently displaying information regarding consumers' eligibility for APTC, allowing consumers to make attestations regarding APTC, enhanced oversight obligations for downstream access to a Web-broker's non-Exchange Web site, expanded standards of conduct pertaining to the use of direct enrollment partner Web sites that could mislead consumers into believing they are visiting *HealthCare.gov*, and demonstrating operational readiness prior to the use of a non-Exchange Web site to complete the QHP selection for Exchange enrollments. At §§ 156.265 and 156.1230, we finalize a number of parallel provisions for issuers using the direct enrollment channel. We will provide additional technical details regarding compliance with the specific requirements under these rules in guidance in the future. At that time, we will estimate the burden associated with these requirements, solicit public comment, and request OMB approval in accordance with the PRA, as may be necessary.

G. ICRs Regarding Standards for HHS-Approved Vendors To Perform Audits of Agents and Brokers Participating in Direct Enrollment (§ 155.221)

We are finalizing requirements related to the application, approval, monitoring and appeals process for vendors to perform audits of agents and brokers participating in direct enrollment. We will provide additional technical details regarding these requirements in guidance in the future. At that time, we will estimate the burden associated with these requirements, solicit public comment, and request OMB approval in accordance with the PRA, as may be necessary.

H. ICR Regarding Eligibility Standards (§ 155.305)

We finalize amendments related to compliance with the income tax filing requirement in § 155.305(f)(4). Under paragraph (f)(4)(ii), the Exchange may determine a tax filer eligible for APTC if other information available to the Exchange indicates that a tax filer or his or her spouse complied with the requirement specified in paragraph (f)(4)(i). The Exchange may obtain such other information by giving Exchange consumers the opportunity to attest to having filed their Federal income taxes and reconciled APTC or to submit documentary proof of filing. We will provide additional technical details about these options in future guidance. At that time, we will estimate the burden associated with these requirements, solicit public comment, and request OMB approval in accordance with the PRA, as may be necessary.

I. ICR Regarding Eligibility Redeterminations (§ 155.330)

We finalize amendments to permit an Exchange to choose among three alternatives when the Exchange identifies updated information regarding compliance with the income tax filing and reconciliation requirement under § 155.305. An Exchange may either follow the process described in paragraph (e)(2)(i), a process specified by the Secretary in guidance, or an alternative process proposed by the Exchange and approved by the Secretary. HHS anticipates that it will require Exchanges requesting approval for an alternative process to submit a brief description of the alternative process, and a justification for how the process satisfies the approval criteria outlined in § 155.330(e)(2)(iii)(C). Given the availability of two alternative processes, we anticipate that fewer than 10 Exchanges will submit a proposal. Therefore, under 5 CFR 1320.3(c)(4), this ICR is not subject to the PRA as it will affect fewer than 10 entities in a 12-month period.

We also finalize amendments to permit the Exchange to recalculate APTC using the procedure described in § 155.330(g)(1) or an alternate procedure approved by HHS. HHS anticipates that it will require participating Exchanges to submit a brief description of the alternate procedure and the extent to which the alternate procedure will protect tax filers from an excess APTC repayment. Here too, we anticipate that fewer than 10 Exchanges will submit a proposal. Under 5 CFR 1320.3(c)(4), this ICR is not subject to the PRA as it will

affect fewer than 10 entities in a 12-month period.

J. ICR Regarding Termination of Exchange Enrollment or Coverage (§ 155.430(b)(2)(iii))

We finalize our amendment of § 155.430(b)(2)(iii) to clarify that when an issuer seeks termination of a QHP purchased on an Exchange via a rescission under § 147.128, it must first demonstrate, to the reasonable satisfaction of the Exchange, that the basis for the rescission is appropriate, if the Exchange requires such a demonstration. This will require the issuer to provide information related to the termination to the Exchange. We do not anticipate that all Exchanges will subject issuers to this requirement. We anticipate that fewer than 10 issuers will be subject to this requirement annually. Under 5 CFR 1320.3(c)(4), this ICR is not subject to the PRA as it will affect fewer than 10 entities in a 12-month period.

K. ICR Regarding QHP Request for Reconsideration (§ 155.1090)

We finalize a provision to add § 155.1090 to create a process for an issuer that has applied to an FFE for certification of QHPs and has been denied certification to request reconsideration. We anticipate that fewer than 10 issuers per year will request reconsideration. Under 5 CFR 1320.3(c)(4), this ICR is not subject to the PRA as it will affect fewer than 10 entities in a 12-month period.

L. ICR Regarding Notification by Issuers Denied Certification (§ 156.290)

In § 156.290, we established a requirement that QHP issuers provide a notification to enrollees when a plan is denied certification for a subsequent, consecutive certification cycle. We anticipate that fewer than 10 issuers will be subject to this requirement annually. Under 5 CFR 1320.3(c)(4), this ICR is not subject to the PRA as it will affect fewer than 10 entities in a 12-month period.

M. ICR Regarding the Discrepancy Reporting Processes for the Reconciliation of the Cost-Sharing Reduction Portion of Advance Payments (§ 156.430(h))

Under § 156.430(h)(1) as finalized in this rule, if an issuer files a discrepancy report to dispute the notification of the amount of reconciliation of the cost-sharing reduction portion of advance payments, it must file the discrepancy report within 30 calendar days of notification of the amount of reconciliation of the cost-sharing

reduction portion of advance payments as described in § 156.430(e), in the manner set forth by HHS.

We estimate that of approximately 360 QHP issuers that submit cost-sharing reduction reconciliation data, less than one third will file a discrepancy report to dispute the notification of the amount of reconciliation of the cost-sharing reduction portion of advance payments for a benefit year. Issuers will review the notification of the amount of reconciliation of the cost-sharing reduction portion of advance payments for this discrepancy reporting process. On average, we estimate that it will take a business operations specialist (at an hourly labor cost of \$78) approximately 6 hours to review the requirements of the discrepancy reporting process, to determine whether the issuer should submit a discrepancy report, to categorize the discrepancy, and to write a description of the discrepancy for submission to HHS. Additionally, we estimate that it will take a computer programmer (at an hourly labor cost of approximately \$78) approximately 12 hours to develop the pipe-delimited file for reporting the discrepancy, based on the technical specifications published by HHS, and to submit the discrepancy file to HHS through the electronic file transfer system. Therefore, we estimate that the total burden for each issuer is approximately 18 hours with an equivalent cost of \$1,404. Assuming that

no more than 120 issuers will submit a discrepancy, we estimate a total aggregate annual burden of approximately 2,160 hours and \$168,480 for issuers as a result of these requirements.

N. ICRs Regarding Administrative Appeals (§ 156.1220)

In § 156.1220, we previously established an administrative appeals process to address any issues or errors for APTC, advance payment and reconciliation of cost-sharing reductions, FFE user fees, and the premium stabilization programs, as well as any assessment of a default risk adjustment charge under § 153.740(b). This final rule revises § 156.1220 to also address administrative appeals relating to the risk adjustment data validation process.

Under § 153.630(d), an issuer may appeal the findings of a second validation audit or the calculation of a risk score error rate. This final rule amends § 153.630(d) by clarifying the process by which an issuer can appeal the findings of a second validation audit or the calculation of a risk score error rate. Under this final rule, issuers are required to use the administrative appeals process set forth in § 156.1220. Under § 156.1220(a), an issuer may file a request for reconsideration to contest a processing error by HHS, HHS's incorrect application of the relevant methodology, or HHS's mathematical error with respect to the findings of a

second validation audit or the calculation of a risk score error rate.

While the hours involved in a request for reconsideration might vary, for purposes of this burden estimate, we estimate that it will take a business operations specialist 1 hour (at an hourly labor cost of \$78) to make the comparison and submit a request for reconsideration to HHS. We estimate that 9 issuers, representing approximately 1 percent of issuers of risk adjustment covered plans, subject to risk adjustment data validation, will submit a request for reconsideration, resulting in a total aggregate annual burden of 9 hours with an equivalent cost of approximately \$702.

O. ICR Regarding Medical Loss Ratio (§ 158.240)

We are amending § 158.240 to allow issuers the option of limiting the total rebate payable over the course of a 3-year period with respect to a given calendar year. We anticipate that implementing this provision will require minor changes to the MLR annual reporting form and we will revise the information collection currently approved under OMB Control Number 0938–1164 to reflect this provision, as may be necessary. However, we anticipate that only a small number of issuers will elect the option of additional reporting and we do not expect that this provision will increase the burden.

TABLE 14—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 (\$)
§ 153.630 Risk Adjustment Data Validation	0938–1155	559	111,800	1.417	158,383	\$72	\$11,403,600	\$11,403,600
§ 153.630(d) Discrepancy Reporting Processes for Risk Adjustment Data Validation.	0938–1155	825	1650	4	6,600	78	514,800	514,800
§§ 155.220, 156.265 Differential Display of Standardized Options.	NEW	160	160	2	320	96.82	30,982	30,982
§ 156.430(h) Discrepancy Reporting for cost-sharing reduction reconciliation.	0938–1266	120	1	18	2,160	78	168,480	168,480
§ 156.1220 Administrative Appeals	NEW	9	9	1	9	68	702	702
Total	1,114	113,620	26.417	167,472	392.82	12,118,564	12,118,564

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 14.

VI. Regulatory Impact Analysis

A. Statement of Need

This rule finalizes standards related to the risk adjustment program for the 2017 and 2018 benefit years, as well as certain modifications to the program that will protect against the potential effects of adverse selection. The Premium Stabilization Rule and previous payment notices provided detail on the implementation of this

program, including the specific parameters for the 2014, 2015, 2016, and 2017 benefit years. This rule finalizes additional standards related to enrollment and eligibility, appeals, consumer assistance tools and programs of an Exchange, Web-brokers, cost-sharing parameters, qualified health plans, network adequacy, stand-alone dental plans, fair health insurance premiums, guaranteed availability and guaranteed renewability, the rate review

program, the medical loss ratio program, the Small Business Health Options Program, FFE user fees, standardized options, and CO-OPs. These standards represent incremental amendments that are intended to continue to strengthen the Exchanges, improve the stability of the market, and enhance the choices available to consumers, while supporting consumers' ability to make informed choices when purchasing health insurance.

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 the provisions in this final rule related to the proposed rule are “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 final rule with respect to those provisions.

Although it is difficult to discuss the wide-ranging effects of these provisions in isolation, the overarching goal of the premium stabilization, market standards, and Exchange-related

provisions and policies in the Affordable Care Act is to make affordable health insurance available to individuals who do not have access to affordable employer-sponsored coverage. The provisions within this final rule are integral to the goal of expanding coverage. For example, the risk adjustment program helps mitigate the effects of adverse risk selection and decrease the risk of financial loss that health insurance issuers might otherwise expect in 2018 and Exchange financial assistance helps low- and moderate-income consumers and American Indians/Alaska Natives purchase health insurance. The combined impacts of these provisions affect the private sector, issuers, and consumers, through increased access to health care services, decreased uncompensated care, lower premiums, 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 final rule will help further HHS’s goal of ensuring that all consumers have access to quality, affordable health care and are able to make informed choices, that Exchanges operate smoothly, that the risk adjustment program works as intended, and that SHOPs are provided flexibility. Affected entities such as QHP issuers and Web-brokers will incur costs to comply with the finalized provisions. In accordance with Executive Order 12866, HHS believes that the benefits of this regulatory action justify the costs.

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

In accordance with OMB Circular A–4, Table 15 below 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 a number of 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, and increased insurance enrollment—and certain costs—such as the cost of providing additional medical services to newly-enrolled individuals. The effects in Table 15 reflect qualitative impacts and estimated direct monetary costs and transfers resulting from the provisions of this final rule. The annualized monetized costs described in Table 15 reflect direct administrative costs to health insurance issuers and Web-brokers as a result of the provisions, and include administrative costs related to requirements that are estimated in the Collection of Information section of this final rule. The annual monetized transfers described in Table 15 include costs associated with the risk adjustment user fee paid to HHS by issuers, and a decrease in MLR rebates to consumers. For 2018, we expect to collect a total of \$40 million in risk adjustment user fees or \$1.68 per enrollee per year from risk adjustment issuers, an increase from \$24 million in benefit year 2017 when we established a \$1.56 per-enrollee-per-year risk adjustment user fee amount. As in 2017, the risk adjustment user fee contract costs for 2018 include costs for risk adjustment data validation.

The annual monetized transfers described in Table 15 include a decrease in MLR rebates to consumers.

TABLE 15—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.
- Improved transparency and shopping experience for consumers due to new, updated standardized options and their differential display; and protections relating to direct enrollment.
- Ensure that newly qualified employees in FF–SHOPs and SBE–FPs using the Federal platform for SHOP functions have adequate time to make informed decisions regarding their coverage and minimize the risk of group health plans in FF–SHOPs and SBE–FPs using the Federal platform for SHOP functions exceeding the limitations on waiting period length.
- Ensure plan choice, allowing individuals to find coverage that fit their needs.

Costs:	Estimate (million)	Year dollar	Discount rate	Period covered
Annualized Monetized (\$/year)	\$12.12	2016	7	2017–2021
	12.12	2016	3	2017–2021

TABLE 15—ACCOUNTING TABLE—Continued

Costs reflect administrative costs incurred by issuers and Web-brokers to comply with provisions in this final rule.

Transfers:	Estimate (million)	Year dollar	Discount rate	Period covered
Annualized Monetized (\$/year)	\$33.8 34.4	2016 2016	7 3	2017–2021 2017–2021

- Transfers include risk adjustment user fees for 2018–2021 (assuming that they remain the same during this time period), which are transfers from health insurance issuers to the Federal government; and a reduction in total rebate payments by issuers which is a transfer from enrollees to shareholders or nonprofit stakeholders in individual, small and large group markets, resulting from adjustment in MLR methodology.

Qualitative:

- More precise risk adjustment charges and payments due to change in risk adjustment methodology.

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 15 or 16 for fiscal years 2019–2021. Table 16 summarizes the effects of the risk adjustment program on the Federal budget from fiscal years 2017 through 2021, with the additional, societal effects of this final rule discussed in this RIA. We do not expect the provisions of this final rule to significantly alter CBO's estimates of the

budget impact of the premium stabilization programs that are described in Table 16. We note that transfers associated with the risk adjustment and reinsurance programs were previously estimated in the Premium Stabilization Rule; therefore, to avoid double-counting, we do not include them in the accounting statement for this final rule (Table 16).

TABLE 16—ESTIMATED FEDERAL GOVERNMENT OUTLAYS AND RECEIPTS FOR THE RISK ADJUSTMENT, REINSURANCE, AND RISK CORRIDORS PROGRAMS FROM FISCAL YEAR 2017–2021

[billions of dollars]

Year	2017	2018	2019	2020	2021	2017–2021
Risk Adjustment, Reinsurance, and Risk Corridors Program Payments	10	8	8	9	9	44
Risk Adjustment, Reinsurance, and Risk Corridors Program Collections *	11	7	8	9	9	44

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 outlaid in the FY 2016–FY 2020 timeframe. CBO does not expect a shortfall in these programs.

Source: Congressional Budget Office. Federal Subsidies for Health Insurance Coverage for People Under Age 65: Tables From CBO's March 2016 Baseline <https://www.cbo.gov/sites/default/files/51298-2016-03-HealthInsurance.pdf>.

1. Fair Health Insurance Premiums

The final rule creates multiple child age bands rather than a single age band for individuals age 0 through 20. Establishing single-year age bands starting at age 15 will result in small annual increases in premiums attributable to age for children age 15 to 20, which will help mitigate large premium increases attributable to age due to the transition from child to adult age rating at age 21.

2. Guaranteed Renewability

The final rule specifies two circumstances in which the discontinuation of all coverage currently offered by an issuer in a market in a State will not be considered a market withdrawal subject to the 5-year ban on market re-entry. These changes are generally consistent with State regulation of health insurance coverage. Consumers will benefit from the rule since imposing the 5-year ban on market

re-entry in these situations could result in disruption for consumers and reduced competition in some markets.

3. Risk Adjustment

The risk adjustment program is a program created by the Affordable Care Act in which States, or HHS on behalf of States, collect charges from health insurance issuers that attract lower-risk populations in order to provide payments to health insurance issuers that attract higher-risk populations, such as those with chronic conditions, thereby reducing incentives for issuers to avoid higher-risk enrollees. We established standards for the administration of the risk adjustment program, in subparts D and G of part 45 of the CFR. The modifications to the risk adjustment model finalized in this rule are intended to improve the methodology and will result in more accurate risk adjustment charges and payments and mitigate any residual incentive for risk selection.

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, 2016 and 2017 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 2018 benefit year, we estimate that the total cost for HHS to operate the risk adjustment program on behalf of States for 2018 will be approximately \$40 million, and under this final rule, the risk adjustment user fee will be \$1.68 per enrollee per year. The risk adjustment user fee contract costs for 2018 include costs related to 2018 risk adjustment data validation, and are higher than the 2017 contract costs as the result of some contracts that were rebid, including since the publication of the proposed rule.

4. SHOP

The SHOPS facilitate the enrollment of eligible employees of eligible small employers into small group market 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.⁷²

In § 155.230(d)(2), we require SHOPS to make electronic notices the default method of sending SHOP notices to employers and employees, unless otherwise required by State or Federal law, or unless the employer or employee elects otherwise. Electronic notices will provide a more cost effective way for SHOPS to distribute required notices and should decrease the SHOPS' costs for notifications.

In § 155.725(g), we amend the enrollment process for newly qualified employees in FF-SHOPS and in SBE-FPs using the Federal platform for SHOP functions, and specify that waiting periods in all SHOPS are calculated beginning on the date an employee becomes a qualified employee who is otherwise eligible for coverage. We believe these amendments will ensure that newly qualified employees in FF-SHOPS and in SBE-FPs using the Federal platform for SHOP functions have adequate time to make informed decisions regarding their coverage, and they are likely to have a negligible impact on plan premiums and to minimize the risk that qualified employers administering group health plans in FF-SHOPS and in SBE-FPs using the Federal platform for SHOP functions exceed the waiting period limits under § 147.116.

5. Direct Enrollment—Standardized Options Differential Display and Privacy/Security and Oversight

In §§ 155.220, 156.265, and 156.1230, we finalize requirements for Web-brokers and issuers related to the direct enrollment process that will provide consumer protections and ensure that consumers have necessary information to select coverage that best fit their needs. Web-brokers and issuers will incur administrative costs to comply with these requirements.

6. Eligibility and Enrollment Provisions

In § 155.400, we provide Exchanges with the discretion to allow issuers experiencing billing or enrollment problems due to high volume or technical errors to implement a reasonable extension of the binder payment deadlines in § 155.400(e)(1).

This will allow consumers to remain enrolled through the Exchanges and to mitigate the problems associated with issuers receiving high-volumes of enrollments in a short timeframe. There will be no added cost to issuers who choose to implement the optional binder payment extensions, while ensuring that they would not lose enrollees who have not paid their binder payments simply because they did not receive their bills due to a processing backlog or a technical error. Consumers will benefit by having a reasonable amount of time to pay their binder payments, which should prevent coverage cancellations due to enrollment irregularities which are not the fault of the consumer.

In § 155.420, we codify several special enrollment periods that are already provided through the Exchange. By codifying these, we seek to ensure that these existing special enrollment periods are applied consistently across Exchanges, and to provide both issuers and consumers with greater certainty in how these special enrollment periods are applied. We believe that this certainty will contribute to greater stability in the market, and in the use of these special enrollment periods, specifically. In addition, we do not anticipate that any of the amendments to the existing parameters of special enrollment periods will reduce their availability to those individuals who should qualify under the provision's original intent.

We amend § 155.430(b)(2)(iii) to require that when an issuer seeks termination of a QHP on an Exchange via a rescission for fraud or misrepresentation of material fact under § 147.128, it must first demonstrate, to the reasonable satisfaction of the Exchange, that the basis for the rescission is appropriate, if the Exchange requires such a demonstration. This will not restrict issuers' ability to rescind coverage when an individual or a party working on behalf of an individual fraudulently enrolls in coverage, while protecting consumers whose enrollments conform to FFE and SBE-FP rules and guidance.

7. Standardized Options

We are finalizing new standardized options for 2018. As in 2017, offering standardized options will be voluntary for QHP issuers for the 2018 Plan Year. In keeping with the methodology used to design standardized options in 2017, we designed the 2018 standardized plans based on the median cost-sharing features of the most popular 2016 QHPs, based on enrollment, to ensure minimal market disruption and impact on

premiums. For 2018, we are finalizing additional standardized options at each metal level and plan variation level (plus an additional bronze HDHP standardized option, within the meaning of section 223(c)(2) of the Code) with the goal of having one option at each metal level and plan variation level (plus the bronze HDHP option) that will comply with State cost-sharing laws as applicable. Each applicable State will have one standardized option at each metal level and plan variation that issuers will then be able to choose to offer. In the 2017 Payment Notice, we attempted to estimate the potential impact that the introduction of standardized options would have on premiums established by QHPs. As we previously estimated, we do not anticipate that standardized options will impact 2018 plan premiums significantly. To the extent it facilitates consumer shopping, it can put modest downward pressure on premiums.

8. 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. Under this final rule, for the 2018 benefit year, the monthly FFE user fee rate is equal to 3.5 percent and, for a State-based Exchange that relies on the Federal platform, 3.0 percent of the monthly premium. We had estimated the user fee transfers in the 2017 Payment Notice and there are no additional incremental charges. To avoid double-counting, we do not include the user fee costs in the accounting statement for this rule (Table 15). For the user fee charges assessed on issuers in the FFE and State-based Exchanges using the Federal platform, we have sought and received an exception to OMB Circular No. A-25R, which requires that the user fee charge be sufficient to recover the full cost to the Federal government of providing the special benefit. We sought this exception to ensure that the FFE can support many of the goals of the Affordable Care Act, including improving the health of the population, reducing health care costs, and providing access to health coverage as advanced by § 156.50(d).

⁷² Available at <http://ccio.cms.gov/resources/files/Files2/03162012/hie3r-ria-032012.pdf>.

9. Levels of Coverage

At § 156.140, we are finalizing a change to the de minimis range of the actuarial value of bronze plans under certain circumstances. We believe that this policy will allow more flexibility in bronze plan designs which will allow increased consumer choice. We further believe that this policy will not be disruptive to the current bronze plan market, because it allows more options for issuers to leave 2017 cost-sharing structures unchanged. We also believe that this policy will allow issuers to continue to offer a range of bronze plans as the AV Calculator is updated in future years. We do not require plans to utilize this expanded bronze de minimis range, and therefore we do not anticipate any significant impact on average bronze plan premiums as a result of this policy.

10. 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.⁷³

We set forth in this final 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 of the reductions described in the Affordable Care Act to the estimated 2018 maximum annual limitation on cost sharing for self-only coverage, which is \$7,350 for the 2018 benefit year, on the QHPs' AVs. We do not believe these changes will result in a significant economic impact. Therefore, we do not believe the provisions related to the cost-sharing reduction portion of advance payments in this final rule will have an impact on the program established by and described in the 2015, 2016, and 2017 Payment Notices.

We also finalized the premium adjustment percentage for the 2018 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 used to determine eligibility for certain exemptions under section 5000A of the Code, and the assessable payments under section 4980H(a) and 4980H(b). We believe that the 2018 premium adjustment percentage of 16.17303196 percent is well within the parameters used in the modeling of the Affordable Care Act, and we do not expect that these provisions will alter CBO's March 2015 baseline estimates of the budget impact.

11. Qualified Health Plan Minimum Certification Standards

In § 156.200(c), we specify that, to satisfy the requirements in these sections, QHPs must be offered through the applicable Exchange at both the silver and gold coverage levels throughout each service area in which the issuer applying for certification offers coverage through the Exchange. Since most issuers are already following these requirements, it is unlikely that there will be any impact on premiums, while the requirements will help ensure continued plan choice for consumers.

In § 156.200(g), we specify that the certification standard regarding issuer participation in an FF-SHOP applies only for plan years beginning before January 1, 2018. The SHOP participation provision will no longer be a certification requirement for plan years that begin on or after January 1, 2018.

Section 156.272 establishes, as a condition of certification, that QHP issuers must make their QHPs available for enrollment through the Exchanges for the duration of the plan year for which the plan was certified, unless a basis for suppression under § 156.815 applies. QHP issuers in FFEs and FF-SHOPs that do not comply with this requirement can be subject to CMPs or a two-year ban. This will raise costs or burdens on some issuers, who may be forced to remain on the Exchange or face a 2-year ban or CMPs in certain situations. However, we believe this impact is minimal due to the small number of issuers that have sought to offer QHPs for less than a full plan year and is balanced by the additional choice and competition this requirement will offer.

12. Medical Loss Ratio

In this final rule, we amend § 158.121 to align with the requirement that, beginning in 2014, issuers must offer non-grandfathered coverage for a consecutive 12-month period and enable more issuers to defer reporting of the experience of new business in the MLR calculation when such business represents 50 percent or more of the total earned premium for an MLR reporting year. In general, the deferral of reporting of new business effectively enables new and rapidly growing issuers to use a 4-year, rather than a 3-year average MLR. This in turn increases the likelihood that low MLRs in the initial years will be offset by higher MLRs in later years and that only a portion of the rebates generated by the experience of initial years will ultimately be paid. Deferred reporting of new business also eliminates the rebate payment following the first year and instead spreads it over the following 3 years (that is, includes the rebate attributable to year 1 with rebates payable for years 2 through 4). Based on data from the 2013 and 2014 MLR reporting years, we estimate that allowing issuers to defer experience of newly sold policies with full 12 months of experience when 50 percent or more of an issuer's earned premium comes from such policies may reduce total rebate payments from issuers to consumers over a 4-year period by up to a total of \$11.6 million.

We additionally amend § 158.240 to allow issuers the option of limiting the total rebate payable over the course of a 3-year period with respect to a given calendar year, as well as to clarify references to single-year and preliminary MLRs in § 158.232. We estimate no impact from the clarifications to § 158.232 because these clarifications are intended to simplify reporting for purposes of calculating the rebate limit provision in § 158.240 and do not change the manner in which issuers currently calculate the credibility adjustment. Because the amendments to § 158.240 generally will only impact new and rapidly growing established issuers whose MLRs initially fall below the standard and increase in subsequent years, the magnitude of the impact of the limit on the rebate liability will depend on how issuers' enrollment and MLRs change in future years. Because estimating the impact of the limit on rebate liability would require multiple years of data, and the majority of new issuers have expanded or intend to expand into new markets in 2014 or later, the 2014 and earlier MLR reports are an insufficient

⁷³ 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>.

source of data on the types of issuers that will be impacted by this amendment. In addition, significant reporting differences exist between 2011–13 and 2014 and later MLR data, and some rebates that were paid for 2014 are believe to be outliers and may therefore exaggerate estimates. Consequently, while we expect the

amendment to decrease the amount of rebates paid by new and rapidly growing issuers to consumers, we are not able to estimate the magnitude of the decrease with a high degree of certainty.

13. CO–OPs

Although most of the original \$6 billion appropriated for the CO–OP program has been rescinded (as mentioned above), the program has issued significant sums to its borrowers. The total loan awards for currently operating CO–OPs are shown in Table 17.

TABLE 17—TOTAL LOAN AWARDS FOR CO–OPs OPERATING IN 2016 CO–OPs

CO–OP name	State	Current obligations
HealthyCT, Inc.	CT	\$127,980,768
Land of Lincoln Mutual Health Insurance Company	IL	160,154,812
Minuteman Health, Inc.	MA, NH	156,442,995
Evergreen Health Cooperative, Inc.	MD	65,450,900
Maine Community Health Options	ME	132,316,124
Montana Health Cooperative	MT, ID	85,019,688
Freelancers Consumer Operated and Oriented Program of New Jersey, Inc.	NJ	109,074,550
New Mexico Health Connections	NM	77,317,782
Coordinated Health Mutual, Inc.	OH	129,225,604
Community Care of Oregon, Inc.	OR	56,656,900
Common Ground Healthcare Cooperative	WI	107,739,354
Total	11	1,207,379,477

With respect to the changes to the CO–OP program that we are implementing, we do not have any data available to estimate the likely number or magnitude of capital-raising transactions that may result from our changes. Directionally, we expect the changes to facilitate the raising of additional capital for some number of CO–OPs, and that the additional capital cushion will strengthen the financial base and allow those CO–OPs to better weather financial stress. We sought but did not receive any comments or supporting data that shed light on that potential impact.

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 interpretation of what constitutes a market withdrawal, we considered imposing the 5-year prohibition on market re-entry when an issuer transfers all of its products to a related issuer or replaces all of its products with new products with changes that exceed the scope of a uniform modification of coverage. However, this approach could result in fewer product offerings, as some issuers would be obligated to leave the market. This approach could also unnecessarily restrict issuer corporate structuring transactions, reduce market competition

and consumer choice, and conflict with States' approaches.

Regarding changes to the uniform child age band, we considered maintaining the use of a single age band for rating purposes for all individuals age 0 through 20. However, establishing multiple child age bands more accurately reflects the health risk of children and minimizes the increase in premium attributable to age when an individual attains age 21.

For the provisions in part 153, we considered various approaches to addressing partial year enrollment in the risk adjustment model, including separate models by enrollment duration, and interaction factors of enrollment duration combined with high- and medium-cost conditions. However, based on commenter feedback to the March 31, 2016 White Paper and our analysis of MarketScan® data, HHS determined that the enrollment duration additive factors are preferred, and will best address partial year enrollees in the short term.

We considered four different hybrid models for the inclusion of prescription drugs in the HHS risk adjustment methodology: An imputation-only model, a prescription drug-dominant model, a flexible model, and a severity-only model. Commenters to the White Paper suggested that we use the imputation only model or the flexible model, with constraints to prevent an issuer from being compensated less for recording prescription drug utilization for an enrollee. We have imposed

constraints on the flexible model so that the coefficients for the drug terms are greater than zero, preventing such a situation. We are adding two severity-only drug-diagnosis pairs on top of ten imputation/severity drug-diagnosis pairs.

We considered various thresholds and coinsurance rates for the high-cost enrollee pool in the risk adjustment proposal. Lower thresholds and higher coinsurance rates could increase the risk of gaming among issuers and could decrease the incentive to contain costs, but would also increase the effectiveness of the high-cost enrollee pool. To balance these objectives, this final rule contains a threshold of \$1 million and a 60 percent coinsurance rate for the high-cost enrollee pool in the risk adjustment model. We also considered a PMPM adjustment to the transfer formula for this high-cost enrollee pool, but we finalize here a percent of per member per month premium adjustment to the transfer formula, to better align with the transfer formula's adjustment at the billable member month premiums and to mitigate interstate transfer effects based on differing medical costs between States.

We considered using only 2014 MarketScan® data for 2018 recalibration. However, commenters to the White Paper preferred to continue using the 3-year blended approach. We considered using the most current MarketScan® data for 2018 recalibration, but commenters objected

to release of the final coefficients after the rate setting period for the benefit year. As provided in this final rule, HHS will publish final 2018 coefficients in early 2017, before issuers price for plan year 2018.

We considered alternative methodologies to recalibrating the 2019 risk adjustment model using EDGE summary level data instead of enrollee level data, as was proposed by one commenter to the White Paper. However, using EDGE summary level data would not enhance the existing risk adjustment models, as the model specifications would need to be known to create the models, and thus would prevent exploratory research and other types of analyses required for research, development, and refinement of the risk adjustment models for their continuous improvement. Further, if summary level data were used, quality checks could not be performed on the input data, and additional improvements to address partial year enrollment could not be explored.

For the provisions regarding standardized options, HHS considered taking no action to design additional plans to account for State cost-sharing laws. However, without this change, issuers in States with conflicting cost-sharing laws would not be able to offer standardized options. HHS believes that it is important for issuers in each State in which an FFE or SBE-FP operates to have the option to offer standardized options. HHS also considered designing a set of standardized plans for each State. However, HHS currently lacks the resources necessary to implement this option.

For the amendments at § 155.205(c)(2)(iii), we considered requiring QHP issuers and Web-brokers subject to the rule to look only to the LEP populations in the State where the entity is registered or licensed, such as through an issuer's Health Insurance Oversight System (HIOS) ID, when identifying the languages in which taglines must be provided under the rule. However, we believe that using such a definition would not recognize that many insurance companies that would fit our definition of a controlled group use a common technology platform across multiple States that is shared by their component health insurance issuers, and would pose difficult operational challenges for many such entities.

For the amendments at §§ 155.220(c)(3)(i)(H) and 156.265(b)(3)(iv), HHS considered not requiring differential display of standardized options by Web-brokers or QHP issuers. However, this would have

made consumers using a non-Exchange Web sites less likely to be aware of available standardized options. HHS believes that the requirement for non-Exchange Web sites to differentially display standardized options will help consumers to more easily compare and choose amongst the available plans. HHS notes that we will not require the manner of differentiation of standardized plans on non-Exchange Web sites to be identical to the one adopted for displaying standardized options on *HealthCare.gov*, but they must have the same level of differentiation and clarity as is provided on *HealthCare.gov*. Further, issuers are not required to offer standardized plans nor are consumers required to purchase standardized options.

For amendments at § 155.400, we considered alternatives to our proposal to allow issuers the option to extend binder payment deadlines when issuers experience volume-related backlogs or technical errors that make it difficult for enrollees to pay their binder payments on time. For example, we considered relying on ad hoc solutions, such as extensions or remedies resembling reinstatements, when problems arise. We believe, however, that codifying the proposed optional extensions will give issuers and consumers alike more certainty and provide for better remedies when consumers experience difficulties during the enrollment process.

For the amendments at § 155.420, we considered not codifying the existing special enrollment periods for consumers who are or were victims of domestic abuse or spousal abandonment and need to enroll in coverage apart from their abusers or abandoners, have been determined ineligible for Medicaid or CHIP, have been impacted by a material plan or benefit display error, or have resolved a citizenship or immigration inconsistency post-expiration, all currently provided through guidance. We also considered not standardizing the availability of the special enrollment period for Indians to non-Indian dependents enrolling at the same time as the Indian. However, we believe that codifying these special enrollment periods provides needed permanence and clarity for these special enrollment periods. This is important to ensure that they continue to be available, are equitably applied across Exchanges, and that consumers, assisters, issuers, and other stakeholders have a common understanding of the parameters and coverage effective dates associated with each of these special enrollment periods. In this rule, we seek to ensure transparency, stability, and

appropriate utilization of special enrollment periods by codifying certain special enrollment periods that we have made available in prior guidance. After weighing our options, we determined that codifying these currently available special enrollment periods is in the best interest of consumers and other Exchange stakeholders.

We considered alternatives to amending § 155.430 in order to protect consumers from having their coverage rescinded for reasons the FFE does not consider reasonable, such as rescissions based on allegations of fraud, despite the disputed information having been verified by the FFE during the enrollment process. One alternative was to issue guidance that would explain to issuers that rescissions based on claims of fraud arising from information provided to and verified by the FFE would not be permissible. Another alternative considered was to work with issuers to prevent rescissions considered unreasonable by the FFE, but to decline to pursue rulemaking. After considering all options, we chose to amend § 155.430(b)(2)(iii) in order to provide more consumer protection.

For the amendments related to SHOPS, HHS considered maintaining several provisions for the SHOPS. Specifically, HHS considered maintaining the current requirements at § 155.725(g)(1) and (2), which provide that an employee who becomes a qualified employee outside of the initial or annual open enrollment period must have an enrollment period beginning on the first day of becoming a qualified employee, and require the effective date of coverage to generally be determined in accordance with § 155.725(h). Similarly, HHS considered maintaining the current requirements at § 155.230(d)(2), which require paper notices to be the default communication option for SHOPS, so that employers and employees must opt into electronic notices. HHS also considered maintaining the current SHOP participation provision at § 156.200(g)(2). Finally, HHS considered maintaining existing requirements in State-based Exchanges using the Federal platform for SHOP eligibility, enrollment, or premium aggregation functions. With respect to the amendments proposed at § 155.725(g), in order to preserve flexibility for State-based Exchanges not using the Federal platform for SHOP functions, HHS decided to generally maintain the current rule for State-based Exchanges not using the Federal platform, and to finalize most of its proposed amendments to apply only in FF-SHOPS and SBE-FPs using the Federal

platform for SHOP functions, in order to minimize the risk that qualified employers administering group health plans in those SHOPs will exceed the waiting period limits under § 147.116, and to provide newly qualified employees in those SHOPs with sufficient time to make plan selections. The only amendment to § 155.725(g) that will apply in all SHOPs is a provision specifying when waiting periods in SHOPs begin. HHS also opted to finalize its proposal with respect to SHOP notices and SBE-FPs using the Federal platform for SHOP functions as proposed, in order to provide SHOPs with more cost-effective alternatives to sending notices, ensure efficient SHOP operations, and minimize the potential customization costs that could be associated with permitting State-based Exchanges to use the Federal platform for SHOP functions. HHS also decided to amend the policy in this final rule regarding the SHOP participation provision in order to encourage issuers to participate in the individual market FFEs.

HHS considered alternatives for increasing the de minimis range for bronze plans. HHS considered simply increasing the de minimis range for bronze plans to $-2/+5$ without requiring that plans include certain plan design features in order to qualify for the extended de minimis range. This option would give issuers, and as a result, consumers, more flexibility and choice in bronze plan designs. However, HHS believes that the final policy better ensures that bronze plans are not less generous than catastrophic plans.

At § 156.200(c)(1), HHS specifies that QHPs must be offered through an Exchange at both the silver and gold coverage levels throughout each service area in which the issuer offers coverage through the Exchange in order to satisfy the requirements of this section. HHS could have opted not to specify this in regulation; however, issuers could have misinterpreted the policy and not offered a silver and gold plan in all applicable service areas. This could result in fewer silver and gold plans available for consumers, and thus less choice for consumers. It also could complicate the calculation of the APTC for an individual market consumer. By revising our regulation, HHS ensures that consumers have adequate choice of QHPs at different coverage levels and that we are able to calculate APTC for all eligible individual market consumers.

In § 156.272, HHS requires issuers offering QHPs through an individual market Exchange or SHOP to make the QHP available for enrollment through

the individual market Exchange or SHOP for the entirety of the period for which the plan was certified, unless a basis for suppression under § 156.815 applies. HHS considered taking no action; however, HHS is concerned that inaction could result in more limited access to QHPs for qualified individuals and qualified employees outside of open enrollment periods.

For the changes to § 156.290, HHS considered a requirement that issuers notify enrollees within 30 days of the denial of QHP certification for a subsequent, consecutive certification cycle. As pointed out by commenters to our proposed rule, such a requirement could have caused consumers to receive multiple notices when a plan is not certified and discontinued. Moreover, the 30 day requirement would not have aligned with the required timing for discontinuation notices. Therefore, HHS finalized a revised rule that aligns with existing requirements for renewal and discontinuation notices, as described above.

For the amendments to part 158, we considered an alternative approach for addressing the impact of MLR and rebate calculation on new and rapidly growing issuers. Specifically, we considered allowing new and rapidly growing issuers to include in the MLR calculation rebates they paid within the first 2 years of entering or expanding in a State market, which would be similar to how the 3-year average calculation was phased in for all issuers when the MLR requirements were first implemented. However, in contrast to the initial years of implementation of the MLR requirements, when all issuers had to calculate their first two MLRs using only 1 or 2 years of data, presently, as described in more detail in the preamble to this rule and the proposed rule, only a small subset of issuers are affected by the 3-year averaging in a manner that merits an adjustment. We note that inclusion of rebates paid for prior years in the MLR calculation for the current year is generally not appropriate for established and certain new issuers, as it would distort the 3-year average and effectively lower the MLR standards required by section 2718 of the PHS Act for these issuers. Therefore, the prior year rebate approach would need to be limited to only the new and rapidly growing issuers that are adversely affected by the 3-year averaging. In practice, it would be extremely challenging to define enrollment or premium levels, growth rates, and patterns in year-over-year changes in MLRs that would appropriately distinguish new and growing issuers that are disadvantaged

by the 3-year averaging from issuers that merely experience ordinary enrollment fluctuations or otherwise would gain an unfair advantage by being able to include prior year rebates in their MLR calculations. Because the adopted approach of limiting the total rebate liability payable with respect to a given calendar year is designed to only benefit new and rapidly growing issuers who are negatively impacted by the 3-year averaging, we believe that the adopted approach is a more effective and objective way to reduce barriers to entry and promote competition in health insurance markets while at the same time preserving the protections promised to consumers by the law.

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 proposed rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. In the proposed rule we certified that this regulation would not result in a significant impact on a substantial number of small entities. We did not receive any comments contradicting the RFA certification, so we are not required to prepare a final regulatory flexibility analysis for this final rule. (5 U.S.C. 604). The RFA generally defines a “small entity” as: (1) A proprietary firm meeting the size standards of the Small Business Administration (SBA); (2) a not-for-profit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of “small entity.” HHS uses a change in revenues of more than 3 to 5 percent as its measure of significant economic impact on a substantial number of small entities.

In this final rule, we provide standards for the risk adjustment program, 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 a final 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 final 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. Only nine of these 118 potentially small entities, all of them part of larger holding groups, are estimated to experience a decrease in the rebate amount owed to consumers under the amendments to the MLR provisions of this final rule in part 158, and the decrease is estimated to not exceed 5 percent of health insurance premium revenue for any of these entities. Therefore, we certify that the provisions of this final rule regarding MLR will not affect a substantial number of small entities.

In this final rule, we finalize standards for employers that choose to participate in a SHOP Exchange. The SHOPs generally are limited by statute to employers with at least one but not more than 50 employees, unless a State opts to provide that employers with 1 to 100 employees are small employers. For this reason, we expect that many employers who will be affected by the proposals will meet the SBA standard for small entities. The policies amend current requirements to ensure that newly qualified employees in FF-SHOPs and in SBE-FPs using the Federal platform for SHOP functions have adequate time to make informed decisions regarding their coverage. However, these provisions are likely to result in minimal increase in administrative costs for employers, and have negligible impact on plan premiums. We believe the processes that we have established for SHOP eligibility and enrollment constitute the minimum amount of requirements

necessary to implement the SHOP program and accomplish our policy goals, and that no appropriate regulatory alternatives could be developed to further lessen the compliance burden.

F. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a proposed rule that includes any Federal mandate that may result in expenditures in any 1 year by State, local, or Tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. In 2016, that threshold is approximately \$146 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 with respect to the final rule.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications. Because States have flexibility in designing their Exchanges 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 program. For States that elected to operate an Exchange or, risk adjustment program, much of the initial cost of creating these programs were funded by Exchange Planning and Establishment Grants. After establishment, Exchanges must be financially self-sustaining, with revenue sources at the discretion of the State. Current State Exchanges charge user fees to issuers.

In HHS's view, while this final rule does not impose substantial direct requirement costs on State and local governments, this regulation has Federalism implications due to direct effects on the distribution of power and responsibilities among the State and Federal governments relating to determining standards relating to health insurance that is offered in the individual and small group markets. However, HHS anticipates that the Federalism implications (if any) are substantially mitigated because under the statute and our regulations, States

have choices regarding the structure, governance, and operations of their Exchanges and risk adjustment program. For example, our provisions relating to binder payment rules and termination of coverage are intended to provide State Exchanges with significant flexibility. Additionally, the Affordable Care Act does not require States to establish these programs; if a State elects not to establish any of these programs or is not approved to do so, HHS must establish and operate the programs in that State. Additionally, States have the option to establish and operate their own SHOP without also establishing and operating their own individual market Exchange. Our provisions requiring SBE-FPs to establish requirements that are consistent with certain FF-SHOP requirements when using the Federal platform for certain SHOP functions will not apply should the State decide not to use the Federal platform for these SHOP functions.

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.

While developing this final rule, HHS has attempted to balance the States' interests in regulating health insurance issuers, and the policy goal of providing access to 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.

States will continue to license, monitor, and regulate agents and brokers, both inside and outside of Exchanges. All State laws related to agents and brokers, including State laws related to appointments, contractual relationships with issuers, licensing, marketing, conduct, and fraud will continue to apply.

The provisions from the interim final rule with comment do not impose substantial direct costs on State and local governments or preempt State law. However, we believe the rule has Federalism implications. In the amendments regarding the CO-OP program, we have amended a prohibition on participation on CO-OP board of directors that previously prevented any State employee from participating to allow certain State employees who are unlikely to have a

potential conflict of interest to participate. In removing the January 1, 2017 implementation deadline for (1) offering advance availability of the special enrollment period for qualified individuals who gain access to new QHPs as a result of a permanent move and (2) for offering the special enrollment period for losing a dependent or no longer being considered a dependent due to divorce, legal separation, or death, we leave implementation at the option of Exchanges, including State Exchanges.

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 for review.

List of Subjects

45 CFR Parts 144, 146, and 147

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 148

Administrative practice and procedure, Health care, Health insurance, Penalties, 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, Advertising, Brokers, Conflict of interest, Consumer protection, Grant administration, Grant programs—health, Health care, Health insurance, Health maintenance organizations (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Intergovernmental relations, Loan programs—health, Medicaid, Organization and functions (Government agencies), Public

assistance programs, Reporting and recordkeeping requirements, Technical assistance, Women and youth.

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 157

Employee benefit plans, Health insurance, Health maintenance organizations (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, Technical assistance, Women and 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 confirms as final, the interim rule published on May 11, 2016 (81 FR 29146) and further amends 45 CFR parts 144, 146, 147, 148, 153, 154, 155, 156, 157 and 158 as set forth below.

PART 144—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

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

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

■ 2. Section 144.103 is amended by revising the introductory text of the definition of “Plan” and by revising the definition of “Product” to read as follows:

§ 144.103 Definitions.

* * * * *

Plan means, with respect to a product, the pairing of the health insurance coverage benefits under the product with a particular cost-sharing structure, provider network, and service area. The

product comprises all plans offered with those characteristics and the combination of the service areas for all plans offered within a product constitutes the total service area of the product. With respect to a plan that has been modified at the time of coverage renewal consistent with § 147.106 of this subchapter—

* * * * *

Product means a discrete package of health insurance coverage benefits that are offered using a particular product network type (such as health maintenance organization, preferred provider organization, exclusive provider organization, point of service, or indemnity) within a service area. In the case of a product that has been modified, transferred, or replaced, the resulting new product will be considered to be the same as the modified, transferred, or replaced product if the changes to the modified, transferred, or replaced product meet the standards of § 146.152(f), § 147.106(e), or § 148.122(g) of this subchapter (relating to uniform modification of coverage), as applicable.

* * * * *

PART 146—REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET

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

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

■ 4. Section 146.152 is amended by adding paragraphs (d)(3) and (4) and revising paragraph (f)(3)(i) to read as follows:

§ 146.152 Guaranteed renewability of coverage for employers in the group market.

* * * * *

(d) * * *

(3) For purposes of this paragraph (d), subject to applicable State law, an issuer will not be considered to have discontinued offering all health insurance coverage in a market in a State if—

(i) The issuer (in this paragraph referred to as the initial issuer) or, if the issuer is a member of a controlled group, any other issuer that is a member of such controlled group, offers and makes available in the applicable market in the State at least one product that is considered in accordance with § 144.103 of this subchapter to be the same product as a product the initial issuer had been offering in such market in such State; or

(ii) The issuer—

(A) Offers and makes available at least one product (in paragraphs (d)(3)(ii)(A) through (C) of this section referred to as the new product) in the applicable market in the State, even if such product is not considered in accordance with § 144.103 of this subchapter to be the same product as a product the issuer had been offering in the applicable market in the State (in paragraphs (d)(3)(ii)(A) through (C) of this section referred to as the discontinued product);

(B) Subjects such new product or products to the applicable process and requirements established under part 154 of this title as if such process and requirements applied with respect to that product or products, to the extent such process and requirements are otherwise applicable to coverage of the same type and in the same market; and

(C) Reasonably identifies the discontinued product or products that correspond to the new product or products for purposes of the process and requirements applied pursuant to paragraph (d)(3)(ii)(B) of this section.

(4) For purposes of this section, the term controlled group means a group of two or more persons that is treated as a single employer under sections 52(a), 52(b), 414(m), or 414(o) of the Internal Revenue Code of 1986, as amended, or a narrower group as may be provided by applicable State law.

* * * * *

(f) * * *

(3) * * *

(i) The product is offered by the same health insurance issuer (within the meaning of section 2791(b)(2) of the PHS Act), or if the issuer is a member of a controlled group (as described in paragraph (d)(4) of this section), any other health insurance issuer that is a member of such controlled group;

* * * * *

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

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

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

■ 6. Section 147.102 is amended by revising paragraphs (d)(1) and (e) to read as follows:

§ 147.102 Fair health insurance premiums.

* * * * *

(d) * * *

(1) *Child age bands.* (i) For plan years or policy years beginning before January

1, 2018, a single age band for individuals age 0 through 20.

(ii) For plan years or policy years beginning on or after January 1, 2018:

(A) A single age band for individuals age 0 through 14.

(B) One-year age bands for individuals age 15 through 20.

* * * * *

(e) *Uniform age rating curves.* Each State may establish a uniform age rating curve in the individual or small group market, or both markets, for rating purposes under paragraph (a)(1)(iii) of this section. If a State does not establish a uniform age rating curve or provide information on such age curve in accordance with § 147.103, a default uniform age rating curve specified in guidance by the Secretary to reflect market patterns in the individual and small group markets will apply in that State that takes into account the rating variation permitted for age under State law.

* * * * *

■ 7. Section 147.104 is amended by revising paragraph (b)(2) to read as follows:

§ 147.104 Guaranteed availability of coverage.

* * * * *

(b) * * *

(2) *Limited open enrollment periods.*

(i) A health insurance issuer in the individual market must provide a limited open enrollment period for the triggering events described in § 155.420(d) of this subchapter, excluding the following:

(A) Section 155.420(d)(3) of this subchapter (concerning Exchange eligibility standards);

(B) Section 155.420(d)(6) of this subchapter (to the extent concerning eligibility for advance payments of the premium tax credit or change in eligibility for cost-sharing reductions other than ineligibility);

(C) Section 155.420(d)(8) of this subchapter (concerning Indians);

(D) Section 155.420(d)(9) of this subchapter (concerning exceptional circumstances);

(E) Section 155.420(d)(12) of this subchapter (concerning plan and benefit display errors); and

(F) Section 155.420(d)(13) of this subchapter (concerning eligibility for insurance affordability programs or enrollment in the Exchange).

(ii) In applying this paragraph (b)(2), a reference in § 155.420 of this subchapter to a “QHP” is deemed to refer to a plan, a reference to “the Exchange” is deemed to refer to the applicable State authority, and a reference to a “qualified individual” is

deemed to refer to an individual in the individual market.

* * * * *

■ 8. Section 147.106 is amended by adding paragraphs (d)(3) and (4) and revising paragraphs (e)(3)(i) and (h)(2) to read as follows:

§ 147.106 Guaranteed renewability of coverage.

* * * * *

(d) * * *

(3) For purposes of this paragraph (d), subject to applicable State law, an issuer will not be considered to have discontinued offering all health insurance coverage in a market in a State if—

(i) The issuer (in this paragraph referred to as the initial issuer) or, if the issuer is a member of a controlled group, any other issuer that is a member of such controlled group, offers and makes available in the applicable market in the State at least one product that is considered in accordance with § 144.103 of this subchapter to be the same product as a product the initial issuer had been offering in such market in such State; or

(ii) The issuer—

(A) Offers and makes available at least one product (in paragraphs (d)(3)(ii)(A) through (C) of this section referred to as the new product) in the applicable market in the State, even if such product is not considered in accordance with § 144.103 of this subchapter to be the same product as a product the issuer had been offering in the applicable market in the State (in paragraphs (d)(3)(ii)(A) through (C) of this section referred to as the discontinued product);

(B) Subjects such new product or products to the applicable process and requirements established under part 154 of this title as if such process and requirements applied with respect to that product or products, to the extent such process and requirements are otherwise applicable to coverage of the same type and in the same market; and

(C) Reasonably identifies the discontinued product or products that correspond to the new product or products for purposes of the process and requirements applied pursuant to paragraph (d)(3)(ii)(B) of this section.

(4) For purposes of this section, the term controlled group means a group of two or more persons that is treated as a single employer under sections 52(a), 52(b), 414(m), or 414(o) of the Internal Revenue Code of 1986, as amended, or a narrower group as may be provided by applicable State law.

(e) * * *

(3) * * *

(i) The product is offered by the same health insurance issuer (within the meaning of section 2791(b)(2) of the PHS Act), or if the issuer is a member of a controlled group (as described in paragraph (d)(4) of this section), any other health insurance issuer that is a member of such controlled group);

* * * * *

(h) * * *

(2) Medicare entitlement or enrollment is not a basis to nonrenew an individual's health insurance coverage in the individual market under the same policy or contract of insurance.

* * * * *

PART 148—REQUIREMENTS FOR THE INDIVIDUAL HEALTH INSURANCE MARKET

■ 9. The authority citation for part 148 continues to read as follows:

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

■ 10. Section 148.122 is amended by—

■ a. Revising paragraph (b)(2);

■ b. Adding paragraphs (e)(4) and (5); and

■ c. Revising paragraph (g)(3)(i).

The revisions and addition read as follows:

§ 148.122 Guaranteed renewability of individual health insurance coverage.

* * * * *

(b) * * *

(2) Medicare entitlement or enrollment is not a basis to nonrenew an individual's health insurance coverage in the individual market under the same policy or contract of insurance.

* * * * *

(e) * * *

(4) For purposes of this paragraph (e), subject to applicable State law, an issuer will not be considered to have discontinued offering all health insurance coverage in a market in a State if—

(i) The issuer (in this paragraph referred to as the initial issuer) or, if the issuer is a member of a controlled group, any other issuer that is a member of such controlled group, offers and makes available in the applicable market in the State at least one product that is considered in accordance with § 144.103 of this subchapter to be the same product as a product the initial issuer had been offering in such market in such State; or

(ii) The issuer—

(A) Offers and makes available at least one product (in paragraphs (e)(4)(ii)(A) through (C) of this section referred to as the new product) in the applicable

market in the State, even if such product is not considered in accordance with § 144.103 of this subchapter to be the same product as a product the issuer had been offering in the applicable market in the State (in paragraphs (e)(4)(ii)(A) through (C) of this section referred to as the discontinued product);

(B) Subjects such new product or products to the applicable process and requirements established under part 154 of this title as if such process and requirements applied with respect to that product or products, to the extent such process and requirements are otherwise applicable to coverage of the same type and in the same market; and

(C) Reasonably identifies the discontinued product or products that correspond to the new product or products for purposes of the process and requirements applied pursuant to paragraph (e)(4)(ii)(B) of this section.

(5) For purposes of this section, the term controlled group means a group of two or more persons that is treated as a single employer under sections 52(a), 52(b), 414(m), or 414(o) of the Internal Revenue Code of 1986, as amended, or a narrower group as may be provided by applicable State law.

* * * * *

(g) * * *

(3) * * *

(i) The product is offered by the same health insurance issuer (within the meaning of section 2791(b)(2) of the PHS Act), or if the issuer that is a member of a controlled group (as described in paragraph (e)(5) of this section), any other health insurance issuer that is a member of such controlled group;

* * * * *

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

■ 11. The authority citation for part 153 continues to read as follows:

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

§ 153.20 [Amended]

■ 12. Section 153.20 is amended by removing the definition of “Large employer”.

■ 13. Section 153.320 is amended by revising paragraphs (a)(1) and (b)(1)(i) to read as follows:

§ 153.320 Federally certified risk adjustment methodology.

(a) * * *

(1) The risk adjustment methodology is developed by HHS and published in

advance of the benefit year in rulemaking; or

* * * * *

(b) * * *

(1) * * *

(i) Draft factors to be employed in the model, including but not limited to, demographic factors, diagnostic factors, and utilization factors, if any, the dataset(s) to be used to calculate final coefficients, and the date by which final coefficients will be released in guidance;

* * * * *

■ 14. Section 153.610 is amended by revising paragraph (f)(2) to read as follows:

§ 153.610 Risk adjustment issuer requirements.

* * * * *

(f) * * *

(2) Remit to HHS an amount equal to the product of its monthly billable enrollment in the risk adjustment covered plan multiplied by 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.

■ 15. Section 153.630 is amended by—

■ a. Redesignating paragraphs (b)(7)(iii) and (iv) as paragraphs (b)(7)(iv) and (v), respectively;

■ b. Adding a new paragraph (b)(7)(iii); and

■ c. Revising paragraph (d).

The addition and revision read as follows:

§ 153.630 Data validation requirements when HHS operates risk adjustment.

* * * * *

(b) * * *

(7) * * *

(iii) Beginning in the 2018 benefit year, validating enrollee health status through review of all relevant paid pharmacy claims;

* * * * *

(d) *Risk adjustment data validation disputes and appeals.* (1) Within 15 calendar days of notification of the initial validation audit sample determined by HHS, in the manner set forth by HHS, an issuer must confirm the sample or file a discrepancy report to dispute the initial validation audit sample determined by HHS.

(2) Within 30 calendar days of notification of the findings of a second validation audit or the calculation of a risk score error rate, in the manner set forth by HHS, an issuer must confirm the audit or error rate, or file a discrepancy report to dispute the findings of a second validation audit or the calculation of a risk score error rate as result of risk adjustment data validation.

(3) An issuer may appeal the findings of a second validation audit or the calculation of a risk score error rate as result of risk adjustment data validation, under the process set forth in § 156.1220 of this subchapter.

* * * * *

PART 154—HEALTH INSURANCE ISSUER RATE INCREASES: DISCLOSURE AND REVIEW REQUIREMENTS

■ 16. The authority citation for part 154 continues to read as follows:

Authority: Section 2794 of the Public Health Service Act (42 U.S.C. 300gg–94).

■ 17. Section 154.102 is amended by revising the definition of “Product” to read as follows:

§ 154.102 Definitions.

* * * * *

Product means a package of health insurance coverage benefits with a discrete set of rating and pricing methodologies offered in a State. The term product includes any product that is discontinued and newly filed within a 12-month period when the changes to the product meet the standards of § 147.106(e)(2) or (3) of this subchapter (relating to uniform modification of coverage).

* * * * *

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

■ 18. 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).

■ 19. Section 155.20 is amended by revising the definition of “Standardized option” to read as follows:

§ 155.20 Definitions

* * * * *

Standardized option means a QHP offered for sale through an individual market Exchange that either—

(1) Has a standardized cost-sharing structure specified by HHS in rulemaking; or

(2) Has a standardized cost-sharing structure specified by HHS in rulemaking that is modified only to the extent necessary to align with high deductible health plan requirements under section 223 of the Internal Revenue Code of 1986, as amended, or

the applicable annual limitation on cost sharing and HHS actuarial value requirements.

* * * * *

■ 20. Section 155.200 is amended by adding paragraph (f)(4) to read as follows:

§ 155.200 Functions of an Exchange.

* * * * *

(f) * * *

(4) A State Exchange on the Federal platform that utilizes the Federal platform for certain SHOP functions, as set forth in paragraphs (f)(4)(i) through (vii) of this section, must—

(i) If utilizing the Federal platform for SHOP eligibility, enrollment, or premium aggregation functions, establish standard processes for premium calculation, premium payment, and premium collection that are consistent with the requirements applicable in a Federally-facilitated SHOP under § 155.705(b)(4);

(ii) If utilizing the Federal platform for SHOP enrollment or premium aggregation functions, require its QHP issuers to make any changes to rates in accordance with the timeline applicable in a Federally-facilitated SHOP under § 155.705(b)(6)(i)(A);

(iii) If utilizing the Federal platform for SHOP enrollment functions, establish minimum participation rate requirements and calculation methodologies that are consistent with those applicable in a Federally-facilitated SHOP under § 155.705(b)(10);

(iv) If utilizing the Federal platform for SHOP enrollment or premium aggregation functions, establish employer contribution methodologies that are consistent with the methodologies applicable in a Federally-facilitated SHOP under § 155.705(b)(11)(ii);

(v) If utilizing the Federal platform for SHOP enrollment functions, establish annual employee open enrollment period requirements that are consistent with § 155.725(e)(2);

(vi) If utilizing the Federal platform for SHOP enrollment functions, establish effective dates of coverage for an initial group enrollment or a group renewal that are consistent with the effective dates of coverage applicable in a Federally-facilitated SHOP under § 155.725(h)(2); and

(vii) If utilizing the Federal platform for SHOP eligibility, enrollment, or premium aggregation functions, establish policies for the termination of SHOP coverage or enrollment that are consistent with the requirements applicable in a Federally-facilitated SHOP under § 155.735.

■ 21. Section 155.205 is amended by revising paragraphs (c)(2)(iii)(A) and (B) to read as follows:

§ 155.205 Consumer assistance tools and programs of an Exchange.

* * * * *

(c) * * *

(2) * * *

(iii) * * *

(A) For Exchanges and QHP issuers, this standard also includes taglines on Web site content and any document that is critical for obtaining health insurance coverage or access to health care services through a QHP for qualified individuals, applicants, qualified employers, qualified employees, or enrollees. A document is deemed to be critical for obtaining health insurance coverage or access to health care services through a QHP if it is required to be provided by law or regulation to a qualified individual, applicant, qualified employer, qualified employee, or enrollee. Such taglines must indicate the availability of language services in at least the top 15 languages spoken by the limited English proficient population of the relevant State or States, as determined in guidance published by the Secretary. If an Exchange is operated by an entity that operates multiple Exchanges, or if an Exchange relies on an entity to conduct its eligibility or enrollment functions and that entity conducts such functions for multiple Exchanges, the Exchange may aggregate the limited English proficient populations across all the States served by the entity that operates the Exchange or conducts its eligibility or enrollment functions to determine the top 15 languages required for taglines. A QHP issuer may aggregate the limited English proficient populations across all States served by the health insurance issuers within the issuer's controlled group (defined for purposes of this section as a group of two or more persons that is treated as a single employer under sections 52(a), 52(b), 414(m), or 414(o) of the Internal Revenue Code of 1986, as amended), whether or not those health insurance issuers offer plans through the Exchange in each of those States, to determine the top 15 languages required for taglines. Exchanges and QHP issuers may satisfy tagline requirements with respect to Web site content if they post a Web link prominently on their home page that directs individuals to the full text of the taglines indicating how individuals may obtain language assistance services, and if they also include taglines on any critical standalone document linked to or embedded in the Web site. Exchanges, and QHP issuers that are also subject to § 92.8 of

this subtitle, will be deemed in compliance with paragraph (c)(2)(iii)(A) of this section if they are in compliance with § 92.8 of this subtitle.

(B) For an agent or broker subject to § 155.220(c)(3)(i), beginning when such entity has been registered with the Exchange for at least 1 year, this standard also includes taglines on Web site content and any document that is critical for obtaining health insurance coverage or access to health care services through a QHP for qualified individuals, applicants, qualified employers, qualified employees, or enrollees. A document is deemed to be critical for obtaining health insurance coverage or access to health care services through a QHP if it is required to be provided by law or regulation to a qualified individual, applicant, qualified employer, qualified employee, or enrollee. Such taglines must indicate the availability of language services in at least the top 15 languages spoken by the limited English proficient population of the relevant State or States, as determined in guidance published by the Secretary. An agent or broker subject to § 155.220(c)(3)(i) that is licensed in and serving multiple States may aggregate the limited English populations in the States it serves to determine the top 15 languages required for taglines. An agent or broker subject to § 155.220(c)(3)(i) may satisfy tagline requirements with respect to Web site content if it posts a Web link prominently on its home page that directs individuals to the full text of the taglines indicating how individuals may obtain language assistance services, and if it also includes taglines on any critical stand-alone document linked to or embedded in the Web site.

* * * * *

■ 22. Section 155.220 is amended by:

- a. Revising paragraph (c)(3)(i)(E);
- b. Removing the word “and” at the end of paragraph (c)(3)(i)(F);
- c. Removing the period at the end of paragraph (c)(3)(i)(G) and adding “; and” in its place;
- d. Adding paragraph (c)(3)(i)(H) through (L); and
- e. Revising paragraphs (c)(4)(i)(E) and (j)(2)(i).

The additions and revisions 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) * * *
- (3)(i) * * *

(E) Maintain audit trails and records in an electronic format for a minimum

of ten years and cooperate with any audit under this section;

* * * * *

(H) Differentially display all standardized options prominently and in accordance with the requirements under § 155.205(b)(1) in a manner consistent with that adopted by HHS for display on the Federally-facilitated Exchange Web site and with standards defined by HHS, unless HHS approves a deviation;

(I) Prominently display information provided by HHS pertaining to a consumer's eligibility for advance payments of the premium tax credit or cost-sharing reductions;

(J) Allow the consumer to select an amount for advance payments of the premium tax credit, if applicable, and make related attestations in accordance with § 155.310(d)(2);

(K) Demonstrate operational readiness and compliance with applicable requirements prior to the agent or broker's Internet Web site being used to complete the QHP selection; and

(L) HHS may immediately suspend the agent or broker's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to Exchange operations or Exchange information technology systems until the incident or breach is remedied or sufficiently mitigated to HHS's satisfaction.

* * * * *

(4) * * *

(i) * * *

(E) Report to HHS and applicable State departments of insurance any potential material breach of the standards in paragraphs (c) and (d) of this section, or the agreement entered into under § 155.260(b), by the agent or broker accessing the Internet Web site, should it become aware of any such potential breach. An agent or broker that provides access to its Web site to complete the QHP selection or the Exchange eligibility application or ability to transact information with HHS to another agent or broker Web site is responsible for ensuring compliance with applicable requirements in paragraph (c)(3) of this section for any Web pages of the other agent's or broker's Web site that assist consumers, applicants, qualified individuals, and enrollees in applying for APTC and CSRs for QHPs, or in completing enrollment in QHPs, offered in the Exchanges.

* * * * *

(j) * * *

(2) * * *

(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 (including by having a direct enrollment Web site that HHS determines could mislead a consumer into believing they are visiting *HealthCare.gov*), coercive, or discriminates based on race, color, national origin, disability, age, sex, gender identity, or sexual orientation;

* * * * *

■ 23. Section 155.221 is added to read as follows:

§ 155.221 Standards for HHS-approved vendors to perform audits of agents and brokers participating in direct enrollment.

(a) *Application for approval.* (1) A vendor must be approved by HHS, in a form and manner to be determined by HHS, to have its auditing services recognized for Web-brokers assisting with or facilitating enrollment in individual market or SHOP coverage through the Exchanges consistent with § 155.220.

(2) HHS will approve vendors on an annual basis for a given plan year, and each vendor must submit an application for each year that approval is sought.

(b) *Standards.* To be approved by HHS and maintain its status as an approved vendor, a vendor applicant must meet each of the following standards:

(1) Submit a complete and accurate application by the deadline established by HHS that demonstrates prior experience successfully conducting auditing or similar services to a large customer base.

(2) Adhere to HHS specifications for content, format, privacy and security in the delivery of auditing services, which includes ensuring that Web-brokers are in compliance with the applicable privacy and security standards.

(3) Collect, store, and share with HHS data from Web-broker users of the vendor's auditing services in a manner, format, and frequency specified by HHS, and protect all data from Web-broker users of the vendor's auditing services in accordance with § 155.260.

(4) Permit any Web-broker registered with the FFEs to access the vendor's auditing services.

(c) *Monitoring.* HHS may periodically monitor and audit vendors approved under this subpart, and their records related to the audit services 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

paragraph (b) of this section, the vendor may be removed from the approved list described in paragraph (d) of this section and may be required by HHS to cease performing the functions described under this section.

(d) *Approved list.* A list of approved vendors will be published on an HHS Web site.

(e) *Appeals.* A vendor that is not approved by HHS after submitting the application described in paragraph (a) of this section, or a vendor whose approval is revoked under paragraph (c) of this section, may appeal HHS's decision by notifying HHS in writing within 15 days from receipt of the notification of not being approved or having its approval revoked and submitting additional documentation demonstrating how the vendor meets the standards in paragraph (b) of this section and (if applicable) the terms of its agreement with HHS. HHS will review the submitted documentation within 30 days from receipt of the additional documentation.

■ 24. Section 155.230 is amended by revising paragraph (d)(2) and adding paragraph (d)(3) to read as follows:

§ 155.230 General standards for Exchange notices.

* * * *

(2) Unless otherwise required by Federal or State law, the SHOP must provide required notices electronically or, if an employer or employee elects, through standard mail. If notices are provided electronically, the SHOP must comply with the requirements for electronic notices in 42 CFR 435.918(b)(2) through (5) for the employer or employee.

(3) In the event that an individual market Exchange or SHOP is unable to send select required notices electronically due to technical limitations, it may instead send these notices through standard mail, even if an election has been made to receive such notices electronically.

■ 25. Section 155.305 is amended by revising paragraph (f)(4) to read as follows:

§ 155.305 Eligibility standards.

* * * *

(f) * * *

(4) *Compliance with filing requirement.* (i) The Exchange may not determine a tax filer eligible for advance payments of the premium tax credit if HHS notifies the Exchange as part of the process described in § 155.320(c)(3) that advance payments of the premium tax credit were made on behalf of the tax filer or either spouse if the tax filer is

a married couple for a year for which tax data would be utilized for verification of household income and family size in accordance with § 155.320(c)(1)(i), and the tax filer or his or her spouse did not comply with the requirement to file an income tax return for that year as required by 26 U.S.C. 6011, 6012, and implementing regulations and reconcile the advance payments of the premium tax credit for that period.

(ii) Notwithstanding the requirement in paragraph (f)(4)(i) of this section, the Exchange may not deny eligibility for advance payments of the premium tax credit under paragraph (f)(4)(i) of this section unless direct notification is first sent to the tax filer, consistent with the standards set forth in § 155.230, that his or her eligibility will be discontinued as a result of the tax filer's failure to comply with the requirement specified under paragraph (f)(4)(i) of this section.

* * * *

■ 26. Section 155.330 is amended by—

- a. Revising paragraphs (d)(1)(ii), and (e)(2)(i) introductory text;
- b. Adding paragraph (e)(2)(iii); and
- c. Revising paragraph (g)(1).

The addition and revisions read as follows:

§ 155.330 Eligibility redetermination during a benefit year.

* * * *

(d) * * *

(1) * * *

(ii) For an enrollee on whose behalf advance payments of the premium tax credit or cost-sharing reductions are being provided, eligibility determinations for or enrollment in Medicare, Medicaid, CHIP, or the Basic Health Program, if a Basic Health Program is operating in the service area of the Exchange.

* * * *

(e) * * *

(2) * * *

(i) Except as provided in paragraph (e)(2)(iii) of this section, if the Exchange identifies updated information regarding death, in accordance with paragraph (d)(1)(i) of this section, or regarding any factor of eligibility not regarding income, family size, or family composition, or tax filing status, the Exchange must—

* * * *

(iii) If the Exchange identifies updated information that the tax filer for the enrollee's household or the tax filer's spouse did not comply with the requirements described in § 155.305(f)(4), the Exchange when redetermining and providing notification of eligibility for advance

payments of the premium tax credit must:

(A) Follow the procedures specified in paragraph (e)(2)(i) of this section;

(B) Follow the procedures in guidance published by the Secretary; or

(C) Follow alternative procedures approved by the Secretary based on a showing by the Exchange that the alternative procedures facilitate continued enrollment in coverage with financial assistance for which the enrollee remains eligible, provide appropriate information about the process to the enrollee (including regarding any action by the enrollee necessary to obtain the most accurate redetermination of eligibility), and provide adequate program integrity protections and safeguards for Federal tax information under section 6103 of the Internal Revenue Code with respect to the confidentiality, disclosure, maintenance, or use of such information.

* * * *

(g) * * *

(1) When an eligibility redetermination in accordance with this section results in a change in the amount of advance payments of the premium tax credit for the benefit year, the Exchange must:

(i) Recalculate the amount of advance payments of the premium tax credit in such a manner as to account for any advance payments already made on behalf of the tax filer for the benefit year for which information is available to the Exchange, such that the recalculated advance payment amount is projected to result in total advance payments for the benefit year that correspond to the tax filer's total projected premium tax credit for the benefit year, calculated in accordance with 26 CFR 1.36B-3 (or, if less than zero, be set at zero); or

(ii) Recalculate advance payments of the premium tax credit using an alternate method that has been approved by the Secretary.

* * * *

■ 27. Section 155.400 is amended by—

- a. Revising paragraphs (e) introductory text and (e)(1) introductory text;
- b. Adding paragraph (e)(2); and
- c. Revising paragraph (g) introductory text.

The revisions and addition read as follows:

§ 155.400 Enrollment of qualified individuals into QHPs.

* * * *

(e) *Premium payment.* Exchanges may, and the Federally-facilitated Exchanges and State-Based Exchanges on the Federal Platform 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 Exchanges and State-Based Exchanges on the Federal Platform will, establish a standard policy for setting premium payment deadlines:

(1) In a Federally-facilitated Exchange or State-Based Exchange on the Federal Platform:

* * * * *

(2) *Premium payment deadline extension.* Exchanges may, and the Federally-facilitated Exchanges and State-Based Exchanges on the Federal Platform will, allow issuers experiencing billing or enrollment problems due to high volume or technical errors to implement a reasonable extension of the binder payment deadlines in paragraph (e)(1) of this section.

* * * * *

(g) *Premium payment threshold.* Exchanges may, and the Federally-facilitated Exchanges and State-Based Exchanges on the Federal Platform 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:

* * * * *

■ 28. Section 155.420 is amended by:

■ a. Revising paragraphs (b)(2)(iii) and (iv);

■ b. Adding paragraph (b)(5);

■ c. Revising paragraphs (c)(2), (d)(1)(i) and (iii), (d)(2)(ii), (d)(3), (d)(6)(iv), and (d)(7), (8), and (9); and

■ d. Adding paragraphs (d)(10) through (13).

The revisions and additions read as follows:

§ 155.420 Special enrollment periods.

* * * * *

(b) * * *

(2) * * *

(iii) In the case of a qualified individual or enrollee eligible for a special enrollment period as described in paragraph (d)(4), (5), (9), (11), (12), or (13) of this section, the Exchange must ensure that coverage is effective on an appropriate date based on the circumstances of the special enrollment period.

(iv) If a consumer loses coverage as described in paragraph (d)(1) or (d)(6)(iii) of this section, gains access to a new QHP as described in paragraph (d)(7) of this section, becomes newly eligible for enrollment in a QHP through the Exchange in accordance with § 155.305(a)(2) as described in paragraph (d)(3) of this section, or becomes newly eligible for advance payments of the premium tax credit in conjunction with a permanent move as described in paragraph (d)(6)(iv) of this section, if the plan selection is made on or before the day of the triggering event, the Exchange must ensure that the coverage effective date is on the first day of the month following the date of the triggering event. If the plan selection is made after the date of the triggering event, the Exchange must ensure that coverage is effective in accordance with paragraph (b)(1) of this section or on the first day of the following month, at the option of the Exchange.

* * * * *

(5) *Option for later coverage effective dates due to prolonged eligibility verification.* At the option of the consumer, the Exchange must provide an appropriate coverage effective date that is later than the effective date specified in paragraph (b) of this section if a consumer's enrollment is delayed until after the Exchange's verification of the consumer's eligibility for a special enrollment period, and the assignment of a coverage effective date consistent with paragraph (b) of this section would result in the consumer being required to pay two or more months of retroactive premium to effectuate coverage or avoid termination for non-payment.

(c) * * *

(2) *Advanced availability.* A qualified individual or his or her dependent who is described in paragraph (d)(1) or (d)(6)(iii) of this section has 60 days before or after the triggering event to select a QHP. At the option of the Exchange, a qualified individual or his or her dependent who is described in paragraph (d)(7) of this section; who is described in paragraph (d)(6)(iv) of this section and becomes newly eligible for advance payments of the premium tax credit as a result of a permanent move to a new State; or who is described in paragraph (d)(3) of this section and becomes newly eligible for enrollment in a QHP through the Exchange because he or she newly satisfies the requirements under § 155.305(a)(2), has 60 days before or after the triggering event to select a QHP.

* * * * *

(d) * * *

(1) * * *

(i) Loses minimum essential coverage. The date of the loss of coverage is the last day the consumer would have coverage under his or her previous plan or coverage;

* * * * *

(iii) Loses pregnancy-related coverage described under section 1902(a)(10)(A)(i)(IV) and (a)(10)(A)(ii)(IX) of the Act (42 U.S.C. 1396a(a)(10)(A)(i)(IV), (a)(10)(A)(ii)(IX)). The date of the loss of coverage is the last day the consumer would have pregnancy-related coverage; or

* * * * *

(2) * * *

(ii) At the option of the Exchange, the enrollee loses a dependent or is no longer considered a dependent through divorce or legal separation as defined by State law in the State in which the divorce or legal separation occurs, or if the enrollee, or his or her dependent, dies.

(3) The qualified individual, or his or her dependent, becomes newly eligible for enrollment in a QHP through the Exchange because he or she newly satisfies the requirements under § 155.305(a)(1) or (2);

* * * * *

(6) * * *

(iv) A qualified individual who was previously ineligible for advance payments of the premium tax credit solely because of a household income below 100 percent of the FPL and who, during the same timeframe, was ineligible for Medicaid because he or she was living in a non-Medicaid expansion State, who either experiences a change in household income or moves to a different State resulting in the qualified individual becoming newly eligible for advance payments of the premium tax credit;

(7) The qualified individual or enrollee, or his or her dependent, gains access to new QHPs as a result of a permanent move and either—

(i) Had minimum essential coverage as described in 26 CFR 1.5000A-1(b) for one or more days during the 60 days preceding the date of the permanent move, or

(ii) Was living outside of the United States or in a United States territory at the time of the permanent move;

(8) The qualified individual—

(i) Who gains or maintains status as an Indian, as defined by section 4 of the Indian Health Care Improvement Act, may enroll in a QHP or change from one QHP to another one time per month; or

(ii) Who is or becomes a dependent of an Indian, as defined by section 4 of the Indian Health Care Improvement Act and is enrolled or is enrolling in a QHP

through an Exchange on the same application as the Indian, may change from one QHP to another one time per month, at the same time as the Indian;

(9) The qualified individual or enrollee, or his or her dependent, demonstrates to the Exchange, in accordance with guidelines issued by HHS, that the individual meets other exceptional circumstances as the Exchange may provide;

(10) A qualified individual or enrollee—

(i) Is a victim of domestic abuse or spousal abandonment, as defined by 26 CFR 1.36B–2T, as amended, including a dependent or unmarried victim within a household, is enrolled in minimum essential coverage and seeks to enroll in coverage separate from the perpetrator of the abuse or abandonment; or

(ii) Is a dependent of a victim of domestic abuse or spousal abandonment, on the same application as the victim, may enroll in coverage at the same time as the victim;

(11) A qualified individual or dependent—

(i) Applies for coverage on the Exchange during the annual open enrollment period or due to a qualifying event, is assessed by the Exchange as potentially eligible for Medicaid or the Children's Health Insurance Program (CHIP), and is determined ineligible for Medicaid or CHIP by the State Medicaid or CHIP agency either after open enrollment has ended or more than 60 days after the qualifying event; or

(ii) Applies for coverage at the State Medicaid or CHIP agency during the annual open enrollment period, and is determined ineligible for Medicaid or CHIP after open enrollment has ended;

(12) The qualified individual or enrollee, or his or her dependent, adequately demonstrates to the Exchange that a material error related to plan benefits, service area, or premium influenced the qualified individual's or enrollee's decision to purchase a QHP through the Exchange; or

(13) At the option of the Exchange, the qualified individual provides satisfactory documentary evidence to verify his or her eligibility for an insurance affordability program or enrollment in a QHP through the Exchange following termination of Exchange enrollment due to a failure to verify such status within the time period specified in § 155.315 or is under 100 percent of the Federal poverty level and did not enroll in coverage while waiting for HHS to verify his or her citizenship, status as a national, or lawful presence.

■ 29. Section 155.430 is amended by revising paragraph (b)(2)(iii) to read as follows:

§ 155.430 Termination of Exchange enrollment or coverage.

* * * * *

(b) * * *

(2) * * *

(iii) The enrollee's coverage is rescinded in accordance with § 147.128 of this subchapter, after a QHP issuer demonstrates, to the reasonable satisfaction of the Exchange, if required by the Exchange, that the rescission is appropriate;

* * * * *

■ 30. Section 155.505 is amended by adding paragraph (h) to read as follows:

§ 155.505 General eligibility appeals requirements.

* * * * *

(h) *Electronic requirements.* If the Exchange appeals entity cannot fulfill the electronic requirements of subparts C, D, F, and H of this part related to acceptance of telephone- or Internet-based appeal requests, the provision of appeals notices electronically, or the secure electronic transfer of eligibility and appeal records between appeals entities and Exchanges or Medicaid or CHIP agencies, the Exchange appeals entity may fulfill those requirements that it cannot fulfill electronically using a secure and expedient paper-based process.

■ 31. Section 155.555 is amended by revising paragraph (b) to read as follows:

§ 155.555 Employer appeals process.

* * * * *

(b) *Exchange employer appeals process.* An Exchange may establish an employer appeals process in accordance with the requirements of this section and §§ 155.505(f) through (h) and 155.510(a)(1) and (2) and (c). Where an Exchange has not established an employer appeals process, HHS will provide an employer appeals process that meets the requirements of this section and §§ 155.505(f) through (h) and 155.510(a)(1) and (2) and (c).

* * * * *

■ 32. Section 155.725 is amended by revising paragraphs (g)(1) and (2) and (j)(2)(i) to read as follows:

§ 155.725 Enrollment periods under SHOP.

* * * * *

(g) * * *

(1) In a State Exchange that does not use the Federal platform for SHOP functions, the following rules apply with respect to enrollment and coverage effective dates for newly qualified employees.

(i) The SHOP must provide an employee who becomes a qualified employee outside of the initial or annual open enrollment period an enrollment period beginning on the first day of becoming a qualified employee. A newly qualified employee must have at least 30 days from the beginning of his or her enrollment period to select a QHP. The enrollment period must end no sooner than 15 days prior to the date that any applicable employee waiting period longer than 45 days would end if the employee made a plan selection on the first day of becoming eligible.

(ii) The effective date of coverage for a QHP selection received by the SHOP from a newly qualified employee must always be the first day of a month, and must generally be determined in accordance with paragraph (h) of this section, unless the employee is subject to a waiting period consistent with § 147.116 of this subchapter, in which case the effective date may be on the first day of a later month, but in no case may the effective date fail to comply with § 147.116 of this subchapter.

(iii) Waiting periods in the SHOP are calculated beginning on the date the employee becomes a qualified employee who is otherwise eligible for coverage, regardless of when a qualified employer notifies the SHOP about a newly qualified employee.

(2) In a Federally-facilitated SHOP or in a State Exchange that uses the Federal platform for SHOP functions, the following rules apply with respect to enrollment and coverage effective dates for newly qualified employees.

(i) The SHOP must provide an employee who becomes a qualified employee outside of the initial or annual open enrollment period with a 30-day enrollment period beginning on the date the qualified employer notifies the SHOP about the newly qualified employee. Qualified employers must notify the SHOP about a newly qualified employee on or before the thirtieth day after the day that the employee becomes a newly qualified employee.

(ii) The effective date of coverage for a QHP selection received by the SHOP from a newly qualified employee is the first day of the month following plan selection, unless the employee is subject to a waiting period consistent with § 147.116 of this subchapter and paragraph (g)(2)(iii) of this section, in which case the effective date will be on the first day of the month following the end of the waiting period, but in no case may the effective date fail to comply with § 147.116 of this subchapter. If a newly qualified employee's waiting period ends on the first day of a month and the employee has already made a

plan selection by that date, coverage must take effect on that date. If a newly qualified employee makes a plan selection on the first day of a month and any applicable waiting period has ended by that date, coverage must be effective on the first day of the following month. If a qualified employer with variable hour employees makes regularly having a specified number of hours of service per period, or working full-time, a condition of employee eligibility for coverage offered through the SHOP, any measurement period that the qualified employer elects to use under § 147.116(c)(3)(i) to determine whether an employee meets the applicable eligibility conditions with respect to coverage offered through the SHOP must not exceed 10 months, beginning on any date between the employee's start date and the first day of the first calendar month following the employee's start date.

(iii) Waiting periods in the SHOP are calculated beginning on the date the employee becomes a qualified employee who is otherwise eligible for coverage, regardless of when a qualified employer notifies the SHOP about a newly qualified employee, and must not exceed 60 days in length. Waiting periods must be 0, 15, 30, 45 or 60 days in length.

* * * * *

(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), (9), (10), (11), or (12);

* * * * *

■ 33. Section 155.740 is amended by revising paragraph (b)(2) to read as follows:

§ 155.740 SHOP employer and employee eligibility appeals requirements.

* * * * *

(b) * * *

(2) The appeals entity must conduct appeals in accordance with the requirements established in this section and §§ 155.505(e) through (h) and 155.510(a)(1) and (2) and (c).

* * * * *

■ 34. Section 155.1090 is added to subpart K to read as follows:

§ 155.1090 Request for reconsideration.

(a) *Request for reconsideration of denial of certification specific to a Federally-facilitated Exchange—(1) Request for reconsideration.* The Federally-facilitated Exchanges will permit an issuer that has submitted a complete application to a Federally-facilitated Exchange for certification of

a health plan as a QHP and is denied certification to request reconsideration of such action.

(2) *Form and manner of request.* An issuer submitting a request for reconsideration under paragraph (a)(1) of this section must submit a written request for reconsideration to HHS, in the form and manner specified by HHS, within 7 calendar days of the date of the written notice of denial of certification. The issuer must include any and all documentation the issuer wishes to provide in support of its request with its request for reconsideration.

(3) *HHS reconsideration decision.* HHS will provide the issuer with a written notice of the reconsideration decision. The decision will constitute HHS's final determination.

(b) [Reserved]

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

■ 35. 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).

■ 36. Section 156.80 is amended by—

■ a. Revising paragraph (d)(1);

■ b. Redesignating paragraph (d)(3) as paragraph (d)(4);

■ c. Adding new paragraph (d)(3); and

■ d. Revising newly redesignated paragraph (d)(4).

The revisions read as follows:

§ 156.80 Single risk pool.

* * * * *

(d) * * *

(1) *In general.* A health insurance issuer must establish an index rate that is effective January 1 of each calendar year for a State market described in paragraphs (a) through (c) of this section.

(i) The index rate must be based on the total combined claims costs for providing essential health benefits within the single risk pool of that State market.

(ii) The index rate must be adjusted on a market-wide basis for the State based on the total expected market-wide payments and charges under the risk adjustment program and Exchange user fees (expected to be remitted under § 156.50(b) or (c) and (d) as applicable, plus the dollar amount under § 156.50(d)(3)(i) and (ii) expected to be

credited against user fees payable for that State market).

(iii) The premium rate for all of the health insurance issuer's plans in the relevant State market must use the applicable market-wide adjusted index rate, subject only to the plan-level adjustments permitted in paragraph (d)(2) of this section.

* * * * *

(3) *Calibration.* The issuer must calibrate the plan-adjusted index rate for its plans within the single risk pool to correspond to an age rating factor of 1.0, a geographic rating factor of 1.0, and a tobacco use rating factor of 1.0, in a manner specified by the Secretary in guidance, to ensure that any rating variation under § 147.102 of this subchapter may be accurately applied with respect to a particular plan or coverage. The calibration must be applied uniformly to all plans within the single risk pool of the State market and cannot vary by plan.

(4) *Frequency of index rate and plan-level adjustments.* (i) A health insurance issuer may not establish an index rate and make the market-wide adjustments pursuant to paragraph (d)(1) of this section, make the plan-level adjustments pursuant to paragraph (d)(2) of this section, or calibrate the plan-adjusted index rate for its plans pursuant to paragraph (d)(3) of this section more or less frequently than annually, except as provided in paragraph (d)(4)(ii) of this section.

(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, make the plan-level adjustments under paragraph (d)(2) of this section, and calibrate the plan-adjusted index rate for its plans pursuant to paragraph (d)(3) 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.

* * * * *

■ 37. Section 156.140 is amended by revising paragraph (c) to read as follows:

§ 156.140 Levels of coverage.

* * * * *

(c) *De minimis variation.* The allowable variation in the AV of a health plan that does not result in a material difference in the true dollar value of the health plan is ± 2 percentage points, except if a health plan under paragraph

(b)(1) of this section (a bronze health plan) either covers and pays for at least one major service, other than preventive services, before the deductible or meets the requirements to be a high deductible health plan within the meaning of 26 U.S.C. 223(c)(2), in which case the allowable variation in AV for such plan is – 2 percentage points and +5 percentage points.

■ 38. Section 156.200 is amended by revising paragraphs (c)(1) and (g) introductory text to read as follows:

§ 156.200 QHP issuer participation standards.

* * * * *

(c) * * *

(1) At least one QHP in the silver coverage level and at least one QHP in the gold coverage level as described in § 156.140 throughout each service area in which it offers coverage through the Exchange; and,

* * * * *

(g) *Certification standard specific to a Federally-facilitated Exchange for plan years beginning before January 1, 2018.* A Federally-facilitated Exchange may certify a QHP in the individual market of a Federally-facilitated Exchange only if the QHP issuer meets one of the conditions below:

* * * * *

■ 39. 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. 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; 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 level satisfies a minimum percentage, specified by HHS, of available essential community providers in the plan's service area. 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; and

* * * * *

■ 40. Section 156.265 is amended by:

■ a. Removing the word “and” at the end of paragraph (b)(3)(ii);

■ b. Removing the period at the end of paragraph (b)(3)(iii) and adding “; and” in its place; and

■ c. Adding paragraph (b)(3)(iv).

The addition reads as follows:

§ 156.265 Enrollment process for qualified individuals.

* * * * *

(b) * * *

(3) * * *

(iv) Differentially display all standardized options in accordance with the requirements under § 155.205(b)(1) in a manner consistent with that adopted by HHS for display on the Federally-facilitated Exchange Web site, unless HHS approves a deviation.

* * * * *

■ 41. Section 156.272 is added to read as follows:

§ 156.272 Issuer participation for the full plan year.

(a) An issuer offering a QHP through an individual market Exchange must make the QHP available for enrollment through the Exchange for the full plan year for which the plan was certified, including to eligible enrollees during limited open enrollment periods, unless a basis for suppression under § 156.815 applies.

(b) Unless a basis for suppression under § 156.815 applies, an issuer offering a QHP through a SHOP must make the QHP available for enrollment through the SHOP for the full plan year for which the QHP was certified.

(c) An issuer offering a QHP through a Federally-facilitated Exchange or a Federally-facilitated SHOP that does not comply with paragraph (a) or (b) of this section may, at the discretion of HHS, be precluded from offering QHPs in a Federally-facilitated Exchange or Federally-facilitated SHOP for up to the two succeeding plan years.

■ 42. Section 156.290 is amended by revising the section heading and paragraphs (a) introductory text and (b) to read as follows:

§ 156.290 Non-certification and decertification of QHPs.

(a) *Non-certification for a subsequent, consecutive certification cycle.* If a QHP issuer elects not to seek certification for a subsequent, consecutive certification

cycle with the Exchange, the QHP issuer, at a minimum, must—

* * * * *

(b) *Notice of QHP non-availability.* When, for a subsequent, consecutive certification cycle, a QHP issuer elects not to seek certification with the Exchange, or the Exchange denies certification of a QHP, the QHP issuer must provide written notice to each enrollee in the form and manner specified by the Secretary under § 147.106 of this subchapter.

* * * * *

■ 43. Section 156.350 is amended by revising paragraph (a)(2) and adding paragraph (a)(4) to read as follows:

§ 156.350 Eligibility and enrollment standards for Qualified Health Plan issuers on State-based Exchanges on the Federal platform.

(a) * * *

(2) Section 156.285(c)(5) and (c)(8)(iii) regarding the enrollment process for SHOP; and

* * * * *

(4) Section 156.265(d) of this subchapter regarding binder payments and premium payment deadlines.

* * * * *

■ 44. Section 156.430 is amended by adding paragraph (h) to read as follows:

§ 156.430 Payment for cost-sharing reductions.

* * * * *

(h) *Reconciliation of the cost-sharing reduction portion of advance payments discrepancies and appeals.* (1) If an issuer reports a discrepancy and seeks to dispute the notification of the amount of reconciliation of the cost-sharing reduction portion of advance payments, it must report the discrepancy to HHS within 30 calendar days of notification of the amount of reconciliation of the cost-sharing reduction portion of advance payments as described in paragraph (e) of this section, in the manner set forth by HHS.

(2) An issuer may appeal the amount of reconciliation of the cost-sharing reduction portion of advance payments, under the process set forth in § 156.1220.

■ 45. Section 156.505 is amended by revising the definitions of “Pre-existing issuer” and “Representative” to read as follows:

§ 156.505 Definitions.

* * * * *

Pre-existing issuer means a health insurance issuer licensed by a State regulator that marketed individual or group health insurance benefit plans

(other than Medicare or Medicaid Managed Care plans) on July 16, 2009.

* * * * *

Representative means an officer, director, or trustee of an organization, or group of organizations; or a senior executive or high-level representative of the Federal government, or a State or local government or a sub-unit thereof.

* * * * *

■ 46. Section 156.515 is amended by revising paragraphs (b)(1)(i) through (v) and (b)(2)(i), (ii), (iii), and (v) to read as follows:

§ 156.515 CO-OP standards.

* * * * *

(b) * * *

(1) * * *

(i) The CO-OP must be governed by an operational board with a majority of directors elected by a majority vote of a quorum of the CO-OP's members that are age 18 or older;

(ii) All members age 18 or older must be eligible to vote for each of the directors on the organization's operational board subject to a vote of the members under paragraph (b)(1)(i) of this section;

(iii) Each member age 18 or older must have one vote in each election for each director subject to a vote of the members under paragraph (b)(1)(i) of this section in that election;

(iv) The first elected directors of the organization's operational board must be elected no later than one year after the effective date on which the organization provides coverage to its first member; the entire operational board must be elected or in place, and in full compliance with paragraph (b)(1)(i) of this section, no later than two years after the same date;

(v) Elections of the directors on the organization's operational board subject to a vote of the members under paragraph (b)(1)(i) of this section must be contested so that the total number of candidates for contested seats on the operational board exceeds the number of contested seats for such directors, except in cases where a seat is vacated mid-term due to death, resignation, or removal.

(2) * * *

(i) Each director must meet ethical, conflict-of-interest, and disclosure standards;

(ii) Each director has one vote;

(iii) Positions on the board of directors may be designated for individuals with specialized expertise, experience, or affiliation (for example, providers, employers, and unions); and

* * * * *

(v) *Limitation on government and issuer participation.* No representative

of any Federal, State or local government (or of any political subdivision or instrumentality thereof) and no representative of any organization described in § 156.510(b)(1)(i) (in the case of a representative of a State or local government or organization described in § 156.510(b)(1)(i), with respect to a State in which the CO-OP issues policies), may serve on the CO-OP's formation board or as a director on the organization's operational board.

* * * * *

■ 47. Section 156.715 is amended by adding paragraph (f) to read as follows:

§ 156.715 Compliance reviews of QHP issuer in Federally-facilitated Exchanges.

* * * * *

(f) *Failure to comply.* A QHP issuer that fails to comply with a compliance review under this section may be subject to enforcement remedies under subpart I of this part.

■ 48. Section 156.1220 is amended by—

■ a. Removing the word “or” at the end of paragraph (a)(1)(v);

■ b. Removing the period at the end of paragraph (a)(1)(vi) and adding a semicolon in its place;

■ c. Adding paragraphs (a)(1)(vii) and (viii); and

■ d. Revising paragraphs (a)(2), (a)(3)(ii), (a)(3)(v) and (a)(4)(ii).

The revisions and additions read as follows:

§ 156.1220 Administrative appeals.

(a) * * *

(1) * * *

(vii) The findings of a second validation audit as a result of risk adjustment data validation with respect to risk adjustment data for the 2016 benefit year and beyond; or

(viii) The calculation of a risk score error rate as a result of risk adjustment data validation with respect to risk adjustment data for the 2016 benefit year and beyond.

(2) *Materiality threshold.*

Notwithstanding paragraph (a)(1) of this section, an issuer may file a request for reconsideration under this section only if the amount in dispute under paragraph (a)(1)(i) through (viii) of this section, as applicable, is equal to or exceeds 1 percent of the applicable payment or charge listed in such paragraphs (a)(1)(i) through (viii) of this section payable to or due from the issuer for the benefit year, or \$10,000, whichever is less.

(3) * * *

(ii) For a risk adjustment payment or charge, including an assessment of risk adjustment user fees, the findings of a second validation audit, or the

calculation of a risk score error rate as a result of risk adjustment data validation, within 30 calendar days of the date of the notification under § 153.310(e) of this subchapter;

* * * * *

(v) For reconciliation of the cost-sharing reduction portion of advance payments, within 60 calendar days of the date of the cost-sharing reduction reconciliation discrepancy resolution decision; and

* * * * *

(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, the issuer notified HHS of the dispute through the applicable process for reporting a discrepancy set forth in §§ 153.630(d)(2), 153.710(d)(2), and 156.430(h)(1) of this subchapter, it was so identified and remains unresolved.

* * * * *

■ 49. Section 156.1230 is amended by adding paragraphs (b)(1), (2), and (3) to read as follows:

§ 156.1230 Direct enrollment with the QHP issuer in a manner considered to be through the Exchange.

* * * * *

(b) * * *

(1) HHS may immediately suspend the QHP issuer's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to Exchange operations or Exchange information technology systems until the incident or breach is remedied or sufficiently mitigated to HHS's satisfaction.

(2) The QHP issuer must demonstrate operational readiness and compliance with applicable requirements prior to the QHP issuer's Internet Web site being used to complete a QHP selection.

(3) The QHP issuer must 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 (including by having a direct enrollment Web site that HHS determines could mislead a consumer into believing they are visiting *HealthCare.gov*), coercive, or discriminates based on race, color, national origin, disability, age, sex, gender identity, or sexual orientation.

■ 50. Section 156.1256 is revised to read as follows:

§ 156.1256 Other notices.

As directed by a Federally-facilitated Exchange, a health insurance issuer that is offering QHP coverage through a Federally-facilitated Exchange or a State-based Exchange on the Federal platform 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)(12) of this subchapter, within 30 calendar days after being notified by a Federally-facilitated Exchange that the error has been fixed, if directed to do so by a Federally-facilitated Exchange.

PART 157—EMPLOYER INTERACTIONS WITH EXCHANGES AND SHOP PARTICIPATION

■ 51. The authority citation for part 157 continues to read as follows:

Authority: Title I of the Affordable Care Act, Sections 1311, 1312, 1321, 1411, 1412, Pub. L. 111–148, 124 Stat. 199.

■ 52. Section 157.205 is amended by revising paragraphs (e)(1) and (f)(1) to read as follows:

§ 157.205 Qualified employer participation process in a SHOP.

* * * * *

(e) * * *

(1) An enrollment period to seek coverage in a QHP in accordance with § 155.725(g) of this subchapter; and

* * * * *

(f) * * *

(1) Newly eligible dependents and newly qualified employees. In a Federally-facilitated SHOP or in a State Exchange that uses the Federal platform for SHOP functions, a qualified employer must provide information about a newly qualified employee on or before the thirtieth day after the day that the employee becomes a newly qualified employee; and

* * * * *

PART 158—ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS

■ 53. 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.

■ 54. Section 158.121 is revised to read as follows:

§ 158.121 Newer experience.

If, for any aggregation as defined in § 158.120, 50 percent or more of the total earned premium for an MLR reporting year is attributable to policies newly issued in that MLR reporting year, then the experience of these policies may be excluded from the report required under § 158.110 for that same MLR reporting year. If an issuer chooses to defer reporting of newer business as provided in this section, then the excluded experience must be added to the experience reported in the following MLR reporting year.

■ 55. Section 158.232 is amended by revising paragraphs (d)(1) and (2) and (e)(1) and (2), and adding paragraph (f) to read as follows:

§ 158.232 Calculating the credibility adjustment.

* * * * *

(d) * * *

(1) Each year in the aggregation included experience of at least 1,000 life-years; and

(2) The issuer's preliminary MLR, as defined under paragraph (f) of this section, for each year in the aggregation was below the applicable MLR standard, as established under §§ 158.210 and 158.211.

(e) * * *

(1) Each year in the aggregation included experience of at least 1,000 life-years; and

(2) The issuer's preliminary MLR, as defined under paragraph (f) of this section, for each year in the aggregation was below the applicable MLR standard, as established under §§ 158.210 and 158.211.

(f) *Preliminary MLR.* Preliminary MLR means the ratio of the numerator, as defined in § 158.221(b) and calculated as of March 31st of the year following the year for which the MLR report required in § 158.110 is being submitted, to the denominator, as defined in § 158.221(c), calculated using only a single year of experience, and without applying any credibility adjustment.

■ 56. Section 158.240 is amended by—

■ a. Revising paragraph (c)(1);

■ b. Redesignating paragraphs (d) and (e) as paragraphs (e) and (f), respectively;

■ c. Adding a new paragraph (d); and

■ d. Amending newly redesignated paragraph (f) by removing the reference “paragraph (d) of this section” each time it appears and adding in its place the reference “paragraph (e) of this section”.

The revision and addition read as follows:

§ 158.240 Rebating premium if the applicable medical loss ratio standard is not met.

* * * * *

(c) * * *

(1) For each MLR reporting year, an issuer must rebate to the enrollee, subject to paragraph (d) of this section, the total amount of premium revenue, as defined in § 158.130, received by the issuer from the enrollee, after subtracting Federal and State taxes and licensing and regulatory fees as provided in §§ 158.161(a) and 158.162(a)(1) and (b)(1), and after accounting for payments or receipts for risk adjustment, risk corridors, and reinsurance as provided in § 158.130(b)(5), multiplied by the difference between the MLR required by § 158.210 or § 158.211, and the issuer's MLR as calculated under § 158.221.

* * * * *

(d) *Limitation on total rebate payable for each year in the aggregation.* For any State and market, an issuer may elect to limit the amount of rebate payable for the MLR reporting year to the issuer's total outstanding rebate liability with respect to all years included in the aggregation. If an issuer elects this option, the outstanding rebate liability with respect to a specific year in the aggregation must be calculated by multiplying the denominator with respect to that year, as defined in § 158.221(c), by the difference between the MLR required by § 158.210 or § 158.211 for the MLR reporting year, and the sum of the issuer's preliminary MLR for that year, as defined under § 158.232(f), and the credibility adjustment applicable to the current MLR reporting year. The outstanding rebate liability with respect to a specific year must be reduced by any rebate payments applied against it in prior MLR reporting years. A rebate paid for an MLR reporting year must be applied first to reduce the outstanding rebate liability with respect to the earliest year in the aggregation.

* * * * *

Dated: November 28, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: December 12, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

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